2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities

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Office of Management and Budget

Office of Information and Regulatory Affairs

2006 REPORT TO CONGRESS
ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND
UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES

EXECUTIVE SUMMARY

This Report to Congress on the Costs and Benefits of Federal Regulations was prepared to implement Section 624 of the Treasury and General Government Appropriations Act of 2001 (Pub. L. No. 106-554, 31 U.S.C. § 1105 note), commonly known as the Regulatory "Right-to-Know Act." The Report was published in draft form in April 2006 and covers the time period Fiscal Year (FY) 1996 through FY 2005. This final Report reflects revisions made to the draft based on public comment, external peer review, and interagency review.

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

- The estimated annual benefits of major Federal regulations reviewed by OMB from October 1, 1995, to September 30, 2005, range from $94 billion to $449 billion, while the estimated annual costs range from $37 billion to $44 billion. The substantial increase in aggregate benefits since last year is attributable to the addition of the Environmental Protection Agency's Clean Air Interstate Rule.

- During FY 2005, 13 "major" final rules with quantified and monetized benefits and costs were adopted. These rules added $28 billion to $178 billion in annual benefits compared to $4.3 billion to $6.6 billion in annual costs.

- There were an additional eight final "major" rules during FY 2005 that did not have quantified and monetized estimates of both benefits and costs. Two of these eight rules implemented homeland security programs where the benefits of improved security are very difficult to quantify and monetize.

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

- The average yearly cost of the major regulations issued during the Bush (43) Administration is about 54 percent less than over the previous 20 years.

- The average yearly benefit of the major regulations issued during the Bush (43) Administration is over double the yearly average for the previous eight years.

- Over the last 25 years, the major regulations reviewed by OMB have added at least $123 billion to the overall yearly costs of regulations on the public.
- The benefits of major regulations issued from 1992 to 2005 exceed the costs by over three fold.

Chapter III of the Report provides an update on various initiatives to improve regulatory cooperation internationally. This chapter focuses on U.S. engagement with the European Union

and with Canada and Mexico, as well as other efforts to promote greater cooperation and regulatory best practices. Appendix D presents a comparison of the European Commission's guidelines on regulatory impact analysis with those issued by OMB to Federal agencies.

Chapter IV provides an update on agency 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)). The chapter summarizes the current status of correction requests that were received by agencies in FY 2005, and includes an update on the status of requests received in FY 2003 and FY 2004.

In Appendix E, OMB reports on the status of the regulatory reforms resulting from three recent public nomination initiatives. These initiatives, which occurred in 2001, 2002, and 2004, have been the subject of periodic status reports.

Continuing OMB's recent practice, this Report is being submitted along with the Eleventh Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104-4). In this Unfunded Mandates Report, OMB reports on agency compliance with Title II of the Act, which requires that each agency, before promulgating any proposed or final rule that may result in expenditures of more than $100 million (annually 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: 2006 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

CHAPTER I: THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

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

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

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

- Rules designated as "major" under 5 U.S.C. § 804(2);[1]
- Rules designated as meeting the analysis threshold under 2 U.S.C. § 1532;[2] and
- Rules designated as "economically significant" under section 3(f)(1) of Executive Order 12866 of September 30, 1993, "Regulatory Planning and Review."[3]

This chapter consists of the accounting statement and a brief report on regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Section A revises the benefit-cost estimates in last year's Report by updating the estimates to the end of fiscal year (FY) 2005 (September 30, 2005). Like the 2005 Report, this chapter uses a 10-year look-back: estimates are based on the major regulations reviewed by OMB from October 1,

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[1] A "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."

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

[3] A 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."

1995, to September 30, 2005.[4] This means that five rules reviewed from October 1, 1994, to September 30, 1995, were included in the totals for the 2005 Report but are not included in this Report. A list of these rules can be found in Appendix C (see Table C-1). Appendix C also includes a summary of eight rules included in the 2004 Report but not included in the 2005 Report (see Table C-2), and a summary of 33 rules included in the 2003 Report but not included in the 2004 Report (see Table C-3[5]).

All of the estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OMB.[6] 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.[7] This discussion is based on data provided by these agencies to the Government Accountability Office (GAO) under the Congressional Review Act.

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

Table 1-1 presents an estimate of the total costs and benefits of 95 regulations reviewed by OMB over the ten-year period from October 1, 1995, to September 30, 2005, that met two conditions.[8] Each rule generated costs or benefits of at least $100 million in any one year, and a substantial portion of its costs and benefits were quantified and monetized by the agency or, in some cases, monetized by OMB. The estimates are therefore not a complete accounting of all the costs and benefits of all regulations issued by the Federal government during this period.[9] As discussed in previous Reports, OMB has chosen a 10-year period for aggregation because pre-regulation estimates prepared for rules adopted more than ten years ago are of questionable relevance today. The estimates of the costs and benefits of Federal regulations over the period October 1, 1995, to September 30, 2005, are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866.

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

[5] Note that the 11 entries in Table C-3 include a combined impact estimate from 23 original FDA food labeling rules.

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

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

[8]OMB discusses, in this report and in previous reports the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies 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 regulatory analysis guidance, OMB Circular A-4, which took effect on January 1, 2004 for proposed rules and January 1, 2005 for final rules. The guidance recommends what OMB defines as "best practice" in regulatory analysis, with a goal of strengthening the role of science, engineering, and economics in rulemaking. The overall goal of this guidance is a more competent and credible regulatory process and a more consistent regulatory environment. OMB expects that as more agencies adopt our recommended best practices, the costs and benefits we present in future reports will become more comparable across agencies and programs. OMB is working with the agencies to ensure that their impact analyses follow the guidance.

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

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

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

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

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

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

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

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

Based on the information contained in this and previous Reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) would be larger, and may be significantly larger, than the sum of the costs and benefits reported in Table 1-1. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program.

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

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

The majority of the large estimated benefits of EPA rules are attributable to the reduction in public exposure to a single air pollutant: fine particulate matter. Thus, the favorable benefit-cost results for EPA regulation should not be generalized to all types of EPA rules or even to all types of clean-air rules. In addition, the ranges of costs and benefits presented in Tables 1-2 need to be treated with some caution. To the extent that the reasons for uncertainty differ across individual rules, aggregating high- and low-end estimates can result in totals that are extremely unlikely. In the case of the EPA rules reported here, however, a substantial portion of the uncertainty is similar across several rules: uncertainty in the reduction of premature deaths associated with reduction in particulate matter and the monetary value of reducing mortality risk. We continue to work with EPA to revise these ranges to 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 SO_2 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.[10]

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

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

In this section, we examine in detail the benefits and costs of the 45 major final rules for which OMB concluded review during the 12-month period beginning October 1, 2004, and ending September 30, 2005. These major rules represent approximately 15 percent of the 292 final rules reviewed by OMB during this period, and approximately one percent of the 3,980 final rules published in the *Federal Register* during this period. OMB believes, however, that the costs and benefits of major rules capture the vast majority of the total costs and benefits of all rules subject to OMB review.[11]

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

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

Social Regulation

Of the 45 economically significant rules reviewed by OMB, 21 regulations require substantial private expenditures or provide new social benefits. We are able to present monetized costs and benefits for about 60 percent (13 of 21) of the rules, and for about 70 percent (13 of 19) of the non-homeland security rules. Since OMB began to compile this report, this is among the highest percentage of economically significant rules presenting both monetized costs and monetized benefits. In last year's Report, we were able to provide such monetized impacts for only 11 of 26 regulations.[14]

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

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

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

[14]V*alidating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, p. 12.

Table 1-3 presents total benefits and costs by agency of these major rules reviewed by OMB over the past year and Table 1-4 provides a summary of each regulation. These tables are the basis for the totals in the accounting statement in Section A of this chapter.

In assembling these tables of estimates of benefits and costs, OMB has applied a uniform format for the presentation of benefit and cost estimates in order to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates) and has monetized quantitative estimates where the agency has not done so. For example, we have converted agency projections of quantified benefits, such as estimated injuries avoided per year or tons of pollutant reductions per year, to dollars using the valuation estimates discussed in Appendices A and B. Table A-1 in Appendix A also reports the available impact information, as reported by the agencies, on all 21 of the social regulations reviewed by OMB in the time period covered by this Report.

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

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

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

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

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

Homeland Security Regulations

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

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

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

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

C. Regulations Implementing Federal Budgetary Programs

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

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

Department of Agriculture
Tobacco Transition Payment Program
Tobacco Manufacturer and Importer Assessments
2004 Livestock Assistance Program
2004 Crop Disaster Program
Conservation Security Program
User Fees for Agricultural Quarantine and Inspection Services
Department of Defense
Radio Frequency Identification

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

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

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

Please note that rules that transfer Federal dollars often have opportunity costs or benefits in addition to the budgetary dollars spent. Including budget programs in the overall totals would, however, overwhelm the incremental new regulatory impacts identified by this Report and would confuse the distinction between rules that impose costs primarily through the imposition of taxes, and rules that impose costs primarily through mandates on the private sector. We also caution the reader not to assume that these rules were subject to less stringent analytical and review

requirements based on our less-detailed presentation of Federal budget rules in this Report. In fact, agencies thoroughly analyze and OMB thoroughly reviews all significant Federal budget rules under E.O. 12866. If economically significant, these rules must be accompanied by regulatory impact analyses that comply with OMB Circular A-4.

D. Major Rules for "Independent" Regulatory Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) (Pub. L. No. 104-121) require the GAO to submit reports on major rules to the committees of jurisdiction, including rules issued by agencies not subject to Executive Order 12866, the so-called "independent" regulatory agencies. We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2004, to September 30, 2005. GAO reported that four of these agencies issued 11 major rules during this period.[15]

In comparison to the agencies subject to E.O. 12866, these agencies provided in their analyses relatively little quantitative information on the benefits of major rules: of the 21 economically significant rules reviewed by OMB, about 60 percent (13) reported monetized costs and benefits, whereas about 20 percent (2 of 11) of the rules finalized by independent agencies reported monetized costs and benefits according to the GAO reports. As Table 1-7 indicates, most of the rules included some 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 the Executive Order, since OMB does not review rules from these agencies.

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

Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Communications Commission	Broadcast Services: Television Stations [69 FR 69325]	No[16]	No	No
Federal Communications Commission	Promoting Efficient Use of Spectrum Through Elimination of Barriers to the Development of Secondary Markets [69 FR 77522]	No[14]	No	No
Federal Communications Commission	Private Land Mobile Services; 800 MHz Public Safety Interference Proceeding [69 FR 67823]	No[14]	No	No

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

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

Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Communications Commission	Facilitating the Provision of Spectrum-Based Services to Rural Areas and Promoting Opportunities for Rural Telephone Companies to Provide Spectrum-Based Services [69 FR 75144]	No[14]	No	No
Federal Trade Commission	Definitions and Implementation Under the CAN-SPAM Act [70 FR 3110]	No[14]	No	No
Nuclear Regulatory Commission	Revision of Fee Schedules [70 FR 30526]	Yes	No	Yes
Securities and Exchange Commission	Securities Offering Reform [70 FR 44722]	Yes	Yes	Yes
Securities and Exchange Commission	Regulation NMS [70 FR 37496]	Yes	Yes	Yes
Securities and Exchange Commission	Mutual Fund Redemption Fees [70 FR 13328]	Yes	No	Yes
Securities and Exchange Commission	Asset-Backed Securities [70 FR 1506]	Yes	No	Yes
Securities and Exchange Commission	Registration Under the Advisers Act of Certain Hedge Fund Advisers [69 FR 7205]	Yes	No	Yes

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

This chapter of the Report benefited from input we received from peer reviewers and commenters who responded to OMB's request for comments on the draft Report published earlier this year. [17] Peer reviewer 3 stated that the accounting statement is "useful and thorough and valuable to researchers interested in regulatory costs and benefits." Commenter F also stated that "OMB has improved upon this year's report by adding links to the Regulatory Impact Analysis for some of the rules listed in its cost and benefit estimates." Several commenters, however, doubted the overall approach, stating that the accounting statement is highly misleading by its nature, provides a false pretense of accuracy and objectivity, and reflects OMB's continued support for cost-benefit analysis, which some commenters stated was a fundamentally flawed methodology (E, F).

[17] See Appendix F for a listing of all the written comments we have received, and the numbers or letters we have assigned to their comments. The public and peer review comments are available for review at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

Comments on Scope/Coverage

Commenter (D) questioned OMB's decision to include only major rules in our benefit and cost totals. The commenter questioned whether this practice led OMB to neglect reporting the impact of many important rules and therefore to underestimate the total costs and benefits of Federal rulemaking. The commenter stated that since agencies themselves decide which rules are major, they are able to "game" their designations in order to avoid analysis of high impact rules.

In the Draft Report, we stated that we included only information on the benefits and costs of major rules because we believe that these costs and benefits capture the vast majority of the total costs and benefits of all rules subject to OMB review. A comprehensive reassessment of every significant rulemaking is beyond the scope of this Report. In the final 2004 Report, we reassessed the relative importance of major versus non-major rules for a selected group of agencies (OSHA, FDA, and NHTSA) and found that the costs and benefits of their significant, non-major rulemakings reviewed by OMB were a small fraction of the costs and benefits of their major rulemakings. We do see merit in periodically providing an in-depth review of major and non-major rules for individual agencies in order to continually test our assumptions regarding the relative importance of major rules.

Commenter D's characterization of the significance determination process is overly simplified. Under E.O. 12866, Section 6, agencies must submit a list of planned regulatory actions to OIRA, and the agencies and OIRA jointly determine which of these actions are significant, economically significant and major. OIRA reviews both significant and economically significant rules, and therefore has ample opportunity to explore whether the agency has properly considered and analyzed costs and benefits for rules that are not economically significant. We believe that this process provides a robust check on the accuracy of agency impact estimates.

Two peer reviewers (1 and 3) and commenter (E) discuss our treatment of homeland security regulations. Peer review (3) stated that although OMB did a good job in the 2003 Report discussing the difficulties associated with homeland security regulations, he hoped that was not our final word on the issue. Peer reviewer (1) suggested that OMB provide guidelines for the analysis of antiterrorism and homeland security regulation. Commenter (E) characterized that lack of monetized benefits for homeland security regulations as OMB giving these regulations a "free ride."

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. We disagree with Commenter E's characterization of our treatment of homeland security 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 requires an estimate of the probability and consequences of a terrorist attack. We recognize this type of analysis of terrorism risk is exceedingly difficult, and would invite comment in future reports on methods and tools to help facilitate this analysis. We also note that OMB Circular A-4, Regulatory Analysis, states that "In unusual cases where no quantified information on benefits, costs and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence." As a result of similar comment in

the 2005 Report, we provide a separate table summarizing the monetized cost and qualitative benefits for every major homeland security regulation.

Commenters (A, E, F) criticized our treatment of rules that implemented Federal budgetary programs, including our practice of excluding rules of this type from the cost and benefit totals. Many of these comments point out that rules designed to spend budget dollars also generate costs and benefits. Costs include the opportunity costs of tax revenue, and benefits are derived from the behavioral changes caused by the spending programs.

We agree that rules that transfer Federal budgetary programs often have opportunity costs or benefits in addition to the budgetary dollars spent. We continue to believe, however, that our approach of separately identifying budgetary rules has merit. OMB feels this Report is properly focused on regulations that impose costs primarily through private sector mandates, and not those regulations that facilitate Federal budget programs. We do see merit in providing more information about these rules, and we encourage agencies to use their professional judgment and to provide this information to the extent that it is available and practicable.

Peer reviewer (3) and Commenter (A) also questioned the designation of the Department of Homeland Security's Allocation of H-1B Visas Created by the H-1B Visa Reform Act of 2004 as a budget rule. OMB included this rule as a budgetary rule because the rulemaking itself only established that DHS would collect fees (specified in the Visa Reform Act) and allocate the new H-1B cap on a first-in, first-out basis. The rule does not change the limit on the number of H-1B Visas. The provision of the Visa Reform Act expanding the H-1B cap for non-immigrant aliens with an advanced degree from the U.S. was self-implementing 90 days after enactment. Since these fees increase revenues to government, and the rule does not otherwise contain a private sector mandate, we considered this a budget rule.

Commenter (A) encourages us to present more detailed information on the costs and benefits of independent agency rulemakings, stating that the exclusion of independent agency rulemakings causes the report to underestimate the total regulatory burden imposed by the government and therefore causes the report to be incomplete. OMB agrees that it is important to assess the benefits and costs of independent agency regulatory actions, and we do encourage independent agencies to conduct benefit-cost analyses that conform to our regulatory analysis guidance, and to submit those analyses of major rules to OMB. OMB also agrees with the suggestion that providing more information about independent agency estimates would be worthwhile, and will explore feasible ways of doing so in future reports.

Two commenters (E and F) claim that OMB arbitrarily excludes deregulatory actions from review, and that we have failed to address this criticism in previous reports. OMB disagrees that we arbitrarily exclude deregulatory actions from review, and we disagree that we have failed to address this criticism in previous reports. We offered a thorough response to this criticism in both the final 2004 Report (see page 29) and the final 2005 Report (see page 21).

Several commenters suggested that we add discussion on various subjects. Peer reviewer (1) suggested that we include a discussion of the costs and benefits of anti-trust activities in the Report. Commenter (A) suggested that we add discussion of regulations issued directly by Congress. OMB feels that a discussion of the costs and benefits of anti-trust activities, and

discussion of the costs and benefits of regulations issued directly by Congress, are beyond the scope of this Report.

Comments on the Overall Quality of Analysis

Most commenters suggest that we stress the limited nature of the statistics on costs and benefits throughout the Report. Commenter (G) disagreed with the "conclusion of the report" that the benefits of regulation exceed the costs. Several commenters (E, F) stated that the methodology of cost-benefits analysis is so unsound and inherently biased that any attempt to add the results together in an accounting statement was inherently misleading. One peer reviewer (1) also suggested that OMB summarize agency compliance with OMB guidance in order to encourage further standardization of agency analysis.

OMB agrees that we should emphasize the limitations of aggregating the costs and benefits of different regulations; we continue throughout these Reports to point out the inherent drawbacks of aggregating costs and benefits. We do not believe, however, that agency methodologies are so different that comparison across agencies is useless. For example, almost all agencies report results with a 7 percent discount rate, long required by OMB. Almost all agencies use similar methodologies for valuing fatalities avoided due to health and safety regulations. In addition, where benefits are primarily due to gains in economic efficiency, the market analysis that leads to an estimate of efficiency gains is fairly standardized.

We further note that in limited cases, as explained in the draft Report, OMB does adjust agency cost and benefit estimates to help ensure consistency in the context of this annual Report. First, all values were adjusted to 2001 dollars; next, quantified but non-monetized estimates were monetized; and finally, estimates of net present values were annualized to provide a yearly stream of benefits and costs. Nevertheless, OMB agrees with the goal of further standardization of agency analyses, and believes the best way to promote this is through the application of OMB Circular A-4, which was designed to promote consistent analytical approaches.

In addition to the uncertainties introduced by the aggregation of costs and benefits across regulations, some comments discussed the inherent uncertainty of regulatory analysis. In particular, commenters (A, E, and F), stated that the Report provides a false pretense of accuracy and objectivity when presenting the costs and benefits of regulation. Commenter A suggested that reporting numbers to the nearest million dollars means the estimates should be "correct" within a range of $1 million dollars, and since these estimates are certainly not precise to within this range, our presentation of estimates down to $1 million is inaccurate and inherently misleading. OMB has received several comments in the past in a similar vein.

OMB disagrees that we provide a false pretense of accuracy when presenting agency estimates of the costs and benefits of regulation. We discuss throughout the Report the many sources of uncertainty within individual rulemakings and the difficulty and uncertainty of aggregating different estimates of costs and benefits. For EPA rulemakings, which these comments discuss, the draft Report explained that the wide range of benefits estimates for clean air rules on controlling particulates does not capture the full extent of the scientific uncertainty.

OMB agrees with Commenter A that the central estimates of impact presented in the report are likely not accurate within a range of $1 million dollars; however, that does not mean that the central estimates of impact should be reported to a significantly fewer number of significant digits. The number of significant digits reflects the *precision* of an estimate, or the degree to which the estimate can be reproduced using the same set of input data. Since most agency impact analyses present estimates with a precision of $1 million, OMB presents estimates to that precision. The *accuracy* of the estimates, or the degree to which the estimate reflects the actual impact value, is different from precision. The uncertainty ranges presented along with the central estimate, however, is the proper way of characterizing accuracy, not presenting the central estimate only to the number of significant digits that reflect the uncertainty range.

Two commenters (E, F) suggest that the use of cost-benefit analysis has a major shortcoming. They state that cost-benefit analysis is inherently biased against regulation because it causes agencies to grossly overestimate the real cost to the economy and systematically underestimate the benefits of regulation. A major reason why benefits are underestimated, they state, is that cost-benefit analysis de-emphasizes important benefits that are non-quantifiable. Commenter (F) takes issue with what they state is OMB's finding, in our 2005 final report analysis comparing *ex-ante* and *ex-post* regulatory impact estimates, that costs are systematically underestimated and benefits are systematically overestimated.

OMB does not agree that cost-benefit analysis is inherently biased for or against regulation. Estimates are inherently uncertain, and we are aware of retrospective analyses that have found *ex-ante* costs and benefits to be both under and over estimated.[18] In addition, we explain in the Report that these major rules have important non-quantified benefits and costs, which may have been a key factor in an agency's decision to promulgate a rulemaking. Table A-1 in the Report thoroughly describes the important non-quantified costs and benefits associated with particular rulemakings.

The commenter also misstated the conclusions of our 2005 analysis. In the subset of impact estimates we studied, we concluded that *ex-ante* costs and benefits were both more likely to be *overestimated.* We did not conclude that *ex-ante* costs in our sample were systematically underestimated, as the commenter suggested. We also stated that our sample was necessarily a convenience sample and should be generalized with caution.

Several commenters made useful recommendations on the presentation of the Report. Peer reviewer (3) pointed out that when comparing the percent of major, economically significant rules reviewed by OMB that have monetized costs and benefits with the percent of major independent agency rules that have monetized costs and benefits, we should have added the two homeland security rulemakings. We agree, and have added these rulemakings to our

[18] For example, Harrington et al (2000), in an analysis of a sample of EPA and OSHA regulatory impact analyses, found that *ex-ante* per-unit abatement costs were overestimated about as often as underestimated. They also found that *ex-ante* total abatement costs were more likely to be overestimated than underestimated. Overestimation of total costs was primarily due to errors in estimating the quantity of benefits achieved by the rule, which suggests that the benefits of these rulemakings were overestimated as well, and to unanticipated technological change. Chapter III in the 2005 final Report discusses this and other retrospective studies of the impact of regulations in more detail.

totals in this comparison. Peer reviewer (3) also made a series of suggested clarifying edits in Chapter 1, most of which we adopted.

Although OMB did not make an explicit call for nominations for regulatory reform in the 2006 draft report, two commenters (B and C) provided comment on or suggestions for reforms. Commenter C reemphasized their 2004 manufacturing reform nomination to update a DOL/OSHA regulation requiring adherence to National Fire Protection Association (NFPA) 1969 fire standards for boat building. We provide an update on the status of this reform in Appendix E. Commenter B provided new suggestions for the reform of regulations implementing the Davis-Bacon Act and National Apprenticeship Act. OMB wishes to thank the commenters for these comments on specific regulatory reforms. We have forwarded these comments to DOL for further consideration.

In addition to the suggestions covered above, peer reviewer (1) made the suggestion that OMB facilitate the use of information markets to increase overall economic efficiency and to inform regulatory decision making. 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.

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

Sec. 624 (a)(2) of the Regulatory Right-to-Know Act calls on OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth.

Impacts on State, Local, and Tribal Governments

Over the past 10 years, 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 Act of 1995).[19]

- *EPA's Rule on Standards of Performance for Municipal Waste Combustors and Emissions Guidelines* (1995): This rule set standards of performance for new municipal waste combustor (MWC) units and emission guidelines for existing MWCs under sections 111 and 129 of the Clean Air Act [42 U.S.C. § 7411, 42 U.S.C. § 7429]. The standards and guidelines apply to MWC units at plants with combustion capacities greater than 35 mega grams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The EPA standards require sources to achieve the maximum degree of reduction in emissions of air pollutants that the Administrator

[19]We note that EPA's proposed rules setting air quality standards for ozone and particulate matter may ultimately lead to expenditures by State, local, or tribal governments of $100 million or more. However, Title II of the Unfunded Mandates Reform Act provides that agency statements of compliance with Section 202 must be conducted "unless otherwise prohibited by law". The conference report to this legislation indicates that this language means that the section "does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule." EPA has stated, and the courts have affirmed, that under the Clean Air Act, the primary air quality standards are health-based and EPA is not to consider costs.

determined is achievable, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements.

EPA estimated the annualized costs of the emissions standards and guidelines to be $320 million per year (in constant 1990 dollars) over existing regulations. While EPA estimated the cost of such standards for new sources to be $43 million per year, the cost to existing sources was estimated to be $277 million per year. The annual emissions reductions achieved through this regulatory action include, for example, 21,000 Mg. of sulfur dioxide; 2,800 Mg. of particulate matter (PM); 19,200 Mg of nitrogen oxides; 54 Mg. of mercury; and 41 Kg. of dioxins/furans.

- *EPA's Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills (1996):* This rule set performance standards for new municipal solid waste landfills and emission guidelines for existing municipal solid waste landfills under section 111 of the Clean Air Act. The rule addressed non-methane organic compounds (NMOC) and methane emissions. NMOC include volatile organic compounds (VOC), hazardous air pollutants (HAPs), and odorous compounds. Of the landfills required to install controls, about 30 percent of the existing landfills and 20 percent of the new landfills are privately owned. The remaining landfills are publicly owned. The total annualized costs for collection and control of air emissions from new and existing MSW landfills are estimated to be $100 million.

- *EPA's National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts (1998):* This rule promulgates health-based maximum contaminant level goals (MCLGs) and enforceable maximum contaminant levels (MCLs) for about a dozen disinfectants and byproducts that result from the interaction of these disinfectants with organic compounds in drinking water. The rule will require additional treatment at about 14,000 of the estimated 75,000 covered water systems nationwide. The costs of the rule are estimated at $700 million annually. The quantified benefits estimates range from zero to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of $0 to $4 billion per year. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

- *EPA's National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment* (1998): This rule establishes new treatment and monitoring requirements (primarily related to filtration) for drinking water systems that use surface water as their source and serve more than 10,000 people. The purpose of the rule is to enhance health protection against potentially harmful microbial contaminants. EPA estimated that the rule will impose total annual costs of $300 million per year. The rule is expected to require treatment changes at about half of the 1,400 large surface water systems, at an annual cost of $190 million. Monitoring requirements add $96 million per year in additional costs. All systems will also have to perform enhanced monitoring of filter performance. The estimated benefits include average reductions of 110,000 to 338,000 cases of cryptosporidiosis annually, with an estimated monetized value of $0.5 to $1.5 billion, and possible reductions in the incidence of other waterborne diseases.

- *EPA's National Pollutant Discharge Elimination: System B Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule expands the existing National Pollutant Discharge Elimination System program for storm water control. It covers smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain sources from the program based on a demonstration of the lack of impact on water quality. EPA estimates that the total cost of the rule on Federal and State levels of government, and on the private sector, is $803.1 million annually. EPA considered alternatives to the rule, including the option of not regulating, but found that the rule was the option that was "most cost effective or least burdensome, but also protective of the water quality."

- *EPA's National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring* (2001): This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 ppb to 10 ppb. It also revises current monitoring requirements and requires non-transient, non-community water systems to come into compliance with the standard. This rule may affect either State, local or tribal governments or the private sector at an approximate annualized cost of $206 million. The monetized benefits of the rule range from $140 to $198 million per year. The EPA selected a standard of 10 ppb because it determined that this was the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits, as required by the Safe Drinking Water Act.

Although these six EPA rules were the only ones over the past 10 years to require expenditures by State, local and tribal governments exceeding $100 million, they were not the only rules with impacts on other levels of governments. For example, 14 percent of the regulations listed in the April 2001 Unified Regulatory Agenda indicated some impact on State governments. The percentage of rules with such impacts on local and tribal governments was nine and six, 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. The Executive Order calls on the agencies to tailor their regulations by business size in order to impose the least burden on society, consistent with obtaining the regulatory objectives. It also calls for the development of short forms and other efficient regulatory approaches for small businesses and other entities. Moreover, in the findings section of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Congress stated that "... small businesses bear a disproportionate share of regulatory costs and burdens" (Section 202(2) of Pub. L. No. 104-121). Each firm has to determine whether a regulation applies, how to comply, and whether it is in compliance. As firms increase in size, fixed costs of regulatory compliance are spread over a larger revenue and employee base, which often results in lower regulatory costs per unit of output.

The Office of the Chief Counsel for Advocacy of the Small Business Administration (hereafter "Advocacy") recently sponsored a study (Crain 2005) that estimated the burden of

regulation on small businesses.[20] This is the third in a series of studies on small business regulation conducted on behalf of the Office of Advocacy.[21] 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 under 20 employees compared to firms with over 500 employees.

Because of this relatively large impact of regulations on small businesses, President Bush issued Executive Order 13272 of August 13, 2002, which reiterates the need for agencies to assess the impact of regulations on small businesses under the Regulatory Flexibility Act (RFA) (5 U.S.C. § 601-612). Under the RFA, whenever an agency comes to the conclusion that a particular regulation will have a significant economic impact on a substantial number of small entities, the agency must conduct both an initial and final regulatory flexibility analysis. This analysis must include an assessment of the likely burden of the rule on small entities, and an analysis of alternatives that may afford relief to small entities while still accomplishing the regulatory goals.

Advocacy reports annually on the overall performance of agency compliance with the RFA and Executive Order 13272, and Advocacy efforts to improve the analysis of small business impacts and to persuade agencies to afford relief to small businesses.[22] The 2005 comprehensive report contains four main sections. Section one provides a brief overview of the RFA, as amended by SBREFA. Section two provides a summary of agency compliance with the RFA and E.O. 13272 for FY 2005. Section three details Advocacy's role in reviewing particular rulemakings during FY 2005. Section four provides a summary of Advocacy's activities encouraging States to adopt Small Business Regulatory Flexibility Model Legislation. Please visit Advocacy's website at http://www.sba.gov/advo to learn more about Advocacy, review regulatory comment letters, and obtain useful research relevant to small entities.

Impact on Wages

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

1. Social Regulation

Social regulation—defined as rules designed to improve health, safety, and the

[20]Crain, W.M. 2001. "The Impact of Regulatory Costs on Small Firms." Report prepared for the Office of Advocacy, U.S. Small Business Administration. Available at http://www.sba.gov.
[21]The other two reports are Hopkins, T., 1995, "Profiles of Regulatory Costs;" and Crain, W.M. and T. Hopkins 1999, "The Impact of Regulatory Costs on Small Firms." These reports are also available on Advocacy's website.
[22]Office of Advocacy, U.S. Small Business Administration 2004. *Report on the Regulatory Flexibility Act, FY 2003: The Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act and Executive Order 13272*. Available at: http://www.sba.gov.

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."[23]

In the occupational health standards case, where the benefits of regulation accrue mostly to workers, workers are likely to be better off if health benefits exceed compliance costs and such costs are not borne primarily by workers.[24] Although wages may reflect the cost of compliance with health and safety rules, the job safety and other benefits of such regulation can compensate for the monetary loss. Workers, as consumers benefiting from safer products and a cleaner environment, may also come out ahead if regulation produces significant net benefits for society.

2. Economic Regulation

For economic regulation, defined as rules designed to set prices or conditions of entry for specific sectors, the effects on wages may be positive or negative. Economic regulation can result in increases in income (narrowly defined) for workers in the industries targeted by the regulation, but decreases in broader measures of income based on utility or overall welfare, especially for workers in general. Economic regulation is often used to protect industries and their workers from competition. These wage gains come at a cost in inefficiency from reduced competition, a cost which consumers must bear. Workers wages do not go as far when prices for goods that are inefficiently produced are relatively higher. Moreover, growth in real wages, which are limited generally by productivity increases, will not grow as fast without the stimulation of outside competition.[25]

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

Economic Growth and Related Macroeconomic Indicators

The strongest evidence of the impact of smart regulation on economic growth is the differences in per capita income growth and other indicators of well being experienced by countries under different regulatory systems. A well-known example is the comparison of the growth experience of the present and former Communist state-controlled economies with the

[23]From Ehrenberg, R. and R. Smith 1991. *Modern Labor Economics*, 4th Edition. HarperCollins, p. 279.
[24]Based 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).
[25]Winston (1998) estimates that real operating costs declined 25 to 75 percent in the sectors that were deregulated over the last 20 years—transportation, energy, and telecommunications. See Winston, C. (1998), "U.S. Industry Adjustment to Economic Deregulation", Journal of Economic Perspectives 12(3): 89-110.

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.[26]

Several groups of researchers have developed indicators of economic freedom to rank countries and compare their economic performance. Since 1995, the Heritage Foundation and the *Wall Street Journal* have published jointly a yearly index of economic freedom for 161 countries. They find a very strong relationship between the index and per capita GDP.[27] The index, based mostly on subjective assessments by in-house experts, is composed of 50 independent variables divided into 10 broad factors that attempt to measure different aspects of economic freedom: trade policy, fiscal burden, government intervention, property rights, banking and finance, wages and prices, regulation, and informal market activity. A correlation between degrees of economic freedom and per capita GDP does not prove that economic freedom causes economic growth. Economic growth could cause economic freedom or both could be correlated with an unknown third factor. More suggestive is the data on changes in these indicators. The authors examine the relationship between the change in the index since 1995 and the average GDP growth rate over seven years. After grouping the 142 countries (for which they had complete data) into quintiles, they find a very strong association between improvement in the index and growth rates. The first quintile of countries grew at a rate of 4.9 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 for 123 countries.[28] The rank of the top ten economies is Hong Kong (1), Singapore (2), New Zealand, Switzerland, the United Kingdom, and the United States (3), Australia and Canada (7), and Ireland and Luxembourg (9). The index, which is based on 38 variables, many of them from surveys published by other institutions, measures five major concepts: size of government, legal structure and security of property rights, access to sound money, freedom of exchange with foreigners, and regulation of credit, labor, and business. The latest report finds that the index is highly correlated not just with per capita income and economic growth, but with other measures of well being, including life expectancy, the income level of the poorest 10 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 costs and benefits produced by regulation.

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

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

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

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

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.[29] The second volume (*Doing Business in 2005, Removing Obstacles to Growth)* updates these measures and adds data about registering property and protecting investors.[30] 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. [31] The first volume contained three major conclusions:

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

The second volume added three more main findings:

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

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

The World Bank also finds that rich countries regulate less in all respects covered in the report and that common law and Nordic countries regulate less than countries whose legal systems are based on socialist principles. The top ten countries ranked on the ease of doing business based on the ten indicators are in order: New Zealand, Singapore, the United States, Canada, Norway, Australia, Hong Kong (China), Denmark, the United Kingdom, and Japan.[32]

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[29]World Bank. *Doing Business in 2004: Understanding Regulation*. Oxford Press. Washington, DC.
[30]World Bank. *Doing Business in 2005: Removing Obstacles to Growth*. Oxford Press. Washington, DC.
[31]Word Bank. *Doing Business in 2006: Creating Jobs*. Washington, DC.
[32]See *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.

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

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

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

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

It is interesting to note that these principles correspond fairly closely to the principles of regulatory reform that the U.S. has attempted to follow over the last 25 years.[33]

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

"The empirical results suggest that regulatory reforms have positive effects not only in

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

product markets, where they tend to increase investment, innovation and productivity, but also for employment rates."[34]

According to the OECD's database of objective measures assembled in 2001, the OECD countries with least restrictive regulation in order are: the United States, the United Kingdom, Canada, Ireland, and New Zealand and the five with the most restrictive regulation in order are: Portugal, Greece, Italy, Spain, and France.[35] One of the most interesting findings of the OECD work is that the least regulated countries tended to show the greatest improvement in their rates of multifactor productivity growth over the 1990s compared to the 1980s. Those countries also tended to show both the largest increase in the number of new small and medium-sized firms and in the rate of investment in research and development in manufacturing. These factors are thought to be important in increasing the growth rate of productivity and per capita income.

The major efforts to determine the effect of regulatory policies on economic performance described all use quite different indicators of regulatory quality and include different types of regulation, yet reach very similar conclusions. Nicoletti and Pryor examined three different indices of regulation, one objectively estimated and two based on subjective surveys of businessmen; one that just examined product markets, one that examined product and labor markets and one that includes financial and environmental regulations. The paper found statistically significant correlations among the three indices despite the differences in coverage and methodologies.[36] A second group of researchers, who have done work for the World Bank, also finds a strong correlation between regulation of entry into markets and the regulation of labor. They attribute this to their finding that the legal origin of regulation explains regulatory style. As they put it … "countries have regulatory styles that are pervasive across activities and shaped by the origin of their laws."[37] Thus, countries with good records on entry regulation (which they point out includes some environmental regulation) also have good records on labor regulation.[38]

A more recent body of literature, which combines the data sets of regulatory indicators discussed above as well as others, provides additional support to the supposition that excess regulation tends to reduce growth. Several papers by Loayza, Ovieda, and Serven 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.[39] These studies also find that when the quality of regulation as measured by indicators of better governance (such as democratic accountability and absence of

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[34]Giuseppe 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).

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

[36]*Ibid.*

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

[38]*Ibid.*

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

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" regulation[40]—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.[41]

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.[42] 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.[43] For social regulation, Circular A-4 requires an analysis of the costs and benefits of regulations and their alternatives. In this case, smarter regulation may cause rules that are more stringent, less stringent, or just better designed to be more cost-effective. Regulation that utilizes performance standards rather than design standards or uses market-oriented approaches rather than direct controls is often more cost-effective because it enlists competitive pressures for social purposes. Social regulation often clarifies or defines property rights so that market efficiency is enhanced. Regulation that is based on solid economic analysis and sound science is also more likely to provide greater benefits to society at less cost than regulation that is not.[44] 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

[40]The U.S. uses the term "Smarter Regulation" and the UK, Canada, Ireland and the EU all use the term "Better Regulation" to describe their reform programs.

[41]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.

[42]Note 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 our now using the term product market and labor market regulation to describe the different types of regulation.

[43]Although many of the rules reviewed by OMB are social regulation, OMB also reviews many economic regulations and many social regulations have economic components. For example, OMB 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.

[44]The 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.

economic growth and well being.

G. Response to Peer Reviews and Public Comments on Economic Growth and Related Macroeconomic Indicators

In contrast to last year's Report, OMB received relatively little comment on this section. Similar to last year's Report, commenter (E) stated that our discussion of the impact of regulations on growth was misleading and "anti-regulatory" and that we concluded that social regulation was harmful to growth. Commenter (F) states that this section poses a false and misleading trade-off between corporate competitiveness and protection of the public. It was our intent to emphasize that these findings implied that economic growth is enhanced by "smarter" or "better" regulation that relies on competition, when appropriate, and careful analysis to design cost-effective regulation when that is appropriate. We have tried to clarify that regulatory reform to enhance growth and social welfare includes improving the quality (including sometimes the amount) of regulation.

CHAPTER II: TRENDS IN BENEFIT AND COST ESTIMATES

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

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

The best measure of the overall value of regulation is net benefits; that is, benefits to society minus costs to society. Below we present cost and benefit measures for the years 1992 to 2005 for 124 rules, for which reasonably complete monetized estimates of both costs and benefits 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.[45]

In exploring the impact of rulemaking on the economy in the early 1980's, we found that several important de-regulatory actions resulted in a net decrease in compliance costs in the first two years of the Reagan Administration. We include the net cost savings generated by these regulations as "negative costs" for those years. To be consistent, we have also modified our estimates for later years to include regulatory actions that reduced net costs. In 2004, DOT issued two regulations that resulted in net cost savings: one rule reduced minimum vertical separation for airspace and the second increased competition in the computer reservation system for airline travel. In addition, OSHA's ergonomics rule issued November 14, 2000 but repealed by Senate Joint Resolution No. 6 passed by Congress and signed by the President in March 2001 (Pub. L. No. 107-5) is recorded as a $4.8 billion cost addition in 2000 and a $4.8 billion cost savings in 2001. This approach is consistent with treatment for earlier years. Another important change is the inclusion of DOT's 1993 air bag rule, which had been left out of our calculations in 1993 because Congress had mandated the rule.[46] We made this change to be consistent with

[45]To present cost and benefit 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.
[46]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 costs and benefits of airbags would have been provided by the market.

OMB Circular A-4, Regulatory Analysis, issued in September 2003. The Circular states that in situations where a rule simply restates statutory requirements, incremental costs and benefits should be measured relative to the pre-statute baseline.

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

Figure 2-1 presents the cost estimates from January 20, 1981 through September 30, 2005. Over the last 25 years, $123 billion of annual regulatory costs (2001 dollars) have been added by the major regulations issued by the Executive Branch agencies and reviewed by OMB. This means that, on average, almost $5 billion in annual costs have been added each year over this period. Several patterns are present. Note, in particular, the tendency for regulatory costs to be highest in the last year before a President leaves office (1988, 1992, and 2000). Note also that, while we have not yet reached the final year of this Administration, to date the annual average increase in regulatory costs in this Administration is lower than in any of the three previous Administrations. While the comparison will not be complete until data from 2008 are included, OMB can report that the average annual costs of the regulations issued during this Administration were 54 percent lower than the average annual costs of the regulations issued during the previous 20 years, and 64 percent lower than those issued during the previous eight years.

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

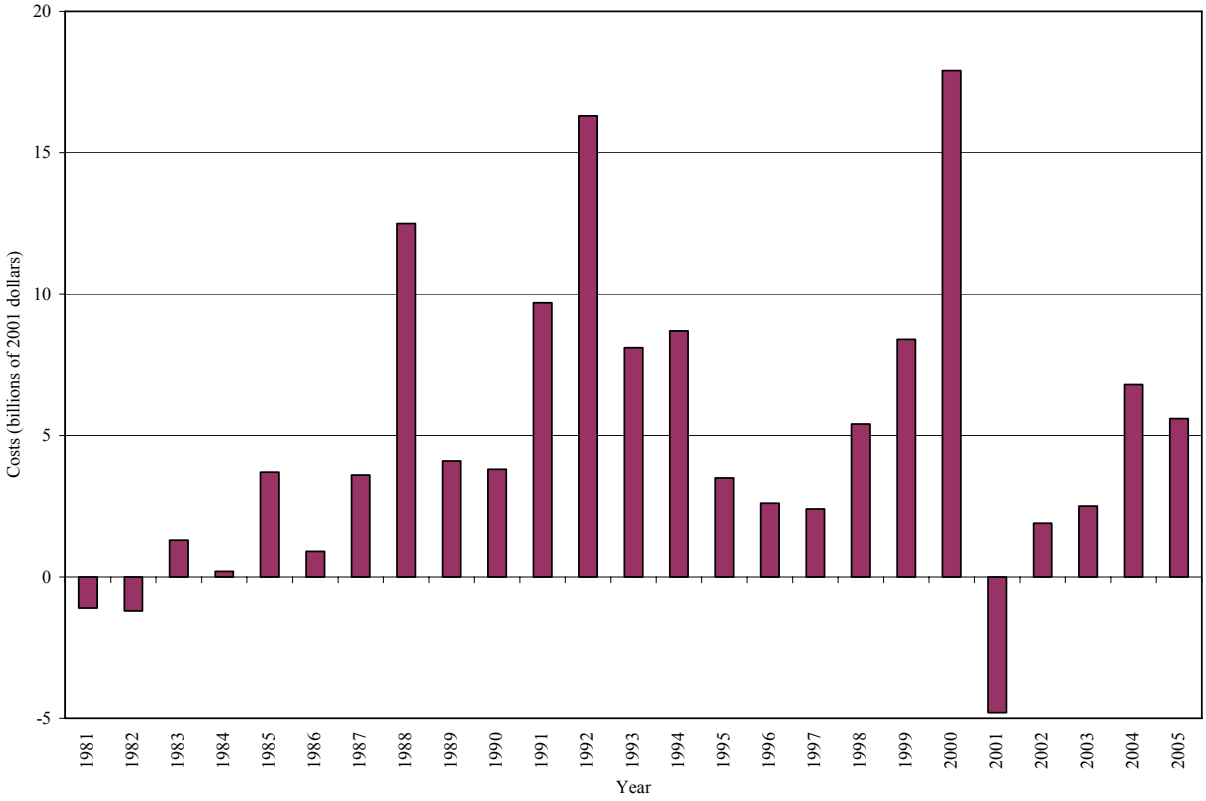
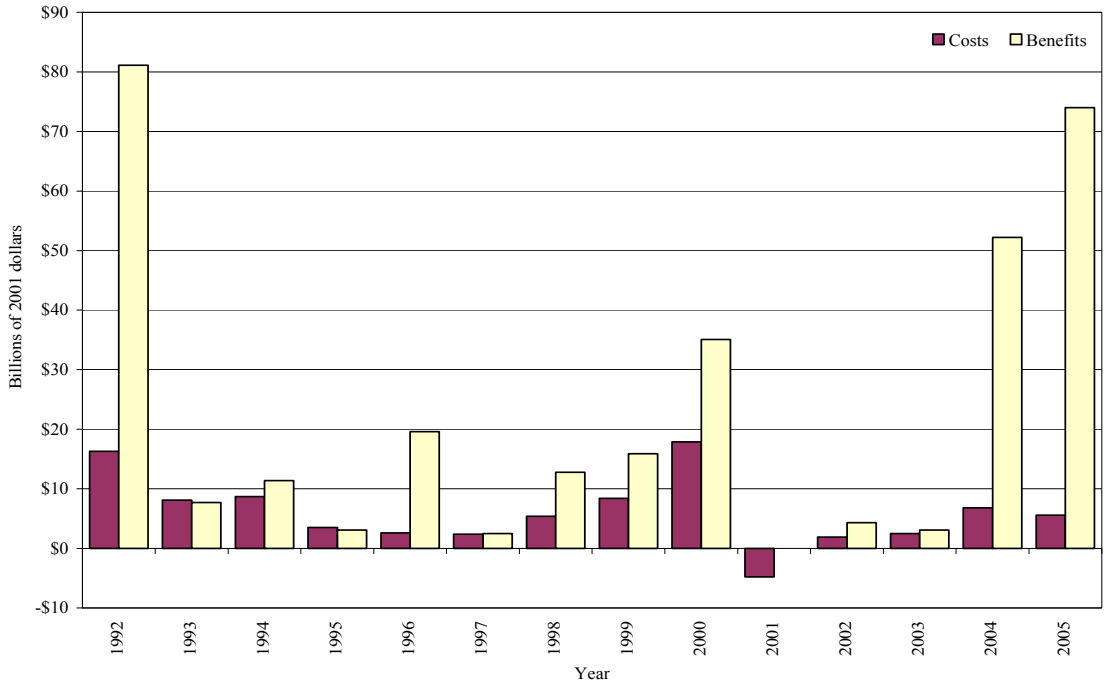


Figure 2-2 shows the costs and benefits of major rules issued from October 1, 1992, to September 30, 2005. Benefit estimates for the rules (with two noted exceptions)[47] that comprise the overall estimates are presented in various tables in the eight annual Reports (including this Report) that OMB has 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 and the 2004 non-road diesel engine rule, and the 2005 interstate air quality rule. Since more major rules had cost estimates than benefit estimates, it is likely that benefit estimates are understated relative to the cost estimates included in Figure 2-2. The figure also shows that, during its first 56 months in office, this Administration has issued regulations with average yearly benefits 112 percent greater than the average annual benefits of the rules issued during the previous eight years.

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

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



The difference between cost and benefits shows the net benefits of major regulations from 1992 though September 2005. 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 cost estimates since some rules had estimated costs but not estimated benefits.[48] Figure 2-2 also shows that this Administration issued regulations with net benefits over its first 56 months at a yearly average rate that is 280 percent greater than the rate of net benefits produced by the regulations issued during the previous Administration.

However, we wish to emphasize that (1) these are ex ante *estimates*, (2) as discussed in other sections of this Report (see Appendices A and B) as well as previous Reports, the aggregate estimates of costs and benefits derived from different agency's estimates and over different time periods are subject to methodological inconsistencies and differing assumptions, and (3) the groundwork for the regulations issued by one administration are often begun in a previous administration.[49]

[48]In 1993 and 1995, costs exceeded benefits by about $400 million in each year.

[49]For 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.

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

One peer reviewer (3)[50] expressed concern about comparisons of regulatory performance across presidential administrations. In making this comment, this peer reviewer noted the absence of a statutory mandate in the Regulatory Right-to-Know Act that OMB make these comparisons, as well as several methodological problems with OMB's approach. First, the commenter questioned why OMB included the costs of OSHA's ergonomics rule but not its benefits, which was a concern raised by peer reviewers of last year's Report. As we discussed in the 2005 Report, the ergonomics rule was overturned in 2001 when Congress—for the first and only time—used a provision of the Congressional Review Act. Moreover, we explained that the benefits that OSHA predicted would occur in ten years as a result of the regulation were exceeded without the regulation by over 50 percent within just three years.

The same peer reviewer also asked that, given the noted pattern of relatively high regulatory costs in the final year of a presidency, OMB acknowledge that comparisons between the current Administration and others is incomplete, since we have not reached its final year. While we have emphasized that these are ex ante estimates, we have acknowledged the specific issue raised by the peer reviewer.

Finally, the peer reviewer argued that comparing average annual costs and benefits of regulations issued during this Administration with previous years is misleading, since other metrics could lead to different conclusions regarding the relative performance of different administrations. The peer reviewer suggested metrics such as total net benefits of regulations or the number of regulations with either net benefits or net costs promulgated by different administrations. OMB would note that Figure 2-2 provides both the costs and benefits of major rules issued from October 1, 1992 to September 30, 2005, and thereby indicates the total net benefits for each year.

One public commenter (E) questioned the usefulness of comparing regulatory costs and benefits in isolation, since costs must be compared with benefits to assess regulatory performance. As a general matter, OMB agrees with the commenter. As this commenter acknowledged, Figure 2-2 does provide a comparison of costs and benefits. The commenter did, however, criticize OMB's treatment of three rules—EPA's non-road diesel engine and the clean air interstate rules and OSHA's ergonomics rule—as unfairly attributing regulatory gains to the Bush Administration rather than the Clinton Administration. As OMB emphasized in the draft Report, one Administration may lay the groundwork for regulations promulgated by the next Administration. OMB's decision to count the costs and benefits of the two EPA implementing rules—versus the 1997 rulemaking—was based on our conclusion that they better described the nature and timing of these impacts. OMB's treatment of the ergonomics rule is consistent with our approach in previous years.

Another commenter (F) criticized the comparison of net benefits across administrations

[50]See Appendix E for a listing of all the written comments we have received, and the numbers or letters we have assigned to their comments. The peer review and public comments are available for review at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

because (1) they are based on underlying cost benefit analyses that the commenter previously questioned on methodological grounds and (2) they are political in nature. OMB disagrees with the commenter on both points. OMB has responded—in Chapter I of this report and in previous reports—to both the methodological criticisms of cost benefit analysis offered by the commenter and the acknowledged limitations of cost benefit analysis and the difficulties inherent in aggregating them. Despite these difficulties, we believe our guidelines ensure that costs and benefits reported by the agencies are not political in nature, but rather represent an objective view of the expected impact of regulations. We also believe this information is useful in reporting to Congress on Federal regulatory performance, and we believe there is interest in how this performance has evolved over time.

CHAPTER III: INTERNATIONAL DEVELOPMENTS IN REGULATORY POLICY

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

It is important to note that efforts to facilitate international trade and harmonize regulation are done in a manner that respects national sovereignty. As has been noted by the United States Trade Representative (USTR), none of the provisions in the World Trade Organization (WTO) agreements, North American Free Trade Agreement (NAFTA), or other Free Trade Agreements restricts the authority of the United States to enact or enforce domestic laws and regulations that protect American businesses, State, local, and tribal governments, consumers, public health and safety, and the environment.[51] Rather, all of these agreements call on governments to ensure that the standards that they develop are non-discriminatory, transparent, and not unnecessarily trade restrictive.

This chapter of the 2006 Report to Congress on the Costs and Benefits of Federal Regulations provides an update on recent developments in international regulatory cooperation. While the U.S. has embarked on several cooperative initiatives with a number of trading partners, this chapter focuses on the U.S.'s cooperation activities with the European Union (EU) and with its North American neighbors, Canada and Mexico. Specifically, we provide a brief description of sectoral activities and horizontal initiatives between the EU and the U.S.[52] We also discuss the Security and Prosperity Partnership of North American, including our joint effort with Canada and Mexico to develop a framework for regulatory cooperation.

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

U.S. and EU efforts to increase transatlantic regulatory cooperation are based on a mutual recognition that most remaining transatlantic trade barriers are due primarily to regulatory differences, not to tariffs. The rationale for promoting transatlantic trade through greater regulatory cooperation is clear. The U.S.-EU bilateral trade and investment relationship is the largest in the world, with approximately 14 million jobs in the U.S. and EU depending on transatlantic commerce.[53] Mutual understanding of the central importance of this bilateral trade relationship led to a 2002 agreement on U.S.-EU Guidelines on Regulatory Cooperation and

[51]See USTR Fact Sheet on State Sovereignty and Trade Agreements, April 14, 2005, available at: http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2005/asset_upload_file870_7578.pdf

[52]For a detailed comparison of the European Commission's guidelines and OMB's guidance to agencies on regulatory impact analysis, see Appendix D.

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

Transparency, which set the stage for subsequent initiatives to facilitate transatlantic trade through the easing of regulatory barriers.[54]

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

The Commission's interest in better regulation was underscored in June 2005 when the Commission issued updated guidelines on conducting impact assessments of Commission regulatory proposals.[55] The guidelines were revised to ensure that Commission policymakers consider policy options other than "classical" forms of regulation, and they emphasized the principles of subsidiarity (determining whether EU regulation is more appropriate than regulation by member states) and proportionality (limiting regulation to what is necessary to achieve policy objectives). In announcing the new guidelines, President Barroso said, "This Commission is serious about cutting-red tape and reducing unnecessary regulation." Commission Vice President Günter Verheugen added, "Better impact assessments will bring more coherence and quality and self-restraint to the Commission's work. We want to be able to say what our proposals mean in practice to have a sound basis for policymakers."[56]

Recent U.S.-EU Summits have underscored the strong transatlantic commitment to improving regulatory cooperation between American and Commission authorities. Stakeholders on both sides of the Atlantic have supported these efforts. Most recently, on June 20, 2005, the United States and the Commission issued the 2005 Roadmap for U.S.-EU Regulatory Cooperation and Transparency,[57] as part of a broader Initiative to Enhance Transatlantic Economic Integration and Growth. The 2005 Roadmap builds upon and expands existing U.S.-EU regulatory activities. Specifically, the 2005 Roadmap called for the

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

The aims of the 2005 Roadmap are to promote better quality regulation, minimize regulatory differences, increase consumer confidence, and facilitate transatlantic commerce, all

[54]U.S. Trade Representative Robert Zoellick and Commerce Secretary Don Evans reached agreement on the guidelines with their EU counterparts on April 12, 2002. The guidelines are available at http://www.ustr.gov/assets/Document_Library/Press_Releases/2002/April/asset_upload_file474_2045.pdf

[55]The EC's Impact Assessment Guidelines are available at http://ec.europa.eu/governance/impact/docs/key_docs/sec_2005_0791_en.pdf

[56]EC Press Release: "Better regulation: Commission strengthens rules for impact assessments," June 15, 2005, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/733&format=HTML&aged=0&language=en&guiLanguage=en

[57]For detailed information about 2005 Roadmap, go to: http://www.ustr.gov/World_Regions/Europe_Middle_East/Europe/U.S._EU_Regulatory_Cooperation/2005_Roadmap_for_EU-U.S._Regulatory_Cooperation_Transparency.html

while respecting the regulatory autonomy of the U.S. and the EU. The Roadmap outlined a range of proposed cooperative initiatives that the United States and the Commission planned to advance in 2005-06, including specific sectoral activities and horizontal initiatives to address cross-cutting matters. These cooperative initiatives are described below.

Sectoral Initiatives

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

Another sector, automobile safety regulation, is the focus of collaboration between the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) and the EC's Directorate General for Enterprise and Industry (DG Enterprise), Automobile Unit. The initiative on automobile safety builds on an existing regulatory dialogue between NHTSA and DG Enterprise that was established in June 2003. This dialogue has addressed a number of topics, including regulatory cooperation on the safety of hydrogen fuel cell vehicles and vehicle compatibility. Moving forward, NHTSA and DG Enterprise will develop workplans for these regulatory cooperation projects. In addition, they have agreed to explore other areas of possible cooperation, such as collision mitigation technologies, electronic stability systems, and international harmonization of dummies used in side-impact vehicle crash tests. Box 3-1 provides background on related efforts by NHTSA and DG Enterprise to promote a science-based approach to global technical regulations (GTRs) under the 1998 United Nations Economic Commission for Europe (UN/ECE) Global Agreement on Vehicle Regulation.

Box 3-1: 1998 Global Agreement on Vehicle Regulation[58]

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

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

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

Horizontal Initiatives

In the Annex to the June 2005 Initiative to Enhance Transatlantic Economic Integration and Growth, U.S. and EU leaders agreed to establish a senior-level dialogue on best regulatory policies and practices and identify resources and mechanisms for exchanges of U.S. and EU regulatory experts.[59] These horizontal, cross-cutting initiatives include general exchanges of information about approaches to regulation in the U.S. and in the EU and discussion of cross-cutting matters of regulatory practice, including comparisons of how regulatory impact assessments are conducted on both sides of the Atlantic.

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

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

[59]http://www.ustr.gov/World_Regions/Europe_Middle_East/Europe/U.S._EU_Regulatory_Cooperation/2005_Road map_for_EU-U.S._Regulatory_Cooperation_Transparency.html

The U.S. and the Commission also agreed to launch a Regulatory Cooperation Forum in 2006. The EC hosted the initial event in Brussels in January 2006, attended by then OIRA Administrator John Graham, that focused on good regulatory practices. A second event held in May 2006 addressed best cooperative practices and identified possible new areas for regulatory cooperation.

B. Security and Prosperity Partnership of North America

On March 23, 2005, the leaders of Canada, Mexico, and the U.S. announced the Security and Prosperity Partnership of North America (SPP). The SPP is a trilateral effort to increase security and enhance prosperity among the three countries through improved cooperation and information-sharing. The work is focused on specific bilateral and trilateral security and prosperity initiatives involving the three governments. The importance of the SPP was emphasized in a September 2006 report to leaders prepared by Secretary of State Condoleezza Rice, Secretary of Homeland Security Michael Chertoff, Secretary of Commerce Carlos Gutierrez, and their Canadian and Mexican counterparts:

> The SPP initiatives form a comprehensive agenda for cooperation among the three countries of North America while respecting the sovereignty and unique cultural and legal heritage of each country. Even more importantly, we believe that the SPP is making an impact in developing a culture of cooperation among three North American neighbors.[60]

U.S. participation in the SPP is grounded in fundamental security and economic interests. With respect to the economic rationale for increasing North American cooperation, trade statistics clearly demonstrate the extent to which American prosperity is dependent on our economic relationship with Canada and Mexico. In 2005, Canada had exports to the U.S. amounting to $290.4 billion (83.9 percent of Canada's total exports). Mexico's exports to the U.S. amounted to $170.1 billion (85.7 percent of Mexico's total exports). The U.S. had exports to Canada of $212 billion (23.4 percent of total U.S. exports) in 2005. U.S. exports to Mexico were $120 billion (13.3 percent of the U.S. total). In comparison, in 2005 the U.S. had exports to the 25 EU countries of $186.4 billion. In fact, U.S. two-way trade in goods with Canada and Mexico in 2005 exceeded U.S. two-way trade with the 25 members of the European Union and Japan combined.[61]

Recent SPP Prosperity Activities

Following up the leaders' initial March 2005 meeting, in June 2005, Secretaries Gutierrez and Chertoff met their Canadian and Mexican counterparts in Ottawa to issue an initial report to the heads of state providing initial results, key initiatives, and an annex containing the workplans for the many working groups involved. Since then, the three governments have sought input from the private sector. In March 2006, the Council of the Americas and the U.S. Chamber of

[60] http://www.spp.gov/2006_report_to_leaders/index.asp?dName=2006_report_to_leaders

[61] U.S. Census Bureau, Foreign Trade Division, "FT-900: U.S. International Trade in Goods and Services - Annual Revision for 2005," available at http://www.census.gov/foreign-trade/Press-Release/2005pr/final_revisions/05final.pdf

Commerce convened a private roundtable discussion with the Secretary of Commerce, the Canadian Deputy Minister of Industry, and an official from the Mexican Presidency. The purpose of this meeting was to bring representatives from the private sector together with the government leaders to discuss the SPP.

In March 2006, President Bush met with Prime Minister Stephen Harper and President Fox in Cancun, Mexico. They announced five high priority initiatives for the Security and Prosperity Partnership that warranted special attention in the coming year: the North American Competitiveness Council (NACC), Advancing Cooperation on Avian and Pandemic Influenza, North American Energy Security Initiative, North American Emergency Management, and Smart, Secure Borders. They also announced a large number of bilateral and trilateral accomplishments enhancing economic prosperity and national security.

In June 2006, North American business leaders met in Washington, D.C. to launch officially the NACC. The NACC is a trilateral group of high level business leaders who will meet annually with the SPP Prosperity and Security ministers to provide recommendations and priorities on promoting North American competitiveness globally.

Regulatory Cooperation Framework

In addition to regulatory-related initiatives contained in the workplans, one of the SPP initiatives commits the three countries to develop a trilateral Regulatory Cooperation Framework by 2007.[62] The three governments are currently working together on this important initiative. The goal of the framework is to support and enhance existing cooperation as well as encourage new cooperation among regulators, including at the outset of the regulatory process. It will also encourage the compatibility of regulations and the reduction of redundant testing and certification requirements, while maintaining high standards of health and safety. At the last leaders' meeting, the two Presidents and the Prime Minister emphasized that:

> We are convinced that regulatory cooperation advances the productivity and competitiveness of our nations and helps to protect our health, safety and environment. For instance, cooperation on food safety will help protect the public while at the same time facilitate the flow of goods. We affirm our commitment to strengthen regulatory cooperation in this and other key sectors and to have our central regulatory agencies complete a trilateral regulatory cooperation framework by 2007.[63]

Officials from the three governments have been working together since December 2005 to draft a Framework. This work included a seminar on North American regulatory cooperation that the Department of Commerce hosted in April 2006, which provided the basis for possible elements to be included in the Framework, such as transparency and information sharing. Discussions about the Framework continue, and it is expected that the Framework will be announced in 2007.

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

[63]The March 2006 Leaders Statement is available at: http://spp.gov/pdf/security_and_prosperity_partnership_of_north_america_statement.pdf

C. Other International Initiatives

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

APEC-OECD Integrated Checklist for Regulatory Reform

U.S. efforts within APEC have focused on the Integrated Checklist for Regulatory Reform. The Integrated Checklist is a self-assessment tool that reflects a holistic approach to regulatory reform, including regulatory, anti-trust, and market-openness policies.[64] The Checklist was the product of the APEC-OECD Cooperative Initiative on Regulatory Reform, a collaborative effort between APEC and the OECD. Following the endorsement of the Integrated Checklist at a June 2005 ministerial-level meeting held in Jeju Island, Korea, APEC has begun a dialogue on capacity building, which will include the voluntary use of the Integrated Checklist in country self-assessments. The Integrated Checklist was discussed at a September 12, 2006, meeting of the APEC Economic Committee at which the United States was one of three economies to present the results of the Integrated Checklist. At this meeting, the U.S. delegation provided a response to the Checklist, which was received with interest from the other economies in APEC.

OECD Work on Regulatory Management and Reform

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

One of these issues is regulatory management and reform. In 1995, OECD Ministers asked the OECD to assess the regulatory policies of member countries. The resulting 1995 Recommendations for Improving the Quality of Government Regulation were the first-ever internationally accepted statement of regulatory principles.[65] The OECD expanded its examination of regulatory policy to include market openness and anti-trust policy in a multidisciplinary framework—embodied in the 1997 Recommendations for Regulatory Reform—which it used to review reform efforts in member countries. To date, the OECD has conducted 20 country reviews, including the first review of a non-member country: Russia.

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

[65] See *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations*, p. 65. http://www.whitehouse.gov/omb/inforeg/2002_report_to_congress.pdf

Based on the lessons learned from the country reviews and developments in member countries, in April 2005 the OECD adopted Guiding Principles for Regulatory Quality and Performance.[66] While the 2005 principles reaffirmed the 1997 recommendations, several issues were given more prominence, including policy coherence through multi-level governmental coordination, ex ante impact assessments of regulatory policies, and market openness.

D. Response to Peer Reviews and Public Comments on International Developments in Regulatory Policy

One peer reviewer (2) provided, at OMB's request, extensive comments on this chapter. Specifically, the peer reviewer recommended that OMB retain the equivalent of this chapter in future Reports, noting the ongoing nature of the international activities. The commenter also suggested that OMB devote significantly more attention to the SPP, particularly with respect to the development of the SPP Regulatory Cooperation Framework and the institutional responsibilities within the Executive Office of the President for overseeing the U.S. Government's participation in the SPP. With respect to the first recommendation, OMB agrees that the regulatory activities described in this report will continue and that future updates on new developments and achievements are likely to warrant inclusion in future Reports.

OMB also agrees that the SPP, and in particular the initiative to develop a Regulatory Cooperation Framework by 2007, is important and likely to achieve important benefits for the U.S. and its neighbors. Accordingly, we have provided additional details about recent and ongoing SPP activities.

The same peer reviewer also recommended that the Office of Information and Regulatory Affairs (OIRA) within OMB be the "central regulatory agency" referred to by the two Presidents and the Prime Minister in their March 31, 2006, statement on the Framework, and that it is OIRA that should take the lead in U.S. efforts to work with Canada and Mexico on the development of a North American Regulatory Cooperation Framework. The peer reviewer expressed the view that "[o]nly OMB, and only OIRA within OMB – with the authorities granted under E.O. 12866 – can serve as the Executive Office catalyst to '[s]trengthen regulatory cooperation, including at the onset of the regulatory process, to minimize barriers.'" In response to this recommendation, OMB would note the important leadership role that the Commerce Department plays in the SPP prosperity initiatives. OMB agrees that, given OIRA's role in coordinating U.S. regulatory policy, OIRA should participate in the effort to create the Framework. OMB hopes that, by providing the overview of SPP activities in this Report, we can contribute to the success of this initiative.

The two other peer reviewers found this chapter informative (3) and useful (1), but both requested additional information on the impact of regulatory oversight mechanisms, specifically the use of regulatory impact analysis. OMB agrees that analysis is an important issue, and we believe that the comparison of OMB and Commission guidelines on regulatory analysis provided in Appendix D this Report addresses many of the critical challenges faced by policymakers in the U.S. and Europe.

[66]See http://www.oecd.org/dataoecd/24/6/34976533.pdf.

CHAPTER IV: 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", requires OMB to develop government-wide standards "for ensuring and maximizing" the quality of information disseminated by Federal agencies.

To implement the Information Quality Act, 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.

In previous reports, OMB has presented a thorough discussion of the Information Quality Act and its implementation, including a discussion of perceptions and realities, legal developments, improving transparency, suggestions for improving correction requests, and the recent release of the OMB Information Quality Bulletin on Peer Review.[67]

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.[68] In their FY04 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 last update on Information Quality.[69] This increase in transparency allows the public to view all the agency responses to correction requests and to keep track of the status of correction requests that may be of interest.

This chapter provides a summary of the current status of correction requests that were received in FY 2005, as well as an update on the status of requests received in FY 2003 and FY 2004. Agency FY 2006 Information Quality reports are due to OMB on December 15, 2006. Our discussion of the individual corrections and agency responses is minimal; all correspondence between the public and the agencies regarding these requests is publicly available on the agencies' Information Quality web pages.

On June 16, 2005, OMB's Information Quality Bulletin on Peer Review became effective for all influential scientific information, including highly influential scientific assessments. As of December 16, 2005, agencies are posting peer review agendas for both influential scientific information and highly influential scientific assessments on their web sites. The agencies first

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[67]See 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.
[68]See http://www.whitehouse.gov/omb/inforeg/info_quality_posting_083004.pdf.
[69]See *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.

annual peer review reports are due to OMB on December 15, 2006. Once this information is evaluated, OMB plans to share peer review updates with readers in our future Information Quality reports.

A. New Correction Requests Received by the Agencies in FY 2005

Table 1 below lists the departments and agencies that received requests for corrections and appeals in FY05.

Table 4-1. Departments and Agencies that Received Information Quality Correction Requests in FY 2005

Agency	Number of FY05 Correction Requests	Number of Appeals Received in FY05
Department of Commerce	2	
Department of Defense	1	
Department of Health and Human Services	5	5
Department of Interior	1	
Department of Labor	4	1
Department of Transportation	3	
Department of State	1	
Environmental Protection Agency	7	6
Federal Communications Commission	1	
Federal Trade Commission	1	
General Services Administration	1	
Total	27	12

As Table 4-1 shows, in FY 2005 there were a total of 27 requests for correction that were sent to 11 different agencies. The Federal Trade Commission and the General Services Administration received their first correction requests in FY 2005. Twelve appeals were received by the agencies in FY 2005. Two of these were on new requests that were initiated in FY 2005 and the remaining 10 were on correction requests that originated in FY 2003 and FY 2004.

The 27 requests and 12 appeals can be found at the agencies' Information Quality websites. The correction requests received in FY 2005 were as diverse and interesting as those received in previous years. For instance, the Administration for Children and Families (part of the Department of Health and Human Services) received a request from Advocates for Youth and the Sexuality Information and Education Council of the United States regarding grantee abstinence curricula; the Environmental Protection Agency received a request for correction from the Wood Preservative Science Council regarding the arsenic cancer risk value; the Department of Labor received a request from a university professor regarding language

pertaining to anesthetic gas use and small animals; the National Oceanic and Atmospheric Administration (part of the Department of Commerce) received a request from a private citizen regarding transparency in weather forecasts; and the Department of Transportation received a request from the Alliance of Automobile Manufacturers regarding the preliminary economic analysis for a rule related to side impact protection.

For the 11 agencies that received correction requests, the links to FY 2005 correction requests are provided below:

Department of Commerce: http://www.osec.doc.gov/cio/oipr/IQ_request_for_correction_05.htm
Department of Defense:
http://www.hq.usace.army.mil/ceci/informationqualityact/2005%20UPPER%20MS%20RIVER%20RFC/index.html
Department of Health and Human Services: http://aspe.hhs.gov/infoquality/requests.shtml
Department of Interior: http://www.blm.gov/nhp/efoia/index.htm
Department of Labor: http://www.dol.gov/cio/programs/InfoGuidelines/IQCR.htm
Department of Transportation: http://dms.dot.gov/cfreports/dataQuality.cfm
Department of State: http://www.state.gov/misc/51090.htm
Environmental Protection Agency: http://epa.gov/quality/informationguidelines/iqg-list.html
Federal Communications Commission: http://www.fcc.gov/omd/dataquality/requests2005.html
Federal Trade Commission: http://www.ftc.gov/ogc/sec515/index.htm
General Services Administration:
http://www.gsa.gov/Portal/gsa/ep/contentView.do?programId=9674&channelId=-13349&ooid=12667&contentId=10552&pageTypeId=8199&contentType=GSA_BASIC&programPage=%2Fep%2Fprogram%2FgsaBasic.jsp&P=IPC

Although there were 27 correction requests received in FY 2005, only 24 of these are considered by OMB to be different in substance from the simple webpage fixes or technical corrections that agencies have always received. Thus we are not including discussion of the three requests to the Department of State, the General Services Administration, and the National Highway Traffic Safety Administration at the Department of Transportation.[70] Figure 4-1 shows the status of the 24 correction requests. For all the details relating to the specific requests, including agency responses, readers are encouraged to visit agency Information Quality websites.

As noted in our previous report,[71] 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, and in FY 2004 there were 37 correction requests.

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[70]The request to State was from a citizen looking for assistance finding notary services at the U.S. Consulate in Chennai; the request to GSA pointed out a publication error in the Federal Travel Regulation (FTR) (41 CFR 300-304); and the request to NHTSA was from a citizen concerned about information connected to them in the National Driver Registry.

[71] See *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.

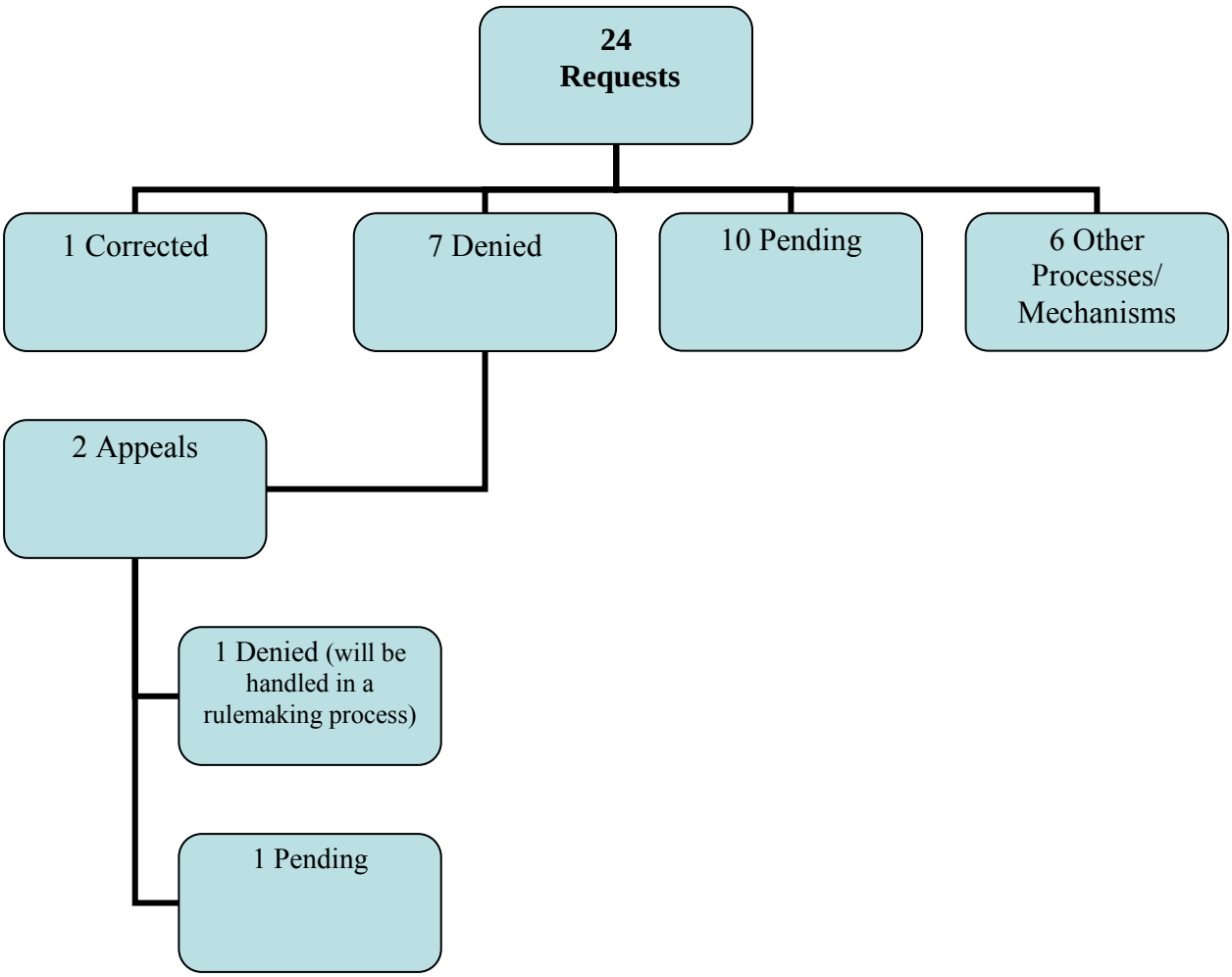

Figure 4-1: Status of IQ correction requests received in FY05.

B. Status of Outstanding Correction Requests Received by the Agencies in FY 2003-04

At the close of FY 2004, 17 Information Quality correction request responses and seven appeal responses were pending from the agencies. Figure 4-2 shows the status of the outstanding correction request responses at the close of FY 2005. As Figure 4-2 shows, agencies had responded to 14 correction requests and were still working on responses to the other three. This figure also shows that while four correction requests were denied, there were five appeal requests. This is due to the fact that one agency received an appeal request on a response that was categorized as partially corrected.

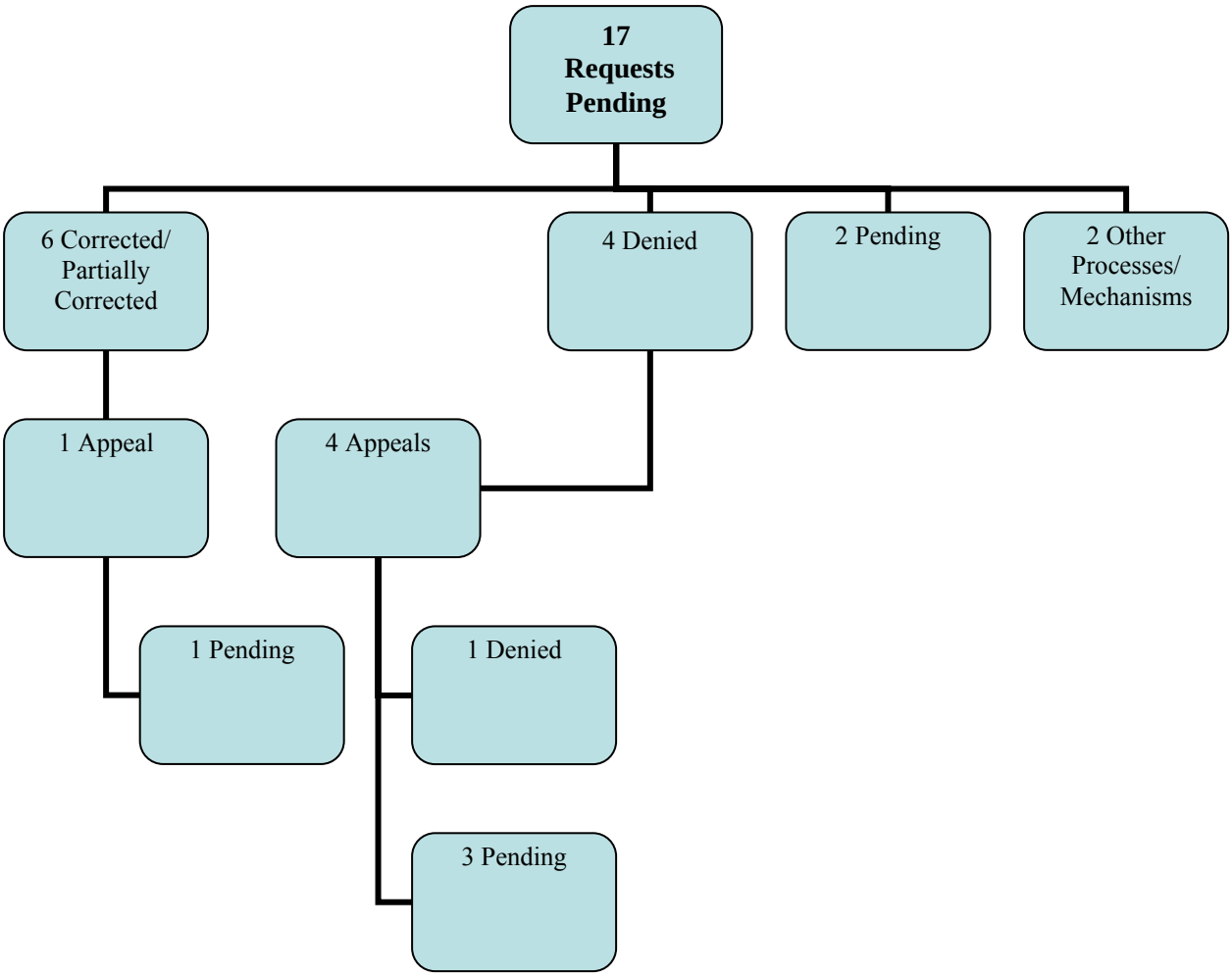

Figure 4-2: FY 2005 Status of Pending Correction Requests from FY 2003 and FY 2004.

Figure 4-3 shows the status of the 7 appeal requests that were pending at the close of FY 2004. As this figure shows, one appeal response is still pending.

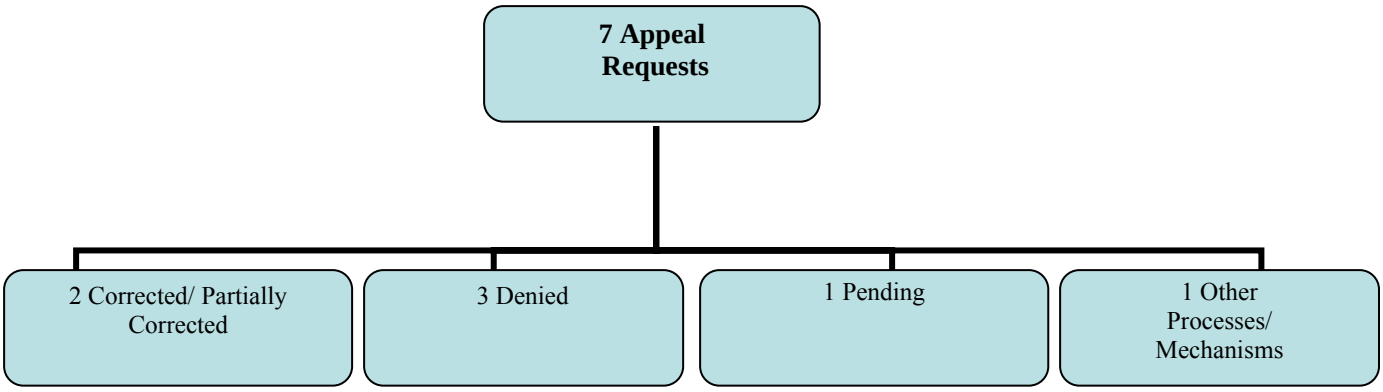

Figure 4-3: FY 2005 Status of Pending Appeal Requests from FY 2003 and FY 2004.

APPENDIX A: CALCULATION OF BENEFITS AND COSTS

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

- Rules from October 1, 1992 to September 30, 1995: Tables C-1 through C-3 in Appendix C of this Report.
- Rules from October 1, 1995 to March 31, 1999 can be found in Chapter IV of our 2000 Report.
- Rules from April 1, 1999 to September 30, 2001: Table 19 of the 2002 Report.
- Rules from October 1, 2001 to September 30, 2002: Table 19 of the 2003 Report.
- Rules from October 1, 2002 to September 30, 2003: Table 12 of the 2004 Report.
- Rules from October 1, 2003 to September 30, 2004: Tables 1-4 and A-1 of the 2005 Report.
- Rules from October 1, 2004 to September 30, 2005: Tables 1-4 and A-1 of this 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.[72] 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 costs and benefits of different regulations over long time periods and across many agencies. In addition, where OMB has monetized quantitative estimates where the agency has not done so, we have attempted to be faithful to the respective agency approaches. The adoption of a uniform format for annualizing agency estimates allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules; however, the agencies

[72]National Income and Product Accounts, available at http://www.bea.gov.

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

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

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

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

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

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

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

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

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

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

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

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Migratory Bird Hunting; 2005-2006 Migratory Game Bird Hunting Regulations: Late Season [70 FR 55665]	DOI-FWS	See "Early Season" benefits above.	Not Estimated	Benefits: The listed benefits represent estimated consumer surplus. Data to estimate producer surplus are not available; producer surplus is likely minimal compared to consumer surplus, but would also be a benefit of the rule if monetized. Costs: The economic model did not produce a separate of estimate the costs of the rulemaking. Other details: DOI performed an economic impact analysis to jointly estimate the impact of all of early and late season migratory bird hunting regulations for the 2004-2005 season, but did not update that estimate for the 2006 season. DOI finalized a total of three Late Season regulations, the Final Framework (70 FR 55665), the Bag and Possession Limits (70 FR 54483), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (70 FR 56531). See above for a summary of the impacts of hunting regulations. The RIA is not available online. To obtain a copy of the RIA, contact John Charbonneau (703) 358-2082.
Electronic Orders for Schedule I and II Controlled Substances [70 FR 16919]	DOJ-DEA	$284 million ($2003 at 7%) $286 million ($2003 at 3%)	$122 million ($2003 at 7%) $112 million ($2003 at 3%)	Benefits: The rule allows registrants who order Schedule I and II controlled substances to issue orders electronically, using a digital certificate provided by DEA to sign the orders. The electronic form system provides for many efficiencies, such as an avoidance of the need to transcribe data from electronic systems to paper and back again, the resources that must be dedicated to physically handling and accounting for the paper documents, and the time required to transmit the paper document from the customer to the supplier before an order can be filled. Costs: Compliance costs for the electronic system include one time costs for the installation of software and the cost of obtaining digital certificates, and ongoing annual costs for processing orders. The electronic order costs assume that registrants take 5 years to adopt electronic orders, so electronic order costs include a mix of paper and electronic for the first four years. Initial compliance costs are also annualized over 5 years. The full RIA is available at http://www.deadiversion.usdoj.gov/fed_regs/rules/2005/index.html

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

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

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

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

APPENDIX B: VALUATION ESTIMATES FOR REGULATORY CONSEQUENCES[73]

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

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

Injury. For NHTSA rules, we adopted NHTSA's approach of converting nonfatal injuries to "equivalent fatalities." These ratios are based on NHTSA's estimates of the value individuals place on reducing the risk of injury of varying severity relative to that of reducing risk of death.[74]

For OSHA rules, we monetized only lost workday injuries using a value of $50,000 per injury averted.

1. Change in Gasoline Fuel Consumption. We valued reduced gasoline consumption at $0.80 per gallon pre-tax. This equates to retail (at-the-pump) prices in the $1.10 - $1.30 per gallon range.
2. Reduction in Barrels of Crude Oil Spilled. OMB valued each barrel prevented from being spilled at $2,000. This is double the sum of the most likely estimates of environmental damages plus cleanup costs contained in a published journal article[75]
3. Change in Emissions of Air Pollutants. Please see the following paragraphs for an explanation of these values. All values are in 2001 dollars.

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

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

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

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

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

EPA believes that there are a number of reasons to expect that reductions in NO_x emissions from ground-level mobile sources achieve different air quality improvements relative to reductions from electric utilities and other stationary sources with "tall stacks." In response, OMB has adopted different benefit transfer estimates for NO_x reductions from stationary sources (e.g., electric utilities) and from mobile sources.[76] For the central estimate of NO_x emissions for mobile sources, we used estimates from the Tier II/Gasoline Sulfur rule RIA, while recognizing that the Tier II analysis was based on an air quality fate and transport model that had limited treatment of atmospheric chemistry.[77] Based on the final Tier 2/Gasoline Sulfur RIA, EPA estimated that NO_x reductions would yield benefits of $4900 (1999$) per ton. Analysis of recent EPA rules yield several estimates for the central estimate of NO_x benefits per ton from stationary electric utility sources (See the Regulatory Impact Analyses for the "NO_x SIP Call" and the Section 126 rules, available on the web at http://www.epa.gov/ttn/ecas/econguid.html. In addition, see Memo to NSR Docket from Bryan Hubbell, Senior Economist, Innovative Strategies and Economics Group, EPA). Based on these studies, the mortality-based benefits of NO_x reductions from stationary sources (electric utilities) are estimated to be $1,300 (1999$) per ton.[78] New results based on EPA's ongoing analyses supporting the suite of Clean Air Rules (including the Clean Air Interstate Rule, Clean Air Visibility Rule, and Clean Air Mercury Rule) may provide better estimates for future reports. NO_x benefit estimates are difficult to transfer to other applications, however. The location of reductions, reductions in other PM precursors, air chemistry, meteorology, emission release heights, baseline conditions, etc. can have dramatic effects on the relationship between NO_x emission reductions and ambient PM concentrations. Further, the understanding of the atmospheric chemistry characterizing PM formation, and photochemical air quality modeling are rapidly evolving.

EPA also developed central estimates for the benefits associated with reductions in SO2 from electric utilities. Based on an analysis outlined in a June 20, 2001 EPA memo to the file, "Benefits Associated with Electricity Generating Emissions Reductions Realized Under the NSR program," we used $7,300 per ton.

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

[76]The five key assumptions underlying the benefit estimates for reductions in NO_x emissions are described on p. 7.
[77]Additional details on the Tier II benefits analysis are available in the Tier II/Sulfur Final Rulemaking RIA, available on the web at http://www.epa.gov/oms/fuels.htm.
[78]This memo reported that: "Based on previous EPA analyses, the average mortality-related benefits per ton of NO_x reduced are around $1300 and the average benefits per ton of SO_2 reduced are around $7300 for electricity-generating units."

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

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

A. Adjustment for Differences in Time Frame across These Analyses

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

B. Further Caveats

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

estimates. In other cases, the agencies may offer a midpoint estimate of benefits and costs. In still other cases the agency estimates may reflect only upper-bound estimates of the likely benefits and costs. While OMB has relied in many instances on agency practices in monetizing costs and benefits, citation of, or reliance on, agency data in this Report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates.

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

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

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

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

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Double-Hull Standards	DOT- Coast Guard	17	583	We amortized the agency's present value estimates over 30 years. We valued each barrel of oil not spilled at $2,000.
Stability Control of Medium and Heavy Vehicles During Braking	DOT- NHTSA	1,650-2,539	694	We valued each "equivalent fatality" at $3 million.
Head Impact Protection	DOT- NHTSA	1,746-1,964	633	We valued each "equivalent fatality" at $3 million.
Bay/Delta Water Quality Standards	EPA	2-26	37-248	
Federal Standards for Marine Tank Vessel Loading and Unloading Operations and NESHAP for Marine Tank Vessel Loading and Unloading Operations	EPA	185-829	131-175	

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

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Occupational Exposure to Asbestos	DOL-OSHA	92	448	We assumed a 20-year latency period between exposure and the onset of cancer or asbestosis and valued each death and each case of asbestosis at $5 million.
Controlled Substances and Alcohol Use and Testing	DOT – FHWA	1,539	114	No adjustments to agency estimates.
Prevention of Prohibited Drug Use in Transit Operations	DOT	107	37	We amortized the agency's present value estimates over 10 years.
Phase II Land Disposal Restrictions	EPA	26	240-272	We valued each cancer case at $5 million.
Phase-out of Ozone-Depleting Chemicals and Listing of Methyl Bromide	EPA	1,260-3,993	1,681	We amortized the agency's present value estimates over 16 years.
Reformulated Gasoline	EPA	122-947	1,085-1,395	Estimates are for Phase II, which include Phase I benefits and costs. We used the benefit estimates that assume the enhanced I/M program is in place. We valued VOC reductions at $600-$2,700 per ton and NO_x reductions at $1,100-$11,600 per ton. We valued each cancer case at $5 million. We assumed the phase II aggregate costs are an additional 25 percent of the Phase I costs based on EPA's reported per-gallon cost estimates.
Hazardous Organic NESHAP	EPA	593-2,628	295-333	We valued VOC emissions at $600-$2700 per ton and NO_x emissions (which are a cost in this instance) at $370 - $3,800 per ton. We did not value changes in CO emissions.
Non-Road Compression Ignition Engines	EPA	647 – 6,821	29-70	We annualized the NO_x emissions which yielded an average annual emission reduction of 588,000 tons beginning in 2000. We valued NO_x emissions at $1,000 - $11,600 per ton.

Table C-3: Estimates of Annual Benefits and Costs of Major Federal Rules
October 1, 1992 to September 30, 1993
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Nutrition Labeling of Meat and Poultry Products	USDA/FSIS	205	25-32	We amortized the agency's present value estimates over 20 years.
Food Labeling (combined analysis of 23 individual rules)	HHS/FDA	438-2,637	159-249	We amortized the agency's present value estimates over 20 years.
Real Estate Settlement Procedures	HUD	258-332	135	No adjustments to agency estimates.
Manufactured Housing Wind Standards	HUD	103	63	No adjustments to agency estimates.
Permit Required Confined Spaces	DOL/OSHA	540	250	We valued each fatality at $5 million and each lost-workday injury at $50,000. We did not value non-lost-workday injuries.
Vessel Response Plans	DHS/USCG	9	295	We amortized the agency's present value estimates over 30 years. We valued each barrel of oil not spilled at $2,000.
Oil and Gas Extraction	EPA	35-129	35	We amortized the agency's first-year costs over 15 years and added these to annual (15^{th} year) costs.
Acid Rain Permits Regulations	EPA	78,454-78,806	1,109-1,871	We valued SO_2 reductions at $7,800 per ton.
Vehicle Inspection and Maintenance (I/M)	EPA	247-1,120	671	We used the estimates of cost and emission reductions of the new I/M program compared to the baseline of no I/M program. We valued VOC reductions at $600-$2,700 per ton. We did not assign a value to CO reductions.
Evaporative Emissions from Light-Duty Vehicles, Light-Duty Trucks, and Heavy-Duty Vehicles.	EPA	274-1,246	161-248	We assumed the VOC emission reductions began in 1995 and rise linearly until 2020, after which point they remain at the 2020 level. Annualizing this stream results in an average of 468,000 tons per year. We valued these tons at $600-$2,700 per ton.
Onboard Diagnostic Systems	EPA	702-3,423	226	We amortized the agency's emission reduction and cost estimates over 15 years. We valued VOC reductions at $600-$2,700 per ton and NO_x reductions at $1,100-$5,500 per ton.

APPENDIX D: COMPARISON OF OMB AND THE EUROPEAN COMMISSION GUIDELINES ON REGULATORY ANALYSIS[79]

Regulatory Impact Analysis (RIA)[80] is now carried out for the majority of significant new legislative proposals in the European Commission and for all economically significant regulatory proposals issued by non-independent agencies within the Executive Branch of the U.S. Federal government. The U.S. Executive Branch has been carrying out RIAs, with emphasis on cost-benefit analysis, for the past two to three decades. In the European Commission, sectoral analysis requirements (for example, analysis that only looked at environmental impacts), were recently combined into a requirement for an integrated and comprehensive impact assessment. There is now recognition shared on both sides of the Atlantic that *ex ante* analysis of likely impacts of regulatory actions are essential for good policy making. The ongoing regulatory dialogue between the United States and the European Union is timely and important for ensuring that regulatory action by both sides does not create unnecessary and thus detrimental economic and trade obstacles. In order to further the understanding of this regulatory dialogue, a thorough knowledge of each other's *ex ante* impact analysis is essential.

This section looks at the two sets of guidelines, OMB Circular A-4, and the European Commission's Impact Assessment guideline.[81] Section one begins with an assessment of the legislative backgrounds against which RIAs are produced in the U.S. and at the EU level, and includes a comparison of the legal or other bases that underpins *ex ante* impact analysis in both systems. In addition, this section looks at how subsidiarity and federalism are handled, the role of consultation, the provisions that have been made for ensuring an efficient use of available resources, and how impacts in and vis-à-vis third countries are taken into account. Section two looks at the more technical aspects that an analysis of impacts includes. The role of cost benefit and cost effectiveness analyses is discussed, as well as how parameter values such as discount rates are dealt with. Assessing the impact of new proposals on administrative costs and monitoring and evaluation requirements, which are peculiar to the Commission's RIA guidelines, is explained and there is a discussion of how risk and uncertainty analysis is handled. Part three provides concluding thoughts and suggested next steps for future research.

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[79] This appendix is adapted primarily from a joint working paper authored by Cavan O-Connor Close, Enterprise and Industry Directorate-General, European Commission and Dominic Mancini, OMB/OIRA, titled "Comparison of U.S. and European Commission guidelines on Regulatory Impact Assessment/Analysis." In particular, this appendix's description of European Commission activities represents Mr. Close's views.

[80] The European Commission uses the term "Impact Assessment," or IA. For simplicity, throughout this appendix we use the abbreviation "RIA" to refer to both Regulatory Impact Analyses in the U.S., and Impact Assessments in the EU when referring to regulatory analysis in the general terms. We retain the abbreviation IA when referring specifically to the European Commission Impact Assessment Guidelines.

[81] For ease of presentation, from this point on the appendix refers to RIAs prepared by U.S. Executive Branch agencies as "U.S." RIAs, and RIAs prepared for European Commission legislative proposals as European Union, or "EU" RIAs

A. General Issues

The Two Legislative Processes

Before looking at the two sets of analytical requirements in more detail, it is important to appreciate that there are significant differences in the legislative process between the U.S. and the EU Awareness of these differences is essential for understanding the underpinnings of the two sets of guidelines[82].

In the U.S., Article I, Section 1, of the Constitution gives the Congress the sole power to make laws. Also, laws can be enacted through overrides of failures to sign and vetoes while Congress in session. Over time, Congress has passed a number of laws authorizing the creation of and assigning a mission to Executive Branch regulatory agencies. There are over 100 federal agencies and subagencies with regulatory mandates from Congress, such as the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency. One of the primary tools these agencies use to fulfill their mission is a "rule" or "regulation" which, when finalized, has the force and effect of law. Regulations are almost always much more detailed than the laws passed authorizing their issuance; in fact, that is often one of the justifications for employing the use of regulations. The closest analogy to the EU is that U.S. laws are similar to EU "primary legislation" and U.S. rules and regulations are similar to EU "secondary legislation." In fulfilling their mission, the regulatory agencies have an obligation (partly created by statute, partly created by direction from the President, who is head of the Executive Branch) to show that their rules have a sound reasonable basis.

The most common procedure under which EU legislation is devised is the so-called co-decision procedure.[83] Under this procedure, the Commission puts forward a legislative proposal, which is sent to the European Parliament (EP) and the Council of the European Union (the Council). The EP discusses the proposal and can make amendments for the Commission to include in the version to be decided on in the Council. The Council will then accept it or adopt a "common position,"[84] If the Council accepts, the act is adopted and published in the Official Journal at which point it becomes law.[85] Thus, although the Commission is the initiator of legislation, it is not the legislator/legislative, nor does it normally determine the final version of a piece of legislation.

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[82]It is, of course, beyond the scope of this section to cover all the different aspects of the two political and legislative systems. For a more elaborate discussion on this please see http://europe.eu.int/eur-lex/en/about/pap/process_and_players3.html.

[83]For a more elaborate discussion on this please see http://ec.europa.eu/codecision/procedure/index_en.htm. It should be noted that an account of all the different ways in which legislation takes place would involve an examination of the different procedures under which the three EU institutions – the European Parliament, the Council and the Commission – work with one another, which is beyond the scope of this section.

[84]The Council will normally take its decision by a qualified majority, except when its position differs from that of the Commission or if the Commission has not incorporated the Parliament's amendments in its proposal; in those cases, unanimity is required.

[85]If not, its common position is sent to Parliament which can accept it, reject it or propose amendments at "second reading." In the latter case, the text is sent to Council for a second reading, which in turn, can approve the amended common position or not. If the Council refuses to approve, the Conciliation Committee is convened, which must try to find a compromise and produce a "joint text," submitted to a "third reading."

The main difference in the role of the RIA in the two systems is that the EU RIAs are produced for both primary and secondary legislation, whereas the U.S RIAs are produced only for regulations, not for statutes. Created at different points in the process, the analyses necessarily serve different purposes.

In the U.S., the RIA is produced by the regulatory agency granted authority through legislation to regulate a particular subject. The RIA's goal is to assess how regulations can be done in the most efficient way for society, and also can be used as evidence in court (discussed in more detail below) to prove that the final regulation has a reasonable basis. Regulatory agencies produce a full RIA for proposed rules, which then may be modified, along with the rule itself, after public comment and further research.

The Commission Impact Assessment (IA) guidelines state that an RIA is needed for "items on the Commission's Work Programme, which means all regulatory proposals, white papers, expenditure programmes and negotiating guidelines for international agreements (with an economic, social or environmental impacts)."[86] The Commission's RIA accompanies the proposed legislation on its way to Parliament and Council, where it is used to inform legislative and public debate and aims to show that new legislation that is proposed by the Commission is based on a sound analysis of all its economic, social and environmental impacts, and that due consideration was given to feasible alternatives to regulations.

The final form that a particular piece of legislation takes is determined by the legislator, who, of course, remains at liberty to amend legislative proposals. The Commission does not view its RIAs as substitutes for the need for political decisions, but rather as something that helps inform the debate, especially within the Commission. The overall aim is the production of better quality legislation. When the EP or Council amends proposals, there is recognition that further RIA work is required if the amendments are substantial. Through the Interinstitutional Agreement between the EP, Council and the Commission, the EP and the Council have committed to such further analytical work when it is needed.

The Commission's RIA first and foremost serves to help the Commission draft proposals that take account of sound analysis. In practice an RIA that produces a 'preferred option' should base that decision on what the most efficient option is in terms of its economic, social and environmental impacts, but there is no automatic link between the RIA and the final policy outcome. Also, the Commission produces RIAs for most items on the Commission's "Work Programme," some of which discuss broad policy orientation and therefore contain analysis of a more general nature, without any quantitative work.

The Underpinnings: Legal and Otherwise

Highlighting in more detail U.S. requirements, regulatory analysis in the U.S. is required by Executive Order[87] (EO) 12866 of September 30, 1993 for all significant regulatory actions

[86]Impact Assessment Guidelines 15 June 2005, SEC (2005) 791, page 6.

[87]An Executive Order, such as EO 12866, is not a law; it is issued by the President as a direction to the federal government agencies on how to conduct their business. EOs do not expire at the end of a particular Presidency; in fact, EO 12866 was issued by President Clinton. Not only does EO 12866 define in general terms the type of

(rules and regulations). In addition, more significant analysis that complies with OMB Circular A-4 is required for all economically significant regulatory actions, where "economic significance" is primarily defined as a rule that has an impact on the economy (costs, benefits, or transfers) of greater than $100 million in any one year. The EO also establishes the procedures by which OMB reviews significant proposed and final agency regulations for compliance with Circular A-4. In addition to a review function, OMB through this EO has the ability to return rules to the agencies due to inadequate analysis.

In other words, not all regulations in the U.S. are accompanied by a regulatory impact analysis. In fact, OMB reviews approximately 600 proposed and final regulations per year, and only roughly 10-15 percent of the regulations are economically significant. These regulations, however, are responsible for almost all of the benefits and costs of all regulations reviewed by OMB.[88]

To a lesser extent, various U.S. laws also require some aspects of regulatory analysis. For example, the National Environmental Policy Act of 1969 (NEPA, Pub. L. No. 91-190, as amended, 42 U.S.C. §§ 4321-4347) requires federal agencies to consider the environmental impacts of their proposed regulatory actions and reasonable alternatives to those actions. To meet this requirement, federal agencies prepare an Environmental Impact Statement (EIS). In addition, the Unfunded Mandates Reform Act requires cost-benefit analysis of all rules imposing expenditures on state or local governments or the private sector of greater than $100 million a year (adjusted for inflation). The "Regulatory Right-to-Know Act" obliges OMB to report yearly on the total costs and benefits of federal regulation. In addition, the Regulatory Flexibility Act requires an impact analysis for any rule expected to have a significant impact on small businesses. Finally, under the Administrative Procedure Act of 1946 (Pub. L. No. 79-404) , which is the major statute governing the process by which agencies develop regulations, agencies have an obligation to provide a "reasonable basis" for their decisions. Although this requirement can be met without providing a complete impact analysis compliant with all aspects of OMB's Circular A-4, or EO12866, RIAs in the U.S. can be used as evidence to show that agencies did in fact provide a reasonable basis for their regulations. This means that analysis has a legal status significantly different from that in the EU.

The EU's impact assessment system is not determined by legal requirements. Instead, it is based on political commitments made by the Commission in a range of documents, e.g. the Lisbon Agenda (2000), the Gothenborg Council Conclusions, the White Paper on Governance and the Sustainable Development Strategy the New Initiative for Growth and Jobs (2005), and the Interinstitutional 'Common Approach to Impact Assessment' (2005) between the Commission, the Council and the European Parliament. Although different from the more legalistic basis that impact analysis enjoys in the U.S., these repeated explicit commitments mean that there is a strong political expectation on the Commission to deliver better regulation based on sound analysis.

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analysis required for regulations in the U.S., it also establishes the procedures under which OMB exercises oversight of the regulatory process, including reviewing regulations and developing detailed analysis guidelines such as OMB Circular A-4.

[88]These totals are derived from OMB's *Reports to Congress on the Costs and Benefits of Federal Regulation*, which present the aggregate costs and benefits of regulations introduced in the last ten years.

B. The Basic Framework of Impact Assessments and Regulatory Impact Analyses

The Commission has explicitly adopted an integrated approach, giving equal consideration to environmental, social and economic impacts. Prior to the first set of IA guidelines, which were put in place in 2003, the Commission had made extensive use of single sector-type impact assessments. The integrated approach combined the then existing separate IA mechanisms into one RIA. The Commission has stated that it views the integrated approach as essential for assessing trade-offs, which was difficult under the partial approach that existed before 2002. In addition, the Lisbon Agenda was agreed to in March 2000, establishing the goal of making the EU the most dynamic, knowledge based economy in the world by 2010, and reaffirmed the EU's commitment to sustainable development.[89] The Commission has structured the analytical requirements in this way because it believes that any particular set of impacts should not take preference over others, regardless of whether they are of an economic, social or environmental nature. The integrated approach has a stated goal of ensuring that the three "pillars" of sustainable development are treated and assessed on an equal basis. One of the main purposes of the RIA is to clearly identify impacts in each of the pillars, and to show any likely trade-offs between the three pillars and thus to allow for an assessment that takes all impacts into account.

The U.S. approach also takes these impacts into account, but integrates environmental, economic, and social impacts within a cost-benefit analysis (CBA) or cost-effectiveness analysis (CEA). Similar to the Commission's IA guidelines, OMB Circular A-4 derives its approach from the stated goals of the Executive Order, which states that the goal of regulation should be to maximize the net benefits to society. Circular A-4 states that "where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society." Circular A-4 certainly does not preclude an analysis from identifying, for example, environmental impact separately. Circular A-4, however, requires that CBA and CEA are the primary way in which analyses present results. In an analogous way, the Commission's IA guidelines do not preclude a CBA or CEA in the Circular A-4 mould; however, it specifies that the primary presentation of impact should separate out social, environmental, and economic impacts.

In practice, however, there are often benefits (and sometimes costs) that are difficult, if not impossible, to monetize. In cases such as this, in both the U.S. and the EU approaches there is no prejudice against costs and benefits that cannot be quantified. According to Circular A-4, officials should use their professional judgment in deciding whether there are significant non-quantifiable costs and benefits that could change the outcome of the analysis based on what is quantifiable. Thus, it is feasible in the U.S. that qualitative environmental or social (or indeed, even economic) impacts can lead to choosing an option that would not be chosen if only quantified and monetized impacts where taken into consideration. In theory therefore, the U.S. approach does not differ significantly from the EU in considering all the potential impacts of regulation.

[89]Information about the EC's implementation of the Lisbon Agenda is available at http://ec.europa.eu/growthandjobs/key/index_en.htm

Federalism and Subsidiarity

The Commission's IA guidelines require verification of the need for EU level action under the concept of subsidiarity. According to the subsidiarity principle, even in cases in which the EU has the authority to legislate, action should be taken at the lowest level possible and only at the EU level if there is evidence that this would provide added value.

A U.S. agency has an obligation under Circular A-4 to assess whether "Federal regulation is the best solution" and to also "consider regulation at the State or local level."[90] U.S. agencies have an additional obligation under Executive Order 13132 of August 4, 1999, to consult state and local governments when pursuing a regulations that may significantly impact them; for example, if a Federal regulation pre-empts similar state level requirements. These obligations try to ensure that regulation at federal level only takes place if the federal regulation is the appropriate level of government to undertake the task.

Ensuring the Efficient Use of Resources

The principle of proportionate analysis applies to the Commission's RIAs, which means that the more significant a proposal's impacts are likely to be, the more analysis is required. Due to the commitment to accompany all items that are on the Commission's Legislative Work Programme[91] by an RIA, there is a need to ensure that resources are used efficiently. Expending a great deal of effort on proposed policy actions that are likely to have only a small economic, social or environmental impact would be an inefficient use of limited resources.

The $100 million threshold for economic significance, and therefore expanded regulatory analysis in Executive Order 12866, is a type of proportionate analysis test as it also tries to ensure that resources are directed to those rules that have the potential to more seriously affect the U.S. economy. In addition, Circular A-4 also asks officials to ensure that there is a "balance" between thoroughness, particularly with regard to considering alternatives to regulation, and "the practical limits on your analytical capacity."[92] However, the obligation to quantify impacts in a certain way, and to use CBA, prescribes a minimum amount of analysis that is always required for economically significant rulemakings. It seems that there is more discretion in the Commission's guidelines for choosing the level of analysis that an individual RIA requires.

Consultation

The Commission's IA guidelines ask officials to consult as much and as widely as possible. It states that consultation should not be restricted to those stakeholders who are easy to engage or to experts; officials are expected to proactively identify all stakeholders and ensure that each group of stakeholders is engaged in what is the most suitable way for them. A reactive approach based on publishing a consultation on the internet and waiting for responses may not always be sufficient or appropriate. The Commission guidelines emphasize the importance of consultation for reducing the likelihood of ignoring important aspects of the proposed action, and

[90]Circular A-4, p. 6.
[91]See above for a more accurate definition.
[92]Circular A-4, p. 7.

in increasing stakeholder buy-in. There is ample guidance on consultation apart from what is in the guidelines, including minimum standards that all services are expected to adhere to in their RIA work. Moreover, all consultations have to be published on the webportal "your voice in Europe" www.europa.eu.int/yourvoice/consultations/index_en.htm and stakeholders can foresee possible contributions by looking at the Commission's Legislative and Work Programme, which includes the publication of roadmaps outlining upcoming impact assessments.

The Commission IA process also requires interservice consultation (ISC). The lead service (the service drafting the IA) should consult with all other services that have an interest in the area. Before a proposal and the IA go into ISC, the lead service should have set up an Interservice Steering Group (ISG), which consists of all other DGs (services) that have an interest in the proposal, in order to give ample opportunity to ensure that their points of view are taken on board and to profit from their particular knowledge in the area. The ISG should be set up early on and will normally accompany, and thus inform, the lead service throughout the process of producing an RIA. The goal of these requirements is to guarantee that legislation is consistent and complementary across the Directorates-General.

Consultation requirements are not specifically spelled out in Circular A-4, but are governed by other statutory and OMB requirements. For example, the U.S. Administrative Procedure Act established the "notice and comment" rulemaking process, where all regulations (not only significant regulations) and their analyses must generally be first published in proposed form in order to give the public a chance to comment. The public can find all regulations currently out for comment on the website http://www.regulations.gov. OMB also put in place guidelines establishing requirements for the peer review of influential scientific documents before they are disseminated by the agency.

There is a general obligation for U.S. agencies to use high quality information and expert advice if appropriate. Circular A-4 states that "Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data." Also, Executive Order 12866 states that, "[e]ach agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies." Agencies with knowledge or a stake in another agency's regulation will review the rule during the OMB review process, and often participate during rule development.

Accounting for International Impacts

Legislation and regulations passed in the EU or the U.S. can often have a significant impact on third country exporters to the U.S./EU markets, and affect the conditions under which home country firms compete with external producers. The Commission impact assessment guidelines require all impacts to be assessed, regardless of where they are likely to occur. In addition, the annex to the Commission Guidelines specifically asks for impacts on international trade and relations, and impacts on third countries or international agreements, to be taken into account.[93] Among other things, this requires an assessment of whether the proposal places EU companies at an advantage or disadvantage vis-à-vis external competitors, whether consumer

[93] Annex to IA Guidelines,pages 29 and 33

demand will shift away from polluting industries or how trade and cross-border investment will be affected.

The Commission is committed to promoting sustainable development at home and abroad. When negotiating international trade agreements a so-called Trade Sustainability Impact Assessment (Trade SIA) is carried out by DG Trade. Trade SIAs may build on a previous RIA carried out in relation to preparing the EU negotiating mandate. They aim to: provide an in-depth assessment of likely changes caused by the trade agreement on economies, social development and the environment in any potentially affected geographical area; provide information to help clarify trade-offs derived from trade liberalisation and the limits of trade negotiating positions; build an open process of consultation around trade policy creating a basis for an informed discussion with a broad range of stakeholders; improve the EU's institutional and political dialogue on sustainable development with its trading partners; shed light on how trade policy can contribute to internationally agreed processes on sustainable development, in particular the Millennium Development Goals and the targets set by the 2002 World Summit on Sustainable Development in Johannesburg; and propose *ex-post* monitoring measures to be put in place during the trade agreement's implementation.[94]

In a bit of a contrast, Circular A-4 states that a regulatory impact analysis "should focus on benefits and costs that accrue to citizens and residents of the United States."[95] Although analyzing the impacts to non-citizens or residents is often undertaken, analyzing the impact on foreign entities not directly conducting business in the U.S. economy is not required by the Circular.[96] Circular A-4 also states that transfers (monetary payments from one group to another that do not affect total resources available to society) between foreign and domestic producers or consumers should be considered costs and benefits of a rulemaking. If the transfer occurred between domestic entities, only the net change in the total surplus should be counted as a real cost or benefit to society.

In practice, U.S. Regulatory Impact Analyses often acknowledge that many direct impacts on foreign entities are passed on to the U.S. economy, and these impacts should be taken into account. For example, if a regulation raises the cost of importing a product, and therefore raises domestic prices, the costs to domestic consumers or intermediate producers due to those price increases should be considered in the impact analysis. Depending on market structure, a significant portion of the direct cost of the rulemaking imposed on foreign entities may be felt in the U.S. economy. Therefore, an analysis of the direct costs on foreign entities is often a useful if conservative proxy of the costs on the U.S. economy, and many U.S. analyses incorporate this approach in order not to underestimate the costs of their rulemakings.

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[94] Trade Sustainability Impact Assessment handbook, p. 12. See: http://trade.ec.europa.eu/doclib/docs/2006/march/tradoc_127974.pdf

[95] Circular A-4, p. 15.

[96] Note that Circular A-4 makes no distinctions between foreign or domestic firms operating in the U.S. For example, in the U.S. Department of Transportation's rulemakings establishing corporate average fuel economy standards, the impacts on foreign firms such as Toyota are analyzed in an identical manner as the impacts on domestic firms such as General Motors. In addition, if agencies, OMB, or the U.S. Trade Representative have a concern that a regulation may act as a non-tariff barrier, the agency will conduct a trade impact analysis likely similar to the analysis required by the IA guidelines. Circular A-4 is not explicit about the form this analysis may take.

C. Key Elements of Regulatory Impact Analysis

The Commission's IA Guidelines specify that an RIA should consist of the following sections: 1) identification of the problem, 2) definition of the objectives, 3) development of the main policy options, 4) analysis of their impacts, 5) comparison of the options and 6) an outline of how the policy will be monitored and evaluated.

The introduction to the OMB Circular A-4 takes a similar approach; a good regulatory analysis consists of 1) a statement of the need for proposed action, 2) an examination of alternative approaches and 3) an evaluation of the costs and benefits – quantitative and qualitative – of the proposed action and the main alternatives.

A notable difference in emphasis in the guidelines is that Circular A-4 states that the evaluation of costs and benefits is not restricted to the preferred option but is required for all reasonable alternatives – indeed, there is an expectation that CBA will be done for more than one policy option. While the Commission guidelines also clearly support this CBA approach, it is often limited to the preferred option, with a less fully developed CBA being produced for the other options when it becomes clear that an option is not as efficient as other alternatives.

Both guidelines specify that analyses should develop a baseline scenario against which all other options have to be compared. However, comparing other options against the no-change option in the U.S. means that the costs and benefits of the baseline option are quantified and projected into the future. This requirement is less pronounced in the Commission guidelines, where often a qualitative assessment that concludes that existing problems are likely to remain is sufficient, although the guidelines do state the need to look at how the problem is likely to evolve over time. The baselines scenario as understood in the Commission RIA system does include taking into account developments such as existing policies already decided and in the pipeline, and predictable technological progress. Part of the goal the IA is to show that another option would lead to net social benefits vis-à-vis the baseline option. If the IA cannot show that, the baseline option should be the preferred option.

Circular A-4 does not obligate RIAs to examine a certain number of options, and a U.S. agency is allowed to dismiss some options without much analytical work if they are clearly not genuine options. There is an expectation that serious analysis is done on *several* alternatives. The Commission's RIA is expected to look into a range of options, usually three to five in total.

An important difference, however, is that the alternatives available and expected to be considered in the EU are often wider in scope than in the U.S. The term "regulatory alternatives" is used in the U.S., whereas the Commission guidelines discuss "alternatives to regulation." The Commission guidelines state, and strongly recommend, that all analyses should consider alternatives to regulation, such as co- and self-regulation or other market based implementation instruments, within the impact assessment. Typical alternative regulatory approaches in the U.S. may include some Commission "alternatives to regulation," but others are narrower in scope than what typically would be considered a Commission alternative, such as different compliance dates, levels of stringency, enforcement methods and different requirements for small firms. This is almost certainly due to the wider scope of the legislative and regulatory

actions covered by the Commission guidelines. Remember that the scope of a U.S. regulatory agency to consider non-regulatory alternatives is limited by the authority granted by previous statutes (or primary legislation). For example, although resource-based taxes are often considered a viable theoretical alternative to direct pollution regulation, the EPA does not have the statutory authority to impose taxes to meet their regulatory objectives.[97]

Both Circular A-4 and the Impact Assessment guidelines have transparency as a major goal. Circular A-4 states that third parties should be able to see clearly how estimates of costs and benefits are arrived at and be able to reproduce any calculations with the information that is given in the impact assessment. The Commission guidelines state that the analysis and conclusions should be transparent to a non-specialist and clearly presented in a standardized format. Both guidelines require that analyses use clear language that does not obfuscate results.

Reasons for Intervention

Almost every regulation is an intervention in the functioning of markets. Markets are generally efficient, but sometimes fail in a way that intervention, including regulation, may be able to address. Both guidelines discuss externalities, public goods, and inadequate or asymmetric information as typical market failures that may require intervention. In addition, both systems allow for intervention on the grounds of other compelling public needs, such as distributional equity and fairness, or rectifying other undesirable social outcomes. Regardless of the need for the intervention, both guidelines state that the rationale should be clearly presented and as concrete as possible.

While there is a great deal of similarity on the rationale for intervention between the two systems, the identification of the market failure argument appears to be given more prominence in Circular A-4 in the U.S. Circular A-4 presents a fuller discussion of the types of market failures that regulations may address, and includes the direction that agencies should have a presumption against "economic regulation," or using such regulatory mechanisms as price and wage controls or entry restrictions to accomplish their regulatory objectives.

The Commission's IA guidelines, however, have a full discussion of how to frame a problem well, or in such a way that it lends itself to appropriate policy alternatives. For instance, the guidelines suggest a problem tree approach, which maps out major problems and how they relate to each other. The IA guidelines state that this is a useful tool for focusing on the core problem that actually needs to be addressed by a regulation.

The slight difference in emphasis between the two approaches to discussing the reasons for an intervention may be due to the wider applicability of the IA guidelines. By its nature, for example, primary legislation may also address issues that lend themselves less to a categorization into what economists would consider classic market failures.

[97]We should note that EO 12866 does require agencies to "identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

D. Analytical Methods

As stated above, Circular A-4 states that the evaluation of how best to achieve the objectives of a regulation is done within the framework of cost-benefit and cost effectiveness analysis (CBA and CEA respectively). Circular A-4 gives considerable detail on how to use the two methods. The Commission's guidelines, on the other hand, see CBA and CEA as valuable methodologies that can add value when assessing likely impacts, but they are not compulsory and a qualitative analysis is often equally acceptable. In practice, however, almost all regulatory impact analyses in the U.S. and the EU will contain both qualitative and quantitative components.

The Commission guidelines provide greater guidance on the specific impacts particular regulations may have and directorates should consider. For example, it provides an impacts menu tool, which is "meant as an aid for you to use in developing your thinking about a wider range of potential impacts for the policy options."[98] This reasoning behind the menu approach chosen by the Commission to identifying impacts may be twofold. It tries to take account of the various limitations of these types of analysis, where obstacles such as a lack of data often allow for only partial monetization or quantification. Moreover, the proportionate analysis criterion of the Commission guidelines often limits the amount of effort that should be expended on an RIA that analyzes a policy with a relatively small impact, which can favor qualitative analysis since it is generally less resource intense. Both guidelines stress that analysis should be proportional to the size and importance of the regulation; therefore, in practice both guidelines support greater analytical rigor when it is especially relevant for decision making.

However, in spite of the absence of an obligation to quantifying and monetizing where possible, there is of course recognition in the Commission that public funds have to be used in accordance with sound financial management, and that private mandates should be imposed only when necessary and that they should be efficient. Interventions should therefore be achieved in a cost efficient manner. The Commission guidelines state that efficiency goals of an intervention are met "if its set of objectives are achieved at least cost, or if its desired impact is maximized at a given level of resources."[99] For highly focused regulatory proposals (those that are likely to have significant economic, social or environmental impacts and where good data exists), using CBA and/or CEA techniques is common and encouraged.

CBA and CEA

Circular A-4 states that CBA should be carried out for all rulemakings and for all options considered in a regulatory analysis. Moreover, overall as well as incremental costs and benefits have to be calculated. Agencies are not entirely free in their choice of how to do CBAs as there is some requirement for consistency across regulations. Circular A-4 introduces the tools of CBA and CEA, such as opportunity cost, willingness to pay and accept, contingent valuation and

[98]IA guidelines, p. 28

[99]Moreover, the same page in the guidelines states that "all proposals with financial implications for the Community budget must also be accompanied by a legislative financial statement that includes a detailed calculation of the financial and human resources to be allocation to the intervention" (IA guidelines, p. 26).

revealed preference, Quality Adjusted Life Years, discount rates, etc. and discusses their limitations.

The main feature of a CBA is that costs and benefits are expressed in monetary terms to the extent feasible, which allows for a direct comparison and evaluation of the different policy options. This policy represents a significantly stronger reliance on CBA than that adopted by the Commission. Taking the net benefit measure as the evaluation indicator may favor options with large costs as long as they are exceeded by high benefit estimates. This is a contrast to the Commission approach, which is perhaps more likely to dismiss an option that has what it considers to be unacceptably high costs, regardless of the overall net benefit.

The Commission guidelines are clearer in stating that a qualitative approach to impact assessment is appropriate in many circumstances. This may be a reflection of the difference in purpose of RIAs compared with the U.S., and recognition that CBA for a broad policy outline would not be sensible in the EU. It also, however, may reflect a slight difference in the perceived limitations of quantitative analysis in the two systems.

Circular A-4, although requiring CBA if feasible, recognizes that monetized CBA, in practice, is not the only consideration in a decision, as many costs and benefits simply cannot be monetized. The U.S. official is encouraged to quantify where possible in such instances, and if that is not possible to present a qualitative discussion of the costs and benefits. In situations such as this Circular A-4 encourages a "threshold" or "break-even" analysis. This analysis answers the following question, "How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?" In addition to threshold analysis, Circular A-4 states that the agency "should indicate, where possible, which non-quantified effects are most important and why."

In addition, Circular A-4 encourages CEA for all rules and requires it for rules in which the primary benefit is an improvement in health or safety. In CEA, a set of regulatory actions with the same outcome(s) is compared (e.g. construction of an index of units of health improvement). CEA should lead to the identification of the most efficient way of achieving a regulatory outcome in the absence of complete monetization of benefits. Circular A-4 gives considerable detail on pitfalls and things that have to be kept in mind for making CEA successful - for example, the need to look at incremental cost-effectiveness and how to construct the cost-effectiveness ratios. Circular A-4 encourages the use of an integrated measure of effectiveness, such as Quality Adjusted Life Years, but does not take a position on what measure of health improvement or other unit of benefit to use, stating that lives saved, life years saved, or a measure such as Quality Adjusted Life Years may all lend a useful perspective to the decision-makers. CEA is a relatively new requirement for RIAs, and the U.S. Institute of Medicine of the National Academy of Sciences recently published a report titled "Valuing Health for Regulatory Cost-Effectiveness Analysis" that studies the issue in more detail.[100]

The Commission guidelines stress that CEA offers a good alternative to CBA, particularly in cases in which the full monetization of all costs and benefits is not possible. It explains that CEA leads one to calculate the costs of a desired outcome for several options and

[100]This report is available at http://www.iom.edu/CMS/3809/19739/32029.aspx

allows one to rank them based on "cost per unit of effectiveness." According to the guidelines CEA can be useful when several options all lead to more or less the same outcome.

It is clear that Circular A-4 itself gives more detail as regards, for example, CBA and CEA than the Commission guidelines do. This is, of course, a reflection of the stronger requirement for CBA/CEA that exists in the U.S. system, which is at least partly a reflection of the slightly different purposes the two RIA systems fulfill. A simple comparison of the proportion of U.S. and EU RIAs that use quantitative analysis may be misleading, however, since RIAs in the EU are prepared for a wider range of general policy documents for which quantification is often not possible. For policy proposals that are likely to have significant impacts, the level of detailed quantitative analysis, and hence the use of CBA, CEA, etc, may be more comparable than such an analysis would imply.

Administrative Costs[101]

Measuring the likely administrative costs of legislation is a requirement unique to the Commission's IA guidelines, although Circular A-4 would consider any impacts of this nature legitimate costs and would require their analysis.[102] The Commission has recently developed a model for measuring net administrative costs.[103] These costs can be a considerable burden on business, voluntary organizations and the public sector. They tend to affect small to medium size enterprises (SMEs) more than larger organizations, and can pose a serious hindrance to a competitive, productive and innovative economic environment. Given the commitments the Commission made in Lisbon 2000 to making the EU the most dynamic, knowledge-based economic area by 2010, their potential to weigh down economic progress by slowing down productivity growth and innovation can be directly at odds with overall Commission policy. The other side of the coin is that data collection, labeling of products and so on often fulfils a very useful and necessary requirement. One only needs to think about the confidence consumers would have in unlabelled products or imagine a world without data collection. In order to strike a balance between the necessity and usefulness of labeling and data collection on the one hand, and ensuring a competitive market economy framework on the other, it is essential to be aware of administrative costs that a given piece or legislation is likely to cause.

The Commission guidelines suggest measuring administrative costs by multiplying the average cost of an action (price) by the total number of actions performed (quantity). The core equation is the following: Σ P x Q (Price = tariff x time; Quantity = no. of businesses x frequency)

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[101]"Administrative costs are defined as the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties. Information is to be taken in abroad sense, including costs of labelling, reporting, and monitoring to provide the information and registration." (Annexes to guidelines, p. 35)

[102]In addition, the U.S. does require a separate analysis of the "paperwork burden" of regulations and, more generally, information collections, under the Paperwork Reduction Act, which was discussed in more detail above. OMB also tracks and reports to Congress yearly on the total paperwork burden imposed by U.S. agencies. This process and analysis, however is not covered in Circular A-4.

[103]Net administrative costs are defined as: costs introduced by the legislation minus the costs suppressed by legislation at EU and/or national level.

The tariff is based on labor cost and overheads, which are normally the main cost factors of meeting administrative obligations.

Since the recent amendment to the guidelines, taking account of administrative costs has been made obligatory. However, these costs were also taken into consideration for some of the most far-reaching IAs the Commission has done so far. In the RIA supporting the REACH[104] proposal, the administrative costs of each man-day required for meeting the obligations were calculated to be EUR 1000. This figure includes overheads which in the case of chemical laboratory work can be quite substantial.

Required Parameter Values

For the most part, neither document requires that analyses use particular values for parameters of interest. The two exceptions are the value of risk and discount rates. First, Circular A-4 discusses the methods and economic research on the value individuals place on risk reduction in some detail. The guidelines do not come to a definitive conclusion on a specific value, but they do recommend a range. Circular A-4 states that "A substantial majority of the resulting estimates of VSL (the "value of a statistical life", or the monetized value of small changes in fatality risk that when summed up equal one life saved) vary from roughly $1 million to $10 million per statistical life."[105] In practice, these values are widely used in U.S. RIAs in many different regulatory contexts that involve small changes in risk. Circular A-4 also discusses the value agencies may place on interventions that change the risks faced by children. Although research on this point is inconclusive, Circular A-4 states that agencies should place at least as high a value on a child's statistical risk as they do to an equivalent risk faced by an adult.

The Commission guidelines discuss VSL in the context of environmental policy. They recommend a value of €1.0 million ($1.3 million at the exchange rate current as of the draft of this appendix) as a best estimate when monetizing benefits, and between €0.65 ($.85) million and €2.5 ($3.25) million as upper and lower bounds in sensitivity analysis. The Commission guidelines state that these figures are "applicable to deaths in a largely elderly population where the reduction in life expectancy is likely to be short – maybe one year or less."[106] They are not the default choice when monetizing the value of life. Depending on the individual case, different methodologies have been used within the Commission, bearing in mind the relatively low number of EU RIAs that have attempted monetization in the context of value of life. The Commission guidelines support monetization of this type, stating that "[a]ny decision in this context means placing an implicit monetary value on health benefits. Decision-making will be easier and become more consistent if we have a monetary estimate of the value of health benefits. The monetary value represents the strengths of society's preferences."[107] Both Circular

[104]The European Commission has proposed a new EU regulatory framework for chemicals called REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). More information is available at: http://ec.europa.eu/enterprise/reach/index_en.htm
[105] Circular A-4, p. 30.
[106] IA guidelines, p. 38
[107]Commission Guidelines Annexes, p. 38

A-4 and the Commission guidelines are clear that these values are only applicable to interventions resulting in small changes in risk.[108]

Both guidelines also specify discount rates which should be used in all impact analyses to adjust benefits and costs when they do not take place in the same time period. The Commission guidelines state that all analyses should use a discount rate of 4 percent, while Circular A-4 requires that all analyses use discount rates of both 3 percent and 7 percent. Both are real rates of return, which means that they do not include inflation, which should be accounted for with an expected inflation rate. The Commission guidelines state that 4 percent "broadly corresponds to the average real yield on longer-term government debt in the EU over a period since the early 1980s."[109] Circular A-4 provides a detailed discussion of the rationale for the different discount rates. The 7 percent rate approximates the average before-tax rate of return to private capital in the U.S. economy, and represents the opportunity cost of capital in the U.S. Circular A-4 states, however, that when regulation primarily and directly affects private consumption, a lower discount rate is appropriate. The alternative most often used is sometimes called the social rate of time preference, which may be fairly approximated by the historical real rate of return on long term government debt, which is around 3 percent.[110] Thus, the rationale for Circular A-4's lower rate of return also applies to the Commission's required rate of return of 4 percent. Circular A-4 requires both rates for all analysis, because it is often difficult to determine whether regulatory costs primarily displace private capital or private consumption.

Uncertainty Analysis

Both guidelines discuss uncertainty analysis. Specifically, the Commission guidelines state that "it is important to remember that in some cases, the level of uncertainty may be too high to make precise quantified estimates. In these cases, ranges of plausible values or different scenarios should be given…"[111] The guidelines provide a brief introduction outlining the importance of dealing with uncertainty by analyzing its potential impacts. For more detail on how to do this type of work and techniques, the Commission guidelines provide a web link to the Commission's Joint Research Centre (JRC).[112] Circular A-4 requires agencies to characterize in some way the uncertainty inherent in the analysis. "The important uncertainties connected with

[108]Techniques such as VSL measure the willingness to accept or not to accept slight increases in mortality risk, and are not applicable to large changes in risk.

[109]Commission Guidelines Annexes, p. 39. Essentially, the Commission believes that the average rate of return on government bonds should be the only proxy used as it more accurately reflects the opportunity cost of public investments. The U.S. argues that the opportunity cost is more accurately reflected by the private sector rate of return, but that the private personal time preference may be approximated by the same government bond returns recommended by the Commission. The U.S. uses two discount rates reflecting these two different opportunity costs.

[110]The SRTP is calculated in the following way: $r - \rho + \mu g$, where r – SRTP, ρ - discount rate of future consumption over present consumption with no change in per capita consumption, μ -elasticity of marginal utility of consumption with respect to utility, g – annual growth in per capita consumption. Studies have shown the value for ρ to lie between 1.0 and 1.6 (e.g. OXERA 2002), for μ to be around 1 with a range of +/- 0.3-0.5 (e.g. OXERA 2002; Cowell and Gardiner 199; Pearce and Ulph 1995). A good estimate of g is generally around 2-2.5% (e.g. various studies, for UK Madison 2001). When substituting these values into the equation one obtains r – 3-4%.

[111]Commission guidelines, pp. 37-38.

[112]http://sensitivity-analysis.irc.cec.eu.int The JRC is an institution that all Commission services (the DGs) can draw on for expertise, particularly on the use of quantitative techniques such as sensitivity analysis

your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis."[113]

In both cases, the analysis often takes the form of sensitivity analysis of one or more important or particularly uncertain parameters. The Commission guidelines identify sensitivity analysis as an especially useful and relatively easy approach. The Commission guidelines may be understood as encouraging a discussion of both variability—uncertainty for which probabilities or distribution functions exist—and uncertainty, for which no probabilities are available. As both normally go hand in hand, obtaining a good idea of those uncertainties with known probabilities alone is not enough. Dealing with uncertainties without known probabilities generally requires a case-by-case or scenario approach, often comprising a qualitative approach describing different plausible scenarios. The application of uncertainty analysis in the EU is of course also subject to the proportionate analysis criterion. Circular A-4, however, goes further with specific requirements: for rules involving annual impacts of $1 billion or more, Circular A-4 requires agencies to conduct what the guidance calls a "formal quantitative analysis" of the relevant uncertainties about benefits and costs. In practice, this will often take the form of a Monte-Carlo analysis, which assumes a distribution around many of the uncertain variables in order to estimate an uncertainty interval around net benefits. For rules with annual impacts under $1 billion, the guidance does not require as in-depth an analysis, and in practice sensitivity analysis is probably the most common approach. Circular A-4 also encourages, similar to the Commission guidance, a scenario approach to discussing uncertainty where the agency cannot estimate the probability of a particular impact.

Future Monitoring and Evaluation of Programs

The Commission's guidelines stipulate that an RIA has to include information on how achieving the policy objectives will be monitored. There is a specific requirement for evaluating the effectiveness of expenditure programs, including generating data on the basis of carefully designed indicators.[114] The RIA itself must discuss the method by which a program will collect data or how its effectiveness after implementation will be verified. Although this is an important part of the RIA, the guidelines recognize that the final form that evaluation and monitoring takes can only be determined after the proposal has been through the Council and Parliament. Officials are therefore required "to provide a *broad* outline of possible monitoring" and "…evaluation arrangements" and to identify *core* progress indicators.[115]

The evaluation and monitoring requirements in the Commission's IA system has a goal of providing policymakers with a way of verifying whether a policy is achieving its objectives. Many of the indicators that are needed for expenditure programs can also be applied to regulatory proposals. A distinction is made in terms of outputs between expenditure programs and purely regulatory (policy) proposals, and the Commission guidelines acknowledge that it can be much more difficult to develop indicators for the latter. For example, if money is spent on building a road, it is relatively easy to come up with indicators, e.g. miles of road build after x months. For a Directive, however, this is more difficult: transposition into national law or

[113]Circular A-4, p. 38.
[114]Commission guidelines, p. 45.
[115]Ibid, p. 45; with italics by authors.

adoption by the European Parliament cannot be considered an as output. The guidelines suggest that "outputs at EU level could in such a case be based on a typology of the 'key types of measures' adopted by the Member States in order to comply with the Directive." Any indicators in this context should be "RACER: relevant, accepted; credible, easy to monitor and robust."

There is no equivalent requirement for an RIA to include performance indicators, or for post implementation validation or effectiveness analysis in the U.S. under Circular A-4 or EO 12866. Often the effects of regulations in the U.S. will be validated by outside parties, or will be re-evaluated in the context of adopting regulatory reforms, but there is no proactive requirement. In the 2005 Report to Congress on the Costs and Benefits of Federal Regulation,[116] OMB studied the extent to which the *ex-ante* regulatory analysis published by agencies before a rule is finalized are validated for their accuracy after the rule has been put in place. OMB found that only a small fraction of the rules reviewed by OMB before publication have been validated *ex-post*. The only proactive requirement in the U.S. for post-regulatory analysis is under the Regulatory Flexibility Act, Section 610, which obliges agencies to revisit the regulations they passed that significantly impact small businesses. This analysis must take place within 10 years following the original final rule; the analysis need not be quantitative and the agency is not required to consider changing a regulation as a result of this review, even if the review concluded that the regulation is not acting as intended.

E. Conclusion

This section began by stressing the different purposes the two RIA systems serve and hence the function the two sets of guidelines perform. Due to the differences in the legislative systems, or more specifically how laws and regulations are made, impact analysis is produced at different stages in the process. In the U.S., an RIA is produced by an agency tasked by Executive Order 12866 with implementing laws or primary legislation in the most cost-beneficial way. The formal OMB Circular A-4 applies to "economically significant" proposed and final rules whose annual costs or benefits are likely to exceed the threshold of U.S. $100 million. Since agencies have a statutory obligation to show that proposed regulation has a reasonable basis, U.S. RIAs may be drawn upon in court cases.

The Commission's RIAs fulfill the purpose of providing additional information internally and to policy makers on its regulatory or legislative proposals, and are prepared for almost all items on its legislative and work program. Although external parties also use the RIAs, e.g. the European Parliament and the Council of the European Union, they are prepared as an input for internal Commission political decision-making. Thus, in the EU decision making process the final legislative product may be less strongly linked to the Commission RIA, bearing in mind that the Parliament and Council are committed to conducting additional impact analysis of substantial amendments they propose. Moreover, the Commission prepares RIAs for a variety of documents and general policy orientation proposals that do not require RIAs in the U.S. system. Hence, one may conclude that the Commission guidelines have to be more flexible and less prescriptive in its analytical requirements than Circular A-4, in order to apply in a meaningful way to work program items that are of a more general nature.

[116] Available at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html

These differences manifest themselves in the level of detailed advice that is given in both sets of guidelines on quantitative analysis. In the U.S., there clearly is a stronger obligation to do cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA) of an economically significant proposed regulatory action and a reasonable set of alternative regulatory approaches. This must not be confused, however with there being no demands for detailed CBA (or CEA) for Commission proposals of similar economic, social and environmental impacts as the U.S. $100 million threshold. The Commission guidelines clearly state that proportionate analysis is required, which by implication means more detailed, and thus often more quantitative, analysis if the likely impacts are sufficiently large.

A defining feature of the Commission RIA system is the integrated approach, taking into account all economic, social and environmental impacts. The U.S. does take account of economic, social, and environmental impacts, but within a CBA framework. Concluding from this that the U.S. IA system is biased against impacts that cannot be quantified, whereas the Commission pays more attention to these impacts, perhaps at the expense of quantification, might however be misleading. There is an obligation in the U.S. guidelines to take account of non-quantifiable impacts and to provide thorough qualitative analysis. In reality, the differences in the guidelines regarding the ability of the two systems to take account of qualitative impacts and to conduct quantitative analysis may be less straight forward than often thought.

Hence, one may conclude that while many similarities exist, there are significant differences, particularly as regards the legal and institutional framework, the resulting different stages at which RIAs are produced, and the difference in purpose they serve in the two systems. Carrying out one *ex-ante* RIA that can be shared by U.S. regulators and the Commission at this moment in time may be challenging. Sharing the same sources of information, making sure the basis of each analytical approach is sound, and building on each analysis based on a better understanding of the other's system are likely to produce better real results in the area of regulatory cooperation.

The next step in this line of analysis may include a more detailed investigation into how these differences or similarities in the guidelines translate into practice, or rather how Impact Assessments and Regulatory Impact Analyses compare that analyze impacts of a comparable policy or regulatory initiative. It should hopefully be clear from this appendix that such an investigation cannot simply compare the proportion of analyses that quantify impacts, evaluate adequate alternatives, or perform sensitivity analysis in the two systems, but rather would have to respect the different systems, as expressed by, for example, the different proportionality criteria, the narrower applicability of the U.S. Circular, and the relatively short time that the Commission Impact Assessment guidance has been in place.

APPENDIX E: UPDATE ON 2001, 2002, AND 2004 REGULATORY REFORM NOMINATIONS

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

This Report's update includes the final progress report that we will issue for the 2001 and 2002 regulatory reforms. To allow the public to obtain further updates on 2001 and 2002 reforms underway, Table E-5 provides contact information for each agency with responsibility for addressing the reforms listed in Tables E-2 and E-3.

A. 2001 Regulatory Reform Nominations

In the draft version of the 2001 Report, OMB asked for suggestions from the public about specific regulations that should be modified to increase net benefits to the public. We received suggestions regarding 71 regulations. In an initial review of the comments, OMB placed the suggestions into three categories: high priority, medium priority, and low priority.[117] As we did in OMB's 2004 Final Report, we are providing updates on the high and medium priority nominations.

While the 2001 call for nominations received responses from fewer than 50 organizations, the 2002 process was far more ambitious and resulted in almost 1,700 nominations. For this reason, and because one year does not allow time for significant regulatory change, many 2001 nominations were reproposed in 2002. For these regulations, we have provided cross-references to the 2002 nominations listed in Table E-2.

Table E-1: 2001 Regulatory Reform Nominations

Agency	Title of Reform	OMB Priority	Status
Labor	Certification of Employment- Based Immigration and Guest Worker Applications	High	The regulation was nominated again in 2002. See 2002 Nomination Number 87.
Labor	Recordkeeping and Notification Requirements Under the Family and Medical Leave Act	High	The regulation was nominated again in 2002. See 2002 Nomination Number 76.
EEOC	Uniform Guidelines for Employee Selection Procedures	High	The regulation was nominated again in 2002. See 2002 Nomination Number 215.
EPA	"Mixture and Derived From" Rule	High	Reform Concluded. (66 FR 50332)

[117] A detailed description of each reform candidate can be found in Appendix A of OMB's 2001 Final Report, which is available at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

Table E-1: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
EPA	Notice of Substantial Risk: TSCA Section 8(e)	High	Reform Completed. See June 3, 2003 policy clarification and reporting guidance (68 FR 33129).
Labor	Definition of "Serious Health Condition" under FMLA	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 76.
Labor	Limits on how employers may take intermittent leave under FMLA	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 76 and 2002 Guidance Nomination Number 12.
Labor	Information needed for Employer to Designate Leave under FMLA	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 76.
Labor	Wage Determination Process for Service Contractors	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 82.
Transportation	Advanced Air Bags	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 131.
EPA	Definition of "solid waste"	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 173.
EPA	Export Notification Requirements, TSCA Section 12(b) Issue 1	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 190.
EPA	Export Notification Requirements, TSCA Section 12(b) Issue 2	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 190.
OCC/FDIC/ OTS Federal Reserve	Second Consultative Package on the New Basel Capital Accord	Medium	Decided not to pursue.
CFTC	Multilateral Transaction Execution Facilities, Intermediaries and Clearing Organizations; Exemption for Bilateral Transactions	Medium	The agency believes that the nomination concerns a set of final rules that the Commission issued on December 13, 2000 (65 FR 77961 (December 13, 2000). Due to the enactment of statutory revisions to the Commodity Exchange Act (CEA) by the Commodity Futures Modernization Act of 2000 ("CFMA") on December 21, 2000, the Commission largely withdrew those final rules, with the exception of amendments to the Commission's rule concerning investment of customer and conforming amendments to related rules 65 FR 82272 (December 28, 2000)). Notably, the CFMA largely codified in the CEA the framework that the December 13, 2000, rulemaking would have imposed on trading facilities, intermediaries, and clearing organizations and bilateral transactions.

Table E-1: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
CFTC	Fast-track Designation and Rule Approval Procedures	Medium	The agency believes that the nomination concerns fast-track procedures for Commission review of new and amended exchange contracts, rules, and rule amendments adopted by the Commission in March 1997 (62 FR 10427 and 10434). The suggestion that the Commission consider a multi-tier pricing structure, including lower contract application fees, has been obviated by the self-certification provision of the Commodity Exchange Act, as amended by the CFMA. CEA Section 5c(c)(2). Under that provision, contract markets may implement new contracts, rules and rule amendments with a simple, cost-free, self-certified submission to the Commission. The vast majority of contracts, rules and rule amendments are so implemented by contract markets.
OCC/FDIC Federal Reserve OTS	Privacy of Consumer Financial Information	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 248.
SEC	Concept Release on Regulation of Market Information, Fees and Revenues	Medium	Reform Underway as of 2004 update.
SEC	Request for Comment on Issues Relating to Market Fragmentation	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 260.
SEC	Self-Regulatory Organizations	Medium	The regulation was nominated again in 2002. See 2002 Nomination Number 259.

B. 2002 Regulatory Reform Nominations

In our 2003 Final Report, OMB determined which of the 316 reform nominations we received in 2002 were under recent or current consideration at the agencies and which of the nominations should be referred to the agencies.[118] Tables E-2 and E-3 below update the status of the 2002 reform nominations for regulations and guidance documents, respectively, as of December 19, 2006. Also included in this table is a reference number to the detailed nomination descriptions available on our website at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

Table E-2: 2002 Regulatory Reform Nomination Status

Agency	Title of Reform	Ref. Number	Status
Agriculture	Child Nutrition Program	1	Decided not to pursue.
Agriculture	Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems	2	Reform Completed. See October 7, 2002, notice on beef contaminated with *E. coli* O157:H7; in its June 6, 2003, interim final rule on the control of *Listeria monocytogenes* in ready-to-eat products (see Reference number 5); and in its interim final rules on bovine spongiform encephalopathy (BSE). FSIS resolved other issues by means of administrative issuances to its field personnel.
Agriculture	Animal Identification	3	Decided Not to Pursue. A voluntary program for animal identification is being considered by the Animal and Plant Health Inspection Service (APHIS); however, it is being developed from a separate framework than the program referenced by the commenter.
Agriculture	Post Mortem Inspection: Extent and Time of Post Mortem Inspection - Staffing Standards	4	Reform Underway. FSIS is continuing to test a new HACCP-based system of inspection in volunteer establishments. The new system is intended to accommodate new technologies and allow increased operational efficiencies. FSIS has evaluated data from the volunteer system and may use that data to develop a proposed rule to establish a new inspection system.
Agriculture	Zero Tolerance for *Listeria monocytogenes* and Performance Standards	5	Reform Underway. FSIS published an interim final rule, "Control of *Listeria monocytogenes* in Ready-to-Eat (RTE) Meat and Poultry Products" (68 FR 34208), on June 6, 2003. FSIS is completing an analysis of the economic impact of the rule and expects to be in a position to affirm the interim rule as a final rule in the first part of 2007.

[118]For a detailed explanation of OMB's review of the 2002 nominations, see *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on the State, Local, and Tribal Entities*, pp. 21-23, available at http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
Agriculture	Salmonella Performance Standards	6	Reform Completed. See April 16, 2003 Federal Register Notice (68 FR 18593) and February 27, 2006 Federal Register Notice (71 FR 9772). FSIS also began in 2006 to monitor the percent positive verification samples month by month over a calendar year. FSIS evaluates these data, reassesses how it reports Salmonella results for each class of products, and then determines what changes may be needed in its reports of results.
Agriculture	National Organic Program	7	Decided not to pursue
Agriculture	Nutrition Labeling of Ground or Chopped Meat and Poultry Products	8	Reform Underway. FSIS is developing a final rule in response to the comments on the January 18, 2001 proposed rule to require nutrition information either on labels or at the point-of-purchase for the major cuts of single-ingredient, raw meat and poultry products, unless an exemption applies. FSIS expects to publish the final rule in 2007.
Agriculture	Plant Pest Regulations	9	Reform Underway. APHIS published a proposed rule in October of 2001 but decided not to finalize after evaluating the comments received in response. APHIS is considering proposing a similar rule, taking 2001 comments into consideration.
Agriculture	Badge as Identification of Inspectors	10	Decided not to pursue.
Agriculture	Mad Cow Disease	11	Reform Underway**.** See January 12, 2004 Interim final rule "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (69 FR 1862), Interim final rule "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (69 FR 1874), Interim final rule "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter" (69 FR 1885), and Notice "Bovine Spongiform Encephalopathy Surveillance Program" (69 FR 1892). FSIS is continuing to evaluate these rules and comments to develop final rules. See also July 14, 2004, Advance Notice of Proposed Rulemaking (ANPR), ``Federal Measures To Mitigate BSE Risks: Considerations for Further Action,"
Agriculture	Phytosanitary Certificates for Seeds	12	Reform concluded. Final rule published April 13, 2006 (71 FR 19097-19102)
Agriculture	Swine Production Contract Library	13	Reform concluded. Final rule published August 11, 2003 (68 FR 47802-47829)
Agriculture	National Forests Land Use: Special Uses	14	Decided not to pursue.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
Agriculture	Roadless Area Conservation	15	Reform Underway. Next action undetermined. See May 13, 2005 final rule and September 20, 2006 order setting aside the 2005 rule and reinstating the 2001 rule. On September 22, 2006, the State of Wyoming filed a motion asking the Wyoming District Court, among other things, to reinstate its order enjoining the 2001 rule. As a result of ongoing litigation, USDA has notified States they may consider petitioning for new rulemaking under the generic petition provisions in the Administrative Procedure Act (5 U.S.C. 553(e)) and Agriculture Department regulation (7 CFR 1.28).
Agriculture	Low Costs Timber Sales and Grazing Fees	16	Decided not to pursue.
Commerce	Annual Capital Expenditures Survey	17	Decided not to pursue.
Education	Title IX and Collegiate Sports Participation	18	Decided not to pursue.
Education	Title IX and Single-Sex Schools	19	Reform Concluded. Final Regulations were published October 25, 2006.
Education	Federal Family Education Loan Program	20	Reform Concluded – Final Regulations were published November 1, 2002.
Energy	Energy Conservation Standards for Clothes Washers	21	Decided not to pursue.
Energy	Energy Conservation Standards for Central Air Conditioners and Heat Pumps	22	Reform Concluded. Final Rule publishedAugust 17, 2004. (Note: Multiple commenters made different reform proposals.)
HHS/CMS	Special Treatment: Direct Graduate Medical Education Payments	23	Decided not to pursue.
HHS/CMS	Medicare Secondary Payer Provision	24	Reform Concluded. On February 24, 2004, the Centers for Medicare and Medicaid Services issued an instruction implementing § 943 of the Medicare Modernization Act.
HHS/CMS	Physician Certification for Non-Emergency Ambulance Services	25	Reform Underway. CMS has conducted a review to ensure that there are no legal obstacles to the removal of this requirement; the issue remains under discussion with the FBI and DOJ.
HHS/CMS	75% Rule	26	Reform Concluded. The issue was addressed in a Federal Register Notice published on June 25, 2005 - "Inpatient Rehabilitation Facility (IRF) Classification Rule Compliance," which explained the percentages of an IRF's inpatient population that must meet at least one of the medical conditions specified in the notice for cost reporting periods beginning July 1, 2004 through, and after, July 1, 2007.
HHS/CMS	Converted Bed Rule	27	Decided not to pursue.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
HHS/CMS	Exemption Date Rule	28	Decided not to pursue.
HHS/CMS	Medical Director Rule	29	Decided not to pursue.
HHS/CMS	Minimum Staffing Standards for Nursing Homes	30	Decided not to pursue.
HHS/CMS	One-Hour Restraint Rule	31	Reform Concluded. See final rule, ""Hospital Conditions of Participation: Patient's Rights (Restraints and Seclusions)" (RIN # 0938-AN30), to be published in late 2006 or early 2007.
HHS/CMS	Revisions to Medicare Payment Policies	32	Decided not to pursue.
HHS/CMS	Certificates of Medical Necessity	33	Decided not to pursue.
HHS/CMS	Medicare Program Prospective Payment System for Hospital Outpatient Services	34	Reform Concluded. A final rule was published Sept. 9, 2003 (68 FR 532210), which accommodated the requesters' comments concerning a need for Medicare carriers to interpret and enforce the Emergency Medical Treatment and Active Labor Act more uniformly.
HHS/CMS	Use of the OASIS for Home Health Agencies	35	Reform Concluded. CMS has streamlined the OASIS instrument. As a result of these changes, the number of items in the OASIS was reduced by 28%. The amount of time to complete the OASIS was reduced by 25%.
HHS/CMS	Clinical Laboratory Improvement Act Rules	36	Decided not to pursue.
HHS/CMS	Health Insurance Portability and Accountability Act Claims Processing Standards	37	Decided not to pursue.
HHS/FDA	Standard of Chemical Quality – Arsenic	38	Reform Concluded. Final rule published June 9, 2005 (70 FR 36694)
HHS/FDA	Standard of Chemical Quality – Uranium	39	Reform concluded. Final rule published March 3, 2003 (68 FR 9873)
HHS/FDA	Standard of Microbiological Quality—Total Coliform	40	Decided not to pursue.
HHS/FDA	Labeling Genetically Modified Foods	41	Decided not to pursue.
HHS/FDA	Hormones in the Food Supply	42	Decided not to pursue.
HHS/FDA	Antibiotics in the Food Supply	43	Decided not to pursue.
HHS/FDA	Food Identity Standards	44	Decided not to pursue.
HHS/FDA	Medical Drug and Device Regulations	45	Decided not to pursue.
HHS/FDA	Premarket Notice for Bioengineered Foods	46	Decided not to pursue.
HHS/FDA	Labeling of Carmine	47	Reform Underway. NPRM published January 30, 2006. Issuance of a final rule is expected after the review of comments is completed.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
HHS/FDA	Labeling of Sorbitol	48	Decided not to pursue.
HHS/FDA	Labeling f Caffeine Content	49	Decided not to pursue.
HHS/FDA	Labeling of Food Allergens	50	Decided not to pursue.
HHS/FDA	Investigational New Drug (IND) Regulations	51	Decided not to pursue.
HHS/FDA	Pediatric Rule	52	Decided not to pursue.
HHS	Individually Identifiable Health Information	53	Decided not to pursue.
HHS	Protection of Human Subjects	54	Reform Underway. NPRM published July 6, 2006 (69 FR 40854). Projected publication of final rule is April 2007.
HUD	Predatory Lending	55	Decided not to pursue.
HUD	Insured Ten-Year Protection Plans	56	Decided not to pursue.
Interior/ Agriculture	Digital Aircraft Radios	57	Reform Underway. Currently being addressed as part of the Presidential Spectrum Management Initiative.
Interior	Conservation Use in Grazing	58	Reform Concluded. Final rule published July 12, 2006 (71 FR 39402).
Interior	Surface Management of Mining Claims	59	Reform Concluded. Final rule published October 30, 2001 (66 FR 54833).
Interior	Endangered Species Act	60	Reform Underway. Still being considered for action.
Interior	Endangered Species Act Delisting	61	Reform Underway. Comment period on delisting bald eagle reopened on February 16, 2006 (71 FR 8238); proposed definition of "disturb" and draft National Bald Eagle Management Guidelines published on same date (71 FR 8265 and 8309, respectively). Final rule for delisting and for definition, and for final guidelines expected in early February 2007. With regard to the gray wolf, court decisions invalidated changes to the ESA listing for the wolf and rendered moot the 2004 delisting proposal. On March 27, 2006 FWS published a new delisting proposal (71 FR15266).
Interior	National Landscape Conservation System	62	Decided not to pursue.
Interior	Possessory Interest Assets	63	Reform Underway. NPRM expected March 2007.
Interior	Snowmobiles in Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr. Parkway	64	Reform Concluded. Final rule governing snowmobile use for the next three winter seasons (i.e., through winter 2006-07) published November 10, 2004 (69 FR 65348).
Interior	Snowmobiles in the Rocky Mountain National Park	65	Reform Concluded. Final rule published September 2, 2004 (69 FR 53626).
Interior	Wild and Scenic Rivers—Water Resources Projects	66	Decided not to pursue.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
Interior	Cooperative Conservation Initiative	67	Reform Underway on NEPA collaboration.
Justice	Hemp Food Products	68	Decided not to pursue.
Justice	List of Terrorist Organizations	69	Decided not to pursue.
Justice (now DHS)	Driver's Privacy Protection Act	70	Decided not to pursue.
Justice (now DHS)	Electronic Storage of I-9 Forms	71	Reform concluded. Interim rule published June 15, 2006 (71 FR 34510).
Justice (now DHS)	Admission Period for B-1/B-2 Visitors	72	Decided not to pursue.
Justice (now DHS)	Forms I-140 and I-485	73	Decided not to pursue.
Justice (now DHS)	I-9 Employment Verification	74	Reform underway. Proposed rule published February 2, 1998 (63 FR 5287) proposing to shorten number of documents acceptable for verification in employment verification (I-9) process. DHS is reviewing the types of documents currently in use and anticipates issuing a final rule or additional rulemaking, as necessary, during FY07.
Labor	Birth and Adoption Unemployment Compensation	75	Reform complete. Final rule published October 2003.
Labor	Family and Medical Leave Act (FMLA) Regulations	76	Review underway. Next action will be a request for comments on the regulation that is scheduled for December 2006.
Labor	Medical Certification	77	Review underway. Next action will be a request for comments on the regulation that is scheduled for December 2006.
Labor	Computer Professional Exemption under FLSA	78	Reform complete. Final rule published April 23, 2004.
Labor	White Collar Exemption	79	Reform complete. Final rule published April 23, 2004.
Labor	FLSA Administrative Exception	80	Reform complete. Final rule published April 23, 2004.
Labor	Permanent Labor Certification	81	Reform concluded. Final rule published December 27, 2004.
Labor	SCA/Wage Determination Process/Wage Surveys	82	Reform complete. A revised Dictionary of Occupational Titles was published April 17, 2006.
Labor	Davis Bacon Act/Service Contract Act B Inclusion of Pension and Benefit Plans	83	Decided not to pursue.
Labor	SCA Wage Increases and Benefit Improvements	84	Decided not to pursue.
Labor	FLSA Medical Leave	85	Decided not to pursue.
Labor	Across the Board Penalties	86	Review underway. Next action will be a request for comments on the regulation that is scheduled for December 2006.
Labor	H-1B LCA	87	Decided not to pursue.
Labor	Explosives	88	Decided not to pursue.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
Labor and EEOC	Affirmative Action and EO Survey	89	Reform concluded. A final rule rescinding the Equal Opportunity Survey (EO Survey) requirement was published September 8, 2006.
Labor/OSHA	Explosives and Process Safety Management	90	Reform underway. NPRM scheduled to be published March 2007.
Labor/OSHA	Hexavalent Chromium	91	Reform concluded. Final rule published February 28, 2006.
Labor/OSHA	Hazard Communication	92	Decided not to pursue. Electronic MSDS access addresses the issue.
Labor/OSHA	Lead in Construction	93	Reform underway. Regulatory Flexibility Act Section 610 review scheduled to be completed March 2007.
Labor/OSHA	Payment for Personal Protective Equipment	94	Reform underway. Final rule scheduled to be published May 2007.
Labor/OSHA	Exposure to Crystalline Silica	95	Reform underway. Peer review of risk assessment scheduled to be completed April 2007.
Labor/OSHA	Sling Standard	96	Reform underway. Guidance document scheduled to be published in 2006. Rule will be revised in a future phase of the National Consensus Standards rulemaking.
Labor/OSHA	Tuberculosis (TB) Standard	97	Decided not to pursue. OSHA withdrew its proposed rulemaking in December, 2003.
Labor/OSHA	Walking/Working Surfaces	98	Reform underway. NPRM scheduled to be published October 2007.
Labor/OSHA	Process Safety Management/Highly Hazardous Chemicals	99	Reform concluded. ICR approved through October 31, 2009.
Labor/OSHA	Bloodborne Pathogens Standard	100	Reform concluded. ICR approved through November 30, 2007.
Labor/OSHA	Metalworking Fluids	101	Decided not to pursue. OSHA has addressed the hazards of metalworking fluids by developing a best-practices guide and making it available on its Web Site in 2001.
Labor/OSHA	Recordkeeping for Work-Related Injuries, Illnesses and Fatalities	102	Reform concluded. Final rules published July 2002 and June 2003.
Labor/OSHA	Ergonomics Standard	103	Decided not to pursue. OSHA is addressing this issue through the issuance of guidelines, enforcement, and compliance assistance.
Labor/EBSA	Claims Procedures	104	Reform concluded. Final rule published November 21, 2000.
State	Flight Simulators	105	Decided not to pursue.
DOT	Disadvantaged Enterprise Business Program	106	Decided not to pursue.
DOT/FAA	General Definitions of Major and Minor Repair	107	Reform concluded. Advisory Circular 43-210 revised 2/17/04.
DOT/FAA	Design and Construction	108	Decided not to pursue.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
DOT/FAA	Standards for Approval for High Altitude Operation of Subsonic Transport Airplanes	109	Reform underway. FAA is considering rulemaking in response to recommendations from the Aviation Rulemaking Advisory Committee. An expected date of next actions has not been determined.
DOT/FAA	Seats, Berths, Safety Belts, and Harnesses	110	Decided not to pursue.
DOT/FAA	Emergency Landing Dynamic Conditions	111	Reform concluded. Advisory Circular 25.562-1B revised 1/10/06.
DOT/FAA	Improved Flammability Standards for Thermal/Acoustic Material	112	Reform concluded. Final rule Amendment 25-111 became effective 9/2/03 (68 FR 45046).
DOT/FHWA	Contract Requirements for Minor Transportation Projects	113	Decided not to pursue.
DOT/FHWA	Historic Preservation Regulations	114	Decided not to pursue.
DOT/FHWA	Outdoor Advertising Control	115	Decided not to pursue.
DOT/FHWA	Highway Design	116	Decided not to pursue.
DOT/FHWA	Traffic Operations	117	Reform Concluded. Final rule 11/20/2003.
DOT/FHWA	Highway Work Zone Safety	118	Reform Concluded. Final rule 9/9/2004; effective 10/12/2007.
DOT/FHWA	Commercial Size and Weight	119	Decided not to pursue. Requires legislative change.
DOT/FHWA and FTA	Transportation Planning and Environmental Review Procedures	120	Reform Underway. Final rule expected early 2007.
DOT/FMCSA	Inspection, Repair, and Maintenance	121	Reform Underway. NPRM expected December 2006.
DOT	Background Checks for Truckers Hauling Hazardous Materials	122	Reform Underway. IFR published 5/5/2003. Final Rule pending DHS publication.
DOT	Commercial Vehicle Cross-Border Safety	123	Reform Underway. IFR published 3/19/2002. Final Rules pending operating experience at the borders.
DOT/FMCSA	Hours of Service for Truckers	124	Reform Concluded. Final rule published 8/25/2005.
DOT/FTA	Buy America Pre-Award and Post-Delivery Certification	125	Decided not to pursue.
DOT/FTA	Set-Aside for Intercity Bus	126	Decided not to pursue.
DOT/MARAD	Vessel Financing Assistance	127	Decided not to pursue.
DOT/NHTSA	Corporate Average Fuel Economy (CAFE) Standards	128	Reform Concluded for light trucks – Final Rule published 4/6/06. Reform Underway for passenger cars – No specific milestone.
DOT/NHTSA	Head Restraints	129	Reform Concluded. Final rule published 12/14/04.
DOT/NHTSA	Tire Pressure Monitoring Systems	130	Reform Concluded. Final rule published 4/8/05.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
DOT/NHTSA	Advanced Airbags	131	Reform Concluded. Final rule responding to petitions for reconsideration was published 08/20/04.
DOT/FHWA	Fuel System Safety Standard B Vehicle Fires	132	Reform Concluded. Final rule published 12/01/03.
DOT/NHTSA	Occupant Crash Protection	133	Decided not to pursue frontal offset rule. Reforms Concluded: a) Final Rule (35 mph maximum speed for frontal barrier crash tests using belted 5th percentile adult female test dummies) published 08/31/06. b) Advanced Air Bags – See #131 above. c) Side Impact – See #152 below.
DOT/NHTSA	Lower Interior Front Impact Protection	134	Decided not to pursue.
DOT/NHTSA	Passenger Vehicle Compatibility	135	Reform Underway. NHTSA will make a regulatory decision after reviewing comments on its11/25/03 technical report and conducting further research. No specific milestone.
DOT/NHTSA	Rollover Protection	136	Reform Underway: a) NCAP Rollover Consumer Information – See #150 below. b) Electronic Stability Control – Final rule by 4/1/09 c) Door Retention Performance – See #139 below. d) Roof Crush Resistance – See #137 below.
DOT/NHTSA	Roof Crush	137	Reform Underway. Final rule by 07/01/08.
DOT/NHTSA	Passenger Vehicle Brakes	138	Decided not to pursue.
DOT/NHTSA	Door Locks	139	Reform Underway. Final rule by 2/10/08.
DOT/NHTSA	Child Restraints	140	Reform Underway: a) 10-year old Dummy –Final Rule; date to coincide with child restraint final rule. b) Child Restraint Standard – SNPRM in 2007. Reform Concluded. Child Restraint Webbing Strength: Final rule published 06/07/06.
DOT/NHTSA	Tire Safety	141	Reform Concluded: a) Tire Safety –Final rule (snow tires and certain specialty tires) published 01/06/06 and held technical workshop 7/11/06. b) Tire Pressure Monitoring Systems –Final rule published 04/08/05.
DOT/NHTSA	Glazing Materials and Crash Avoidance	142	Reform Concluded. Final rule published 07/12/05.
DOT/NHTSA	Lamps, Reflective Devices and Associated Equipment	143	Reform Underway. Final rule in 2007; Report to Congress by 02/10/07.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
DOT/NHTSA	Commercial Vehicle Operator Visibility	144	Reform Underway. Final rule in 2007.
DOT/NHTSA and FMCSA	On-Board Crash Recorders	145	Reform Concluded. Final rule published 8/28/06. Reform Underway. FMCSA NPRM expected in early 2007.
DOT/NHTSA	Driver Distractions	146	Reform Underway. Regulatory decision based on completion of research.
DOT/NHTSA	Pedestrian Crash Protection	147	Reform Underway. Regulatory decision based on completion of research.
DOT/NHTSA	Bumper Strength	148	Decided not to pursue.
DOT/NHTSA	Commercial Vehicle Brakes	149	Reform Underway. Final rule expected in 2007.
DOT/NHTSA	Consumer Information	150	Decided not to pursue: Braking NCAP. Reform Concluded: a) Frontal NCAP –Notice of Decision 12/20/05 b) Rollover Consumer Information – Expanded rollover consumer information provided starting with model year 2004 vehicles. c) New Car Safety Labeling – Final Rule 9/12/06 Reform Underway: Side NCAP; Head Injury Side Impact Data. Specifics of regulatory decisions for both of these reforms are dependent on anticipated 2007 upgrade of FMVSS 214 (see #152 below). No specific milestones.
DOT/FHWA and NHTSA	Commercial Vehicle Rollover	151	Decided not to pursue.
DOT/NHTSA	Side-Impact Protection	152	Reform Underway - Final Rule May 2007
DOT/NHTSA	.08 Alcohol Incentive Program	153	Reform Concluded. NHTSA sent a letter to the Wisconsin Department of Transportation July 2002.
DOT/FHWA and NHTSA	Emergency Response and Auto Crash Notification	154	Decided not to pursue.
DOT/NHTSA	Commercial Vehicle Design Compatibility	155	Decided not to pursue.
DOT/RSPA	Collection of Annual Registration Fees	156	Reform Concluded. Final Rule published 4/15/05
DOT/RSPA	Emergency Preparedness Grants	157	Reform Underway. Review by Fall 2007
DOT/RSPA	Hazardous Materials Training	158	Decided not to pursue.
Treasury	Currency and Foreign Financial Accounts	159	Decided not to pursue.
Treasury	Alcohol Labeling	160	Reform Concluded. Treasury Decision (T.D.)-TTB. No 1, Final Rule on Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages, 68 FR 10076 (March 3, 2003).

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
Treasury/IRS	Employer Identification Numbers	161	Decided not to pursue.
Treasury/IRS	Flexible Spending Accounts	162	Reform Concluded. Notice 2005-42 allows participants in an FSA to carryover unused benefits for 2½ months following the end a plan year.
Treasury/IRS	Government Fleet Fuel Cards	163	Reform Concluded. See section 4 of Notice 2005-80 (October 21, 2005), which provides guidance on provisions of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (Pub. L. 109-59) (SAFETEA) relating to credit card sales of taxable fuel to certain exempt entities.
Treasury/IRS	Interest Reporting Requirements	164	Reform Underway. NPRM published August 2, 2002 (67 FR 50386). Next action undetermined.
Treasury/IRS	Domestic Relations Tax Reform Act Rules	165	Reform Concluded. Treasury Decision (T.D.) 9035, Final Rule, 68 FR 1534 (January 13, 2003). The suggestion was not accepted because IRS and Treasury concluded it would not be appropriate to apply the regulations retroactively.
Treasury/IRS	Monthly Tax Deposits	166	Decided Not to Pursue.
Treasury/IRS	Mortgage Revenue Bond Purchase Price Limits	167	Reform Concluded. Treasury and IRS issued new IRS Revenue Procedures that update the relevant purchase price information to be more current and applying a new methodology. See Rev. Proc. 2006-17, 2006-14 I.R.B. (April 3, 2006), Rev. Proc. 2005-15, 2005-9 I.R.B. (February 28, 2005), and Rev. Proc. 2004-18, 2004-8 I.R.B. (February 23, 2004).
Treasury/IRS	Partnership Investments in Small Business Stock	168	Decided not to pursue.
Treasury/IRS	Business Use of Home	169	Decided not to pursue.
EPA	Regulatory Reform for Handling Refrigerants	170	Reform concluded. Final Rules published July 24, 2003 (68 FR 43786) (Technical Correction also published) and March 12, 2004 (69 FR 11946).
EPA	Chemical Plant Safety Standards	171	Reform Concluded. Review of RMP database completed in 2005.
EPA	Risk Management Plans (Worst Case Scenario)	172	Decided not to pursue.
EPA	Definition of Solid Waste	173	Reform Concluded. NPRM published October 28, 2003.
EPA	RCRA Burden Reduction Initiative	174	Reform Concluded. Final Action published April 4, 2006.
EPA	RCRA Subtitle C Hazardous Waste Regulations	175	Reform Concluded. Conducted internal and external stakeholder meetings. Issued guidance on satellite accumulation areas on March 17, 2004
EPA	Best Available Retrofit Technology	176	Reform Concluded. Final Action published 07/06/2005 (70 FR 39104)

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
EPA	1997 EPA Standards for Ozone and Particulate Matter	177	Reform Underway. Final Action on Particulate Matter is expected in early 2007. On November 29, 2005, EPA published Phase 2 of the final rule to implement the 8-hour ozone national ambient air quality standard (NAAQS). On December 11, 2006, EPA announced its decision to reconsider and take additional comment on three provisions in that final rule.
EPA	Protections for Farm Children from Pesticide Exposures	178	Decided not to pursue. In response to a petition raising the same issue, EPA declined to name farm children as a separate major, identifiable subgroup, pointing out that any pesticide exposures to children as a result of proximity to agricultural fields can be fully taken into account as part of the consideration of EPA's already existing major identifiable subgroups of children. The Agency published its decision and rationales in two separate Federal Register notices; one in relation to objections filed by NRDC et al to a tolerance for Imidacloprid (69 FR 30069; May 26, 2004) and in relation to objections filed to numerous tolerances for several other pesticides (70 FR 46706; August 10, 2005).
EPA	Definition of Volatile Organic Compound	179	Reform concluded. Notice of Interim Guidance published 09/13/2005 (70 FR 54047)
EPA	Motor Vehicle Emission Standards for Greenhouse Gases	180	Reform concluded. Notice of denial of petition for rulemaking, September 8, 2003 (68 FR 52922).
EPA	Heavy-Duty Engines and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements	181	Decided not to pursue.
EPA	Protection from Pollution from Diesel Engines	182	Decided not to pursue.
EPA	Proposed Tier 2 Motor Vehicle Emission Standards and Sulfur Gasoline Control Requirements	183	Decided not to pursue.
EPA	Withdrawal of State Delegations	184	Decided not to pursue.
EPA	New Source Review	185	Reform concluded. Final rules published on November 7, 2003 and October 27, 2003. Stay granted December 24, 2003.
EPA	Risk Assessment for Rodenticides	186	Reform concluded. Comparative ecological assessment completed 2003.
EPA	Ban on Chromated Copper Arsenate (CCA)	187	Reform concluded. Granted cancellation on March 17, 2003.
EPA	TRI Alternate Reporting Threshold (Form A)	188	Decided not to pursue.
EPA	Collection of Health Screening Data	189	Decided not to pursue.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
EPA	Export Notification Requirements	190	Reform concluded. Final rule published November 14, 2006 (71 FR 66245); Technical correction published November 28, 2006(71 FR 68750).
EPA	PCB Spill Cleanup Policy	191	Reform concluded. Completed internal review, no further action planned.
EPA	Storage for Reuse	192	Reform concluded. FR Notice published September 7, 2004.
EPA	RCRA Cement Kiln Dust (CKD)	193	Reform underway. Still contemplating further action.
EPA	Spill Prevention Plans	194	Reform concluded. Final rule published on April 17, 2003 extending compliance dates and outreach.
EPA	NPDES and Sewage Sludge Monitoring Reports	195	Decided not to pursue.
EPA	Watershed Rule (Total Maximum Daily Load)	196	Decided not to pursue.
EPA	TRI Lead	197	Decided not to pursue.
EPA	Arsenic in Drinking Water	198	Decided not to pursue.
EPA	Concentrated Animal Feeding Operations	199	Reform concluded. Final rule published February 12, 2003. Guidance published November 3, 2003.
EPA	Stormwater Construction General Permit	200	Reform concluded. Final rule published July 1, 2003.
EPA	Stormwater Phase I	201	Decided not to pursue.
EPA	Stormwater Phase II	202	Decided not to pursue.
EPA	Removal Credits for POTWs	203	Reform concluded. Final Issue Paper released September 27, 2005.
EPA	Sanitary Sewer Overflows	204	Reform underway. Report to Congress signed August 5, 2004. Final rule expected November 2007.
EPA	Effluent Guidelines for Metal Products and Machinery	205	Reform concluded. Final rule published May 15, 2003.
EPA	Drinking Water Standards for Emerging Contaminants	206	Reform concluded. Final notice published July 18, 2003.
EPA	Drinking Water Standards for Radionuclides	207	Decided not to pursue.
EPA	Radon in Drinking Water	208	Reform underway. Final action projected to publish in 2009
EPA	TRI Form R Reporting	209	Reform underway. Final action projected for winter, 2007/2008.
EPA	TRI: Lowering Reporting Thresholds for PBT Chemicals	210	Decided not to pursue.
EPA	Groundwater Rule	211	Reform concluded. Final rule published January 4, 2006 (71 FR 65574).
EPA	Disinfection Byproducts Rule	212	Reform concluded. Final rule published April 4, 2006 (71 FR 388).
EEOC	Employer Information Report EEO-1	213	Decided not to pursue.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
EEOC	Waivers Under Age Discrimination in Employment Act	214	Decided not to pursue.
EEOC and DOL	Affirmative Action and EO Survey/Definition of Applicant	215	EEOC reform is underway for Definition of Applicant. Next Action: 30 Day PRA Notice; date undetermined. DOL reform is complete. Final rule on applicants was published on October 7, 2006, and the final rule on the Equal Opportunity Survey was published on September 8, 2006.
FCC	Ground Penetrating Radar and Other Ultrawide Band Devices	216	Reform Underway. 17 FCC Rcd 13522 (2002), 18 FCC Rcd 3857 (2003), and 18 FCC Rcd 3857 (2003).
FCC	Telephone Number Portability	217	Reform Underway. 14 FCC Rcd 3092, 17 FCC Rcd 14972; affirmed on appeal in *CTIA v. FCC,* 330 F.3d 502 (D.C. Cir. 2003), 18 FCC Rcd 23697, 18 FCC Rcd 20971, 18 FCC Rcd 23,697, *U.S. Telecom Ass'n v. FCC*; 400 F.3d 29 (D.C. Cir. 2005), and 20 FCC Rcd 8616.
FCC	Broadband Access to the Internet Over Cable	218	Reform Completed. *In re Inquiry Concerning High-Speed Access to the Internet Over Cable and Other Facilities, 17 FCC Rcd* 4798 (2002), affirmed by the Supreme Court in *NCTA v. Brand X Internet Services*, 125 S. Ct. 2688 (2005).
FCC	Open Network Architecture Reporting	219	Reform Underway. In 2005, the Commission eliminated ONA requirements for facilities-based wireline broadband Internet access services. *See In the Matter of Appropriate Framework for Broadband Access to the Internet over Wireline Facilities*, 20 FCC Rcd. 14583 (2005). That order is currently on appeal before the United States Court of Appeals for the Third Circuit.
FCC	International Section 214 Authorizations	220	Decided not to pursue.
FCC	Complaints, Applications, Tariffs, and Reports	221	Reform Completed. The Commission sought comment on these reporting requirements in an NPRM, 19 FCC Rcd 764 (2004) and decided on August 21, 2006, to retain these requirements. *See In the Matter of Biennial Regulatory Review of Regulations Administered by the Wireline Competition Bureau*, FCC 06-86, 2006 WL 2433825, ¶¶ 4-5.
FCC	Content of Applications	222	Reform Underway. NPRM, 19 FCC Rcd 708 (2004), 20 FCC Rcd 13,900 (2005), 19 FCC Rcd 3267 (2004), 18 FCC Rcd 4243 (2002).
FCC	Competitive Bidding Proceedings	223	Reform Underway. The Commission rejected the proposal to eliminate ownership information from the short form auction application; 18 FCC Rcd 4243, 4274-75 (2002). It continues to consider the recommendation that the filing of the transaction documents for applications for transfers of control or licenses may no longer be necessary.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
FCC	Procedures Implementing NEPA	224	Reform Underway. See *Nationwide Programmatic Agreement Regarding the Section 106 National Historic Preservation Process*, FCC 04-222 (rel. Oct. 5, 2004), February 2004 creation of the Tower Construction Notification System (TCNS), and October 6, 2005, *Declaratory Ruling*, FCC 05-176.
FCC	Access to Telecom Service	225	Reform Underway. 18 FCC Rcd 4726 (2003). The Commission again sought comment in its pending 2006 Biennial Review. *See The Commission Seeks Public Comment in the 2006 Biennial Review of Telecommunications Regulations*, 21 FCC Rcd 9422 (2006)
FCC	Construction, Marking, and Lighting of Antenna Structures	226	Reform Underway. On June 13, 2006, the FAA issued a proposed rule (17 Fed. Reg. 34029). A public notice and request for comments on October 30, 2006 addressed construction and maintenance of antenna structures.
FCC	911 Services	227	Reform Underway. The FCC adopted, as a result of voluntary efforts of an industry working group, a standard to identify 911 calls made from non-initialized phones. The Commission modified its rules to require that carrier-donated, non-service initialized phones and new "911-only" handsets be programmed with a sequential number beginning with "911," plus seven digits. Carriers were further required to complete any network programming necessary to deliver this "telephone number" from carrier-donated non-service initialized phones and "911-only" handsets to PSAPs.
FCC	Cellular Radiotelephone Service	228	Reform Underway. Section 22.367 and 22.919 of the rules, 47 C.F.R. §§ 22.367 and 22.919, were eliminated in 17 FCC Rcd 18401 (2002). As part of its Biennial Review proceeding, the Commission adopted the proposal to eliminate the transmitter-specific posting requirement of Part 22 licensees in section 22.303. *See* 20 FCC Rcd 13900, 13907 ¶ 12 (2005).
FCC	Required New Capabilities Pursuant to CALEA	229	Decided not to pursue.
FCC	Personal Communications Services	230	Reform Completed. 21 FCC Rcd 5360, 5366-68 (2006), 21 FCC Rcd 5360, 5396-97 (2006).
FCC	Reports of Communications Common Carriers	231	Decided not to pursue.
FCC	Abbreviated Dialing Codes	232	Reform Underway. Public Notice, DA 04-3219 (Oct. 8, 2004), March 14, 2005 order designating 811; two-year implementation period underway.
FCC	Fees for Switching Long Distance Carriers	233	Reform Underway. 20 FCC Rcd 3855 (2005).

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
FCC	Remedying Interference to Public Safety Communications 800MHz	234	Reform Underway. Orders issued in 19 FCC Rcd 14,969 (2004); 19 FCC Rcd 25120 (2004); and 20 FCC Rcd. 16015 (2005); petition for review of the orders denied in *Mobile Relay Assocs. v, FCC*, 457 F.3d 1 (D.C. Cir. 2006). Other challenges in the D.C. Circuit related to this proceeding are being held in abeyance pending the Commission's resolution of reconsideration petitions.
FCC	Mitigation of Orbital Debris	235	Reform Underway. *Orbital Debris Mitigation Order*, 69 FR 54581, 19 FCC Rcd 11567, 19 FCC Rcd 16333 (2004).
FCC	Customer Proprietary Network Information	236	Reform Underway. See February 14, 2006 NPRM on steps needed to further protect the privacy of customer proprietary network information, 21 FCC Rcd 1782 (2006). Congress is also currently considering legislation to address these issues.
FCC	Private Land Mobile Radio Services	237	Reform Underway. See 2004 FCC request for public comment; 19 FCC Rcd 708 (2004), 20 FCC Rcd 13900, 13904 ¶ 7 (2005) and addition of subsection 90.175(j)(17); 20 FCC Rcd 13900, 13904. See also 20 FCC Rcd 16015, 16070 ¶ 121 (2005) amendment of section 90.175(j)(8).
FCC	Selection and Assignment of Frequencies	238	Reform Underway. 20 FCC Rcd 13900 (2005), 18 FCC Rcd 4243, 4364 (2002).
FCC	Competitive Bidding Procedures for 900 and 800 Mhz Service	239	Reform Underway. A Public Notice issued on November 22, 2006 lists this section 90.911 as among those to be reviewed in the next 12 months pursuant to the Regulatory Flexibility Act.
FERC	Generator Interconnection Agreements	240	Reform Concluded. Final Rule, Order No. 2006, Issued May 12, 2005 (70 FR34189, June 13, 2005); Final Rule on Rehearing, Order No. 2006-A, Issued November 22, 2005, (70 FR 71760, November 30, 2005); Final Rule on Rehearing, Order No. 2006-B, Issued July 20, 2006 (71 FR 42587, September 13, 2006).
Federal Reserve	Regulation C: Annual Percentage Rate Reporting	241	For a status update, please call the agency contact listed in Table E-5.
Federal Reserve	Regulation D: Definition of Restricted and Unlimited Withdrawals	242	For a status update, please call the agency contact listed in Table E-5.
Federal Reserve	Monetary Policy Reserves, Regulation D	243	For a status update, please call the agency contact listed in Table E-5.
Federal Reserve	Electronic Account/Loan Applications	244	For a status update, please call the agency contact listed in Table E-5.
Federal Reserve	Truth in Lending/ RESPA	245	For a status update, please call the agency contact listed in Table E-5.
Federal Reserve	Definition of Electronic Address	246	For a status update, please call the agency contact listed in Table E-5.
Federal Reserve	Collection of Data and Race and Ethnicity	247	For a status update, please call the agency contact listed in Table E-5.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
Federal Reserve	Regulation P: Privacy of Consumer Financial Information	248	For a status update, please call the agency contact listed in Table E-5.
FTC	Fair Packaging and Labeling Requirements	249	Reform Underway. FTC plans to review this rule during 2007 or 2008 as part of its ongoing systematic review of all Federal Trade Commission rules and guides.
FTC	Cooling Off Period for Sales Made at Home	250	Reform Underway. FTC plans to review this rule during 2008 as part of its ongoing systematic review of all Federal Trade Commission rules and guides.
FTC	Truth in Lending Requirements	251	Decided Not to Pursue. FTC is ready to participate with Federal Reserve Board, the promulgating agency, and several other enforcing agencies to improve effectiveness of consumer credit disclosure requirements
FTC	Retail Electricity Competition Plans	252	Reform Underway. Agency monitors developments in the industry and provides policy advice when asked at the state and federal levels; part of interagency task force to study and report on competition in the electric power industry at the wholesale and retail levels.
NARA	Disposition of Federal Record	253	Reform Concluded. Final rule published August 29, 2005.
OPM	Federal Employee Health Benefits	254	Decided not to pursue.
SEC	Regulation S-K: Environmental Liability Reporting	255	Reform Underway. Rulemaking Petition 4-463 encompassing this comment remains under advisement.
SEC	Disclosure of Mutual Fund After-Tax Returns	256	Reform Concluded. The scope of the required disclosure was reduced in a final rule on disclosure of mutual fund after-tax returns that was adopted on February 5, 2001.
SEC	Disclosure of Order of Execution and Routing Practices	257	Reform Concluded. These issues were considered in connection with a final rule on disclosure of order execution and routing policies that was adopted on December 1, 2000.
SEC	Registration of Broker-Dealers	258	Reform Concluded. The issues were considered in connection with a simplified final rule on registration of broker-dealers adopted on August 27, 2001, in response to a statutory mandate to adopt the rules and form.
SEC	Self-Regulatory Organizations	259	Reform Concluded. These issues were considered in connection with a final rule on proposed rule changes of self-regulatory organizations adopted on April 5, 2004.
SEC	Market Fragmentation	260	Reform Concluded. Final rule, Regulation NMS, adopted on June 29, 2005 addresses issues relating to market fragmentation.

Table E-2: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Ref. Number**	**Status**
SEC	Confirmations of Securities Transactions	261	Reform Underway. Commission requested comments on costs and benefits in a proposed rule on confirmation requirements released on February 10, 2004.
SEC	Recordkeeping by Registered Investment Companies	262	Decided not to pursue. Most of the records required to be maintained by the rule are of the type that generally would be maintained as a matter of good business practice and to prepare a fund's financial statements.
SEC	Investment Advisor Registration Updates	263	Decided not to pursue. Requirements to register investment adviser representatives are State law requirements.
SBA/FAR	Contract Bundling	264	Reform Concluded. a): Final rule: Small Business Government Contracting Programs; subcontracting, 69 FR 75820 (Dec 20, 2004). b)Final rule: Small Business Government Contracting Programs, 68 FR 60006, (Oct. 20, 2003).
US Corps	Nationwide Permits	265	Decided not to pursue.
US Corps, EPA	Definition of Fill Material	266	US Corps: Reform concluded. Final rule published in FR May 9, 2002 (Vol 67, Num 90). EPA: Decided not to pursue.
USPS	Commercial Mail Receiving Agencies	267	Decided not to pursue.

Table E-3: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Ref. Number**	**Status**
USDA	Policy on Beef Contaminated with *E. coli* O157:H7	1	Reform Completed. See October 7, 2002 Notice stating that establishments producing raw beef products were required to reassess their HACCP plans for these products in light of relevant data on *E. coli* O157:H7 (67 FR 62325). See also March 31, 2004 revised instructions to inspection program personnel concerning sampling and testing raw beef products for *E. coli* O157:H7 and May 26, 2005 Notice to establishments that produce mechanically tenderized beef products (70 FR 30331).
HHS/CMS	Medicare Carrier Manual/Medicare Intermediary Manual	2	Reform Underway. CMS has conducted a review to ensure that there are no legal obstacles to the waiving of deductibles in payments for private ambulance services, but the issue remains under discussion with the FBI and DOJ.
HHS/CMS	Signature on File Requirement for Ambulance Services	3	Decided not to pursue.
HHS/CMS	Payment to Health Care Delivery System	4	Decided not to pursue.
HHS/CMS	Individual Health Insurance Rules	5	Decided not to pursue.
HHS/CMS	Guidance to Surveyors-Long Term Care	6	Decided not to pursue.
HHS	Discrimination Against Persons with LEP	7	Reform Concluded. See August 8, 2003 Federal Register Notice (68 FR 47311) adopting the uniform guidance for federal agencies issued in March 2002 and the subsequent model guidance published by DOJ in June 2002.
HHS/FDA	Nine-Compounds Monitoring	8	Decided not to pursue.
HHS/FDA	Coverage of Personal Importations	9	Decided not to pursue.
Interior	Endangered Species Act Survey Protocols	10	Decided not to pursue.
Justice	Guidance on Federal Prison Industries	11	Decided not to pursue.
Labor	Coordination of FMLA with other Leave Policies	12	Review Underway. Next action will be a request for comments on the regulation that is scheduled for December 2006.
DOL	Guidance on Equal Employment Opportunity	13	Reform Underway. OFCCP plans to publish a proposed rule in March 2007 that will amend certain sections of its regulations to correspond to new Employer Information Report (EEO-1) as published on November 28, 2005.
DOL/OSHA	Inspection Procedures and Interpretive Guidance for Control of Hazardous Energy (Lockout/Tagout)	14	Reform Underway.

Table E-3: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Ref. Number**	**Status**
DOL/OSHA	OSHA Directive CPL 2.100, Application of the Permit-Required Confined Spaces (PRCS) Standards	15	Reform Underway.
Labor/OSHA	Multi-Employer Citation Policy	16	Reform Underway. Agency gathering information.
DOT/FAA	General Operating and Flight Rules	17	Decided not to pursue.
DOT/Coast Guard (now DHS)	Marine Safety Manual	18	Reform concluded. Final rule published9/26/2003 (68 FR 55436). Internal policy guidance provided by letter to Coast Guard units in June 2003.
Treasury/IRS	Low-Income Housing Tax Credit	19	Decided not to pursue.
Access Board	ADA/ABA Guidelines	20	Reform Concluded. Final rule published on July 23, 2004.
EPA	EPA Index of Applicability Decisions	21	Reform concluded. FR Notice published February 13, 2003
EPA	New Source Review	22	Reform concluded. Final rule published on October 27, 2003
EPA	"Once In, Always In" Policy	23	Reform underway.
EPA	Improving Air Quality Through Land Use Activities	24	Decided not to pursue.
EPA	Improving Air Quality Using Economic Incentive Programs	25	Decided not to pursue.
EPA	TRI Reporting Forms and Instructions	26	Reform concluded. Final rule published July 12, 2005 (70 FR 1674).
EPA	TRI Reporting Questions and Answers	27	Reform concluded. Addendum to Q and A document published in early winter 2005.
EPA	Waterborne Diseases	28	Reform concluded. Published in the Journal of Water and Health - Estimating Disease Risks Associated With Drinking Water Microbial Exposures (ISSN 1477-8920) Vol. 4 Supplement 2 July/August 2006.
EPA	Food Quality Protection Act Policy Papers	29	Decided not to pursue.
EPA	Integrated Risk Information System	30	Reform underway. Constantly performing assessments
EPA	Investigating Title VI Administrative Complaints	31	Decided not to pursue.
EPA	Economic Benefit of Noncompliance in Civil Penalty Cases	32	Reform concluded. Direct Final published June 18, 2002.
EPA	TRI Lead Reporting	33	Decided not to pursue.
EPA	Pesticide Registration Notices	34	Decided not to pursue.
EPA	Site-Specific Risk Assessments in RCRA	35	Reform concluded. Final response issued October 12, 2005 in Final NESHAP rulemaking for Hazardous Waste Combustors (70 FR 59402).

Table E-3: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Ref. Number**	**Status**
EPA	Cancer Risk Assessment Guidance	36	Reform concluded. Final Guidance published April 7, 2005 June 18, 2002.
EPA	RCRA Spent Catalyst Policy	37	Decided not to pursue.
EPA	Superfund Indirect Costs	38	Decided not to pursue.
EPA	Ecoregional Nutrient Criteria Documents	39	Decided not to pursue.
EPA	Submetering Water Systems	40	Reform concluded. Final policy memorandum signed on December 16, 2003.
EPA	Drinking Water Affordability	41	Reform underway. Published proposal on March 2, 2006 (71 FR 10671) and plan to publish the final in February, 2007.
EPA	Clean Water Act Jurisdiction ("SWANCC Decision")	42	Reform concluded. ANPRM published January 15, 2003
EEOC	Guidance Document: Mandatory Binding Arbitration	43	Reform Underway. Next Action: Circulation of Proposal to Commission; date undetermined.
FTC	Guidance Document: FCRA & Workplace Investigations	44	Decided not to pursue.
OMB	OMB Analytic Guidance	45	Reform Concluded: OMB's revised final guidance was issued as Circular A-4 on September 17, 2003.
OMB	Performance of Commercial Activities	46	Reform Concluded: OMB issued a revised Circular A-76 on May 29, 2003.
OMB	Cost Accounting Standards for Educational Institutions	47	Decided not to pursue.
SBA	Guidance on Credit Unions	48	Reform Concluded. Legal opinion to Mr. Daniel A. Mica and Mr. Fred R. Becker Jr. of Credit Union National Association and National Association of Federal Credit Unions. (Feb. 14, 2003).
U.S. Army Corps	Wetlands Delineation Guidance Documents	49	Reform Underway. Supplement for Alaska expected final by May 2007, for Arid West expected Interim final by December 2006, for Great Plains Interim final by Spring 2007, for Western Mountains draft expected by January 2007, for Midwest and Atlantic Gulf Coasts drafts expected by summer 2007.

C. 2004 Manufacturing Regulatory Reform Nominations

In OMB's 2004 draft Report to Congress on the Costs and Benefits of Federal Regulations, we asked the public to suggest specific reforms to regulations, guidance documents or paperwork requirements that would improve manufacturing regulation. In response to the solicitation, OMB received 189 nominations. OMB and the agencies evaluated the nominations, and in March 2005, OMB issued the Regulatory Reform of the U.S. Manufacturing Sector Report.[119] In this report, we determined that 76 of the 189 nominations should be priorities, and also identified milestones and deadlines.

OMB continues to work closely with the regulatory agencies responsible for each of these reforms, and the agencies continue to make progress. Table E-4 below provides a further item-by-item update of the status of the regulatory reforms. The table indicates that 40 of the 76 reform items are now complete as of October 2006.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status

#	Reform Name	Nominator	Agency	Promised Action	Date	Status
4	Coastal Zone Management Act Federal Consistency Regulations	National Association of Manufacturers (9)	DOC NOAA	Final Rule	Anytime 2005	Complete. Final rule published on January 5, 2006 (71 FR 787)
6	North American Free Trade Agreement (NAFTA) Certificates of Origin	Motor & Equipment Manufacturers Association (41); Recreational Vehicle Industry Association (25)	DHS and Treasury	Report to OMB	May-05	Complete. Report submitted to OMB in May 2005. The reported summarized NAFTA activities and other electronic facilitation of Certificates of Origin. The report also noted that Rules of Origin are part of a trilateral agreement between U.S., Canada, and Mexico & cannot be changed unilaterally by the U.S. The USG has undertaken many initiatives to simplify NAFTA requirements. The United States Trade Representative (USTR) is leading an initiative to further simplify NAFTA requirements under the Strategy for Peace and Prosperity, a cooperative effort of the Governments of the U.S., Canada, and Mexico.

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

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
7	Maritime Security	American Shipbuilding Association (44)	DHS Coast Guard	Report to OMB	May-05	Complete. Report submitted to OMB in May, 2005. The report noted that Department of Defense (DOD) security plan requirements may not be sufficient for the purposes of the Maritime Transportation Security Act (MTSA) regulations for shipyards, because DOD plans generally do not cover non-DOD work at a facility. The report also noted, however, that the Coast Guard will consider waiving MTSA requirements in cases where the DOD plan is found to be equivalent to a plan required under MTSA. The Navy and the Coast Guard will continue to work together to ensure that effective security measures are in place for protecting shipyards that do not impose unnecessary or duplicative burdens on the affected Federal and private sector parties.
12	Motor Vehicle Brakes	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	DOT FMCSA	Proposed Rule	Sep-05	Complete. Proposed rule published on October 7, 2005 (70 FR 58657)
12	Motor Vehicle Brakes	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	DOT FMCSA	Final Rule	Sep-06	In progress.
14	Hours of Service	SBA Office of Advocacy (39)	DOT FMCSA	Final Rule	Aug-05	Complete: Final rule published on August 25, 2005 (70 FR 49977)

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
16	Lighting & Reflective Devices	National Association of Manufacturers (9); Motor & Equipment Manufacturers Association (41)	DOT NHTSA	Proposed Rule	Dec-05	Complete: Proposed rule published on December 30, 2005 (70 FR 77453)
16	Lighting & Reflective Devices	National Association of Manufacturers (9); Motor & Equipment Manufacturers Association (41)	DOT NHTSA	Final Rule	Oct-07	In progress.
18	Occupant Ejection Safety Standard	Public Citizen (2)	DOT NHTSA	Proposed Rule	Dec-06	Complete: Side impact proposal published on May 17, 2004 (69 FR 27989). Door retention proposal published on December 15, 2004 (69 FR 75020)
18	Occupant Ejection Safety Standard	Public Citizen (2)	DOT NHTSA	Final Rule	Anytime 2007	In progress.
22	Vehicle Compatibility Standard	Public Citizen (2)	DOT NHTSA	Report to OMB	Jun-05	Complete: Report submitted to OMB in June 2005. The report summarized current and projected future NHTSA research into vehicle compatibility.
26	EEO-1	U.S. Chamber of Commerce (19)	EEOC	Final Notice	Jun-05	Complete: Final EEO-1 report posted on January 27, 2006, and is available at http://www.eeoc.gov/eeo1/index.html.
28	Document AP-42: "Coke Production" Emission Factors	American Coke and Coal Chemicals Institute (3)	EPA	Model software	Jun-05	Complete: Software modeled by September 30, 2005.
28	Document AP-42: "Coke Production" Emission Factors	American Coke and Coal Chemicals Institute (3)	EPA	Revise EF development process	Sep-05	Complete: Emission factor development process revised by September 30, 2005.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
28	Document AP-42: "Coke Production" Emission Factors	American Coke and Coal Chemicals Institute (3)	EPA	Report on EF uncertainty assessment	Sep-05	Overdue. Report on emission factors uncertainty is expected in February 2007.
30	Document AP-42: Science and Site-Specific Conditions	National Association of Manufacturers (9)	EPA	Model software	Jun-05	Complete: Software modeled by September 30, 2005.
30	Document AP-42: Science and Site-Specific Conditions	National Association of Manufacturers (9)	EPA	Revise EF development process	Sep-05	Complete: Emission factor development process revised by September 30, 2005.
30	Document AP-42: Science and Site-Specific Conditions	National Association of Manufacturers (9)	EPA	Report on EF uncertainty assessment	Sep-05	Overdue. Report on emission factors uncertainty is expected in February 2007.
33	Clean Up Standards for PCBs	Motor and Equipment Manufacturers Association (41)	EPA	Report to OMB	Sep-05	Complete: EPA conducted an internal review in the first half of 2005. Stakeholder consultations occurred in May and June of 2005. EPA submitted a plan to OMB in September 2005 detailing the issue and outlining next steps. Currently OMB and EPA are discussing the details of the plan and information that has been submitted by stakeholders.
34	Common Company Identification Number in EPA Databases	Deere & Company (1)	EPA	Ensure Underground Injections and Institutional Controls database utilizes the Facility Registration System identification number	Sep-05	Complete: EPA completed study to ensure that the Underground Injections and Institutional Controls database utilizes the Facility Registration System identification number by September, 2005.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
34	Common Company Identification Number in EPA Databases	Deere & Company (1)	EPA	Work with remaining States as the States are ready to accept the common unique identification number	Anytime 2006	Complete: EPA is working with the States as they are ready to accept the unique Facility Registration System identification number. This is an ongoing project initiated in December, 2005. EPA continues to work with states to develop a common framework for information sharing.
35	ECHO Website	American Iron and Steel Institute (34)	EPA	Improve text explanations	Jun-05	Complete: EPA has improved the ECHO text explanations in order to guard against misinterpretation. This task was completed in June, 2005.
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	Identify what existing regulatory form formats are currently available	Jul-05	Complete: EPA has identified what existing regulatory form formats are currently available in July, 2005.
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	Determine if it is reasonable to assume most regulated entities have access to needed software	Oct-05	Complete: see final entry for #36 below
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	Determine value and cost of offering form in additional format	Dec-05	Complete: see final entry for #36 below

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
36	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	EPA	For those forms where conversion to other formats is warranted, make form available in new format	Feb-06	Complete: EPA determined that the best solution for a common format is to make public use forms available in Portable Document Format (PDF), which is non-proprietary and widely-used. Of the 197 forms EPA determined were being used to collect information from the public, 96% are currently being made available to the public in PDF. EPA determined that it was not necessary to offer the remaining forms in electronic format, because hardcopy is the more appropriate means for these collections. These forms include such things as forms that are mailed to EPA along with physical samples, and forms used by Agency interviewers. EPA continues to work with states and other stakeholders to ease the burden of electronic reporting through initiatives such as EPA's central data exchange and SBA's e-government.
38	Expand the Comparable Fuels Exclusion (CFE) under RCRA	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Discuss and Receive input from stakeholders	Jan-06	Complete: EPA discussed and received input on this nomination from stakeholders in December, 2005.
38	Expand the Comparable Fuels Exclusion (CFE) under RCRA	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Proposed Rule	Sep-06	Overdue.
38	Expand the Comparable Fuels Exclusion (CFE) under RCRA	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Final Rule	Nov-07	Awaiting issuance of proposed rule.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
39	Export Notification Requirements	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Proposed Rule	Jan-06	Complete: Proposed rule published on February 9, 2006 (71 FR 6733) EPA expects to issue a final rule by the end of 2006.
42	Hazardous Waste Rules Should Be Amended to Encourage Recycling (Definition of Solid Waste)	National Association of Manufacturers (9); American Petroleum Institute (12); Synthetic Organic Chemical Manufacturers Association (17); National Paint and Coatings Association (18); U.S. Chamber of Commerce (19); Alliance of Automobile Manufacturers (23); Specialty Graphic Imaging Association (27); American Chemistry Council (31); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	EPA	Final Rule or Re-proposal (which would be due in Winter of 2008)	Nov-06	Overdue.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
43	Lead Reporting Burdens Under the Toxic Release Inventory	National Federal of Independent Business (8); National Association of Manufacturers (9); Synthetic Organic Chemical Manufacturers Association (17); National Paint and Coatings Association (18); The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); The Copper and Brass Fabricators Council (45)	EPA	Report to OMB on the status of applying the metals framework to lead and lead compounds	Sep-05	Overdue. In progress: EPA is reviewing the Framework documents in accordance with the recommendations made by the SAB and will provide a report to OMB by April 2007.
44	Maximum Achievable Control Technology (MACT) standard for Chromium Emissions	The Policy Group (28)	EPA	Final Rule	No Deadline	Complete: Final rule published on July 19, 2004 (69 FR 42885)
45	PCB Remediation Wastes	Utility Solid Waste Activities Group (7)	EPA	Internal Review and Stakeholder Consultations	May-05	Complete: EPA conducted an internal review in the first half of 2005. Stakeholder consultations occurred in May and June of 2005. EPA submitted a plan to OMB in September 2005 detailing the issue and outlining next steps. Currently OMB and EPA are discussing the details of the plan and information that has been submitted by stakeholders.
45	PCB Remediation Wastes	Utility Solid Waste Activities Group (7)	EPA	Report to OMB	Sep-05	Complete: Report submitted to OMB in September 2005.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
46	Permit Use of New Technology to Monitor Leaks of Volatile Air Pollutants	National Association of Manufacturers (9); U.S. Chamber of Commerce (19)	EPA	Proposed Rule or Guidance	Mar-06	Complete: Proposed rule published on April 6, 2006 (71 FR 17401)
46	Permit Use of New Technology to Monitor Leaks of Volatile Air Pollutants	National Association of Manufacturers (9); U.S. Chamber of Commerce (19)	EPA	Final Rule or Guidance	Mar-07	In progress: Final rule is expected to be complete in Spring 2007
47	Pretreatment Streamlining Rule	The Policy Group (28); SBA Office of Advocacy (39); Motor and Equipment Manufacturers Association (41)	EPA	Final Rule	Jun-05	Complete: Final rule published on October 14, 2005 (70 FR 60133)
48	Provide More Flexibility in the Management of Wastewater Treatment Sludge to Encourage Recycling	The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	EPA	Proposed Rule	Dec-05	Overdue. In progress.
48	Provide More Flexibility in the Management of Wastewater Treatment Sludge to Encourage Recycling	The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	EPA	Final Rule	Jun-06	Overdue. In progress.
51	Remove Regulatory Disincentive to Recycle Spent Hydrotreating and Hydrorefining Catalysts	American Petroleum Institute (12)	EPA	Respond to Petition	Dec-05	Complete: EPA concluded that there is sufficient data to support a rulemaking that addresses the issues raised by the petitioner (a catalyst recycler) and the commenter. EPA is proceeding with developing this rulemaking, but has not yet set estimated dates for the proposed and final rule.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
52	Reporting and Paperwork Burden in the Toxic Release Inventory	Deere & Company (1); National Association of Manufacturers (9); American Petroleum Institute (12); National Small Business Association (24); Specialty Graphic Imaging Association (27); Society of Glass and Ceramic Decorators (33); SBA Office of Advocacy (39)	EPA	Final Rule (forms modification)	Jun-05	Complete: Final Rule published on July 12, 2005 (70 FR 39931)
52	Reporting and Paperwork Burden in the Toxic Release Inventory	See above	EPA	Proposed Rule (burden reduction)	Aug-05	Complete: Proposed rule published on October 4, 2005 (70 FR 57822)
52	Reporting and Paperwork Burden in the Toxic Release Inventory	See above	EPA	Final Rule (burden reduction)	Dec-06	In progress.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	Utility Solid Waste Activities Group (7); National Association of Manufacturers (9); Synthetic Organic Chemicals Manufacturing Association (17); National Paint and Coatings Association (18); General Electronic Company (26); American Furniture Manufacturers Association (35); SBA Office of Advocacy (39); American Public Power Association (42); Copper and Brass Fabricators Council (45)	EPA	Guidance to Inspectors	Jul-05	Complete: Guidance document released in October, 2005. The guidance is available at http://www.epa.gov/oilspill/guidance.htm
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Proposed Rule (related to NODA)	Aug-05	Complete: Proposed rule published on December 12, 2005 (70 FR 73523)
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Final Rule (related to NODA)	Feb-06	Complete: Final rule expected in late 2006 or early 2007.
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Proposed Rule for Regulatory Modifications	Jun-06	Overdue. In progress.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
54-58	Spill Prevention Control and Counter-measures (SPCC) Rule	See above	EPA	Final Rule for Regulatory Modifications	Jun-07	Awaiting issuance of proposed rule.
59	Water Permit Rules (mass-based standards, direct dischargers)	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Review as part of biennial plan	Aug-05	Complete: Published the 2006 Effluent Guidelines Program [304(m)] plan in August, 2005. The plan is available at http://www.epa.gov/waterscience/guide/plan.html. The final plan is expected in Fall 2006.
61	Annual Reporting of Pesticide Information	National Association of Manufacturers (9)	EPA	Post revised policy on website	Mar-05	Complete: EPA posted their revised reporting policy in February, 2005: http://www.epa.gov/compliance/monitoring/programs/fifra/establishments.html
68	Cooling Water Intake Structures, Phase III	American Public Power Association (42)	EPA	Final Rule	May-06	Complete: Published final rule on June 16, 2006 (71 FR 35005)
75	Electronic Filing by Manufacturing Firms	American Furniture Manufacturers Association (35)	EPA	Report to OMB	Dec-05	Complete: Report submitted to OMB in December, 2005. EPA has concluded that this action cannot be implemented at the present time. EPA will continue to monitor the situation to gauge the interest in developing common forms for use by this industry and, where applicable, promote the use of central data exchange-type networks as the basis for reporting and document management.
83	Leak-Detection and Repair Regulatory Programs	National Association of Manufacturers (9)	EPA	Proposed Rule	Mar-06	Overdue. In progress.
83	Leak-Detection and Repair Regulatory Programs	National Association of Manufacturers (9)	EPA	Final Rule	Mar-07	Awaiting issuance of proposed rule.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	National Association of Manufacturers (9); Inter-Industry Analytic Group (14); Alliance of Automobile Manufacturers (23)	EPA	Complete FACA Process	Sep-06	In progress: The Federal Advisory Committee (FAC) engaged in a pilot study of alternate procedures. The pilot study is currently expected to be completed in November 2006. The FAC will complete its work in May 2007. Any needed rulemaking will follow completion of the FAC's work.
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	See above	EPA	Conclude Pilot Project	Nov-06	Overdue.
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	See above	EPA	Proposed Rule	Jun-07	In progress.
86	Method of Detection Limit/Minimum Level Procedure under the Clean Water Act	See above	EPA	Final Rule	Jun-08	Awaiting issuance of proposed rule.
87	Operating Permits Under the Clean Air Act	National Association of Manufacturers (9)	EPA	Final Report on whether to change Title V	Dec-05	Complete: Final report to the Clean Air Advisory Committee on Title V published in April 2006. Report is available at http://www.epa.gov/oar/caaac/titlev.html. EPA is reviewing the recommendations from the report and will determine in Fall 2006 how to move forward.
88	Potential to Emit (PTE) Test	Deere & Company (1); Motor and Equipment Manufacturers Association (41)	EPA	Proposed Rule	Jan-06	Overdue. In progress.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
88	Potential to Emit (PTE) Test	Deere & Company (1); Motor and Equipment Manufacturers Association (41)	EPA	Final Rule	Jan-07	Awaiting issuance of proposed rule.
90	Prohibit Use of Mercury in Automobile Manufacturing	American Iron and Steel Institute (34)	EPA	Conduct Preliminary Analysis	Jun-05	Complete: EPA finished its preliminary analysis in June, 2005
90	Prohibit Use of Mercury in Automobile Manufacturing	American Iron and Steel Institute (34)	EPA	Discuss Regulatory options with stakeholders	Sep-05	Complete: EPA finished its discussions with stakeholders by June, 2005
90	Prohibit Use of Mercury in Automobile Manufacturing	American Iron and Steel Institute (34)	EPA	Make determination on appropriate regulatory or voluntary approach	Nov-05	Complete: Proposed rule published on July 11, 2006 (71 FR 39035)
92	Reduce the Inspection Frequency from Weekly to Monthly for Selected RCRA Facilities	Deere & Company (1)	EPA	Final Rule	Nov-05	Complete: Final rule published on April 4, 2006 (71 FR 16861)
97	Reportable Quantity (RQ) Threshold for Nitrogen Oxide and Dioxide at Combustion Sources	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Proposed Rule	Sep-05	Complete: Proposed rule published on October 4, 2005 (70 FR 57813)
97	Reportable Quantity (RQ) Threshold for Nitrogen Oxide and Dioxide at Combustion Sources	National Association of Manufacturers (9); American Chemistry Council (31)	EPA	Final Rule	Sep-06	Complete: Final rule published on October 4, 2006 (70 FR 58525)

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
101	Sulfur and Nitrogen Monitoring at Stationary Gas-Fired Turbines	National Association of Manufacturers (9)	EPA	Report to OMB on the status of discussions with Commenter to determine whether rule promulgated April 2004 addresses commenter's concerns	May-05	Complete: Report submitted to OMB in May, 2005. The report stated that the 2004 rule on sulfur and nitrogen monitoring satisfied the reform nomination. EPA subsequently checked with commenter (NAM) which agreed the 2004 rule was responsive to the reform nomination.
103	Systematic Program for Developing and Validating Analytic Methods	Inter-Industry Analytic Group (14); American Public Power Association (42)	EPA	Form a Federal Advisory Committee	Sep-06	In progress.
103	Systematic Program for Developing and Validating Analytic Methods	See above	EPA	Conclude Pilot Project	Nov-06	In progress.
103	Systematic Program for Developing and Validating Analytic Methods	See above	EPA	Proposed Rule	Jun-07	In progress.
103	Systematic Program for Developing and Validating Analytic Methods	See above	EPA	Final Rule	Jun-08	Awaiting issuance of proposed rule.
108	Deferral of Duplicative Federal Permitting	The Policy Group (28)	EPA	Proposed Rule	Mar-05	Complete: Proposed rule published on March 25, 2005 (70 FR 15250)
108	Deferral of Duplicative Federal Permitting	The Policy Group (28)	EPA	Final Rule	Aug-05	Complete: Final rule published on December 19, 2005 (70 FR 75319)

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
110	SARA Title 312, 313 Programs	American Iron and Steel Institute (34)	EPA	Final Rule (TRI forms modification)	Jun-05	Complete: Final Rule published on July 12, 2005 (70 FR 39931)
110	SARA Title 312, 313 Programs	See above	EPA	Proposed Rule (TRI burden reduction)	Aug-05	Complete: Proposed rule published on October 4, 2005 (70 FR 57822)
110	SARA Title 312, 313 Programs	See above	EPA	Final Rule (TRI burden reduction)	Dec-06	In progress.
112	Vapor Recovery at Gasoline Stations	American Petroleum Institute (12)	EPA	Report to OMB on cost-effectiveness	Sep-05	Complete: Report submitted to OMB September 2005. The report examines the cost-effectiveness of maintaining Stage II control at the gasoline pump under various assumptions on the penetration of onboard recovery controls in the mobile source fleet. At current levels of penetration of onboard control, the incremental maintenance cost of Stage II control ranges from $1300 to $2000 per ton of reduction in Volatile Organic Carbon emissions.
116	Publicly Owned Treatment Work (POTW) removal credits	Copper and Brass Fabricators Council (45)	EPA	Internal Issue Paper	Mar-05	Complete: EPA developed an internal issue paper in March, 2005.
117	Categorical Wastewater Sampling and Testing	Copper and Brass Fabricators Council (45)	EPA	Final Rule	Jun-05	Complete: Part of Pretreatment Streamlining final rule, published on October 14, 2005 (70 FR 60133)

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
118	Definition of Volatile Organic Compound	Copper and Brass Fabricators Council (45)	EPA	Advance Notice of Proposed Rulemaking (ANPRM)	May-05	Complete: On September 13, 2005 (70 FR 54046), EPA issued guidance, as an alternative to issuing an ANPRM, on State implementation plans designed to meet the national ambient air quality standard for ozone. This guidance summarizes recent scientific findings, provides examples of innovative applications of reactivity information in the development of Volatile Organic Compound (VOC) control measures, and clarifies the relationship between innovative reactivity-based policies and EPA's current definition of VOC.
119	Thermal Treatment of Hazardous Waste Guidance	Copper and Brass Fabricators Council (45)	EPA	Report to OMB	Feb-06	Complete: Report submitted to OMB in February 2006. The report reviewed the risks and benefits of the reform nomination.
121	Do Not Fax Rule	National Federal of Independent Business (8); National Association of Manufacturers (9); U.S. Chamber of Commerce (19); National Small Business Association (24); SBA Office of Advocacy (39)	FCC	Resolution of petition for reconsider-ation of rulemaking. July 2005 is the effective date for the final rule	Jul-05	Complete: Proposed rule published on December 19, 2005 (70 FR 75102)
122	Broadband	Heritage Foundation (5)	FCC	Resolution of Rule following Supreme Court decision	Jul-05	Complete: Final rule published on October 17, 2005 (70 FR 60222)
125	HIPAA	Motor & Equipment Manufacturers Association (41)	HHS CMS	Proposed Rule	Dec-05	Overdue. In progress.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
125	HIPAA	Motor & Equipment Manufacturers Association (41)	HHS CMS	Final Rule	Dec-06	Awaiting issuance of proposed rule.
134 135 136 137 139 141 142 143 144	FMLA	FMLA Technical Corrections Coalition (4); Heritage Foundation (5); National Federation of Independent Business (8); National Association of Manufacturers (9); U.S. Chamber of Commerce (19); American Furniture Manufacturers Association (35); Motor & Equipment Manufacturers Association (41); Society for Human Resource Management (46)	DOL ESA	Proposed Rule	Anytime 2005	Overdue. DOL is continuing its systematic study, including review of court decisions, on regulations issued under the authority of the Family Medical and Leave Act. Request for Information published on December 1, 2006 (71 FR 69504).
145	Permanent Labor Certification	U.S. Chamber of Commerce (19)	DOL	Final Rule	No Deadline; rule already issued	Complete: Final rule published on December 27, 2004 (69 FR 77325)

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
151	Annual Training Requirements for Separate Standards	American Furniture Manufacturers Association (35)	DOL OSHA	Report to OMB	May-05	Complete: Report submitted to OMB in May, 2005. The report noted that OSHA does not require separate training programs for each standard that requires training. The report also noted that OSHA has sought to avoid duplication of EPA's training requirements on subjects where both agencies have jurisdiction. OSHA plans to revise and update its publication, Training Requirements in OSHA Standards and Training Guidelines, to clarify training requirements, and will add training consideration to its Standards Improvement Project Phase III. OMB concluded review of an Advance Notice of Proposed Rulemaking on OSHA's Standards Improvement Project, Phase III, on December 11, 2006.
152	Coke Oven Emissions	American Coke and Coal Chemicals Institute (3); American Iron and Steel Institute (34)	DOL OSHA	Final Rule	No Deadline; rule already issued	Complete: Final rule published on January 5, 2005 (70 FR 1111)
153	Flammable Liquids	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	DOL OSHA	Rulemaking	No Deadline	In progress: OMB concluded review of an Advance Notice of Proposed Rulemaking on OSHA's Standards Improvement Project, Phase III, on December 11, 2006. Updates to the flammable liquids standard will be considered during this rulemaking.
155	Hazard Communication Training	National Association of Manufacturers (9)	DOL OSHA	Final Guidance	Anytime 2005	Overdue. In progress.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
156	Hazard Communication Material Safety Data Sheets	Deere & Company (1); National Association of Manufacturers (9); American Furniture Manufacturers Association (35)	DOL OSHA	Proposed Guidance	Anytime 2005	Overdue. In progress.
156	Hazard Communication Material Safety Data Sheets	See above	DOL OSHA	Final Guidance	Feb-06	Overdue. In progress.
157	Hexavalent Chromium	The Policy Group (28); SBA Office of Advocacy (39)	DOL OSHA	Final Rule	Jan-06	Complete: Final rule published on February 28, 2006 (70 FR 10100)
159	Sling Standard	U.S. Chamber of Commerce (19); Associated Wire Rope Fabricators (42)	DOL OSHA	Guidance, with rulemaking considered at a later date	Feb-06	Overdue. In progress.
160	Guardrails Around Stacks of Steel	American Iron and Steel Institute (34)	DOL OSHA	Report to OMB	May-05	Complete: Report submitted to OMB in May, 2005. This report noted that OSHA is currently conducting a rulemaking on its Walking and Working Surfaces standard, and will consider the guardrail requirement as part of that rulemaking. It also stated that the agency had contacted the commenter to discuss OSHA's plans and that the commenter supported addressing the issue in the Walking and Working Surfaces rulemaking. OSHA plans to publish this proposed rule in April, 2007.

Table E-4: 2004 Manufacturing Regulatory Reform Nomination Status						
#	Reform Name	Nominator	Agency	Promised Action	Date	Status
169	Walking and Working Surfaces	Copper and Brass Fabricators Council (45)	DOL OSHA	Report to OMB	May-05	Complete: Report submitted to OMB in May, 2005. This report noted that OSHA is currently conducting a rulemaking on its Walking and Working Surfaces standard, and will consider the allowance of ship stairs in certain circumstances as part of that rulemaking. It also stated that the agency had contacted the commenter and that the commenter supported including a flexible policy for ship stairs in the final rule. OSHA plans to publish this proposed rule in April, 2007.
175	Duty Drawback	National Association of Manufacturers (9)	Treasury Customs	Incorporate drawback simplification into the ACE project	No Deadline	Customs is working with the trade to streamline and simplify drawback as part of the Automated Commercial Environment (ACE) project. As of July, 2006, forty-four land border ports are now using ACE. More information on ACE is available at http://www.cbp.gov/xp/cgov/toolbox/about/modernization/
178	Election to Expense Certain Depreciable Business Assets	SBA Office of Advocacy (39)	Treasury IRS	Support legislation making the $100,000 expensing limit permanent	No Deadline	Complete: On May 17, 2006, the President signed into law the Tax Increase Prevention and Reconciliation Act of 2005. The Act extends through 2009 the ability of small businesses to expense up to $100,000 (indexed for inflation) of investments in depreciable assets under section 179 of the Internal Revenue Code. The Administration continues to support making the $100,000 expensing limit permanent.
188	Ready to Eat Meat Establishments to Control for Listeria	National Association of Manufacturers (9); SBA Office of Advocacy (39); William Russell & Associates, Inc. (30)	USDA FSIS	Final Rule	Jun-05	Overdue. In progress.

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

Table E-5: Agency Contact Information for Further Updates			
Agency	**Person/Office**	**Phone Number**	**E-Mail Address/URL**
Agriculture	Mike Poe	202-720-3257	poe@opba.usda.gov
HHS	John Gallivan	202-205-9165	john.gallivan@hhs.gov
DHS	Mary Kate Whalen	202-282-9160	marykate.whalen@dhs.gov
Interior	Office of Executive Secretariat and Regulatory Affairs	202-208-3181	fay_iudicello@ios.doi.gov
Labor	Susan Howe	202-693-5959	howe.susan@dol.gov
Transportation	Office of Asst. General Counsel for Regulation	202-366-4723	dot.regulation@dot.gov
Treasury	Office of the Executive Secretary	202-622-2000	http://www.treas.gov/education/execsec/contact-us.shtml
EEOC	Office of Legal Counsel	202-663-4645	carol.miaskoff@eeoc.gov
EPA	Nicole Owens	202-564-1550	Owens.Nicole@epamail.epa.gov
Federal Reserve	Financial Reports Section of the Federal Reserve Board	202-452-3829	RSMA-FinancialReports@frb.gov
FCC	Office of the Managing Director	202-418-2910	Karen.Wheeless@fcc.gov
FTC	Richard Gold	202 326-3355	rgold@ftc.gov
SBA	Martin Conrey	202-619-0638	Martin.Conrey@sba.com
SEC	Anne Sullivan	202-551-5019	sullivana@sec.gov.
Army Corps	Katherine Trott	202-761-5542	Katherine.L.Trott@hq02.usace.army.mil

APPENDIX F: PEER REVIEW AND PUBLIC COMMENTS

OMB wishes to express its sincere appreciation for the thoughtful comments we received on the draft April 2006 Report. In particular, we would like to thank our invited peer reviewers: Robert Hahn and Robert Litan (AEI-Brookings Joint Center for Regulatory Studies), Jeff Hill (Jacobs & Associates), and Stuart Shapiro (Rutgers University). Below is a listing of all the written comments submitted to OMB, and the numbers or letters we have assigned to their comments. The public and peer review comments are available for review at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

Peer Reviewers

1. Robert W. Hahn and Robert E. Litan, AEI-Brookings Joint Center for Regulatory Studies
2. Jefferson B. Hill, Jacobs & Associates
3. Stuart Shapiro, Edward J. Bloustein School of Planning and Public Policy, Rutgers University

Public Comments

A. Richard B. Belzer, Regulatory Checkbook
B. Anita Drummond, Associated Builders and Contractors, Inc.
C. Lawrence A. Fineran, National Association of Manufacturers
D. William L. Kovacs, Chamber of Commerce
E. Amy Sinden, Center for Progressive Reform
F. J. Robert Shull and Genevieve Smith, OMB Watch

ELEVENTH ANNUAL REPORT TO CONGRESS ON AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT

INTRODUCTION

This report represents OMB's eleventh annual submission to Congress on agency compliance with the Unfunded Mandates Reform Act of 1995 (the Act). It details agency actions to involve State, local, and tribal governments in regulatory decisions that affect them, including expanded efforts to involve them in agency decision-making processes.

As has been done in recent years, this report is being included along with our annual report to Congress on the benefits and costs of Federal regulations. This 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 costs and benefits of rules and takes into consideration the interests of our intergovernmental partners. As OMB stated in previous reports, we intend to continue to publish these two reports together. This report on agency compliance with the Act covers the period of October of 2004 through September of 2005 (rules published before October of 2004 were described in last year's report.)

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 costs and benefits to assist with these consultations;
- the scope of consultation should reflect the cost and significance of the mandate being considered;
- effective consultation requires trust and significant and sustained attention so that all who participate can enjoy frank discussion and focus on key priorities; and
- agencies should seek out State, local, and tribal views on costs, benefits, risks, and alternative methods of compliance, and whether the Federal rule will harmonize with and not duplicate similar laws in other levels of government.

The scope of consultation activities undertaken by Federal departments such as, Agriculture, Education, Health and Human Services, Interior, Justice, Transportation, 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 the appendix to this report.

Sections 206 and 208 of the Act direct OMB to send copies of required agency analyses to the Congressional Budget Office (CBO), and to submit an annual report to Congress on agency compliance with Title II.

The remainder of this report discusses the results of agency actions in response to the Act between October 1, 2004 and September 30, 2005. 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. Four rules have met this threshold – one (EPA's Rulemaking on Section 126 Petition from North Carolina to Reduce Interstate Transport of Fine Particulate Matter and Ozone) was an intergovernmental mandate. 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 I: IMPACTS ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

Since passage of the Unfunded Mandates Reform Act, 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 Act of 1995). EPA issued all six of these rules, which are described here.[120]

- *EPA's Rule on Standards of Performance for Municipal Waste Combustors and Emissions Guidelines* (1995): This rule set standards of performance for new municipal waste combustor (MWC) units and emission guidelines for existing MWCs under sections 111 and 129 of the Clean Air Act [42 U.S.C. 7411, 42 U.S.C. 7429]. The standards and guidelines apply to MWC units at plants with combustion capacities greater than 35 mega grams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The EPA standards require sources to achieve the maximum degree of reduction in emissions of air pollutants that the Administrator determined is achievable, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements.

  EPA estimated the annualized costs of the emissions standards and guidelines to be $320 million per year (in constant 1990 dollars) over existing regulations. While EPA estimated the cost of such standards for new sources to be $43 million per year, the cost to existing sources was estimated to be $277 million per year. The annual emissions reductions achieved through this regulatory action include, for example, 21,000 Mg. of sulfur dioxide; 2,800 Mg. of particulate matter (PM); 19,200 Mg of nitrogen oxides; 54 Mg. of mercury; and 41 Kg. of dioxins/furans.

- *EPA's Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills (1996):* This rule set performance standards for new municipal solid waste landfills and emission guidelines for existing municipal solid waste landfills under section 111 of the Clean Air Act. The rule addressed non-methane organic compounds (NMOC) and methane emissions. NMOC include volatile organic compounds (VOC), hazardous air pollutants (HAPs), and odorous compounds. Of the landfills required to install controls, about 30 percent of the existing landfills and 20 percent of the new landfills are privately owned. The remaining landfills are publicly owned. The total annualized costs for collection and control of air emissions from new and existing MSW landfills are estimated to be $100 million.

[120]We note that EPA's proposed rules setting air quality standards for ozone and particulate matter may ultimately lead to expenditures by State, local, or tribal governments of $100 million or more. However, Title II of the Unfunded Mandates Reform Act provides that agency statements of compliance with Section 202 must be conducted "unless otherwise prohibited by law". The conference report to this legislation indicates that this language means that the section "does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule." EPA has stated, and the courts have affirmed, that under the Clean Air Act, the primary air quality standards are health-based and EPA is not to consider costs.

- *EPA's National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts (1998):* This rule promulgates health-based maximum contaminant level goals (MCLGs) and enforceable maximum contaminant levels (MCLs) for about a dozen disinfectants and byproducts that result from the interaction of these disinfectants with organic compounds in drinking water. The rule will require additional treatment at about 14,000 of the estimated 75,000 covered water systems nationwide. The costs of the rule are estimated at $700 million annually. The quantified benefits estimates range from zero to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of $0 to $4 billion per year. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

- *EPA's National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment* (1998): This rule establishes new treatment and monitoring requirements (primarily related to filtration) for drinking water systems that use surface water as their source and serve more than 10,000 people. The purpose of the rule is to enhance health protection against potentially harmful microbial contaminants. EPA estimated that the rule will impose total annual costs of $300 million per year. The rule is expected to require treatment changes at about half of the 1,400 large surface water systems, at an annual cost of $190 million. Monitoring requirements add $96 million per year in additional costs. All systems will also have to perform enhanced monitoring of filter performance. The estimated benefits include average reductions of 110,000 to 338,000 cases of cryptosporidiosis annually, with an estimated monetized value of $0.5 to $1.5 billion, and possible reductions in the incidence of other waterborne diseases.

- *EPA's National Pollutant Discharge Elimination: System B Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule expands the existing National Pollutant Discharge Elimination System program for storm water control. It covers smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain sources from the program based on a demonstration of the lack of impact on water quality. EPA estimates that the total cost of the rule on Federal and State levels of government, and on the private sector, is $803.1 million annually. EPA considered alternatives to the rule, including the option of not regulating, but found that the rule was the option that was "most cost effective or least burdensome, but also protective of the water quality."

- *EPA's National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring* (2001): This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 ppb to 10 ppb. It also revises current monitoring requirements and requires non-transient, non-community water systems to come into compliance with the standard. This rule may affect either State, local or tribal governments or the private sector at an approximate annualized cost 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.

CHAPTER II: A REVIEW OF SIGNIFICANT REGULATORY MANDATES

In FY2005, Federal Agencies issued four 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 2005, the Department of Health and Human Services issued one proposed rule and one final rule, the Department of Transportation issued one final rule, and the Environmental Protection Agency issued one proposed rule. EPA's "Rulemaking on Section 126 Petition from North Carolina to Reduce Interstate Transport of Fine Particulate Matter and Ozone" was the only rule for which expected expenditures to State, local or tribal governments, and the private sector, in the aggregate, totaled more than $110 million. All of the other rules cited in this section were rules that required only private sector expenditures in any year, in the aggregate, to total more than $110 million.

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.

A. Department of Health and Human Services

Standards for Electronic Health Care Claim Attachments (Proposal): This proposed rule sets forth an electronic standard for claims attachments. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It will be used to transmit clinical data, in addition to the data contained in the claims standard, to help establish medical necessity for coverage and payment.

HHS estimated that the private sector would expend in excess of $110 million to implement all of the transaction standards. Since electronic health care claims attachments are only one of the eight transactions, and since there are only six attachment types at this time, its assumption is that expenditures to meet just the electronic health care claims attachment requirements may not exceed the UMRA threshold for the private sector. However, if that assumption is incorrect, and the costs of implementing the electronic health care claims attachments standards exceed the UMRA threshold, HHS believes that anticipated benefits of the proposed rule justify the added costs.

Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Final): This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 414(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act), authorizes the Secretary, through FDA, to promulgate final regulations by

December 12, 2003. The Act authorizes regulations that require the establishment and maintenance of records, for not longer than two years, which would allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. The required records would be those that are needed by FDA in order to address credible threats of serious adverse health consequences or death to humans or animals. Specific covered entities are those that manufacture, process, pack, transport, distribute, receive, hold, or import food.

FDA determined that this final rule does constitute a significant rule under the Unfunded Mandates Reform Act. The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after promulgation of the final rule. These costs will be incurred by all domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food except very small retail facilities. Recurring costs from collecting new information as well as the learning costs for new entrants will be incurred in each future year. For year 3 and later years, FDA expects those costs to range from $121,980,000 to $125,788,000.

B. Department of Transportation

Tire Pressure Monitoring Systems (Final) - The Transportation Recall Enhancement Accountability and Documentation (TREAD) Act required the Secretary of Transportation to initiate rulemaking to require a warning system in new motor vehicles to indicate to the operator when a tire is significantly under-inflated. The agency issued a final rule for tire pressure monitoring systems (TPMS)(establishing FMVSS No. 138) on June 5, 2002; however, the final rule establishing the issued by the U.S. Court of Appeals for the Second Circuit in August 2003. The agency has taken action in accordance with the Administrative Procedures Act to reestablish FMVSS No. 138, in a manner consistent with the court's decision, and also provided a new phase-in period.

This final rule is not expected to result in the expenditure by State, local, or tribal governments, in the aggregate, or more than $112 million annually, but it is expected to result in an expenditure of that magnitude by vehicle manufacturers and/or their suppliers. In this final rule, NHTSA is adopting a four-tire, 25-percent requirement, which we believe is consistent with safety and the mandate in the TREAD Act. We note that in promulgating a performance standard, NHTSA has left the door open for an array of technologies that may be used to meet the standard's requirements. With further TPMS development, we expect that vehicle manufacturers will have a number of technological choices that will provide broad flexibility to minimize their costs of compliance with the standard.

C. Environmental Protection Agency

Rulemaking on Section 126 Petition from North Carolina to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Proposed) - This action includes two separate but related rulemakings to address interstate transport with respect to the 8-hour ozone and fine particulate matter (PM2.5) National Ambient Air Quality Standards. In one part, EPA is responding to a petition submitted to the Agency in March 2004, by the State of North Carolina pursuant to

section 126 of the Clean Air Act. The petition requests that EPA make findings that emissions of nitrogen oxides (NOx) and sulfur dioxide (SO2) from large electric generating units (EGUs) in 12 States are significantly contributing to PM2.5 nonattainment or maintenance problems in North Carolina and that NOx emissions from large EGUs in 5 States are significantly contributing to 8-hour ozone nonattainment or maintenance problems in North Carolina. The second part of this rulemaking is related to EPA's Clean Air Interstate Rule (CAIR), promulgated on March 10, 2005, which addresses interstate transport of NOx and SO2. CAIR requires 28 States and the District of Columbia to revise their State implementation plans (SIPs) to reduce emissions of NOx and/or SOx. Controlling these emissions will assist the downwind areas in meeting the PM2.5 and 8-hour ozone national ambient air quality standards. This current rulemaking action is also proposing certain revisions to the CAIR and the Acid Rain Program.

The EPA is taking the position that the requirements of UMRA apply because this action could result in the establishment of enforceable mandates directly applicable to sources (including sources owned by State and local governments) that could result in costs greater than $100 million in any one year. According to EPA's analysis, the total net economic impact on government-owned entities is expected to be negative in both 2010 and 2015. Government entities projected to experience compliance costs in excess of 1 percent of revenues have some potential for significant impact resulting from implementation of this rulemaking. In a manner consistent with the intergovernmental consultation provisions of section 204 of the UMRA, EPA carried out consultations with the governmental entities potentially affected by this rule during the CAIR rulemaking process.

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

Sections 203 and 204 of the Act require agencies to seek input from State, local and tribal governments on new Federal regulations imposing significant intergovernmental mandates. This appendix summarizes consultation activities by agencies whose actions affect State, local and tribal governments.

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 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. Department of Agriculture

Animal and Plant Health Inspection Service (APHIS)

1. Biotechnology Regulations:

APHIS is planning to revise its existing biotechnology regulations for genetically engineered (GE) plants and other organisms that are potential plant pests (7 CFR 340). One regulatory revision may include utilizing the expanded authority of the Plant Protection Act to broaden the scope of regulations beyond GE organisms that are potential plant pests to include GE biological control organisms and GE plants which may have the potential to be noxious weeds. Also under consideration is the development of a multi-tiered, risk-based permitting system to replace the current permit/notification system. Separately, APHIS is developing a regulation that would establish conditions under which APHIS would share with States confidential business information (CBI) we receive related to our biotechnology program. APHIS' Biotechnology Regulatory Services (BRS) program administers these regulations.

APHIS-BRS makes continuous efforts to reach out to partners and to parties affected by our regulations to increase confidence in the effectiveness of our biotechnology regulatory system. In FY 2005, BRS entered into a cooperative program with the National Plant Board (NPB) to collect input and perspectives from the States on the most important aspects of the

Agency's regulatory system and items that APHIS should consider during State evaluations. State agencies are often on the front line as the Agency's biotechnology regulations are being implemented on a daily basis. NPB and BRS are using this project as a springboard to improve cooperation on a wide range of issues related to the regulation of biotechnology, in particular those issues that have the greatest impacts upon the States. BRS held several follow-up meetings with the NPB concerning how the regulatory system works, the safety of the products that are deregulated by BRS' system, and the process for revising the regulations.

Beginning in 2004 and continuing in 2005, BRS used input from meetings and discussions with the National Association of State Departments of Agriculture (NASDA) and the NPB to start shaping the proposed revisions to the regulations. BRS' interaction with NPB concerning the sharing of CBI led to the initiation of the rulemaking to address this issue.

As a result of interactions with NASDA and NPB, BRS received many diverse and helpful suggestions which will be considered in the process of revising our regulations. For example, BRS heard renewed concerns about how it handles CBI, which will be addressed through rulemaking. Another significant comment that BRS will be considering is the States' need for assurance that the biotech regulations for imported commodities will not provide advantages for foreign versus domestic products. In addition to receiving valuable comments such as these, interactions with the States have resulted in a renewed commitment and partnership between State and Federal agencies. While the consultations with stakeholder groups, NASDA, and the 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.

2. Plant Protection and Quarantine (PPQ):

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, *Phytophthora ramorum* (a fungus commonly known as Sudden Oak Death), emerald ash borer (an exotic pest of ash trees), and citrus canker (a bacterial disease).

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 its 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 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: During 2005, an unusually active year for hurricanes changed the distribution of citrus canker, as well as other citrus diseases and pests, in Florida. Through cooperative survey with the State of Florida, APHIS determined the new range of citrus canker. 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 minimize the economic and operational costs borne by Florida.

Emerald ash borer: Through continuous consultations with the States of Ohio, Indiana, 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.

Phytophthora ramorum: Through extensive consultations with the States of California, Oregon, and Washington, which produce a major portion of U.S. nursery stock, and with States that purchase nursery stock from California, Oregon and Washington, APHIS was able to devise 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 and helped to ensure that nursery stock could continue to move interstate. During 2004, APHIS also consulted with various tribes in Northern California to discuss possible effects of *P. ramorum* regulations.

3. Elimination of Brucellosis 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 Wyoming, Montana, and Idaho; the U.S. Dept. of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (USDA, APHIS, VS); the U.S. Forest Service; the National Park Service; the U.S. Fish and Wildlife Service; and the Bureau of Land Management as voting members of the GYIBC executive committee. There are also three nonvoting members represented on the GYIBC executive committee: U.S. Geological Survey; Agricultural Research Service; and the InterTribal Bison Cooperative.

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 developed for the management of Yellowstone National Park brucellosis infected bison in Montana. In addition, 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. VS also consulted with the public and intergovernmental agencies to determine how best to help the GYA States regain or maintain their brucellosis Class Free classification.

USDA and the Department of the Interior have agreed upon a draft GYIBC memorandum of understanding (MOU) to replace an expired MOU for operation of the GYIBC, focused toward brucellosis elimination planning. The MOU will be presented to the governors of the GYA States for their review and approval. VS also consulted with the State of Wyoming to assist it in regaining its brucellosis Class Free classification.

4. U.S. Program to Eradicate Bovine Tuberculosis (TB) In Domestic Livestock.

APHIS consulted with State and industry officials regarding the TB status of New Mexico. Officials from New Mexico proposed that the State be divided into two zones with different disease classifications. Stakeholders felt that the boundaries of the affected zone were sufficiently clear to make this distinction.

APHIS amended the bovine tuberculosis regulations by recognizing two separate zones with different tuberculosis risk classifications in New Mexico, raising the designation of one of those zones from modified accredited advanced to accredited free. The change was published in the Federal Register in July 2005 and made final in October 2005.

5. National Animal Identification System (NAIS).

The implementation of NAIS will affect other 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, USDA held public meetings with various stakeholder groups affected by the program.

Issues/Concerns Raised by Public/Intergovernmental Partners include: the costs of national identification, the ability to maintain confidentiality, flexibility of the program, and 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.

As a result of the consultation, public and private funding will be required for the NAIS to become fully operational. USDA has provided funds to States and Tribes through cooperative agreements and has provided the information systems for the program. 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 determined that certain information should be held outside USDA. Animal tracking information will be held in private and State databases. USDA will only access certain information when needed to respond to a disease investigation. USDA also continues to consider information gained through consultations to update the draft strategic plan and program standards, as well as further develop and revise an implementation plan for the NAIS.

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

On June 21, 2005 (70 FR 35782), the Department published a notice of proposed rulemaking (NPRM) under Part B of the Individuals with Disabilities Education Act (IDEA), as amended by the Individuals with Disabilities Education Improvement Act of 2004. The NPRM proposed to implement the substantial statutory changes and to restructure the existing regulations for this program.

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 educational agencies, local school districts, public elementary and secondary schools, special education teachers and related service providers, children with disabilities and their parents.

Prior to publishing the NPRM, the Department solicited advice and recommendations from the public on the regulatory issues under Part B of the IDEA. On December 29, 2004 (69 FR 77968), the Department published a notice inviting written comments and recommendations regarding changes that might be needed to existing regulations, particularly to provide clarification to new statutory requirements or facilitate the implementation of the program. In this notice the Department also announced a series of seven regional public meetings to gather comment on what should be included in the regulations.

The Department received over 6000 comments in response to the December 29, 2004 notice, including comments received at the public meetings. They included comments from children with disabilities, parents, teachers and related service providers, State and local agency personnel, and parent-advocate and professional organizations. The comments addressed each of the major provisions of the revised law, including those on personnel qualifications and highly qualified special education teachers, evaluations of children, individualized education programs, participation of private school children with disabilities, due process procedures and discipline procedures for children with disabilities.

The comments were reviewed and considered in developing the June 2005 NPRM. States and local school districts were very concerned about the statutory provisions requiring highly qualified special education teachers. As a result, the Department attempted to clarify these complicated requirements in the NPRM.

D. Department of Health and Human Services

1. 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.[121] 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, for example, was successful in working with the State of Florida to approve the first ever Statewide child welfare waiver demonstration in March 2006.

Currently, 15 States have active waiver demonstrations, involving 19 demonstration components.[122] 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.

2. Health Status Disparities Affecting American Indians and Alaska Natives

The Department of Health and Human Services 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 and the HHS policy guidance signed and issued January 2005.

During FY 2005, HHS leadership worked closely on health-disparities 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

[121]Normally, Title IV-E funds may only be used to pay for foster care maintenance payments and related allowable administrative costs.

[122]Some States have more than one approved waiver demonstration project and some waiver agreements involve more than one type of service intervention.

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.

Below are some examples of HHS consultations with Indian tribes during FY 2005

- *7th Annual Tribal Budget Consultation Session*: HHS agencies engage Tribes in an annual conversation about budget priorities. Through this process, Tribes have been able to state their funding priorities to HHS. On May 17-18, 2005, HHS held its Seventh 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 an average of 4.1 percent 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 2005, HHS Regional Directors coordinated its 3rd annual year of Regional Tribal consultation sessions. Nine sessions were conducted in the field and all were coordinated with IHS Area Directors and supported by IGA. The sessions were attended by over 890 people and had over 145 Tribes represented at the sessions.

- *"Barriers to American Indian/Alaska Native/Native American Access to HHS Programs"*: In 2004, HHS began to study its discretionary grant programs to identify barriers that kept American Indian/Alaska Native/Native Americans from accessing funding opportunities from HHS sources. The study was conducted through the use of a survey instrument sent to both HHS program offices and tribal members. In FY 2005, a final report on the barriers was presented to the Intradepartmental Council on Native American Affairs (ICNAA). The report identified 24 barriers. The report also included 46 suggestions that may be implemented to overcome the barriers. Some are currently addressed by individual Operating Divisions; and some were identified as actions the Tribes themselves could correct without the involvement of HHS.[123]

- *Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Committee (TTAG)*: During 2005, CMS established a Tribal consultation policy Subcommittee that developed a proposed policy for CMS review. CMS has made changes and the TTAG will be conducting consultations on the plan in early 2006.

- *CMS Consultation with the Tribal Technical Advisory Group*: CMS consulted with this group, comprised of elected Tribal Leader representatives, regarding ways in which to implement effectively the new Medicare prescription drug benefit at pharmacies operated by IHS, Tribes and Urban (I/T/U) programs. As a result, CMS:

  - added a provision to final regulation requiring that Part D plans offer contracts to all I/T/U pharmacies in their service area.;

[123]The report is available on the HHS website at the following address: *http://aspe.hhs.gov/hsp/06/barriers2access/*

- authorized Part D Plans to count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies required by the Part D regulations.
- developed a Part D model contract addendum that served as a "floor" for contracting with pharmacies operated by IHS, Tribes and Urban Indian health programs.

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 the elimination of health disparities. Tribes also expressed specific interest in health promotion and disease prevention; Medicare and Medicaid; emergency preparedness; health and human service facilities construction, and reauthorization of the Indian Health Care Improvement Act.

In FY 2005, HHS resources provided to Tribes (or expended for the benefit of Tribes) was approximately $4.66 billion, an increase of approximately $95.5 million over the FY 2004 amount of $4.57 billion. These gains came in both appropriated funding as well as through increased tribal access to non-earmarked funds and increases in discretionary set-asides.

E. Department of Housing and Urban Development

1. Working with Public Housing Agencies (PHAs) and Residents on Revisions to the Public Housing Operating Fund.

Authorized by the United States Housing Act of 1937 (42 U.S.C. 1437 *et seq*.), the Operating Fund makes assistance available to PHAs to operate and manage public housing. On September 19, 2005 (79 FR 54984), HUD published a final rule amending the regulations of the Public Housing Operating Fund Program at 24 CFR part 990, to provide a new formula for distributing operating subsidy to PHAs and establish requirements for PHAs to convert to asset management.

HUD developed the final rule with the active participation of PHAs, public housing residents, and other relevant parties using the procedures of the Negotiated Rulemaking Act of 1990. HUD convened a negotiated rulemaking advisory committee (Committee) for the purposes of developing potential changes to the Operating Fund Program. The Committee consisted of 28 members, including representatives of PHAs, public housing tenant organizations, public housing advocacy groups, the Public Housing Authorities Directors Association (PHADA), the Council of Large Public Housing Authorities (CLPHA), and the National Association of Housing and Redevelopment Officials (NAHRO), multifamily housing providers, and HUD. The Committee held four meetings. Members of the public were permitted to make statements during the meetings at designated times and to file written statements with the Committee for its consideration.

The Committee made recommendations on ways to improve and clarify the regulations governing the Operating Fund Program taking into consideration the recommendations of the congressionally-funded study by the Harvard University Graduate School of Design on the cost

of operating well-run public housing. After a comprehensive review of the existing regulations, the Committee made recommendations concerning, among other things, streamlining and simplifying operating subsidy calculations, the inclusion of a public entity fee, operating subsidy for vacant units, factor for inflation, and various issues involved with conversion to asset management.

The negotiated rulemaking process resulted in the development of an improved operating fund formula. Using the Committee's recommendations, the new formula's calculations are simplified and the procedures are streamlined. The new formula also requires that PHAs convert to asset-based management, and establishes certain benchmarks regarding conversion to this new management model.

2. Working with Stakeholders to Improve Community Planning and Development (CPD) Performance Measures.

On June 10, 2005 (70 FR 34043), HUD published a notice in the Federal Register announcing a proposed outcome performance measurement system for its community development programs. This proposed system would enable HUD to collect information on the outcomes of activities funded with CPD formula grants including Community Development Block Grant (CDBG) Program, HOME Investment Partnerships Program (HOME), Emergency Shelter Grants (ESG), or the Housing Opportunities for Persons with AIDS Program (HOPWA), and to aggregate that information at the national and local level. With input from a working group that included HUD and community development entities, a final outcome performance measurement system was established and published on March 7, 2006 (71 FR 11470).

On September 3, 2003, HUD issued CPD Notice 03-09 entitled, "Development of State and Local Performance Measurements Systems for Community Planning and Development Formula Grant Programs." The notice encouraged CPD formula grantees assistance to develop and use performance measurement systems.

In March 2004, the Council of State Community Development Agencies (COSCDA) convened a meeting with representatives from the National Community Development Association (NCDA), the National Association for County Community Economic Development (NACCED), the National Association of Housing and Redevelopment Officials (NAHRO), the National Council of State Housing Agencies (NCSHA), CPD, and HUD's Office of Policy Development and Research to discuss the development of a performance measurement system that would be used by CPD formula grantees to gather information and determine the effectiveness of their programs.

That meeting resulted in the formation of a working group composed of representatives from those agencies and associations. The working group met at various times from June until November 2004 and developed the proposed outcome performance measurement system, which formed the basis of HUD's June 10, 2005, and March 7, 2006, Federal Register notices.

This performance measurement system that resulted from the working group will enable HUD to collect information on the outcomes of activities funded with CPD formula grant

assistance, and to aggregate that information at the national and local level. The system will be incorporated into HUD's Integrated Disbursement and Information System (IDIS), allowing for simplified data collection.

F. Department of Justice

Community Oriented Policing Services (COPS)

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.

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 our mission to advance community policing be 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.

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.

G. Department of Transportation

Federal Transit Administration

As a grant-making agency, the Federal Transit Administration (FTA) is responsible for providing federal financial assistance to State, local, and tribal governments. FTA consults with and addresses concerns raised by affected State, local, and tribal governments on regulatory issues.

For example, on April 4, 2006, and April 7, 2006, FTA held two public meetings with tribal nations to discuss FTA's new program "Public Transportation on Indian Reservations." This $45 million dollar program will provide grants directly to tribal nations for eligible public transportation activities. Based on the comments received from the two outreach sessions and from a notice in the Federal Register, FTA modified its proposed requirements for the program by expanding eligible activities and lowering the local share requirements. FTA expected to receive 20 applications for funding under this new program. Instead, FTA received 99 applications for funding. FTA believes its outreach efforts and willingness to modify its requirements based on feedback is one of the reasons this program was so well-received.

H. Environmental Protection Agency

EPA continues to strengthen its partnership with Tribal governments through implementing Executive Order 13175: Consultation and Coordination with Indian Tribal Governments. It is completing guidance for Executive Order 13175 that will include procedures for implementing the Executive Order, and information on how to analyze regulatory impacts on Tribes and areas of Indian Country. It will also provide guidance on selecting proper techniques for sharing information and gathering advice from Tribal officials during the early stages of the policy process.

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 and participates in a Federal

government-wide State and local Governments Web site. It 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 advises the Agency on issues and concerns facing smaller U.S. communities, and provides recommendations 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. EPA's 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 our national environmental programs, and our 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.

1. 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, including the following outreach mechanisms.

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 National Tribal Environmental Council (NTEC) to ensure appropriate and adequate State and Tribal representation at the FOSTTA meetings. In recent years, OPPT established a Tribal program to better communicate our 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.

In 2002, OPPT established the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) as the national advisory body to provide advice, information and recommendations on the overall policy and operation of programs managed by OPPT, in performing its duties and responsibilities under the Toxics Substances Control Act (TSCA) and the Pollution Prevention Act (PPA). NPPTAC has provided a forum for public discussion and the development of independent advice to EPA by leveraging the experience, strengths and responsibilities of a broad range of Agency constituents and stakeholders, including State and Tribal officials. For example, NPPTAC has provided policy advice and recommendations in areas such as assessment and management of chemical risk, pollution prevention, risk

communication, and opportunities for coordination. NPPTAC produced four recommendations on High Production Volumes Chemicals; two recommendations on Pollution Prevention; two recommendations on Tribal issues; and one recommendation on non-paint sources of lead. OPPT also relies very heavily on our Regional programs to interact with States and Tribes on Regional specific and national issues to ensure adequate perspectives are included in this Office's decision making processes.

In 2005 OPPT worked on development of a proposed regulation under Section 402(c)(3) of TSCA for addressing the risks from lead based paint hazards that may be created during renovation and remodeling activities in buildings. In establishing a regulatory program under Title IV of TSCA, interested States and Tribes can develop their own renovation and remodeling programs which may be authorized by EPA to operate in lieu of the federal program as long as the State or Tribal program is at least as protective. EPA encourages States and Tribes to administer their own lead-based paint programs, because this results in more effective and efficient risk reduction efforts. Currently, 38 States, the District of Columbia, and three Tribes are operating lead-based paint training and certification programs.

EPA's experience in administering existing lead-based paint activities program under TSCA section 402(a) suggests that the adoption and successful implementation of a national program by State, local, and Tribal governments will play a critical role in reduced exposures to lead-based paint hazards associated with renovation, repair and painting activities. The Agency consulted with its State and Tribal partners on a number of occasions throughout the development of the proposal to discuss renovation issues and to gauge their interest in developing and implementing renovation and remodeling programs.

The Office of Pesticide Programs (OPP) in OPPTS uses the State Federal FIFRA Issues Research and Evaluation Group (SFIREG), established in 1974 by cooperative agreement between EPA and the American Association of Pesticide Control Officials (AAPCO), the association that represents State level pesticide regulatory officials. SFIREG identifies, analyzes and provides State comment on pesticide regulatory issues and provides a mechanism for ongoing exchange of information about EPA and State pesticide programs. With a full committee and two subcommittees, there are eight regularly scheduled meetings each year that offer State officials the opportunity to meet with EPA to discuss 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.

The Office of Pesticide Programs (OPP) Tribal Program organized the Tribal Pesticide Program Council (TPPC) in late 1999. 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 Office of Prevention, Pesticide, and Toxic Substances (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. 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.

2. 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 consults with States to promote regulatory efficiency and improved environmental results. Several NCEI programs engaged States in creating a more performance-based environmental regulatory system. In FY 2005, the Performance Track Program worked closely with States to respond to a report from the Environmental Council of the States (ECOS) related to State interest in, and commitment to, performance-based environmental programs. While performance-based programs are not mandatory features of a State's overall environmental program, over 20 States do have active programs. During FY 2005, EPA organized three workgroups with State representatives to respond to the ECOS report and develop approaches to work together -- and thus more efficiently -- in implementing these programs. In FY 2005, NCEI consulted with States to address regulatory issues that can hinder smart growth at the local level and improved environmental performance by specific industry sectors. Through the Sector Strategies Program, NCEI and other stakeholders focused on tailored approaches for 13 sectors 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 2005, EPA worked closely with States to develop 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 2005, NCEI continued to work as a partner with State regulatory agencies through a variety of mechanisms. NCEI continued to expand its State Innovation Grants Program, selecting seven projects for funding from the 2005 competition. These projects reflected NCEI's strategic investment in assisting States implement innovation in permitting programs, specifically:

- the expansion (3 new projects/sectors) of the Environmental Results Program model (a compliance-assistance, performance self-certification and statistically-based auditing approach) for small business sectors;
- the implementation of the National Performance Track Program and parallel performance-based programs by States (3 states/projects);
- 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 (26 proposals submitted in the FY 2005 competition totaling almost $4M in requests). 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 FY 2006 sixteen States pursued ERP in eight 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; by voluntarily, 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 ESRP 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.

3. Reaching out to Local and Small Governments

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 must complete to determine whether the regulatory requirements of a rule might uniquely affect small governments. Under the plan, EPA encourages attention to such factors as whether small governments will experience higher per-capita costs because of economies of scale. The Plan also considers whether they would need to hire professional staff or consultants for implementation or be required to purchase and operate expensive or sophisticated equipment. EPA publishes the findings under the Small Government Agency Plan in the *Federal Register*

with proposed and final rules. When there are unique or significant impacts on small governments, EPA takes action to inform and assist them.

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.

Consultations that Changed EPA Policies

It is the Agency's policy to conduct outreach and seek accommodations, proportionate to the anticipated burden, to minimize adverse impacts on States, Tribes or local governments, in any rulemaking to which they are directly subject. Following are examples of when consultations resulted in substantive changes to rules:

1. Office of Solid Waste and Emergency Response

EPA's Manifest Forms Rule created a truly uniform manifest for the very first time. The rule was promulgated in March 2005.

EPA consulted with states through the Association of State and Territorial Solid Waste Management Officials (ASTSWMO) and had numerous state representatives on our internal EPA working group. We also consulted with the Department of Transportation, which also has an interest in transboundary movement of hazardous waste. Over a 10 year period, multiple meetings were held with state representatives to pursue development and implementation of a truly uniform hazardous waste manifest. This led to decisions on a general approach to be taken in developing the uniform manifest form. Subsequently, individual state representatives sat on our internal EPA working group over the 4 year period that the rule was under development. It

has always been OSWER policy to involve States in the development of rules that affect their solid and hazardous waste programs.

The regulated community urged development of a truly uniform manifest form to take the place of the current 25 different forms (one generic manifest form and 24 different state forms). The States wanted to make sure they could obtain necessary important information on non-federal hazardous wastes that are regulated in their States.

EPA issued a regulation that required use of a single uniform hazardous waste manifest form to be used by all generators, transporters, and TSDFs (treatment, storage, and disposal facilities). This paves the way for development of an electronic manifest system that will save States, hazardous waste generators, and the waste management industry on the order of $100 million per year in operating expenses.

2. Office of Prevention, Pesticides and Toxic Substances (OPPTS)

The Office of Pesticide Programs (OPP) issued a final rule (in January 2006) that streamlined the existing pesticide emergency exemption process based on recommendations from the States. Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA may issue emergency exemptions that allow unregistered uses of pesticides to address emergency pest conditions for a limited time. This action reduces the burden to States in the application process, allows for quicker emergency response, and provides more consistently equitable determinations of "significant economic loss" as the basis of an emergency, without compromising protections for human health and the environment.

Applicants for pesticide emergency exemptions, which are Federal and State Agencies responsible for pesticide regulatory authority, are affected by this final rule. Although federal agencies may apply for emergency exemptions, the vast majority of requests are from individual States for use by farmers to avert a pest-related economic emergency. Consultations were conducted with the American Association of Pesticide Control Officials (AAPCO), the association that represents State level pesticide regulatory officials.

The final rule was the culmination of nearly 10 years of outreach and consultations. After EPA held a workshop in 1996 to solicit stakeholder input to improve the emergency exemption process, AAPCO formed a Task Force to address emergency exemption issues with EPA. OPP consulted with the AAPCO Section 18 Task Force numerous times during the rulemaking process. OPP also consulted with the State Federal FIFRA Issues Research and Evaluation Group (SFIREG), established in 1974 by cooperative agreement between EPA and AAPCO. 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. 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.

In response to a request from EPA in 2002, AAPCO submitted three recommendations to the Agency to streamline and improve the emergency exemption process. The final rule addressed two of the three recommendations.

AAPCO, comprised of OPP's State regulatory partners, submitted specific recommendations based on their concerns that arose during the consultations. They recommended basing the necessary "significant economic loss" finding on yield losses, rather than revenue, where appropriate, and allowing States to re-certify continuing emergencies.

The two primary provisions in the final rule were the direct result of the State recommendations coming out of the consultation process. The resulting regulatory revisions streamlined the application process for States and the review process for EPA, reducing the burden and expediting EPA's response to emergency pest situations. The final rule also revised the assessment of "significant economic loss," providing for more consistently equitable determinations to qualify for an emergency exemption.