

**DRAFT 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF
FEDERAL REGULATIONS**

Executive Summary	3
Chapter I: The Costs and Benefits of Federal Regulations.....	5
A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB.....	6
B. Estimates of the Benefits and Costs of This Year's Major Rules	10
C. Regulations Implementing Federal Budgetary Programs	23
D. Major Rules for "Independent Regulatory Agencies"	24
E. The Impact of Federal Regulation on State, Local, and Tribal Government, Small Business, Wages, and Economic Growth	25
Chapter II: Validation of Benefit and Cost Estimates Made Prior to Regulation.....	35
A. Trends in Federal Regulatory Activity.....	35
B. Validation of Estimates	39
C. Brief Summaries of Ex-Post Evaluations of Regulations	40
Chapter III: Implementation of the Information Quality Act.....	45
A. Correction Requests Processed by Agencies in FY03	46
B. General Evaluation: Perceptions and Realities	50
C. Legal Developments under the Information Quality Act.....	54
D. Increasing Transparency under the Information Quality Act	54
E. Characteristics of an Effective Correction Request.....	55
F. Role of OMB's New Peer Review Policy	57
Appendix A: Calculation of Benefits and Costs.....	59
Appendix B: Valuation Estimates for Regulatory Consequences	62
A. Adjustment for Differences in Time Frame across These Analyses.....	64
B. Further Caveats	64
Appendix C: The Benefits and Costs of 1993-1994 Major Rules	65

EXECUTIVE SUMMARY

This draft Report to Congress was prepared to implement Section 624 of the Treasury and General Government Appropriations Act of 2001 (Public Law 106-554, 31 U.S.C. 1105 note), commonly known as the Regulatory Right-to-Know Act. It provides a statement of the costs and benefits of Federal regulations and recommendations for regulatory reforms. The report will be published in its final form later this year, after revisions to this draft are made based on public comment, external peer review, and interagency review.

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

- The estimated annual benefits of major Federal regulations reviewed by OMB from October 1, 1994 to September 30, 2004 range from \$68.1 billion to \$259.6 billion, while the estimated annual costs range from \$34.8 billion to \$39.4 billion. A substantial portion of both benefits and costs is attributable to a handful of Environmental Protection Agency clean-air rules that reduce public exposure to fine particulate matter.
- During the past year, 11 “major” final rules with quantified and monetized benefits and costs were adopted. These rules added \$12.6 billion to \$108.5 billion in annual benefits compared to \$3.8 billion to \$4.1 billion in annual costs.
- There were an additional 15 final “major” rules that did not have quantified and monetized estimates of both benefits and costs. Seven of these 15 rules implemented homeland security programs where the benefits of improved security are very difficult to quantify and monetize.

In addition, we report the latest results of our ongoing historical examination of the trends in Federal regulatory activity. Last year's report included preliminary estimates of the overall costs of major rules issued by Federal agencies each year from 1987 to 2003, and also suggested that a better measure of the overall impact of regulation on the economy would be net benefits; that is, benefits minus costs. This report presents preliminary net benefit estimates for the years 1992 to 2004. In addition, the cost estimates are extended back to 1981, the beginning of the regulatory review program at OMB. Based on a preliminary review, the data reveal that:

- Over the last 24 years, the major regulations reviewed by OMB have added at least \$117 billion to the overall yearly costs of regulations on the U.S. economy.
- The average yearly cost of the major regulations issued during the Bush (43) Administration is about 70% less than over the previous 20 years.
- The average yearly net benefit of the major regulations issued during the Bush (43) Administration is over double the yearly average for the previous eight years.

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

- The benefits of major regulations issued from 1992 to 2004 exceed the costs by over three fold.

The draft report also asks for comments on the usefulness of these measures and on the reasonableness of the assumptions that necessarily go into their construction. These estimates are based on the *ex ante* cost estimates found in agency regulatory impact analyses reviewed by OMB. The report notes some concerns with these estimates, such as the limitations of prospective analyses in providing an accurate picture of actual impacts, especially in cases where agencies estimated impacts 10 or more years ago. Hence, this year's report also explores what we know about the validation of *ex ante* estimates of costs and benefits of Federal regulation by *ex post* studies and asks for comments on these studies and suggestions on others that may have been missed.

In this draft report, we have also included an update of our FY 2003 Report to Congress on the implementation of Section 515 of the Treasury and General Government Appropriations Act, 2001 (Public Law 106-554, 31 U.S.C. 3516 note), commonly known as the Information Quality Act. This chapter includes discussion of the perceptions and realities related to some of the major concerns we have heard about the Information Quality Act and its implementation. Additionally, we share progress that has been made in increasing transparency as well as helpful tips for stakeholders interested in writing an effective correction request. Agency submissions on FY04 activities related to the Information Quality Act were due to OMB on January 1, 2005. We are currently evaluating those reports.

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," (Public Law 106-554, 31 U.S.C. 1105 note) calls for the Office of Management and Budget (OMB) to submit "an accounting statement and associated report" including:

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

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

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

(C) recommendations for reform.

This chapter consists of two parts: the accounting statement, and a brief report on regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth.

Part A revises the benefit-cost estimates in last year's report by updating the estimates to the end of fiscal year 2004 (September 30, 2004). Like the 2004 report, this chapter uses a 10-year look-back: estimates are based on the major regulations reviewed by OMB from October 1, 1994 to September 30, 2004. This means that 9 rules reviewed from October 1, 1993 to September 30, 1994 were included in the totals from last year's report but are not included here. A list of these rules can be found in Appendix C. All of the estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OMB.

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. This discussion is based on data provided by these agencies to the Government Accountability Office (GAO) under the Congressional Review Act, and also includes Federal Communications Commission (FCC) rules promulgated under authority of the Telecommunications Act of 1996, which are excluded from the GAO database by statute.

A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB¹

Table 1-1 presents estimates by agency of the benefits and costs² of major rules³ reviewed by OMB over the past year (October 1, 2003 to September 30, 2004). OMB reviewed 45 final major rules during that period. They represent approximately 12 percent of the 364 final rules reviewed by OMB during this 12-month period, and approximately one percent of the 4,088 final rules published in the *Federal Register* during this 12-month 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.⁴

Of the 45 rules, 19 implemented Federal budgetary programs, which caused income transfers, usually from taxpayers to another group. Rules that transfer Federal dollars among parties are not included in the benefit-cost totals because transfers are not social costs or benefits. If included, they would add equal amounts to benefits and costs. The remaining 26 regulations were “social regulations,” which may require substantial additional private expenditures as well as provide new social benefits.

Of the 26 “social regulations,” we are able to present estimates of both monetized costs and benefits for 11 rules. Seven 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. See Chapter 4 in the 2003 Report (pp 64-80) for a more detailed discussion of this issue. All seven of these rules did estimate costs.

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

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

² In many instances, agencies were unable to quantify all benefits and costs. We attempted to capture the essence of these effects on a rule-by-rule basis in the columns titled “Other Information” in the various tables reporting agency estimates. The monetized estimates we present necessarily exclude these unquantified effects.

³ The *Federal Register* citations for these major rules are found in Table 1-4.

⁴ 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. Because of this finding, we believe our decision to report only on the impact of major rules continues to have merit.

A.⁵ The 8 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 through 3. We attempt to summarize the available information on the impact of these rules in the “other information” column of Table 1-4.

Table 1-1: Estimates of the Annual Benefits and Costs of Major Federal Rules October 01, 2003 to September 30, 2004 (millions of 2001 dollars)		
Agency	Benefits	Costs
Department of Health and Human Services	1,567-7,686	812-893
Department of Transportation*	94	-32
Environmental Protection Agency	10,935-100,703	3,060-3,211
Total	12,596-108,483	3,840-4,073
*Department of Transportation rules include the final rule reducing the vertical separation minimum in domestic U.S. airspace. Since this is a deregulatory action, we have subtracted the cost savings from the costs imposed by other rulemakings.		

Table 1-2 presents an estimate of the total costs and benefits of 88 regulations reviewed by OMB over the ten-year period from October 1, 1994 to September 30, 2004 that met two conditions. 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. 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, 1994 to September 30, 2004 are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866.

⁵ 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.

Table 1-2: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1994 to September 30, 2004 (millions of 2001 dollars)		
Agency	Benefits	Costs
Department of Agriculture	2,387-5,923	1,586-1,608
Department of Education	632-786	349-589
Department of Energy	5,194-5,260	2,958
Department of Health and Human Services	10,226-19,714	3,817-3,992
Department of Homeland Security (Coast Guard)*	60	869
Department of Housing and Urban Development	190	150
Department of Labor	1,138-3,440	349
Department of Transportation	4,979-7,742	3,591-5,617
Environmental Protection Agency	42,827-216,514	21,166-23,284
Total	68,084-259,630	34,836-39,416

*Presented here are the costs and benefits of two Coast Guard rules that pre-date the establishment of DHS. These totals do not include the 7 major homeland security regulations adopted in 2004 by DHS and HHS. These regulations imposed costs of approximately \$1.8 billion to \$3.7 billion per year.

The aggregate benefits reported in Table 1-2 are substantially larger than the aggregate benefits presented in the 2004 Report, while the aggregate costs are roughly comparable to the last report's totals. This is due primarily to the addition of two Environmental Protection Agency (EPA) rulemakings: a final rule limiting emissions of air pollution from nonroad diesel engines (\$28.6 billion in annual benefits and \$1.3 billion in annual costs), and a final rule implementing National Emission Standards for Hazardous Air Pollutants from industrial, commercial, and institutional boilers and process heaters (\$17 billion in annual benefits and \$900 million in annual costs). As can be seen in Tables 2 and 3, EPA rules continue to be responsible for the majority of costs and benefits generated by Federal regulation during this time period.

Table 1-3 provides additional information on aggregate benefits and costs for specific agency programs. In order for a program to be included in Table 1-3, the program needed to have finalized 3 or more rules in the last 10 years with monetized costs and benefits. The Center for Department of Health and Human Services (HHS), Medicare and Medicaid Services (CMS) is a new entry on this table, due to the final rule published in the *Federal Register* on January 23, 2004 implementing requirements for a standard unique health care provider identifier.

The ranges of costs and benefits presented in Tables 1-3 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 \$2.5 billion to positive \$5.1 billion per year.

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

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) could easily be a factor of ten or more larger than the sum of the costs and benefits reported in Table 1-2. 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 treatments of uncertainty—these differences remain embedded in Tables 1-3. 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 benefits and cost estimates.

Many of these major rules have important non-quantified benefits and costs. These qualitative issues are discussed in the agency rulemaking documents, in previous versions of this Report, and in Table 1-4 of this Report.

Table 1-3: Estimates of Annual Benefits and Costs of Major Federal Rules: Selected Programs and Agencies October 1, 1994-September 30, 2004 (millions of 2001 dollars)		
Agency	Benefits	Costs
Department of Energy		
Energy Efficiency and Renewable Energy	5,194-5,260	2,958
Department of Health and Human Services		
Food and Drug Administration	3,348-12,399	985-1,160
Center for Medicare and Medicaid Services	5,634	2,538
Department of Labor		
Occupational Safety and Health Administration	1,138-3,440	349
Department of Transportation		
National Highway Traffic Safety Administration	4,154-6,917	2,267-4,292
Environmental Protection Agency		
Office of Air	39,738-200,505	15,171-16,765
Office of Water	1,165-8,307	3,160-3,684

The majority of the large estimated benefit of EPA rules is attributable to 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 to all types of clean-air rules. In addition, the ranges of costs and benefits presented in Tables 1-3 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. For the final report, we plan to work with EPA to revise these ranges to reflect only the uncertainty stemming from these sources.

As Table 1-3 indicates, the degree of uncertainty in benefit estimates for clean air rules is large. In addition, the wide range of benefits estimates for particle control does not capture the full extent of the scientific uncertainty. The five key assumptions in the benefits estimates are as follows:

- Inhalation of fine particles is causally associated with a risk of premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
- All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles formed from power plant SO₂ and NO_x emissions are chemically different from directly emitted fine particles from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects estimates 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 recent 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.⁶

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 each major rule for which OMB concluded review during the 12-month period beginning October 1, 2003, and ending September 30, 2004.

The statutory language that categorizes the rules we consider for this report differs from the definition of “economically significant” in Executive Order 12866. It also differs from

⁶ 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>.

similar statutory definitions in Title II of the Unfunded Mandates Reform Act of 1995 (U.S.C. 1531-1538) and Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996: Congressional Review of Agency Rulemaking (5 U.S.C. 801-808). Given these varying definitions, we were broadly inclusive for the purposes of this report and included all final rules promulgated by an Executive branch agency that meet any one of the following three measures:

- Rules designated as “economically significant” under section 3(f)(1) of Executive Order 12866;
- Rules designated as “major” under 5 U.S.C. 804(2); and
- Rules designated as meeting the threshold under 2 U.S.C. 1532

Social Regulation

Of the 45 economically significant rules reviewed by OMB, Table 1-4 lists 26 regulations requiring substantial private expenditures or providing new social benefits. The Table summarizes the costs and benefits of these rules, as reported by the agencies, and provides other descriptive information taken from rule preambles and Regulatory Impact Analyses (RIAs). The totals are:

- United States Department of Agriculture (USDA) - Food Safety and Inspection Service (FSIS), 1 rule;
- HHS - Food and Drug Administration (FDA), 4 rules; HHS-CMS, 2 rules;
- Department of Homeland Security (DHS) - Customs and Border Protection (CBP), 1 rule; DHS - U.S. Coast Guard (USCG), 3 rules; DHS - Border and Transportation Security (BTS), 1 rule;
- Department of the Interior (DOI), 2 rules;
- Department of Transportation (DOT) - Research and Special Programs Administration (RSPA), 1 rule; DOT - Federal Aviation Administration (FAA), 1 rule; DOT - Office of the Secretary of Transportation (OST), 1 rule;
- Department of Commerce (DOC) - Bureau of Industry and Security (BIS), 1 rule;
- Department of Labor (DOL) - Employment Standards Administration (ESA), 1 rule;
- EPA, 7 rules.

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Prohibition of the Use of Specified Risk Materials (SRM), and Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems requirements. [69 FR 1862]	USDA-FSIS	Not quantified	\$110.3million to \$149.1 million annually	<p>The agency performed one analysis for both rules. The primary costs of the SRM interim final rule are the exclusion of SRMs from use in the human food supply (\$35.6million to \$36.7 million); the prohibition on non-ambulatory disabled cattle (\$35.6million to \$71.3 million); and modifications of safety programs and record keeping requirements (\$27.6 million). The annual total cost of the AMR interim final rule is estimated at \$10.7million to \$12.5 million. The primary impacts of the AMR interim final rule are restrictions on incorporating certain non-meat components in AMR products (\$4.4million to \$5.6 million); testing AMR products (\$4.7million to \$6.2 million); and revisions to safety plans and bookkeeping requirements (\$1.0million to \$1.3 million). The annual cost of additional inspection, testing, and surveillance by FSIS is estimated at \$3 million.</p> <p>The benefits of the SRM and AMR interim final rules are primarily those resulting from the reduction in human exposure to BSE infectivity and the restoration of beef exports. USDA estimates that a reduction in human exposure of 4 ID50s (90% confidence interval of 0-20 ID50s) may occur as a result of this rulemaking. An ID50 is the amount of BSE infectious agent that can cause an exposed bovine to become infected with 50 percent probability. Because the exact quantitative relationship between human exposure to the BSE agent and the likelihood of human disease is unknown, USDA did not evaluate the quantitative likelihood that humans will develop variant Creutzfeldt Jakob Disease (vCJD) if exposed to the BSE agent.</p>
General Order Implementing Syria Accountability and Lebanese Sovereignty Act of 2003 [69 FR 26766]	DOC-BIS	Not estimated	Approximately \$140 million per year in lost exports	Costs based on trade before implementation of the rule. In calendar year 2003, U.S. exports to Syria, excluding food and medicine, totaled approximately \$140 million.

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Bar Code Label Requirements for Human Drug Products and Blood Products [69 FR 9120]	HHS-FDA	\$5.2 billion per year (7%), \$4.9 billion per year (3%).	Direct regulatory costs per year: \$8 million (7%), \$7 million (3%). Anticipated hospital costs of \$660 million (7%), \$600 million (3%).	FDA estimates that the rule provides net benefits to society of \$4.3 billion to \$4.5 billion annually, depending on whether a discount rate of 3 percent or 7 percent is used. These costs and benefits are annualized over 20 years. Costs include the estimated opportunity costs of the expected accelerated investment in bar coding systems by the hospitals. These investment expenditures are necessary to achieve the societal benefits expected from the rule. Benefits are from fewer medication errors. FDA also estimated a range of possible efficiencies in hospital activities associated with accelerated adoption of technology of \$360-\$600 million per year, although the benefits reported here do not include estimated hospital efficiencies as FDA considered these estimates very uncertain. FDA also anticipates income transfers because of reduced awards for medical malpractice.
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [68 FR 58975]	HHS-FDA	Homeland Security and Food Safety	Annual costs: \$272 million (7%), \$269 million (3%).	Reported costs annualized over 20 years at 7% and 3% discount rate. FDA describes benefits as knowing in advance what articles of food are being imported or offered for import, before they arrive at the port of entry into the U.S. In the event of a credible threat, FDA will be able to mobilize and assist in the detention and removal of specific products that may pose a serious health threat to human or animals. FDA also anticipated non-security benefits of this rule because the information provided FDA through the prior notice system will facilitate non-security related outbreak investigations.
Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [68 FR 58894]	HHS-FDA	Homeland Security and Food Safety	Present Value: \$2.9 billion (7%), \$4.0 billion (3%).	Present value costs are calculated over a 20-year horizon using a 7% and 3% discount rate. FDA also performed a sensitivity analysis of the costs to foreign facilities. The lowest cost combination of assumptions gives a total cost of \$220.5 million for the first year and \$144.6 million in subsequent years. The highest cost combination gives a total cost of \$364.6 million in the first year and \$267.4 million annually. In the event of an actual or threatened bioterrorist attack on the U.S. food supply or other food-related emergency, this information will help FDA and other authorities determine the source and cause of the event, and communicate with potentially affected facilities.

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated [69 FR 6787]	HHS-FDA	Annual health benefits of \$43million to \$132 million.	Annual utility losses for consumers: \$6million to \$81 million. Product Reformulation \$1million to \$9 million.	The benefits of this final rule stem from the reduction of risks brought about by removing dietary supplements containing ephedrine alkaloids from the market. FDA measures the risk reduction, for the purpose of estimating benefits, as the number of illnesses and deaths averted. FDA estimates net effects would be between -\$47 million and \$125 million per year from this rule, if consumer behavior does not already incorporate the health risks posed by these products, and between -\$90 million and -\$7 million per year, if consumer behavior already incorporates the health risks.
Standard Unique Health Care Provider Identifier (national provider identification, or NPI) [69 FR 3433]	HHS-CMS	Total savings (2007-2011): health care, \$341 million, provider, \$840 million.	Total costs (2007-2011): health care, \$426 million; provider, \$213 million; application and update, \$15 million; national provider ID system, \$128 million.	<p>The impact analysis shows a net savings of \$526 million over a 5-year period. The figures have been adjusted to reflect dollars expressed for 2007.</p> <p>CMS estimates that the NPI would entail 10 percent of the costs and 5 percent of the savings for health plans. Health plans would need to make some system changes from their current identifiers to the NPI. They would save in not having to maintain a system of identifiers that exist today. We would estimate that for health care providers, the NPI would represent 5 percent of the costs and 10 percent of the savings. Health care providers need only to substitute the NPI for their current identifier(s). They reap greater savings by not having to keep track of separate identifiers for each health plan and possibly for each location, address, or arrangement.</p> <p>The cost of administering the national provider system itself is a Federal budget cost.</p>

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Medicare Prescription Drug Discount Card [68 FR 69839]	HHS-CMS	Maximum additional revenue from fees per endorsed sponsor: \$13 million in 04, \$13 million in 05, none in 06.	Administrative costs: \$10-18 million in 04, \$4 - \$7 million in 05, \$600 - \$900 thousand in 06.	<p>According to the RIA for the interim final rule, the savings to beneficiaries from discount card activities, including negotiated prices on prescription drugs and education about generic substitution by endorsed sponsors, will represent an economic impact ranging from \$1.4 billion to \$1.8 billion in the last nine months of 2004 (assuming for the purposes of this impact analysis implementation beginning second quarter 2004), \$2.0 billion to \$2.7 billion in 2005, and \$0.4 billion to \$0.6 billion in the first four and one-half months of 2006. This impact would not affect the Federal budget, but would be a transfer of money due to a decrease in the revenues of entities providing the supply of drugs to consumers. This represents at most 1.18 percent of projected total retail prescription drug spending during the respective periods of analysis. In addition to savings from discount card activities, a subset of discount card enrollees—those who qualify for transitional assistance—are projected to save \$2.6 billion in 2005 and up to \$0.1 billion in 2006 due to the annual \$600 transitional assistance. Beneficiary savings from transitional assistance are funded through the Federal budget, so these savings are a transfer from budget revenue to beneficiaries.</p> <p>Since this rulemaking facilitates a new market, the administrative costs firms must incur to enter this market and the surplus firms will receive in this new market are costs and benefits from this rulemaking. Net benefits are generally projected to be positive but small relative to the savings generated for beneficiaries. The net present value benefits range from near zero to approximately \$10 million.</p>
Required Advance Electronic Presentation of Cargo Information [68 FR 68139]	DHS-CBP	Homeland Security	\$1.1 billion per year central estimate, with a range of \$.3billion to \$2.2 billion per year.	<p>The economic analysis focused on those sectors where shippers or carriers are likely to have to change current practices to come into compliance. For air, the rule will impose substantial new costs, mandating electronic data entry at a level of detail not currently required prior to arrival and causing operational changes to meet the filing requirements for flights into the U.S. from airports north of the equator in the western hemisphere. For trucking, the costs are offset by the time savings gained by faster clearance across the border. The faster movement across the border also provides benefits to other traffic at the border, which the analysis quantified. The principal benefit of the rule, improved security, was not quantified. The costs reported here are annualized over 5 years at a 7% discount rate.</p>

Table 1-4. Summary of Agency Estimates for Final Rules October 1, 2003 to September 30, 2004 (As of Date of Completion of OMB Review)				
Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Required Advance Electronic Presentation of Cargo Information [68 FR 68139]	DHS-CBP	Homeland Security	\$1.1 billion per year central estimate, with a range of \$.3billion to \$2.2 billion per year.	The economic analysis focused on those sectors where shippers or carriers are likely to have to change current practices to come into compliance. For air, the rule will impose substantial new costs, mandating electronic data entry at a level of detail not currently required prior to arrival and causing operational changes to meet the filing requirements for flights into the U.S. from airports north of the equator in the western hemisphere. For trucking, the costs are offset by the time savings gained by faster clearance across the border. The faster movement across the border also provides benefits to other traffic at the border, which the analysis quantified. The principal benefit of the rule, improved security, was not quantified. The costs reported here are annualized over 5 years at a 7% discount rate.
Area Maritime Security [68 FR 60472]	DHS-USCG	Reduced risk from a transportation security incident	\$477 million (present value) for the period 2003 to 2012	<p>This final rule, superseding the area maritime security interim rule, was published on October 22, 2003. The Coast Guard published a series of six temporary Interim Final Rules, three of which were economically significant, in order to promulgate requirements mandated by the Maritime Transportation Security Act (MTSA) of 2002 (Public Law 107-295). These were effective from July 1, 2003, until November 25, 2003.</p> <p>The impact analysis accompanying these rules assumed they would be in place for the foreseeable future. Costs include committee meetings, travel, and security drilling. Benefits are estimated in “risk points reduced,” a qualitative measure designed to help estimate the overall increase in security many different activities would produce. The area maritime security rule had an estimated cost per risk point reduced of \$469 (present value, 2003–2012) (68 FR 39288).</p>
Vessel Security [68 FR 60483]	DHS-USCG	Reduced risk from a transportation security incident	\$1.368 billion (present value) for the period 2003 to 2012	<p>This final rule superseding the vessel security interim rule was published on October 22, 2003.</p> <p>The impact analysis accompanying these rules assumed they would be in place for the foreseeable future. Costs include purchasing, installing, and maintaining security-related equipment; hiring security officers, and preparing paperwork. Benefits are estimated in “risk points reduced,” a qualitative measure designed to help estimate the overall increase in security many different activities would produce. The vessel security rule had an estimated cost per risk point reduced of \$233 (present value, 2003–2012) (68 FR 39299).</p>

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Facility Security [68 FR 60515]	DHS-USCG	Reduced risk from a transportation security incident	\$5.399 billion (present value) for the period 2003 to 2012	<p>This final rule superseding the facility security interim rule was published on October 22, 2003.</p> <p>The impact analysis accompanying these rules assumed they would be in place for the foreseeable future. Costs include purchasing, installing, and maintaining security-related equipment; hiring security officers, and preparing paperwork. Benefits are estimated in “risk points reduced,” a qualitative measure designed to help estimate the overall increase in security many different activities would produce. The facility security rule had an estimated cost per risk point reduced of \$1,517 (present value, 2003–2012) (68 FR 39319).</p>
Authority To Collect Biometric Data From Additional Travelers and Expansion to the 50 Most Highly Trafficked Land Border Ports of Entry (US-VISIT) [69 FR 53318]	DHS-BTS	Homeland Security	\$155 million for all 50 ports during 2004, or approximately \$3.1 million at each of the ports.	<p>The anticipated benefits of this rule include: (1) Improving identification of travelers who may present threats to public safety and the national security of the United States through use of biometric identifiers; (2) enhancing the government’s ability to match an alien’s fingerprints and photographs to other law enforcement or intelligence data associated with identical biometrics; (3) improving the ability of the United States to identify individuals who may be inadmissible to the United States; (4) improving cooperation across international, Federal, State and local agencies through better access to data on foreign nationals who may pose a threat to the United States; (5) improving facilitation of legitimate travel and commerce by improving the timeliness and accuracy of the determination of a traveler’s immigration status and admissibility; (6) enhancing enforcement of immigration laws, contributing to the increased integrity of the system of immigration in the United States; (7) reducing fraud, undetected impostors, and identity theft; and, (8) increasing integrity within the VWP program, through better data collection, tracking, and identification, allowing better compliance monitoring through increased and more accurate data.</p> <p>The costs associated with implementation of this interim rule for travelers not otherwise exempt from US–VISIT requirements include an increase of approximately 15 seconds in inspection processing time per applicant over the current average inspection time of one minute, whether at a land, air, or sea port-of-entry.</p>

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Early-Season Migratory Bird Hunting Regulations [69 FR 52970; 53564; 53990]	DOI	Consumer surplus lost without duck hunting regulations: \$734 million to \$1.1 billion (2003\$) annually, with a mid-point estimate of \$899 million.	Not Estimated	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. DOI finalized a total of three Early Season regulations, the Final Framework (69 FR 52970), the Bag and Possession Limits (69 FR 53564), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (69 FR 53990). The listed benefits represent estimated consumer surplus. Approximately 1.6 million people reported hunting ducks or geese in the U.S. 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. Also, data to estimate producer surplus are not available; producer surplus is likely minimal compared to consumer surplus.
Late-Season Migratory Bird Hunting Regulations [69 FR 57140; 57752; 58236]	DOI	See "Early Season" benefits above.	Not Estimated	DOI finalized a total of three Late Season regulations, the Final Framework (69 FR 57140), the Bag and Possession Limits (69 FR 57752), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (69 FR 58236). See above for a summary of the impacts of hunting regulations.

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees [69 FR 22122]	DOL-ESA	Not Quantified	First-year implementation costs to employers are estimated to be \$738.5 million, of which \$627.1 is related to reviewing the regulation and revising overtime policies, and \$111.4 million is related to conducting job reviews.	This rule has major distributional effects, as well as major unquantified costs and benefits. The major monetized transfer estimates are payroll impacts and decreases in liquidated damages. Transfers from employers to employees, in the form of greater overtime pay or higher base salaries, are estimated to be \$375 million per year. The rule also may lead to decreased payrolls, which were unquantified, due to a less strict test for high income workers. The rule also will lead to less litigation, which will generate transfers and benefits. The decrease in liquidated damages is based on less back wages being paid out because the employees were correctly paid overtime in the first place; this is likely to save businesses at least \$252 million a year. More efficient litigation of FLSA disputes also generates real resource savings that are unquantified. This is due to fewer scarce resources being devoted to lawsuit resolution, and less of a need for sophisticated time motion studies to determine eligibility. The unquantified cost is the additional inefficiency introduced into the labor market, which may lead to some dead weight loss. These costs are in approximately 2003 year dollars.
Pipeline Integrity Management in High Consequence Areas (Gas Transmission Pipelines) [68 FR 69777]	DOT-RSPA	Over 20 years: accident reduction, \$1.1 billion; supply disruption, \$1 billion; replacement waivers, \$1 billion.	\$4.7 billion over 20 years.	The costs are direct implementation costs. Quantified benefits include a reduction in accidents that result in injury and death, avoiding economic impacts associated with supply disruption, and giving RSPA a basis to waive current replacement requirements designed to reduce operating stresses in pipelines when population near them increases. Unquantified benefits include an improved ability to site pipelines in certain critical markets. Inability to site future pipelines could affect the Nation's ability to use the increased quantities of natural gas that the Energy Information Administration estimates will be needed to fuel our economy over the next 20 years.

Table 1-4. Summary of Agency Estimates for Final Rules October 1, 2003 to September 30, 2004 (As of Date of Completion of OMB Review)				
Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Reduced Vertical Separation Minimum (RVSM) in Domestic United States Airspace [68 FR 61303]	DOT-FAA	Fuel savings of \$5.3 billion for 2005 to 2016, or \$3 billion discounted.	Equipment upgrade of \$869.2 million for 2002-2016, or \$764.9 million discounted.	For costs, FAA assumed that that operators would choose to upgrade almost all of their aircraft to meet RVSM standards. The benefits of this rulemaking (some of which were not quantified) are: (1) An increase in the number of available flight levels; (2) enhanced airspace capacity; (3) greater opportunities to operate more fuel/time efficient routes and altitudes; and (4) enhanced air traffic controller flexibility by increasing the number of available flight levels, while maintaining an equivalent level of safety.
Computer Reservations System Regulations [69 FR 976]	DOT-OST	Not Estimated	Not Estimated	Computer reservations systems (CRSs) provide software to travel agents to allow them to book fares posted from air carriers. The 20-year-old CRS rules were intended to prevent carriers from using the CRS systems they owned at that time from undermining other carriers' ability to compete. After a comprehensive review, DOT concluded that the rules are no longer necessary and existing enforcement mechanisms can address any anticompetitive or consumer deception problems. According to two industry studies, allowing the rules to sunset will lead to savings between \$200 million and \$666 million per year.
Effluent Guidelines and Standards for the Meat and Poultry Products Point Source Category (Revisions) [69 FR 54475]	EPA	\$0-\$10 million	\$41-\$56 million	Monetized benefits include recreational and non-use benefits from improved water quality in freshwater rivers, lakes and streams. The estimate may not fully capture benefits from reductions in pathogens, oil and grease, and nutrients due to limitations in water quality modeling. In addition, the benefits from reduced eutrophication due to reductions in nutrient discharges may not be fully captured in monetized estimates. All benefits and costs estimates are in 2001 dollars

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
Establishing Location, Design, Construction, and Capacity Standards for Cooling Water Intake Structures at Large Existing Power Plants [69 FR 41575]	EPA	\$82.9 million	\$389.2 million	Monetized benefits include use benefits such as increased fish catch to commercial and recreational fisherman. The estimates do not include ecological and other non-use benefits.
National Emission Standards for Hazardous Air Pollutants (NESHAP) for Stationary Reciprocating Internal Combustion Engines [69 FR 33473]	EPA	\$265 million (7%); \$280 million (3%)	\$248 million	Benefits are based on health effects of reducing PM10, and effect of NOx reductions on reducing PM10 and O3. The estimated annual tons reductions are the following: 5,600 HAP; 234,400 Carbon Monoxide; 167,900 NOx; 3,700 PM10. Both benefits and costs are estimated for the year 2005, and are presented in 1998 dollars.
NESHAP for Plywood and Composite Wood Products [69 FR 45943]	EPA	11,000 tons per year reduction of HAP; 27,000 tons per year in VOC (as total HC); 13,000 tons per year of PM10; 11,000 tons per year of CO	143 million per year in 2001 dollars. 4,000 tons per year increase in both NOx and SO2.	Costs include price increases nationally of 0.9 to 2.5 percent for products affected by this rule, and a reduction in output of 0.1 to 0.7 percent nationally for the affected industries. The total cost takes into account the behavioral response of consumers and producers to higher pollution control costs. To the extent facilities can demonstrate eligibility of some sources for the low-risk subcategory and forego installing pollution control devices, both benefits and costs would be reduced.

**Table 1-4. Summary of Agency Estimates for Final Rules
October 1, 2003 to September 30, 2004
(As of Date of Completion of OMB Review)**

Rule [FR Cite]	Agency	Benefits	Costs	Other Information
NESHAP for Industrial, Commercial, Institutional Boilers and Process Heaters [69 FR 55297]	EPA	\$15 billion per year (7%), \$16 billion per year (3%).	\$863 million per year for existing sources, \$19 million per year for new sources.	The rule leads to a reduction in pollutants from existing plants (in tons per year) of: HAP - 59,000; PM10 - 560,000; SO2 - 113,000. The rule also leads to a reduction in pollutants from new plants (in tons per year) of: HAP - 73, and PM10 - 65. Unquantified benefits include health benefits from Hg and other heavy metals, reduced threat to fish, wildlife, and ecosystems. To the extent facilities can demonstrate eligibility of some sources for the low-risk subcategory and forego installing pollution control devices, both benefits and costs would be reduced.
NESHAP for Surface Coating of Automobiles and Light-Duty Trucks [69 FR 22601]	EPA	Reductions in tons per year: HAP - 6000 (toluene, xylene, glycol ethers, MEK, MIBK, ethylbenzene, & methanol); VOC - 12,000 to 18,000	\$154 million per year.	EPA concluded that there is no scientifically supportable method for placing value on Volatile Organic Compound (VOC) reductions; therefore these benefits were not monetized. Costs are presented in 1999 dollars.
Control of Emissions of Air Pollution From Nonroad Diesel Engines and Fuel [69 FR 39057]	EPA	Total annual benefits in 2030 are estimated to be \$83 billion (3%) for premature mortality and non-fatal myocardial infarctions (\$78 billion at 7%). The present value of benefits over the period from 2004 to 2036 is \$805 billion (3%), \$350 billion (7%).	Total annual costs are estimated to be \$53 million in 2008. Total annual costs are expected to increase to \$2,059 million in 2030 and \$2,239 million in 2036. The present value of costs over the period from 2004 to 2036 is estimated to be \$27.1 billion (3%), \$13.8 billion (7%).	In order to characterize the benefits attributable to the Final Nonroad Diesel Engines standards, the analysis used a benefits transfer method to scale the benefits of the modeled control options from the Proposed Nonroad Diesel Engines standards. The scaling procedure reflects the differences in emission reductions achieved under the Final standards compared to the Proposed standards. For a discussion of the benefits estimation technique, see Chapter 9 of the final regulatory analysis of the Nonroad Rule. Note that the Final Nonroad Rule did not quantify a minimum and maximum monetized benefit estimate around the primary estimate of benefits. The final nonroad regulatory analysis, however, does present a range of benefits based on the analysis of the proposed rule. The estimates provided in these appendixes have not been scaled to the Final Rule's stringency level, as the scaling methodology adds a new element of uncertainty that cannot be appropriately characterized.

C. Regulations Implementing Federal Budgetary Programs

Of the 45 economically significant rules reviewed by OMB, Table 1-1 through 1-5 lists the 19 that implement Federal budgetary programs. The budget outlays associated with these rules are “transfers” from taxpayers to program beneficiaries (or fees collected from program beneficiaries); therefore in past reports OMB has referred to these rules as “transfer” rules. The totals are: USDA, 2 rules; Department of Defense (DOD), 2 rules; DOC, 1 rule; HHS, 9 rules; DHS, 1 rule; DOI, 2 rules; and DOT, 2 rules.

This table also lists 9 HHS/CMS “Notices” which are used to set parts of their payment systems such as premiums and annual deductibles. Although 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 have included these rules in this table since they are considered major and are reported to the GAO.

Here, we highlight one of the rules presented below. The DOD's Army Corps of Engineers promulgated a final rule putting in place programmatic regulations for the Comprehensive Everglades Restoration Plan. These final regulations guide the \$8 billion joint Federal-State restoration of the Everglades, a plan with 68 separate project components, including interim hydrologic and ecological goals. These regulations were developed by the Corps of Engineers in close consultation with DOI and the State of Florida.

Table 1-5: Agency Rules Implementing Federal Budgetary Programs (October 1, 2003 to September 30, 2004)
Department of Agriculture
2002 Farm Bill: Conservation Reserve Program
2001 Agriculture, Rural Development, Food & Drug Administration and Related Agencies Appropriation Act: Vehicle and Maximum Excess Shelter Expense Deduction Provisions
Department of Commerce
Fishing Capacity Reduction Program for the Crab Species Covered by the Fishery Management Plan for the Bering Sea/Aleutian Islands King and Tanner Crabs
Department of Defense
Programmatic Regulations for the Comprehensive Everglades Restoration Plan
TRICARE; CHAMPUS; Appeals and Hearings Procedures
Department of Health and Human Services
Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for CY 2004
Medicare Program: Changes to the Hospital Outpatient Prospective Payment System (OPPS) and CY 2004 Payment Rates
Medicare Program: Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for CY 2004
Medicare Program: Hospital Outpatient Prospective Payment System Payment Reform for CY 2004—CMS-1371-IFC
Medicare Program Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2005 -- CMS-1360-N
Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes
Medicare Program: Continuation of Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity – CMS-4018-F

Table 1-5: Agency Rules Implementing Federal Budgetary Programs (October 1, 2003 to September 30, 2004)
Medicare Program: Medicare Ambulance MMA Temporary Rate Increases Beginning, July 1, 2004 – CMS-1492-IFC
Medicare Program Changes to the Hospital Inpatient Prospective Payment Systems and FY 2005 Rates – CMS-1428-F
Medicare Program; Part A Premium for 2004 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement --CMS-8018-N
Medicare Program: Part A Premiums for Calendar Year 2005 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement --(CMS-8022-N)
Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2005 CMS-8020-N
Medicare Program: Part A Premiums for Calendar Year 2005 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8022-N)
Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2005 (CMS-8021-N)
Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Beginning January 1, 2004 -- CMS-8017-N
Medicare Program: Notice of One-Time Appeal Process for Hospital Wage Index Classification
Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2004 -- CMS-8016-N
Department of Homeland Security
Adjustment of the Immigration Benefit Application Fee Schedule
Department of Interior
Indian Roads Reservation Program
Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Relief or Reduction in Royalty Rates, Deep Gas Provisions
Department of Transportation
Automotive Fuel Economy Manufacturing Incentives for Alternative Fueled Vehicles
Maritime Security Program

D. Major Rules for "Independent Regulatory Agencies"⁷

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) (Public Law 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"⁸. We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2003 to September 30, 2004. GAO reported that 4 of these agencies issued 4 major rules during this period.

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

⁸ An exception to this exclusion is rules promulgated by the Federal Communications Commission (FCC) under the authority of the Telecommunications Act of 1996, which are exempt from GAO reporting (5 U.S.C. 804). We are working with FCC to identify their Telecommunications Act rules and will include them in Table 1-6 in the final report.

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

In comparison to the agencies subject to E.O. 12866, these agencies provided in their analyses relatively little quantitative information on the benefits of major rules: of the 19 economically significant rules reviewed by OMB that did not implement homeland security related regulations, about 60 percent (11) reported monetized benefits, whereas only 25 percent (1 of 4) of the rules finalized by independent agencies reported monetized benefits. As Table 1-6 indicates, most of the rules included some discussion of benefits and costs, and reported monetized costs. OMB does not know whether the rigor and the 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 1-6: Rules for "Independent Regulatory Agencies" (October 1, 2003 to September 30, 2004)				
Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Communications Commission	Promoting Efficient Use of Spectrum Through Elimination of Barriers to the Development of Secondary Markets [68 FR 66252]	Yes	No	Yes
Federal Reserve	Availability of Funds and Collection of Checks [69 FR 47289]	Yes	No	No
Nuclear Regulatory Commission	Revision of Fee Schedules; Fee Recovery for FY 2004 [69 FR 22664]	Yes	No	Yes
Securities and Exchange Commission	Alternative Net Capital Requirements for Broker-Dealers that are Part of Consolidated Supervised Entities [69 FR 34428]	Yes	Yes	Yes

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

Sec. 624 (a)(2) of the Regulatory Right-to-Know Act (Public Law 106-554, 31 U.S.C. 1105 note) calls on OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth.

Impacts on State, Local, and Tribal Governments

Over the past 8 years, 6 rules have imposed costs of more than \$100 million per year on State, local, and tribal governments and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995 (Public Law 104-4, U.S.C. 1501 et seq.). The EPA issued all 6 of these rules, which are described in some detail below.

- *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 for existing sources was \$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.
- *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 water systems nationwide. The costs of the rule are estimated at \$700 million (\$1998) 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 (\$1998) 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 463,000 cases of cryptosporidiosis and 14-64 lives saved annually, with an estimated monetized value of \$0.35 billion to \$1.6 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 (\$1999). The monetized benefits of the rule range from \$140million to \$198 million per year. EPA was unable to monetize other benefits, including reductions in skin and kidney cancers. 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 6 EPA rules were the only ones over the past 8 years to require expenditures by State, local and Tribal governments exceeding \$100 million, they were not the only rules with impacts on other levels of governments. For example, 14 percent, 9 percent, and 6 percent of rules listed in the April 2001 Unified Regulatory Agenda cited some impact on State, local, or tribal governments, respectively.

Impact on Small Business

The need to be sensitive to the impact of regulations and paperwork on small business was recognized in Executive Order 12866, “Regulatory Planning and Review.” The Executive Order calls on the agencies to tailor their regulations by business size in order to impose the least burden on society, consistent with obtaining the regulatory objectives. It also calls for the development of short forms and other efficient regulatory approaches for small businesses and other entities. Moreover, in the findings section of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Congress stated that “... small businesses bear a disproportionate share of regulatory costs and burdens” (Section 202(2) of Public Law 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 resulting in lower unit costs.

The Office of the Chief Counsel for Advocacy of the Small Business Administration (hereafter "Advocacy") recently sponsored a study (Crain and Hopkins 2001) that estimated the burden of regulation on small businesses.⁹ That study found that regulatory costs per employee decline as firm size—as measured by the number of employees per firm—increases. Crain and Hopkins estimate that the total cost of Federal regulation (environmental, workplace, economic, and tax compliance regulation) was 60 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, this Administration's E.O. 13272 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. OIRA has a Memorandum of Understanding of March 19, 2002 with Advocacy that supports our review of these analyses. Please visit OMB's website at <http://www.whitehouse.gov/omb/inforeg/regpol.html> for a copy of this Memorandum.

The Advocacy (2004) report summarizes 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.¹⁰ This comprehensive report contains four main sections. Section one provides a brief overview of the RFA, as amended by SBREFA. Section two details the role of Advocacy. This section also breaks down Advocacy activities in Fiscal Year 2003, many of which were facilitated by the Memorandum of Understanding between Advocacy and OMB. Section three provides a snapshot of several of the rulemakings in which Advocacy effectively represented the interests of small entities. Section four of this annual report provides a brief overview and update on the report submitted to OMB on agency compliance with E.O. 13272 for Fiscal Year 2003. Please visit Advocacy's website at <http://www.sba.gov/advo> to learn more about Advocacy, review regulatory comment letters, and obtain useful research relevant to small entities.

Impact on Wages

The impact of Federal regulations on wages depends upon how "wages" are defined and on the types of regulations involved. If we define "wages" narrowly as workers' take-home pay, social regulation usually decreases average wage rates, while economic regulation often

⁹ Crain, W.M. and T.D. Hopkins 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>.

¹⁰ 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>.

increases them, especially for specific groups of workers. If we define “wages” more broadly as the real value or utility of workers’ income, the directions of the effects of the two types of regulation can sometimes be reversed.

1. Social Regulation

Social regulation—defined as rules designed to improve health, safety, and the environment—creates benefits for workers, consumers, and the public. Compliance costs, however, must be paid for by some combination of workers, business owners, and/or consumers through adjustments in wages, profits, and/or prices. This effect is most clearly recognized for occupational health and safety standards. As one leading textbook in labor economics suggests: “Thus, whether in the form of smaller wage increases, more difficult working conditions, or inability to obtain or retain one’s first choice in a job, the costs of compliance with health standards will fall on employees.”¹¹

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.¹² 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.¹³

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.

¹¹ From Ehrenberg, R. and R. Smith 1991. *Modern Labor Economics*, 4th Edition. HarperCollins, p. 279.

¹² 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).

¹³ 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.

Economic Growth and Related Macroeconomic Indicators

The strongest evidence of the impact of smart regulation on economic growth is the differences in per capita income growth and other indicators of well being experienced by countries under different regulatory systems. A well-known example is the comparison of the growth experience of the present and former Communist state-controlled economies with the more market-oriented economies of the West and Pacific Rim. State-controlled economies may initially have had growth advantages because of their emphasis on investment in capital and infrastructure but, as technology became more complex and innovation a more important driver of growth, the state-directed economies fell behind the more dynamic and flexible market-oriented economies. Less well known are the significant differences in growth rates and indicators of well being, perhaps for the same reasons, seen among economies with smaller differences in the degree of government control and regulation.¹⁴

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.¹⁵ The index, based mostly on subjective assessments by in-house experts, is composed of 50 independent variables divided into 10 broad factors that attempt to measure different aspects of economic freedom: trade policy, fiscal burden, government intervention, property rights, banking and finance, wages and prices, regulation, and informal market activity. A correlation between degrees of economic freedom and per capita GDP does not prove that economic freedom causes economic growth. Economic growth could cause economic freedom or both could be correlated with an unknown third factor. More suggestive is the data on changes in these indicators. The authors examine the relationship between the change in the index since 1995 and the average GDP growth rate over seven years. After grouping the 142 countries (for which they had complete data) into quintiles, they find a very strong association between improvement in the index and growth rates. The first quintile of countries grew at a rate of 4.9% per year, almost twice the 2.5% growth rate of the fifth quintile.

Since 1997, the Fraser Institute of Vancouver, B.C. has published the Economic Freedom of the World index for 123 countries.¹⁶ 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

¹⁴ 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.

¹⁵ Marc A. Miles, Edwin J. Feulner, Jr., Mary Anastasia O'Grady, and Ana I. Eiras, *2004 Index of Economic Freedom*. (Heritage Foundation/WallStreet Journal).

¹⁶ James Gwartney and Robert Lawson, *Economic Freedom of the World: 2004 Annual Report*. Fraser Institute, Vancouver, BC.

economic growth, but with other measures of well being, including life expectancy, the income level of the poorest 10%, adult literacy, corruption-free governance, civil liberties, the United Nations' Human Development Index, infant survival rates, and the absence of child labor. Economic growth does not appear to come at the expense of these other measures of well being. This is reassuring because GDP and other economic measures do not capture all the costs and benefits produced by regulation.

Although these statistical associations provide broad support for the claim that excessive 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 differences in the scope and manner of regulations among 145 countries 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 five of the fundamental aspects of a firm's life cycle: starting a business, hiring and firing workers, enforcing contracts, obtaining credit, and closing a business.¹⁷ The second volume (*Doing Business in 2005, Removing Obstacles to Growth*) updates these measures and adds data about registering property and protecting investors.¹⁸ Later volumes will examine trade logistics and corporate taxation. 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 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

¹⁷ World Bank. *Doing Business in 2004: Understanding Regulation*. Oxford Press. Washington, DC.

¹⁸ World Bank. *Doing Business in 2005: Removing Obstacles to Growth*. Oxford Press. Washington, DC.

business based on the seven indicators are in order: New Zealand, the United States, Singapore, Hong Kong (China), Australia, Norway, the United Kingdom, Canada, Sweden, and Japan.¹⁹

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% of business activity takes place in the informal sector. The study also found that women's share of private sector employment was also correlated with less rigid regulation of labor markets.

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

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

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

It is interesting to note that these principles correspond fairly closely to the characteristics of the U.S.'s program of regulatory reform.²⁰

The strong relationship between excessive regulation and economic performance persists even when the sample of countries is confined to the 30 mostly high-income democracies in the

¹⁹ See *Doing Business in 2005*, p. 2. 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.

²⁰ 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.

Organization for Economic Cooperation and Development (OECD). The OECD also has underway major work on this subject. A recent report by Giuseppe Nicoletti summarizes the findings of the OECD work as follows:

“The empirical results suggest that regulatory reforms have positive effects not only in product markets, where they tend to increase investment, innovation and productivity, but also for employment rates.”²¹

According to the OECD’s database of objective measures assembled in 2001, the 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.²² 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.²³ 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.”²⁴ Thus, countries with good records on entry regulation (which they point out includes some environmental regulation) also have good records on labor regulation.²⁵

This pattern of findings provides strong support for policies that pursue smarter regulation -- 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

²¹ 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).

²² 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.

²³ *Ibid.*

²⁴ Juan Botero, Simeon Djankov, Rafael La Porta, Florencio Lopez-de-Salinas, and Andrei Shleifer, “The Regulation of Labor,” NBER Working Paper, (May 2004).

²⁵ *Ibid.*

enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase state influence.²⁶

The World Bank measures of regulation, in particular, are weighted toward economic policy. However, it is important to point out that these findings may hold for social as well as economic regulation.²⁷ 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.²⁸ 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.²⁹ Thus a smarter 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) influence economic growth and well being.

²⁶ 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 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.

²⁸ 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.

²⁹ 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.

CHAPTER II: VALIDATION OF BENEFIT AND COST ESTIMATES MADE PRIOR TO REGULATION

In this annual regulatory accounting report, we summarize in Chapter I the estimates of the benefits and costs of each major rule that was prepared by a Federal agency prior to issuance of the rule. These *ex ante* estimates are "pre-regulation" forecasts of what the agency expects will happen, with regard to both benefits and costs, if the rule takes effect. However, an *ex ante* estimate is no more than an informed guess and, like other forms of prospective modeling, the estimates may or may not prove to be accurate once real-world experience with the rule is accumulated and analyzed. Moreover, new data may become available after a rule is promulgated that renders the pre-regulation estimates outdated and erroneous.

For major rules that are subject to "*ex post*" (retrospective) benefit-cost analysis, it may be feasible to determine whether the pre-regulation estimates were accurate. Where inaccuracies are discovered, it is useful to understand the direction and magnitude of estimation errors, including the nature and sources of those errors. This process of comparing post-regulation to pre-regulation estimates is considered a form of validation analysis because an effort is being made to determine the validity (accuracy) of the pre-regulation forecasts.

Validation of such analyses can assist policy makers in determining how much weight to give to benefit-cost information compared to other kinds of information in the regulatory process. Validation studies can also help pinpoint ways to improve the accuracy of benefit-cost estimates in the future. Finally, and perhaps most importantly, validation studies can help identify specific rules that are ripe for regulatory reform, since their benefit-cost balance may be more or less favorable than originally expected.

A. Trends in Federal Regulatory Activity

Since OMB began to compile records in 1981, Federal agencies have published 113,798 final rules in the *Federal Register*. Of these final rules, 20,393 were reviewed by OMB under Executive Order procedures. Of these OMB-reviewed rules, 1,119 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). To the best of OMB's knowledge, most of these rules have never been subject to an "*ex post*" analysis to determine whether they worked as intended and what their actual benefits and costs were. There is no systematic and comprehensive requirement for Federal agencies to validate their pre-regulation estimates of benefits and costs based on actual experience with the rule.³⁰

Last year's report presented some preliminary estimates of the overall costs of major rules issued by Federal agencies from 1987 to 2003. The estimates are based on the *ex ante* cost estimates found in agency regulatory impact analyses reviewed by OMB under EO 12291 prior

³⁰ Section 610 of Title V of the U.S. Code requires each Federal agency to develop a plan for a periodic review of its rules that have a significant economic impact on a substantial number of small businesses or entities and to publish a list of its intended reviews in the *Federal Register*. However, Section 610 does not require a validation study of the rule's *ex ante* and *ex post* costs and benefits.

to September 1993 and EO 12866 since then. The report pointed out some of the concerns we had with these estimates, including the concern that because they are prospective, they might not present an accurate picture of these regulations' actual impacts. This chapter surveys what we know about the validation of *ex ante* estimates of costs and benefits of Federal regulation by *ex post* studies, and asks for comments on these studies and suggestions on others that we may have missed.

Last year's report also suggested that a theoretically superior measure of the overall value of regulation would be net benefits; that is, benefits to society minus costs to society. We said we would explore the feasibility of constructing such a measure. Below we present a net benefits measure for the years 1992 to 2004. In addition, we extend the cost estimates back to 1981, the beginning of the regulatory review program at OMB.³¹ In this draft report, we are also asking for comments on the usefulness of these measures and on the reasonableness of the assumptions that necessarily go into their construction.

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 Public Law 107-5 and signed by the President on March 20, 2001 is recorded as a \$4.8 billion cost addition in 2000 and a \$4.8 billion cost savings in 2001. This better reflects the regulatory policy impacts of the two Administrations and is consistent with the 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.³² We made this change to be consistent with OMB Circular A-4, Regulatory Analysis, issued September 2003. The Circular states that, in situations where a rule simply restates statutory requirements, incremental costs and benefits should be measured relative to the pre-statute baseline.

Finally, EPA adopted significantly more stringent National Ambient Air Quality Standards (NAAQS) for ozone and fine particulate matter (PM) in 1997. At that time, EPA estimated that the actions necessary to meet the revised standards would yield benefits ranging from \$20 billion to \$120 billion per year and would impose costs of \$10 billion to \$22 billion per year. In the five years following the promulgation of the 1997 ozone and fine PM NAAQS, EPA 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

³¹ To present cost and benefit estimates by year, we used agency estimates of central tendency when available and took midpoints when not available.

³² Our estimate of \$4 billion in annual benefits and \$3 billion in annual costs reflects the assumption that without the rule, 50% of the costs and benefits of airbags would have been provided by the market.

"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 actual implementing rules, the actual impacts and timing of those impacts is better measured by the cost and benefit estimates associated with the implementing regulations.

Figure 2-1 presents the new cost estimates from January 20, 1981 through September 30, 2004. Over the last 24 years, \$117 billion of annual regulatory costs (2001 dollars) have been added by the major regulations issued by the executive branch agencies and reviewed by OMB. This means that, on average, almost \$5 billion in annual costs have been added each year over this period. Several patterns are present. Note, in particular, the tendency for regulatory costs to be highest in the last year before a President leaves office (1988, 1992, and 2000). Note also that the annual average increase in regulatory costs in this Administration is lower than in any of the three previous Administrations. The average annual costs of the regulations issued during President Bush's (43) Administration were 68% lower than the average annual costs of the regulations issued during the previous 20 years, and 76% lower than those issued during the eight years of the previous Administration.

Figure 2-1: Costs of Major Rules (1981-2004)

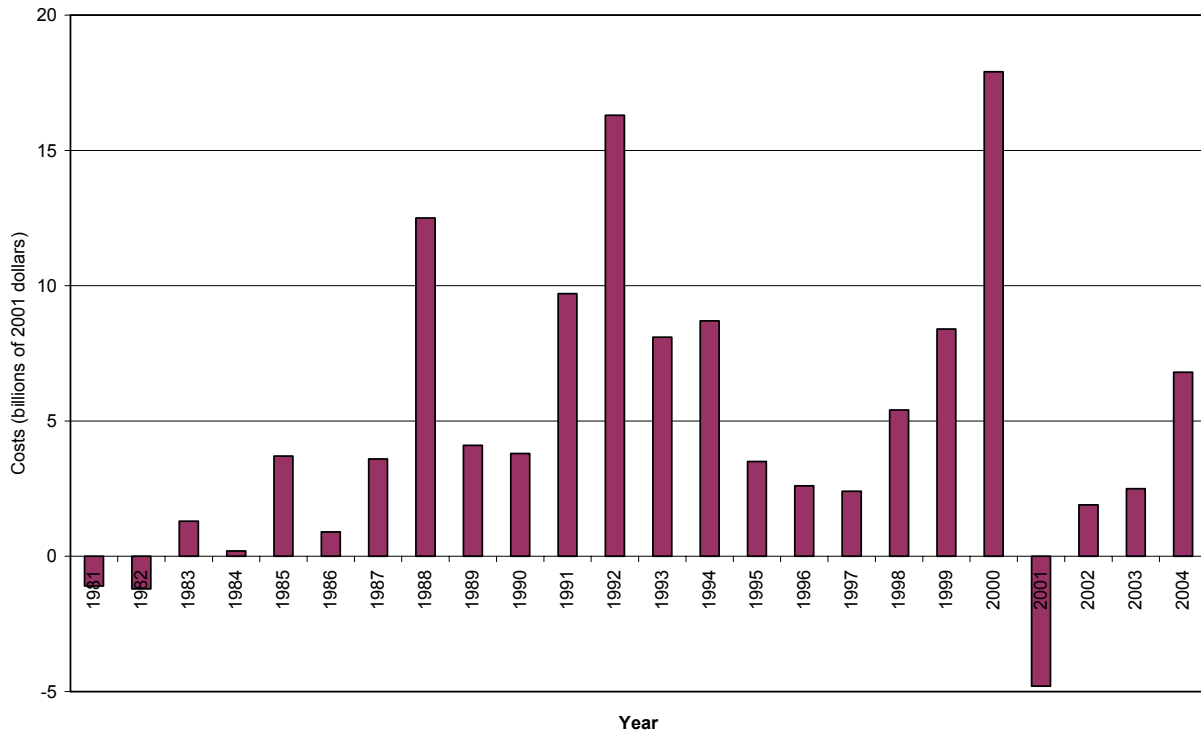


Figure 2-2 shows the benefits of major rules issued from October 1, 1992 to September 30, 2004. Benefit estimates for the rules (with two noted exceptions)³³ that comprise the overall

³³ 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.

estimates are presented in various tables in the eight annual reports (including this draft report) that OMB has completed. Note that the two highest years for benefits, 1992 and 2004, are mostly explained by two EPA regulations, the 1992 acid rain permits regulation and the 2004 nonroad diesel engine 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 44 months in office, the Bush (43) Administration issued regulations with average yearly benefits 20% greater than the average annual benefits of the rules issued during the previous eight years.

Figure 2-2: Benefits of Major Rules (1992-2004)

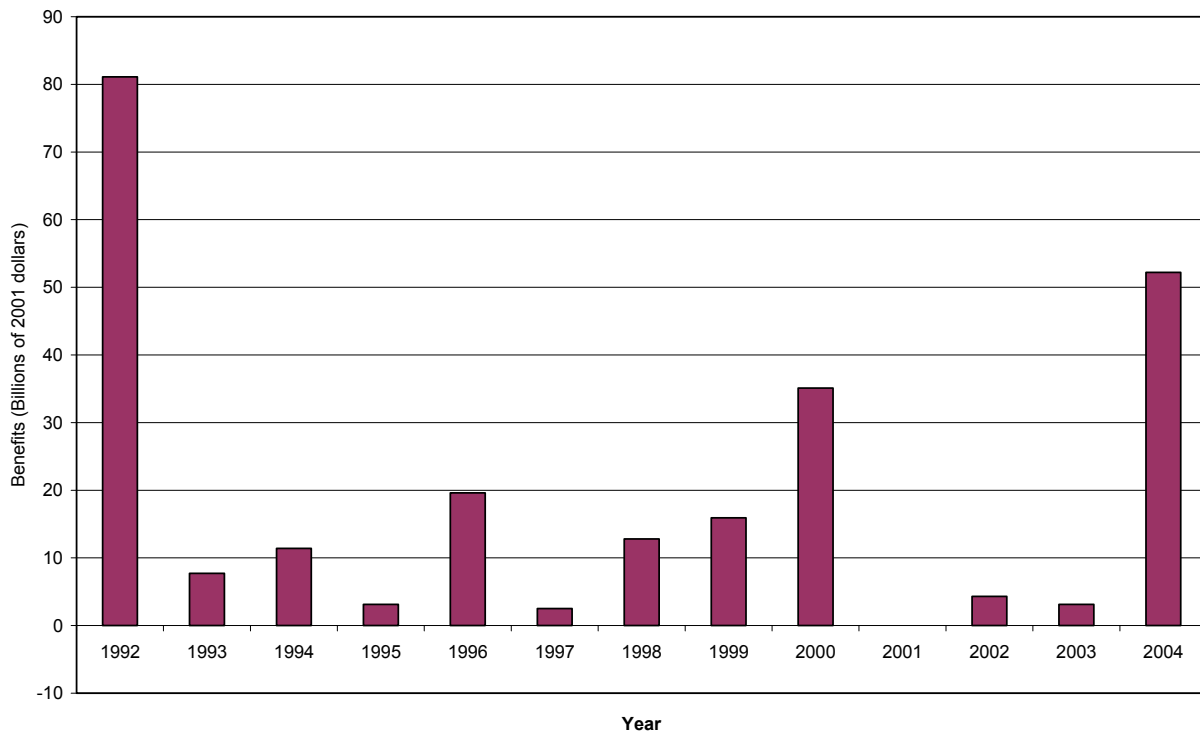
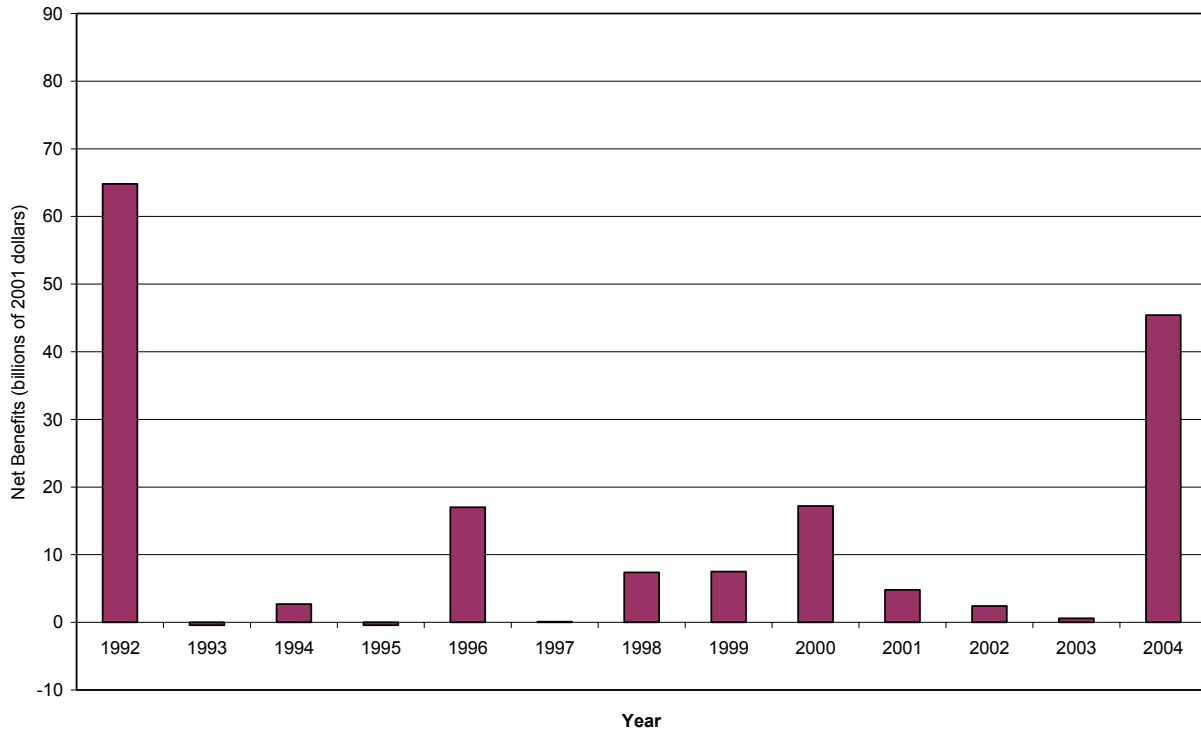


Figure 2-3 presents the net benefits of major regulations from 1992 through September 2004 as constructed from Figures 2-1 and 2-2. We were unable to go back beyond 1992 because of a lack of comparable data on benefits. Note that again the two end years dominate. In addition, the benefits of regulations issued from 1992 to 2004 exceed the costs by over three fold. Figure 2-3 also shows that the Bush (43) Administration issued regulations with net benefits over its first 44 months at a yearly average rate that is more than double the rate of net benefits produced by the regulations issued during the previous Administration.

Figure 2-3: Net Benefits of Major Rules (1992-2004)



However, we wish to emphasize that (1) these estimates are preliminary (2) as discussed in other sections of this report (see Appendices A and B) as well as previous reports, the aggregate estimates of costs and benefits derived from different agency’s estimates and over different time periods are subject to methodological inconsistencies and differing assumptions, and (3) the groundwork for the regulations issued by one administration are often begun in a previous administration.³⁴ We continue work to improve our estimates and request commentators to suggest improvements.

B. Validation of Estimates

Fortunately, there is a small yet growing body of literature where analysts have attempted to validate pre-regulation estimates of benefit and cost. This chapter reproduces, without comment, abbreviated summaries, conclusions, and/or/abstracts from a variety of ex-post studies that have examined (or would enable a direct evaluation of) the validity of benefit and/or cost estimates of one or more individual rules. OMB is in the process of reviewing this body of literature to determine whether overall inferences or lessons can be drawn for analysts and/or regulators.

³⁴ For example, FDA’s *trans* fat rule was proposed by the previous Administration and issued by the Bush (43) Administration while the groundwork for EPA’s nonroad diesel engine rule was set by the NAAQS rules issued in 1997.

With regard to this literature, we are particularly interested in public comments on the following questions:

1. We have tentatively decided to limit the studies in our review to those that would enable an assessment of the validity of the ex-ante benefit and/or cost estimates of one or more individual rules. Is this the appropriate scope?
2. Which additional studies provide useful information on the validity of pre-regulation estimates of benefits and costs?
3. Are there any particularly fruitful examples of rules where it would be feasible and useful for analysts to undertake validation studies?
4. What sources of data are available but have not yet been adequately tapped to undertake useful validation studies?
5. How strong is the technical quality of validation studies and how might they have been strengthened?
6. What general inferences can be drawn from the available literature regarding the accuracy of pre-regulation estimates of benefit and cost?

With a better understanding of this small yet growing literature, OMB intends to explore regulatory reforms that would promote rigorous validation studies. Comments should address which institutions, both inside and outside of government, are best equipped to undertake objective, high-quality validation studies. Comments are also welcome regarding what regulatory reforms would be appropriate to consider as the body of knowledge about the actual benefits and costs of existing rules expands in the future.

C. Brief Summaries of Ex-Post Evaluations of Regulations

Environment and Occupational Safety and Health

Harrington, Winston, Richard Morgenstern, and Peter Nelson (2000), "On the Accuracy of Regulatory Cost Estimates," *Journal of Policy Analysis and Management*, 19(2): 297-332. Abstract: "This study compares ex ante estimates of the direct costs of individual regulations to ex post assessments of the same regulations. For total costs the results support conventional wisdom, namely that the costs of regulations tend to be overestimated. This is true for 14 of the 28 rules in the data set discussed, while for only 3 rules were the ex ante estimates too low. For unit costs, however, the story is quite different. At least for EPA and OSHA rules, unit cost estimates are often accurate, and even when they are not, overestimation of abatement costs occurs about as often as underestimation. In contrast, for those rules that use economic incentives, unit costs are consistently overestimated. The difference between the total-cost and the unit cost results is caused by frequent errors in estimates of the effects of individual rules, which suggests, in turn, that the rule's benefits may also be overestimated. The quantity errors

are driven both by difficulties in determining the baseline and by incomplete compliance. In cases of unit-cost overestimation, unanticipated technological innovation appears to be an important factor-especially for economic incentive rules, although procedural and methodological explanations may also apply.”

Hammit, James K. (2000), “Are the Costs of Proposed Environmental Regulations Overestimated? Evidence from the CFC Phaseout,” *Environmental and Resource Economics*, 16(3): 281-301.

Abstract: “Benefit-cost and cost-effectiveness analysis are often advocated for decision making about environmental, health, and safety regulations, but there has been little research evaluating the accuracy of prospective estimates of regulatory costs and benefits. Prospective estimates of the marginal cost of limiting chlorofluorocarbon (CFC) consumption in the United States, published shortly before and after the September 1987 adoption of the Montreal Protocol, are compared with retrospective estimates based on realized market prices. Estimates published before international regulations were adopted (in May 1986) substantially overestimate the marginal costs of limiting CFC-11 and CFC-12 consumption but modestly underestimate the costs of limiting CFC-113 consumption. In contrast, estimates published shortly after adoption of the Protocol (in August 1988) appear to underestimate the marginal cost of limiting CFC consumption.”

Burtraw, Dallas, Alan Krupnick, Erin Mansur, David Austin, and Dierdre Farrell (1998), “Costs and Benefits of Reducing Air Pollutants Related to Acid Rain,” *Contemporary Economic Policy*, 16(4): 379-400.

Conclusion: “Although important limitations, caveats, and major uncertainties inhibit the comprehensiveness of this benefit-cost analysis, the clear conclusion that emerges is that the benefits of Title IV [of the Clean Air Act Amendments of 1990] exceed the costs by a substantial margin...This assessment differs from the information available to policymakers at the time the program was enacted in 1990...At that time...the expected benefits and costs appeared to be about equal for Title IV, in part because cost savings were expected to result from the innovative allowance trading program. Benefits are now thought to be greater than expected *and* compliance costs have fallen significantly compared to prior expectations, though compliance costs do not include all social costs of the program.”

Seong, Si Kyung and John Mendeloff (2004), “Assessing the Accuracy of OSHA’s Projections of the Benefits of New Safety Standards,” *American Journal of Industrial Medicine*, 45(4): 313–328.

“In the preambles to the safety and health standards that it has issued since 1987, the Occupational Safety and Health Administration (OSHA) projected that new safety standards would prevent over 2,600 deaths each year. For six safety standards issued since 1990, we compare OSHA’s projections of the impact of full compliance on fatalities with actual fatality changes and examine the reasons for the differences.

We reviewed the preambles to OSHA standards and the Regulatory Impact Analyses (RIAs) prepared for them to identify the baseline and the prevention factor that the agency used to project the number of deaths that would be prevented. We used three data sources to track the relevant categories of fatalities: the Census of Fatal Occupational Injuries (CFOI), the National Traumatic Occupational Fatality program, and OSHA’s Fatality/Catastrophe investigations.

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

For all six standards, OSHA appeared to overestimate the number of deaths prevented. The availability of CFOI led to better estimates of the fatality baseline, but the prevention factor was always overestimated, especially for standards which emphasized training.”

Transportation – National Highway Traffic Safety Administration (NHTSA)

NHTSA (2004), *Evaluation of FMVSS 214 Side Impact Protection for Light Trucks: Crush Resistance Requirements for Side Doors*, NHTSA Publication DOT HS 809 719.

"Light trucks (pickup trucks, vans, and sport utility vehicles) were required to meet a crush resistance standard for side doors beginning September 1, 1993. Side door beams were installed to reduce the velocity and depth of door intrusion in side impact crashes. The beams are estimated to reduce fatalities by 19 percent in single vehicle side impacts. When all light trucks on the road have head restraints, they will save an estimated 151 lives per year. Little or no fatality reduction was found in multivehicle crashes."

NHTSA (2001), *The Effectiveness of Head Restraints in Light Trucks*, NHTSA Publication DOT HS 809 247.

“The purpose of a head restraint is to prevent whiplash injuries in rear-impact crashes. Head restraints reduce overall injury risk in light trucks in rear impacts by a statistically significant 6 percent. When all light trucks on the road have head restraints, they will be preventing approximately 15,000 nonfatal injuries per year.”

NHTSA (2001), *The Effectiveness of Retroreflective Tape on Heavy Trailers*, NHTSA Publication DOT HS 809 222.

“Retroreflective tape enhances the visibility of heavy trailers in the dark. The tape reduces side and rear impacts by other vehicles into trailers by 29 percent in dark conditions (including dark-not-lighted, dark-lighted, dawn and dusk). In dark-not-lighted conditions, the tape reduces side and rear impacts by 41 percent. When all heavy trailers have the tape, it will prevent an estimated 191-350 fatalities, 3,100-5,000 injuries and 7,800 crashes per year.”

NHTSA (2001), *Evaluation of the American Automobile Labeling Act*, NHTSA Publication DOT HS 809 208.

“In a survey of 646 recent or imminent new-vehicle buyers, over 75 percent were unaware of the existence of automobile parts content labels. Among those who had read the labels, many said they used the country-of-assembly information, but none said they used the numerical U.S./Canadian parts content score. Overall U.S./Canadian parts content in new cars and light trucks dropped from an average of 70 percent in model year 1995 to 67.6 percent in 1998. However, it increased from 47 to 59 percent in transplants while dropping from 89 to 84 percent in Big 3 vehicles: trends undoubtedly influenced by the 1995 U.S.-Japan Agreement on Autos and Auto Parts and the North American Free Trade Agreement (NAFTA).”

NHTSA (2000), *Fatality Reduction by Safety Belts for Front-Seat Occupants of Cars and Light Trucks: Updated and Expanded Estimates Based on 1986-99 FARS Data*, NHTSA Publication DOT HS 809 199.

“Manual three-point belts reduce fatality risk, relative to the unrestrained front-seat occupant, by 45 percent in passenger cars and by 60 percent in pickup trucks, vans and sport utility vehicles. The analyses reconfirm the agency's earlier (1984-89) estimates of fatality reduction.”

NHTSA (1999), *Evaluation of FMVSS 214 - Side Impact Protection: Dynamic Performance Requirement*, NHTSA Publication DOT HS 809 004.

“The test injury criterion TTI(d) has a statistically significant association with fatality risk in actual side-impact crashes on the highway. In model years 1981-93 cars, make-models with low TTI(d) on the FMVSS 214 test tend to have low fatality risk. The relationship is stronger in 2-door than 4-door cars. Reducing TTI(d) by one unit is associated with an estimated 0.927 percent reduction of fatality risk in side impacts of 2-door cars. The association in the corresponding analysis of 4-door cars was not statistically significant.”

NHTSA (1999), *Effectiveness of Lap/Shoulder Belts in the Back Outboard Seating Positions*, NHTSA Publication DOT HS 808 945.

“Lap/shoulder belts reduce fatality risk by 44 percent relative to unrestrained back-seat occupants of passenger cars, and by 15 percent relative to lap-belted occupants. Lap belts reduce fatality risk by 32 percent relative to unrestrained occupants. Lap/shoulder belts are effective in all crashes, but lap belts only in nonfrontal crashes. Lap-belted occupants have substantially higher abdominal-injury risk than unrestrained back-seat occupants in frontal crashes, but lap/shoulder belts reduce abdominal injuries by 52 percent and head injuries by 47 percent relative to lap belts.”

NHTSA (1998), *The Long-Term Effectiveness of Center High Mounted Stop Lamps in Passenger Cars and Light Trucks*, NHTSA Publication DOT HS 808 696.

“Throughout 1989-95, cars equipped with Center High Mounted Stop Lamps were 4.3 percent less likely to be struck in the rear than cars without the lamps. (In 1987, when the lamps were first introduced, the reduction was 8.5 percent.) The effectiveness of CHMSL in light trucks is about the same as in cars. At the 1989-95 effectiveness level, when all cars and light trucks on the road have the lamps, they would prevent 194,000-239,000 crashes, 58,000-70,000 nonfatal injuries and \$655 million in property damage per year.”

NHTSA (1996), *Fatality Reduction by Air Bags: Analyses of Accident Data through Early 1996*, NHTSA Publication DOT HS 808 470.

“Driver air bags reduce overall fatality risk by an estimated 11 percent in passenger cars and light trucks (essentially unchanged from the 1994 and 1992 NHTSA analyses). Passenger air bags are beneficial for right-front passengers age 13 or older. Air bags provide a life-saving benefit for belted as well as unbelted drivers. The fatality risk for child passengers age 0-12 in cars with passenger air bags is currently higher than in cars without them. Current air bags are significantly less effective for drivers age 70 or older than for younger drivers.”

Thompson, Kimberly M., Maria Segui-Gomez, and John D. Graham (2002), “Validating Benefit and Cost Estimates: The Case of Airbag Regulation,” *Risk Analysis*, 22(4): 803-811.

“Preregulation estimates of benefits and costs are rarely validated after regulations are implemented. This article performs such a validation for the mandatory automobile airbag requirement. We found that the original 1984 model used to estimate benefits became invalid

when 1997 values were input into that 1984 model. However, using a published 1997 cost-effectiveness model, we demonstrate, by replacing the model inputs with the values from 1984, that the 1997 cost-effectiveness ratios, based on real-world crash data and tear-down cost data, are less attractive than what would have been originally anticipated. The three most important errors in the 1984 input values are identified: the overestimation of airbag effectiveness, the overestimation of baseline fatality and injury rates, and the underestimation of manual safety belt use. This case study, which suggests that airbags are a reasonable investment in safety, shows that the regulatory analysis tools do not always produce findings that are biased against health, safety, and environmental regulation.”

CHAPTER III: IMPLEMENTATION OF THE INFORMATION QUALITY ACT

Section 515 of the Treasury and General Government Appropriations Act, 2001 (Public Law 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.

The OMB government-wide guidelines impose three core responsibilities on the agencies. First, the agencies must embrace a basic standard of "quality" as a performance goal, and build quality into their information-dissemination practices. OMB's guidelines explain that "quality" encompasses "utility" (usefulness to its intended users), "integrity" (security), and "objectivity." "Objectivity" focuses on whether the disseminated information is accurate, reliable and unbiased as a matter of presentation and substance. Second, the agencies must develop quality assurance procedures that are applied *before* information is disseminated. The practice of peer review plays an important role in the guidelines, particularly in establishing a presumption that peer-reviewed information is "objective." Third, the OMB guidelines require that each agency develop an administrative mechanism whereby affected parties can request correction of poor quality information that has been or is being disseminated. Furthermore, if the public is dissatisfied with the initial agency response to a correction request, an administrative appeal opportunity must be provided.

The scope of the OMB Information Quality Guidelines is broad. "Information" is defined as "any communication or representation of knowledge such as facts or data" in any medium, including information related to regulatory, statistical, research, and benefits programs. It covers all Federal agencies subject to the Paperwork Reduction Act, including the independent regulatory commissions. OMB did provide a variety of exemptions from the guidelines to protect individuals' privacy and commercial secrets, and to facilitate press releases, third party submissions in public filings, archival records, personal articles by agency employees, testimony, and subpoenas and adjudicative determinations. OMB also provided agencies with the discretion to reject correction requests that are groundless, made in bad faith, or reflect only a difference of opinion.

OMB recognized that information quality can be costly and encouraged agencies to consider the social value of better information in different contexts. Ordinary information is distinguished from "influential" information -- that is, scientific, financial and statistical information having a clear and substantial impact on important public policies or important private sector decisions. "Influential" information is subject to higher standards of quality. With several important exceptions and qualifications (e.g., privacy, intellectual property rights, and

other confidentiality protections), influential information must be reproducible by qualified third parties.

The OMB guidelines also require that agencies report annually to OMB on the number and nature of requests received and how such correction requests were handled. The first annual reports, the FY03 agency Information Quality Reports, were due to OMB on January 1, 2004. These reports are summarized, discussed, and evaluated throughout this document.

The Bush (43) Administration is committed to vigorous implementation of the Information Quality Act. We believe it provides an excellent opportunity to enhance both the competence and accountability of government.

A. Correction Requests Processed by Agencies in FY03

On April 30, 2004, OMB released the Information Quality Report to Congress for FY03.³⁵ That report provided a summary of the first year of implementation of the Information Quality Act. Additionally, the appendix of that report contained all the FY03 Information Quality Reports from the departments and agencies that received correction requests. Below is an overview, which in some cases provides clarifications, of information presented in the *Information Quality Report to Congress FY03*. FY04 annual agency reports on Information Quality were due to OMB on January 1, 2005. OMB is now evaluating these reports.

All of the Federal agencies and departments that have Information Quality Guidelines submitted an FY03 Information Quality Report to OMB. The 19 departments and agencies that received requests for correction in FY03 are listed in Table 3-1.

Table 3-1. Departments and Agencies that Received Information Quality Correction Requests in FY03

Agriculture (5)	Veterans Affairs (1)
Commerce (4)	Consumer Product Safety Commission (4)
Defense (1)	Environmental Protection Agency (13)
Education (1)	Federal Emergency Management Agency (24,433)
Health and Human Services (10)	National Aeronautics and Space Administration (1)
Interior (6)	National Archives and Records Administration (8)
Justice (3)	Office of Science and Technology Policy (1)
Labor (18)	Commodity Futures Trading Commission (1)
Transportation (89)	Federal Deposit Insurance Corporation (1)
Treasury (19)	

The numbers in parentheses represent the total number of correction requests received by each organization.

³⁵ Information Quality, A report to Congress, FY 2003, OMB
http://www.whitehouse.gov/omb/inforeg/fy03_info_quality_rpt.pdf

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

As Table 3-1 shows, the number of correction requests received varied greatly by department and agency. This reflects the way in which the correction requests were categorized by the agencies. For instance, each year FEMA receives thousands of requests for revisions and amendments to flood insurance rate maps. Since the FEMA Information Quality Guidelines have come into effect, the agency has been handling the requests through its Information Quality process, but these requests were not stimulated by the Information Quality Act. Similarly, 87 of the 89 requests received by the Department of Transportation were requests to correct individual data items on Federal Motor Carrier Safety Administration (FMCSA) reports.

The details of the correction requests received by the agencies are available in the Appendix of the *Information Quality Report to Congress FY03*. This appendix includes all FY03 reports submitted from agencies that received correction requests. Reports from departments and agencies that did not receive correction requests are not included, as each report simply stated that no correction requests were received by the agency.

Classifying correction requests as to whether or not they were influential has not been easy for the agencies. Of all the correction requests received, OMB believes that somewhere between 30 and 40 of these requests were of a substantive nature, as they sought something more than a straightforward webpage or data fix. Among the correction requests received in FY03, only 8 were classified as being “influential” by the agencies. The classification regarding the influential status of 12 requests was designated as “undetermined,” reflecting the reluctance of some agencies to classify requests as “influential”. Reasons for this include concerns from legal staff, lack of clarity throughout the department or agency regarding the influential definition, and potential implications of classifying a correction request as influential.

At least some agencies have told OMB that the lack of an “influential” designation does not alter how the agency actually treats the correction request. For example, although HHS categorized only 1 of its 10 correction requests as “influential,” HHS has told OMB that the department treats all of its correction requests with the same high level of attention and standards of quality, regardless of the classification. Similarly, although EPA categorized only 1 correction request as influential, it appears that EPA treated each request and appeal with a similar high level of rigor.

The large majority of “non-influential” requests for correction did lead to some corrections by the agencies. These requests were typically straightforward, regarding questions pertaining to non-working weblinks, map correction changes, missing data, or other similar requests. Of the “influential” correction requests received by the agencies, 1 was partially addressed through a process change, 4 were denied, and 3 were pending. The status of these correction requests is depicted in Figure 3-1. Of the 12 “undetermined” requests, 1 was corrected, 3 were addressed through other mechanisms (e.g., treated as comments), 6 were denied and 2 were still pending at the end of FY03. Figure 3-2 shows the status of these requests.

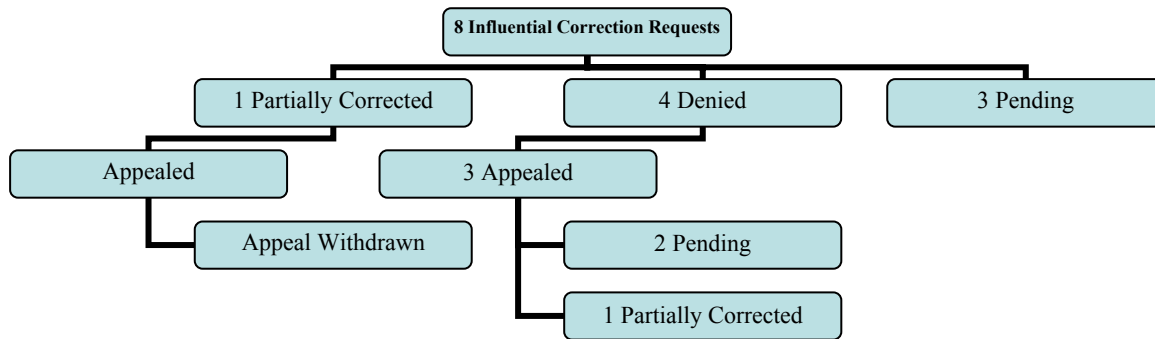


Figure 3-1. The status of the FY03 correction requests classified as “Influential” by Agencies, as reported in their FY03 reports.

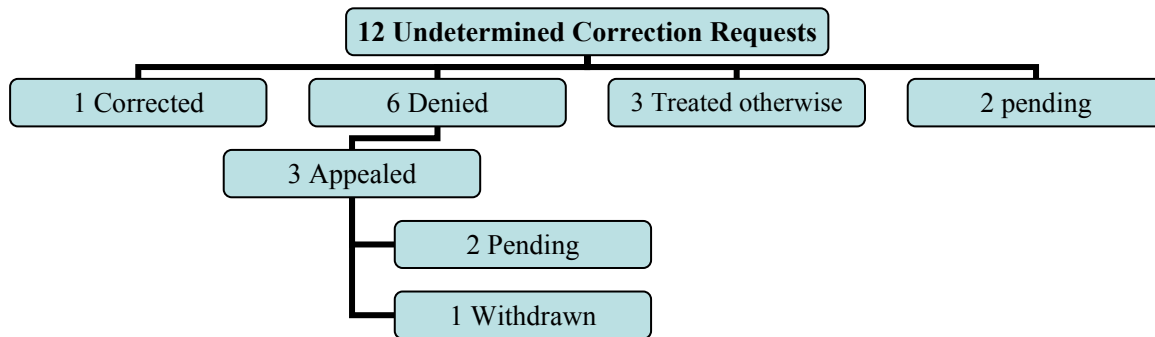


Figure 3-2. The status of the FY03 correction requests classified as “Undetermined” by Agencies, as reported in their FY03 reports.

A total of 16 correction requests were appealed. Of these appeals, 8 of the requests were classified as “non-influential”, 3 were “undetermined”, 4 were “influential” and 1 was defined as “not-applicable”. Six of the appeals were still pending at the end of FY03. Of the appeals that were responded to, 4 resulted in either full or partial corrections, 4 were denied and 2 were withdrawn. The status of the 16 appeals is shown graphically in Figure 3-3.

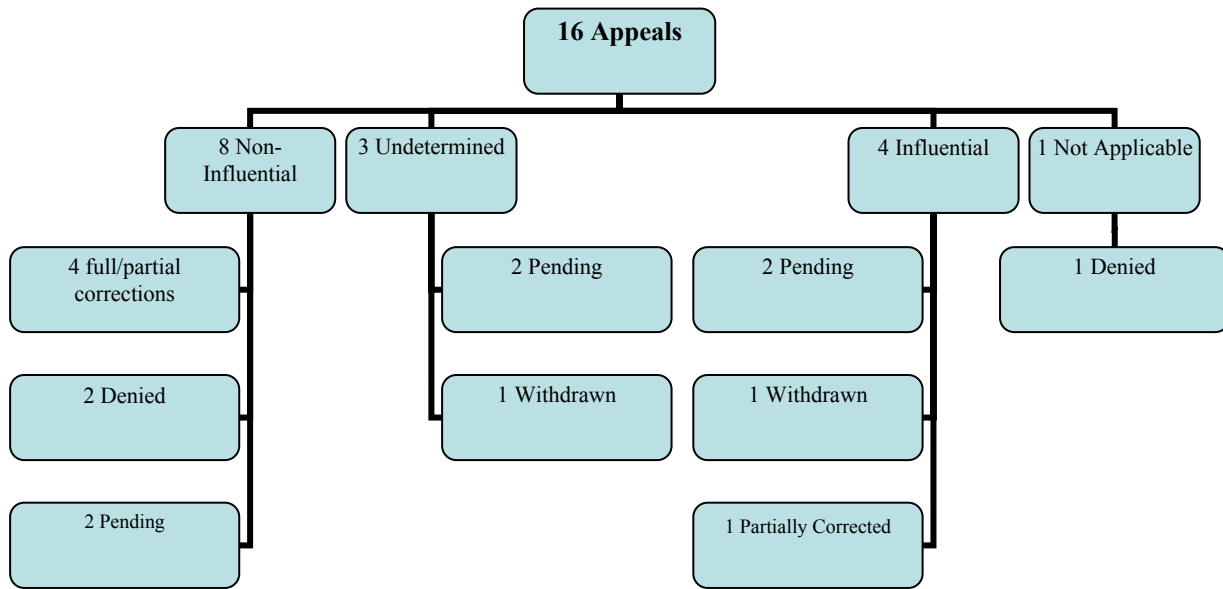


Figure 3-3. The Status of the 16 FY03 Appeals as presented in Agency FY03 reports.

Agencies have implemented varying processes for handling appeal requests. The Occupational Safety and Health Administration (OSHA) and HHS have used a single senior official to review each appeal. The Department of the Interior (DOI) has used a panel approach involving several senior managers from two agencies within DOI. For the appeal that went to Education, three subject matter experts and an attorney reviewed the appeal. The Department of Agriculture (USDA) has used independent panel review and EPA has used executive panel review.

Approximately 35 substantive correction requests have been submitted by the public to the departments and agencies in FY03. As the agency FY03 reports show (see Appendix of the *Information Quality Report to Congress FY03*), the types of correction requests received are extremely diverse. Within the departments and agencies, many different program offices have received correction requests. For instance, 7 distinct programs within HHS and 6 distinct programs within EPA had received correction requests.

Implementing a new process has not been without challenges as the agencies endeavor to create oversight mechanisms that are responsive, yet not overly bureaucratic and time consuming. Whereas most of the departmental and agency guidelines state that correction requests will typically be responded to within 60 to 90 days, OMB has noticed that many of the agencies take significantly longer to respond. In fact, it took the agencies more than five months to respond to correction requests in eight different cases. HHS, EPA, USDA, and the Department of Transportation (DOT) are agencies that have had difficulties responding within 60 to 90 days. OMB anticipates that once the program offices have worked through their first

correction requests and appeals, they will be able to process and respond to future requests more rapidly.

It is also too early to make a determination as to whether or not the agencies are making the correct judgment calls regarding their handling of substantive correction requests. Of the 8 “influential” correction requests received in FY03, 3 were still pending. Of the 7 appeals received on “influential” and “undetermined” correction requests in FY03, 4 were still pending at the end of FY03. Given the small number of completed responses at the end of FY03, it is premature to make broad statements about both the impact of the correction request process and the overall responsiveness of the agencies.

B. General Evaluation: Perceptions and Realities

Some complexities have arisen in implementing the Information Quality. For instance, we have learned that the notion of what constitutes a “dissemination” is not straightforward. Agencies have had to figure out if an oral statement made by a regional employee at a public meeting, or if statements in an email to a citizen, constitute a dissemination. Similarly, determining when an agency-commissioned study becomes subject to the Information Quality Guidelines raises complex questions.

When one agency’s dissemination is used by another agency, determinations become more complicated. The Department of Education grappled with this issue when it received a correction request regarding information in one of the Secretary’s commission reports that claimed the report relied on a study that was flawed. The study in question was produced by the United States Government Accountability Office (GAO). Deciphering the best answer to questions such as these has been challenging.

In contrast to the Department of Education example, many of the “non-influential” Information Quality correction requests have identified and described clear corrections for specific information disseminations. These corrections usually have been made by the agencies (see the Appendix of the *Information Quality Report to Congress FY03* for agency details on correction requests).

OMB has also learned that improving the quality of information may involve multiple judgments. Often correction requests hinge on interpretations of science or analyses. When dealing with uncertain scientific issues, it is possible to draw several reasonable inferences depending on the perspective of the reviewer. Thus, more than one plausible answer or methodology may exist. We are learning that it is possible for neither the agency nor the requestor to be incorrect. In FY03, the majority of non-frivolous correction requests have been denied, usually on the basis that a reasonable scientist could interpret the available information the way the agency had. Such correction requests might have been better focused if they had addressed the agency’s inadequate treatment of uncertainty rather than the accuracy of information.

OMB has heard some concerns about the Information Quality Act and the implementation process. Some of those concerns, as well as the perceptions and the realities that have come to be associated with them, are presented below.

Perception #1: "Information Quality Act was a last minute addition to the appropriations bill"

Though not subject to a congressional hearing, Section 515 was not a last-minute addition to the Treasury and General Government Appropriations Act, 2001 (Public Law 106-554). Previously, language in the House Report on the Treasury, Postal Service, and General Government Appropriations Bill, 1999 (House Report No. 105-592) had urged OMB to develop "rules providing policy and procedural guidance" for ensuring the quality of information disseminated by Federal agencies. Later, the version of the Treasury and General Government Appropriations Bill, FY2001 approved by the House Subcommittee contained a requirement for OMB to issue rules on information quality. In response, a June 18, 2000 letter from the OMB Director to the Chairman of the House Committee on Appropriations included a discussion of support for certain changes in the information quality language.³⁶ The Treasury and General Government Appropriations Act, 2001 (Public Law 106-554) enacted on December 21, 2000 called for OMB to issue guidance.

Perception #2: "Agencies might be inundated with requests for corrections."

The assumption that certain agencies would be overwhelmed by the volume of correction requests was one of the most common early perceptions. To the surprise of many, that has not been the case. In total, in FY03, the agencies received about 35 substantive correction requests that appeared to be stimulated by the Information Quality Act.³⁷ However, at some of the agencies, the Information Quality websites and email addresses have been used for correction requests for types of information that had previously been addressed through a different mechanism at the agency. Thus, although the use of the Information Quality process is novel, these types of correction requests are not new to the agencies and were not generated by the Information Quality Act. For instance, as mentioned previously, there have been a large volume of requests (over 24,000) to the Federal Emergency Management Agency (FEMA) regarding requests for map correction changes as part of the national flood insurance program, and a large volume of requests (about 90) to the Federal Motor Carrier Safety Administration (FMCSA) regarding the incorrect reporting of individual accidents. These types of correction requests were commonplace prior to the Information Quality Act. Of the approximately 35 distinctive

³⁶ Letter from Jacob J. Lew, OMB to The Honorable C. W. Bill Young, June 8, 2000 (copies also sent to the Honorable David R. Obey, the Honorable Jim Kolbe, and the Honorable Steny H. Hoyer).

³⁷ A Washington Post analysis of government records found 39 petitions with potentially broad economic, policy, or regulatory impact. See Rick Weiss, "'Data Quality' Law is Nemesis of Regulation," *Washington Post*, Aug. 16, 2004, p.A-1. An analysis by OMB Watch found that 98 substantive requests were received. See OMB Watch "The Reality of Data Quality Act's First Year: A Correction of OMB's Report to Congress", July 2004 (available at: <http://www.ombwatch.org/info/dataqualityreport.pdf>). The OMB Watch total included all requests except those received by FEMA and FMCSA. This number includes requests which OMB did not consider substantive or generated by the Information Quality Act. Summaries of correction requests received by agencies in FY03 are available for review in the Appendix of the *Information Quality Report to Congress FY03* (available at: http://www.whitehouse.gov/omb/info/fy03_info_quality_rpt.pdf).

correction requests, the Environmental Protection Agency (EPA), Health and Human Services (HHS), and Interior have received the majority of the requests.

Perception #3: “The Information Quality correction process is a review mechanism that would be used only by industry.”

OMB is pleased to report that the Information Quality has been used by virtually all segments of society. Correction requests have been filed by private citizens, corporations, farm groups, trade organizations, and a variety of non-governmental organizations as well as by government agencies and U.S. Senators.

Analysis by *The Washington Post* of the data provided in the *Information Quality Report to Congress FY03* found that of the 39 petitions with potentially broad economic, policy or regulatory impact, 32 were filed by regulated industries, business or trade organizations or their lobbyists.³⁸ OMB Watch found that, excluding FEMA, industry accounted for 72 percent of all requests for correction.³⁹ These numbers are not surprising, as one would expect that private-sector groups most affected by disseminations would be active users of the correction request process. Unevenness in the use of the correction process may also stem from the fact that some nonprofit groups are apparently boycotting the Act, as reported in *The Washington Post*.⁴⁰

Perception #4: “The Information Quality Act could result in slowing down the regulatory process and chilling agency disseminations.”

To our knowledge, the Information Quality Act has not affected the pace or length of rulemakings. We have no evidence to suggest that the Act has lead to a reduced number of agency disseminations nor has anyone provided such evidence.

As discussed previously, OMB believes that only 30 to 40 of the requests received by agencies were of a substantive nature or stimulated by the Information Quality Act. Although the total number may differ due to interpretation, OMB believes that only 5 correction requests were directly related to a rulemaking. The list includes: two correction request to USDA (Forest Service) regarding a proposed rulemaking for National Forest System Land and Resource Management Planning; one request to DOT regarding the age 60 rule; one request to EPA regarding a proposed rule on National Pollutant Discharge Elimination System Permit deadlines; and one request to DOI (Fish and Wildlife Service) regarding a proposed rulemaking related to manatees.

The small number of correction requests related to rulemakings is not surprising. The genesis of the Information Quality Act was a concern not necessarily about agency rulemakings, but rather a concern about the widespread dissemination of agency information on web pages. Most of this information exists in the form of reports, notices, and guidance documents. The Administrative Procedure Act already exists to address the rulemaking process, so it is not

³⁸ See Rick Weiss, “‘Data Quality’ Law is Nemesis of Regulation,” *Washington Post*, Aug. 16, 2004, p.A-1.

³⁹ See OMB Watch “The Reality of Data Quality Act’s First Year: A Correction of OMB’s Report to Congress”, July 2004 (available at: <http://www.ombwatch.org/info/dataqualityreport.pdf>).

⁴⁰ See Rick Weiss, “‘Data Quality’ Law is Nemesis of Regulation,” *Washington Post*, Aug. 16, 2004, p.A-1.

surprising that the majority of Information Quality correction requests are not related to rulemakings.

Perception #5: “The appeals process, the public’s opportunity to ask for reconsideration of a correction request, will not improve anything.”

Most of the responses to requests for correction that were denied in FY03 have subsequently been appealed. The appeals process requires an independent agency review of the reconsideration request, its justification, and its validity. The majority of the appeals were still in the process of being answered in FY03; thus, it was too early to assess the value added in our *Information Quality Report to Congress FY03*. However, this added step appears to have fostered some corrections. We recently saw this process play out at HHS where, upon appeal, a correction request to the National Toxicology Program resulted in the discontinuation of the webpage dissemination of a draft abstract that contained results that were flawed (the compound tested contained a contaminant that was believed to have influenced the test results). In this situation, the appeals step was critical in order for the agency to recognize that a correction was needed.

Perception #6: “The Information Quality Act is only about numerical data.”

If one thinks that the word “data”, as defined by Webster, includes “information organized for analysis or used as the basis for decision-making,” then there has been no misperception.⁴¹ However, if one believes that data covered by the Information Quality Act must be numerical information, that is incorrect. The Information Quality Act has been used to address complex issues and analyses that go beyond correcting errors entered into a spreadsheet. For instance, whether or not the Trumpeter Swans (native North American swans characterized by their unmistakable trumpet-like call) constitute a distinct population around the Yellowstone area, and whether or not the nickel section of the 10th edition of the HHS Report on Carcinogens is representative of the full body of scientific studies, are not questions that can be answered solely by looking at numerical inputs. These are just two examples of the types of correction requests that deal with the information and analyses used in the decision-making process.

Perception #7: “Colleges and universities are regulated by the Information Quality Act.”

OMB has heard claims that college professors and their students, if funded by the Federal government, are covered by the Information Quality Act and agency guidelines. However, it is clear that the Information Quality Act covers only disseminations by Federal agencies, specifically those agencies covered by the Paperwork Reduction Act. The law covers only agency disseminations, not disseminations made by third parties (e.g., academics, stakeholders and the public). If third-party submissions are to be used and disseminated by Federal agencies, it is the responsibility of the Federal Government, under the Information Quality Act, to make sure that such information meets relevant information quality standards. The agency guidelines establish performance goals and procedures to assist in the agency’s evaluation of all information for which agency dissemination is under consideration, whether that information was generated by the agency or by third parties.

⁴¹ Websters II New Riverside Dictionary, Houghton Mifflin Company, Boston MA, 1984.

C. Legal Developments under the Information Quality Act

Two court decisions have held that judicial review is not available under the Information Quality Act. On June 21, 2004, the U.S. District Court for the District of Minnesota issued a memorandum opinion, *In re: Operation of the Missouri River System Litigation*,⁴² briefly holding that the Information Quality Act does not provide a private cause of action in Federal court and that there is no cause of action under the Administrative Procedure Act (Chapter 7 of Title V, United States Code) because the Information Quality Act lacks meaningful standards a court could use to assess agency conduct.

On November 15, 2004, the U.S. District Court for the Eastern District of Virginia dismissed the first case to focus extensively on the potential for judicial review of claims under the Information Quality Act in *Salt Institute v. Thompson*.⁴³ In this case, the Salt Institute and the U.S. Chamber of Commerce filed suit against the Department of Health and Human Services (HHS), alleging that HHS, and the National Institutes of Health (NIH) in particular, violated the Information Quality Act and the applicable agency information quality guidelines because NIH declined to obtain, and release to plaintiffs, the raw data of grant-funded studies that NIH cited in public health messages concerning salt intake and hypertension, and because NIH disseminated such health messages, which were alleged to lack sufficient scientific quality.

The Court held that the injuries arising from the alleged errors in NIH's public health messages were insufficient to confer constitutional standing to sue. In addition, the court held that the Information Quality Act does not provide a private right of action and that the Administrative Procedures Act does not provide an independent basis for judicial review of the agency's public health messages. In January 2005, the plaintiffs appealed the district court's decision to the U.S. Court of Appeals for the Fourth Circuit.

D. Increasing Transparency under the Information Quality Act

In the FY03 Information Quality Report to Congress, OMB made suggestions for future improvements in implementation of the Information Quality Act. Due to the relatively small number of substantive correction requests received by the agencies in FY03, OMB was not prepared to make suggestions for legislative changes. The types of correction requests received by agencies have been extremely diverse. We still believe that the agencies have not yet received and responded to a sufficient number of correction requests to allow us to confidently suggest changes that would improve implementation of the Information Quality Act. Agencies are still learning from their early experiences in FY03 and FY04, and OMB plans to continue to work with the agencies to help improve agency processes. However, we did point out a few actions that would help improve those processes. These recommendations included: increasing transparency, increasing timeliness of agency responses, increasing engagement of agency scientific and technical staff, and earlier consultation with OMB.

⁴² *In re: Operation of the Missouri River System*, No. 03-MD-1555, 2004 WL 1402563 (D. Minn. June 21, 2004).

⁴³ 345 F.Supp.2d 589 (E.D.Va. 2004).

Consistent with these recommendations, 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.⁴⁴ OMB requested that these web pages be operational by December 1, 2004. In their FY04 Information Quality Reports to OMB, agencies will be providing OMB with the specific links to these web pages. At press time, OMB has available only a list of those agencies that provided their FY04 Information Quality Reports to OMB before January 1, 2005. OMB will provide an updated list in the final version of this report. In the FY03 Information Quality Report to Congress, we provided links to 4 agency websites. Currently, OMB is aware of similar web pages for 26 agencies. This list is provided below. OMB requests comment from the public on other suggested actions that will increase transparency in implementing the Information Quality Act.

List of Agencies currently known to have OMB compliant Information Quality Websites:

CFTC: <http://www.cftc.gov/cftc/cftcquality.htm>
FWS: <http://informationquality.fws.gov/>
OGE: http://www.usoge.gov/pages/about_oge/info_quality.html
DOT: <http://dms.dot.gov/cfreports/dataQuality.cfm>
EPA: <http://epa.gov/quality/informationguidelines/iqg-list.html>
FS: <http://www.fs.fed.us/qoi/disclosure.shtml>
HHS: <http://aspe.hhs.gov/infoquality/requests.shtml>
DNFSB: http://www.dnfsb.gov/about/information_quality.html
DOC: http://www.osec.doc.gov/cio/oipr/info_qual.html
DOE: <http://cio.doe.gov/informationquality/index.html>
DOL: <http://www.dol.gov/cio/programs/InfoGuidelines/IQCR.htm>
ED: <http://www.ed.gov/policy/gen/guid/infoqualguide.html>
EEOC: <http://www.eeoc.gov/policy/guidelines/index.html>
FCC: <http://www.fcc.gov/omd/dataquality/requests2004.html>
FERC: <http://www.ferc.gov/help/how-to/file-correct.asp>
NARA: http://www.archives.gov/about_us/information_quality/requests/fy2004_requests.html
NEA: <http://www.arts.gov/about/infoquality.html>
NRC: <http://www.nrc.gov/public-involve/info-quality.html>
NSF: <http://www.nsf.gov/home/pubinfo/webpolicy.htm>
OHFEO: <http://www.ofheo.gov/information.asp?section=17>
MSPB: http://www.mspb.gov/mspb_library.html#Informationqualityguidelines
USAID: http://www.usaid.gov/about/info_quality/
PBGC: <http://www.pbgc.gov/laws/lawsregs/guidelines.htm>
CSB: http://www.csb.gov/index.cfm?folder=legal_affairs&page=index
SSA: <http://www.ssa.gov/515/requests.htm>
FMC: <http://www.fmc.gov/Reading%20Room.htm>

E. Characteristics of an Effective Correction Request

⁴⁴ See http://www.whitehouse.gov/omb/inforeg/info_quality_posting_083004.pdf

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

During the first two years of implementation, OMB has been working with agencies on implementation of the correction-request process. In the course of this work, OMB has observed affected parties take a variety of different approaches to making correction requests and has observed agencies in the response process. Based on this multi-agency experience, OMB has listed below a few tips that will bolster the quality of correction requests and make them easier for agencies to address in a rigorous and timely fashion.

Use Traditional Comment Processes When Available: When a party is concerned about draft information that is currently under public review (e.g., as part of a rulemaking or technical comment process), the party is encouraged to submit the correction request as part of the traditional mechanism for public participation. In these situations, OMB and agency guidelines suggest that agencies should use the traditional mechanism to address the concerns in the correction request. Parties submitting correction requests in this manner can expect that agencies will provide a substantive response to the concerns raised in the correction request (e.g., agency responses in a "response to comment" document). If the agency makes no substantive response, the appeal process exists under OMB and agency guidelines to ensure responsiveness by the agency. It is important to note that the currently ongoing process which the agency uses should provide a response to the comments submitted; if no response to requestors comments will be provided through this process, then the Information Quality correction process would not be considered redundant.

Provide Peer-reviewed Evidentiary Support for the Correction Request Whenever Feasible: We have found that agencies are most responsive when the requestor supplies specific, peer-reviewed references to scientific sources that support their viewpoint.

Go Beyond Criticism and Suggest A Specific Correction or Series of Corrections: As a starting point, it is critical that requestors be as specific as possible in pinpointing what information (e.g., paragraphs, tables or figures) needs to be corrected. Moreover, requests are most useful when they go beyond technical criticism and suggest an operational change in language, figures or numbers.

Focus on Substantive Quality of Information Rather than Agency Procedures: While agencies should be open to suggestions on how their information-quality procedures can be improved in the future, the correction process is aimed at improving the substantive quality of specific disseminations. Correction requests should focus on the substance of information quality, not agency procedures.

Request Complete Withdrawal of a Dissemination Only as a Last Resort: When considering what kind of correction to request, one option is to request complete withdrawal of a dissemination (e.g., terminating dissemination of a report). However, it is a rare case where all the information in a report is flawed. Describing a specific fix to the information that has been disseminated (e.g., an addendum or substitute paragraph or table) may prove to be more helpful to the agency.

Explain How the Requestor is Affected by the Dissemination: It is helpful to agencies when requestors provide a clear discussion of how they have been affected by the dissemination or how they may be affected in the future.

F. Role of OMB's New Peer Review Policy

Whereas the correction request and appeals processes are designed to address information quality after dissemination, the Information Quality Guidelines also recognize the importance of pre-dissemination quality assurance measures such as peer review. Specifically, OMB's guidelines say that information that has been peer reviewed carries with it the presumption of objectivity. Peer review is a highly regarded procedure used in the scientific community to promote independent review and critique by qualified experts and which is respected by the courts.⁴⁵ In keeping with the goal of improving the quality of government information, on December 16, 2004, OIRA issued a Final Information Quality Bulletin on Peer Review.⁴⁶

This Bulletin, which benefited from two rounds of public comment, a National Academy workshop, and an interagency process, is designed to enhance the practice of peer review of government science documents. The Bulletin, which is available at <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf> describes the factors that should be considered in choosing an appropriate peer review mechanism and stresses that the rigor of the review should be commensurate with how the information will be used. Agencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. Highly influential scientific assessments require much more rigorous review than does other scientific information.

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

⁴⁵ See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

⁴⁶ <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>

APPENDIX A: CALCULATION OF BENEFITS AND COSTS

Chapter I presents estimates of the annual costs and benefits of selected final major regulations reviewed by OMB between October 1, 1994 and September 30, 2004. OMB presents more detailed explanation of these regulations in several documents. The explanation of the calculations for the major rules reviewed by OMB between April 1, 1995 and March 31, 1999 can be found in Chapter IV of our 2000 report. Table 19, Appendix E, of the 2002 Report presents OMB's estimates of the benefits and costs of the 20 individual rules reviewed between April 1, 1999 and September 30, 2001. Tables 18 and 19 in Appendix A in the 2003 report present the results for October 1, 1993 to March 31, 1995 (Table 18), and October 1, 2001 to September 30, 2002 (Table 19). Table 12 in Appendix A of the 2004 report presents the rules from October 1, 2002 to September 30, 2003. Table A-1 in this Appendix presents the rules from October 1, 2003 to September 30, 2004. All benefit and cost estimates were adjusted to 2001 dollars.

In assembling estimates of benefits and costs, 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 inflation adjustments are performed using the latest available GDP deflator. In instances where the nominal dollar values the agencies use for their benefits and costs is unclear, we assume the benefits and costs are presented in nominal dollar values of the year before the rule is finalized. In periods of low inflation such as the past few years, this assumption does not impact the overall totals. All amortizations are performed using a discount rate of 7%, unless the agency has already presented annualized, monetized results using a different explicit discount rate.

OMB discusses, in this report and in previous reports, the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies. In addition, where OMB has monetized quantitative estimates where the agency has not done so, we have attempted to be faithful to the respective agency approaches. The adoption of a uniform format for annualizing agency estimates allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules; however, the agencies have used different methodologies and valuations in quantifying and monetizing effects. Thus, an aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable.

In part to address this issue, the 2003 report included OMB's new regulatory analysis guidance, also released as OMB Circular A-4, which took effect on January 1, 2004, for proposed rules and January 1, 2005 for final rules. The guidance recommends what OMB

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

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. OMB will work with the agencies to ensure that their impact analyses follow the new guidance.

Table A-1. Estimates of Annual Benefits and Costs of Major Rules Issued Between October 1, 2003 to September 30, 2004 (millions of 2001 dollars per year)				
Rule	Agency	Benefits	Costs	Explanation
Bar Code Label Requirements for Human Drug Products and Blood Products	HHS/FDA	1,352-7,342	647	The range of benefits is based on the sensitivity analysis assuming higher or lower interception rates of medical errors due to the rulemaking. This range encompassed the range of most of the other sensitivity analyses.
Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated	HHS/FDA	0-130	7-89	
Standard Unique Health Care Provider Identifier	HHS/CMS	214	158	We annualized the stream of impacts reported over 5 years at 7%.
Pipeline Integrity Management in High Consequence Areas	DOT/RSPA	154	288	Annual value calculated from 20 year stream of costs presented in RIA using a discount rate of 7%. Also, analysis only presented qualitative discussion of uncertainty
Reduced Vertical Separation Minimum in Domestic United States Airspace	DOT/FAA	-60	-320	Annualized costs and benefits derived from reported present values calculated over 15 years at 7%. No cost to safety. Subtracted from total costs and benefits because it is deregulatory.
Control of Emissions of Air Pollution from Nonroad Diesel Engines	EPA/Air	6,853-59,401	1,336	We annualized EPA’s reported stream of impacts over 32 years. We also calculated an uncertainty interval for benefits using a new method explained in Appendix B.
NESHAP Boilers	EPA/Air	3,752-38,714	876	We calculated an uncertainty interval for benefits using a new method explained in Appendix B.
NESHAP Plywood	EPA/Air	152-1,437	155-291	
NESHAP Stationary Reciprocating Internal Combustion Engines	EPA/Air	105-1,070	270	We calculated an uncertainty interval for benefits using a new method explained in Appendix B. Note that EPA did present a monetized central estimate for benefits in this rulemaking of \$265 million per year (see Table 1-4), which is somewhat lower than the midpoint of the uncertainty range presented here.

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

Table A-1. Estimates of Annual Benefits and Costs of Major Rules Issued Between October 1, 2003 to September 30, 2004 (millions of 2001 dollars per year)				
National Pollutant Discharge Elimination System—Cooling Water Intake Structures	EPA/Water	72	383	
Effluent Guidelines and Standards for the Meat and Poultry Products Point Source Category (Revisions)	EPA/Water	0-10	41-56	Although the annualized impact for this rule did not reach the economic significance threshold, this rule did have startup costs exceeding \$100 million in any one year.
Total		12,596- 108,483	3,840- 4,073	

APPENDIX B: VALUATION ESTIMATES FOR REGULATORY CONSEQUENCES⁴⁷

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 other types of 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's 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.⁴⁸ 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. For the 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 article⁴⁹
3. Change in Emissions of Air Pollutants. Please see the following paragraphs for an explanation of the derivation 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):	\$730 to \$7,500 per ton
Sulfur Dioxide:	\$1,700 to \$18,000 per ton
Particulate Matter:	\$10,000 to \$100,000 per ton

⁴⁷ The following discussion updates the monetization approach used in previous reports and draws on examples from this and previous years.

⁴⁸ 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>

⁴⁹ Brown and Savage, "The Economics of Double-Hulled Tankers," *Maritime Policy and Management*, Volume 23(2), 1996, pages 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).

We have revised somewhat from last year's report our estimates of the ranges of the per-ton value of benefits of emission reduction in nitrogen oxides and sulfur dioxide. The new ranges reflect EPA estimates of the 5th and 95th percentile benefits ranges, which consistently span approximately a factor of 10 across several rulemakings. We used the average of those factors, which was 10.3, and rounded to the nearest 2 significant figures. Reductions in the risk of premature mortality dominate the benefits estimates in all of these analyses. The size of the mortality risk estimates from the underlying epidemiological studies, the serious nature of the effect itself, and the high monetary value ascribed to prolonging life make mortality risk reduction the most important health endpoint quantified in these analyses.⁵⁰

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. In cases where EPA monetized benefits for rules in our 10-year list based on older values for air pollutant emissions, we are currently working with EPA on updating the range of benefits in order to more accurately represent the substantial range of uncertainty inherent in these estimates.

We applied these values to several rules regulating mobile sources of emissions. These rule are: Reformulated Gasoline and Non-Road Diesel Engines (1993-1994); 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); and 2004 Heavy Duty Engines (2000-2001).

In addition, we applied these values to several rules regulating stationary sources of emissions. These rules are: Acid Rain NO_x and Hazardous Organic NESHAP (1993-1994); 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

⁵⁰ There are several key assumptions underlying the benefit estimates for reductions in NO_x emissions, including:

1. Inhalation of fine particles is causally associated with 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.
2. All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles formed from power plant SO₂ and NO_x emissions are chemically different from directly emitted fine particles from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects estimates by particle type.
3. 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.
4. The forecasts for future emissions and associated air quality modeling are valid.
5. 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.

(NESHAP) for Stationary Reciprocating Internal Combustion Engines; NESHAP for Plywood and Composite Wood Products.

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 or different discounting methods—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 1993-1994 MAJOR RULES

Tables C-1 and C-2 list the rules that were reported in Chapter 1 of the 2004 report as part of the 10-year totals of costs and benefits, but are not included in Chapter 1 of the 2005 report. Table C-1 presents only the rules that had annualized, monetized costs and benefits used for the purposes of calculating the totals in previous reports. Please note that since the 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 I impacts, for rules presented in Table C-1 where OMB monetized EPA estimates of the tons of pollutants avoided, we updated the impact estimates to reflect the new benefits per ton ranges. Table C-2 presents the unmodified details of all major rules from this time period, including rules that did not have monetized costs or benefits and were therefore not included in the totals in previous reports.

Table C-1. Estimate of Annual Benefits and Costs of 9 Major 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	
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	114-856	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 \$730-\$7,500 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.

Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations

Table C-1. Estimate of Annual Benefits and Costs of 9 Major Rules October 1, 1993 to September 30, 1994 (millions of 2001 dollars per year)				
REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Acid Rain NO _x Title IV CAAA	EPA	433-4,446	297	The costs and benefits of Acid Rain NO _x regulations are divided between the Phase I and Phase II rulemakings. This is the Phase I rule. We valued NO _x reductions at \$370 - \$3,800 per ton.
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	429-4,410	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 \$730 -\$7,500 per ton.
Total		4,593-18,097	4,226-4,647	

Table C-2. Agency Estimates of Benefits and Costs of Major Rules
October 1, 1993 to September 30, 1994

RULE	AGENCY	BENEFITS	COSTS	OTHER INFORMATION
Manufactured Home Construction and Safety Standards on Wind Standards	HUD	\$103 million annually	\$63 million annually	The cost estimates do not include costs associated with “out of pocket expenses related to deductibles or non-covered losses” (RIA, pp. 1-2). Non-quantified benefits include: “purchasers will experience less dislocation caused by damage to or destruction of their manufactured homes. Fourth, residents who choose to remain in their units during storms will suffer fewer injuries and deaths” (RIA, p. 1) Discount rate used=6.64 percent (RIA, p. 8) Basis for public benefit assessment: Hurricane Andrew (RIA, p. 9)
Designate critical habitat for four endangered Colorado River fishes	DOI	Net benefit: \$7.92 million		Increase employment by 710 jobs, increase earnings by \$6.62 million, increase government revenue by \$3.20 million from 1995-2020 (59 FR 13374-)
Occupational Exposure to Asbestos	DOL-OSHA	Reduction in annual cancer risk: 2.12 cancer deaths in general industry, 40.48 cancer deaths in construction industry, 14.2 cancers among building occupants Reduction in asbestosis: 14 cases annually	\$361.4 million annually	Non-quantified benefits include: avoided cases of asbestosis for building occupants and others secondarily exposed, reduced risks of cancer and fires (from rags contaminated with solvent), more rapid building reoccupation, reduced probability of asbestos-related lawsuits (RIA, pp 52-57)
Financial Responsibility for Water Pollution (Vessels)	DOT-USCG	525,316 barrels of oil not spilled (NPV)	\$451,440,918 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; \$1996
Antidrug Program for Personnel Engaged in Specified Aviation Activities	DOT-FAA	\$206.64 million (NPV)	\$138.13 million (NPV)	Timeline of the analysis: 1994-2003 (RIA, p.12) \$1992 (RIA, p. 12) Discount rate=7% (RIA, p. 20)

Table C-2. Agency Estimates of Benefits and Costs of Major Rules
October 1, 1993 to September 30, 1994

RULE	AGENCY	BENEFITS	COSTS	OTHER INFORMATION
Controlled Substances and Alcohol Use and Testing	DOT-FHWA	<p>Reduced fatal accidents: \$680 million in 1st year, \$952 million per year in 2nd and subsequent years</p> <p>Reduced injury cost: \$152.4 million in 1st year, \$213.4 million per year in 2nd and subsequent years assuming the highest deterrence scenario</p> <p>Reduced property damage: \$47.5 million in 1993, \$66.5 million per year from 1994-2002</p> <p>Reduced traffic delays: \$3.5 million in 1993, \$4.9 million per year thereafter assuming highest deterrence rate</p> <p>Reduced other costs of freeway accidents: \$1.9 million in 1995 and \$2.7 million thereafter</p>	\$93,947,750 in 1995, and \$92,453,950 per year in 1996 and thereafter	

Table C-2. Agency Estimates of Benefits and Costs of Major Rules
October 1, 1993 to September 30, 1994

RULE	AGENCY	BENEFITS	COSTS	OTHER INFORMATION
Light Truck Average Fuel Economy Standards, Model Years 1996-1997	DOT	Not Estimated	Not Estimated	
Prevention of Prohibited Drug Use in Transit Operations	DOT	\$608,520,643 (NPV)	\$208,970,087 (NPV)	Timeline: 1995-2004 Discount rate: 7% \$1991
Land disposal restrictions phase II, universal treatment standards and treatment standards for organic toxicity, characteristic wastes, and newly listed wastes	EPA	0.22 cancer cases per year avoided from groundwater, 0.037 cancer cases per year avoided from air \$20 million avoided property value damage (annualized)	\$194-219 million (annualized)	“The timeframe to which these benefits are attributable begins 30 years following promulgation of the rule.” (59 FR 47982-) “However, there are some benefits which the Agency has not attempted to quantify which are potentially attributable to today’s rule. For example, the Agency has not attempted to quantify any potential non-use value benefits from protection of resources through treatment of hazardous wastes. Furthermore, the risk analysis performed by the Agency for today’s rule does not account for many other potential benefits from today’s rule. Ecological risk reduction from treatment of wastes under today’s rule has not been quantified. Nor do the Agency’s air and groundwater benefit estimates account for karst terrain, complex flow situations, or other factors which could contribute to underestimates of benefits.” (59 FR 47982-)
Accelerated phase-out of ozone depleting chemicals and listing and phase-out of methyl bromide	EPA	Ozone depleting chemicals: \$8-24 billion (NPV) Methyl Bromide: \$1.6-6.4 billion (NPV)	Ozone depleting chemicals: \$12 billion (NPV) Methyl Bromide: \$0.8 billion (NPV)	Discount rate: 7% (58 FR 65018-) Timeline for methyl bromide cost: 1994-2010 (58 FR 65018-) Timeline for methyl bromide benefits: 1994-2011 (58 FR 65018-)

Table C-2. Agency Estimates of Benefits and Costs of Major Rules

October 1, 1993 to September 30, 1994

RULE	AGENCY	BENEFITS	COSTS	OTHER INFORMATION
Fuel and fuel additives: standards for reformulated gasoline	EPA	<p>Phase I Summertime VOC emission reduction: 90-140 thousand tons per year Reduction in cancer incidence: 16 per year (assuming enhanced I/M in place) or 24 per year (assuming basic I/M in place)</p> <p>Phase II (incremental to Phase I) Summer time VOC emission reduction: approximately 42,000 tons Summer time NO_x emission reduction: approximately 22,000 tons Number of cancer avoided: 3-4 fewer cancer incidence per year</p>	<p>Phase I Annual costs: \$700-940 million</p> <p>Phase II (incremental to Phase I): Increase gasoline production cost by 1.2 cents/gallon during the VOC control period, since only the toxics standard changes, and there is not expected to be a cost for year-round toxics control above that required for Phase I EPA doesn't expect non-production related costs, such as distribution costs, recordkeeping and reporting costs, etc., to increase significantly relative to Phase I</p>	<p>“Reductions in mobile source emissions of the air toxics addressed in the reformulated gasoline program (benzene, 1, 3-butadiene, formaldehyde, acetaldehyde, and POM) may result in fewer cancer incidences. A number of adverse noncancer health effects have also been associated with exposures experience in particular microenvironments such as parking garages and refueling stations. These other health effects include blood disorders, heart ad lung diseases, and eye, nose and throat irritation. Some of the toxics may also be developmental and reproductive toxicants, while very high exposure can cause effects on the brain leading to respiratory paralysis and even death. The uses of reformulated gasoline meeting the Phase II standards will likely help to reduce some of these health effects as well.” (59 FR 7716-)</p> <p>Phase I: The cost of producing reformulated gasoline is expected to increase by approximately 3-5 cents per gallon in 1995. (59 FR 7716-)</p> <p>The cost of testing, enforcement, and recordkeeping not reflected in the annual cost estimate. (59 FR 7716-)</p>

Table C-2. Agency Estimates of Benefits and Costs of Major Rules
October 1, 1993 to September 30, 1994

RULE	AGENCY	BENEFITS	COSTS	OTHER INFORMATION
Acid Rain NO _x Regulations under Title IV of the Clean Air Act Amendments of 1990	EPA	Phase I: 400,000 tons NO _x reduced Phase II: 1.89 million tons NO _x reduced	Phase I: \$77 million/year Phase II: \$300 million/year	Qualitative human health benefits: Lower ambient levels of NO _x (and associated lower PM and lower ozone levels) may mean fewer lost school days, fewer disability days for children; for all, less eye irritation, (and with lower ozone levels) less airway irritation and its associated acute and chronic health effects; for exercising asthmatics, improved pulmonary function. Also ambient concentrations of nitrates will be lower and fewer toxic nitrogenous compounds will be formed. (RIA, pp. 9-1 to 9-4) Qualitative welfare effects: reduced materials damage, increased visibility that is associated with enhanced enjoyment of vistas and fewer aircraft and motor vehicle accidents. The potential ecological effect include minimizing the adverse effects of excess nitrogen deposition in forest soils and surface waters, including the "acid pulses" that precede fish kills and consequently, reduced biodiversity. (RIA, pp. 9-1 to 9-4) "Moreover, EPA expects that most or all utility expenses from meeting NO _x requirements will be passed along to ratepayers... Under today's rule the cost to ratepayers is very small, relative to their current expenditures on electricity. The average increase in electric rates across the United States is estimated to be only 0.03 and 0.13 percent under Phases I and II respectively." (59 FR 13538-)
Hazardous Organic NESHAP (HON) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) and Other Processes Subject to the Negotiated Regulation for Equipment Leaks	EPA	HAP reduction: 510,000 tons/year VOC reduction: 1,000,000 tons/year	Total nationwide annual cost: \$230 million/year (\$1989) CO emission increase: 1,900 tons/year NO _x emission increase: 19,000 tons/year	"Thus, the estimates represent annual impacts occurring in the fifth year." (59 FR 19402-) "As discussed in section III.B.3 of this preamble, the EPA has deferred the final decision regarding control of medium-sized storage vessels at existing sources. Therefore, emission reductions for storage vessels shown in table 1, and consequently the total, may be slightly overstated." (59 FR 19402-) "Because of the EPA's deferral of a final decision on control of medium-sized storage vessels at existing sources, as discussed in section III.B.3 of this preamble, the cost impacts for storage vessels, and consequently the total cost impact, may be slightly overstated." (59 FR 19402-) "Market analyses for a subset of 21 of the chemicals estimated price increases from 0.1 percent to 3.9 percent and quantity decreases from 0.1 percent to 4 percent." (59 FR 19402-)

Table C-2. Agency Estimates of Benefits and Costs of Major Rules

October 1, 1993 to September 30, 1994

RULE	AGENCY	BENEFITS	COSTS	OTHER INFORMATION
Control of air pollution from new motor vehicles and new motor vehicle engines, refueling emission regulations for light-duty vehicles and trucks and heavy-duty vehicles	EPA	Without Stage II controls, average VOC annual emission reductions: over 420,000 tons per year; With Stage II phase-out when ORVR and Stage II would cover the same percent of fuel, average annual emission reduction: 378,000 tons; If retain Stage II controls, an incremental emission reduction: 285,000 tons	Without Stage II controls, the average annual cost: -\$6 million (1998-2020); With Stage II and phasing out at 2010, the average annual cost: \$2 million (1998-2020); With Stage II and no phase out, the average annual cost: \$27 million (1998-2020) In 1998 NPV, costs are \$102 million, \$264 million and \$435 million respectively	“It should be noted that the RIA was completed prior to EPA’s decision to delay the requirements for LDTs and to exclude HDVs. These controls were included in the analysis and were assumed to begin in 1998. EPA expects that inclusion of these items in the analysis has no significant effect on the results and does not affect the conclusions which are based on the analysis.” (59 FR 16262-) “In the cases where costs are negative, it is because the value of the recovery credits exceeds the hardware and R, D, & T costs.” (59 FR 16262-)
Determination of significance for nonroad sources and emission standards for new nonroad compression ignition engines at or above 37 kilowatts, control of air pollution...-- SAN 3112	EPA	NO _x annual reduction in 2010: 800,000 tons NO _x annual reduction in 2025: over 1,200,000 tons	Average annual cost: \$29-70 million (59 FR 31306)	“EPA maintains that the impact of this rule on fleet average fuel consumption will be minimal.” (59 FR 31306-)