Progress in Regulatory Reform:

2004 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities

2004

Office of Management and Budget

Office of Information and Regulatory Affairs

EXECUTIVE SUMMARY

This Report to Congress on regulatory policy was prepared consistent with Section 624 of the Treasury and General Government Appropriations Act of 2001 (31 U.S.C. § 1105 note, Pub. L. 106-554), often called the Regulatory Right-to-Know Act. It provides a statement of the costs and benefits of Federal regulations and recommendations for regulatory reforms.

A major feature of this report is the estimates of the total costs and benefits of regulations reviewed by OMB. Major Federal regulations reviewed by OMB from October 1, 1993, to September 30, 2003, were examined. The estimated annual benefits range from $63 billion to $169 billion, while the estimated annual costs range from $35 billion to $40 billion. A substantial portion of both benefits and costs is attributable to a handful of clean-air rules that reduce public exposure to fine particulate matter. Technical limitations in these estimates are significant and are discussed in the text of the Report.

During the past year, six "major" final rules with quantified and monetized benefits and costs were adopted. These rules added $1.6 to $4.5 billion in annual benefits compared to $1.9 billion in annual costs. There were an additional eight final "major" rules that did not have quantified and monetized estimates of both benefits and costs.

The Report also reviews the international literature on the effects of regulation on national economic growth and performance. Based on a comparison of 145 countries, the ten least regulated economies are New Zealand, the United States, Singapore, Hong Kong, Australia, Norway, the United Kingdom, Canada, Sweden, and Japan. These same economies have experienced relatively good economic performance measured by economic growth and per capita income. They also rate highly in human development as measured by life expectancy and infant mortality. The adverse impacts of regulation may be mediated through factors such as the number of procedures required to start a new business, the flexibility of labor markets, and the enforceability of contracts. More research is needed to determine the precise causal relationships between regulation, including different types of regulation, and economic growth and performance.

In light of recent concerns about the health of manufacturing in the United States, the Report reviews the economics literature on the impacts of regulation on manufacturing enterprises. The cumulative costs of regulation on the manufacturing sector are large compared to other sectors of the economy. In response to this large burden, OMB requested public nominations of promising regulatory reforms relevant to this sector. In particular, commenters were asked to suggest specific reforms to rules, guidance documents, or paperwork requirements that would improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty, and increasing flexibility. In response to this request, OMB received 189 distinct nominations from 41 commenters. Federal agencies are expected to review the merits of each of the 189 reform nominations and prepare a response for OMB by January 24, 2005. After agencies have performed their

evaluations, OMB will work with the agencies to identify the Administration's regulatory-reform priorities, which we will announce in February, 2005.

An additional feature of this Report is a summary of the Administration's regulatory reform accomplishments in the fields of labor, health, safety, the environment, transportation, and homeland security. The Report also provides a list of additional reforms that merit priority consideration by agencies. Many of these reform ideas were nominated for consideration by OMB and the agencies in 2001 and 2002. Taken together with the manufacturing initiative, the promising reforms described in this Report provide a blueprint for comprehensive regulatory reform.

This final Report was issued in draft form in February of this year and was, as a matter of policy, submitted for and revised in response to public comment, external peer review, and interagency review. OMB has already begun to prepare the 2005 Report to Congress on the Costs and Benefits of Federal Regulations. OMB's objective is to publish the Draft 2005 Report with the President's FY 2005 budget in February, 2005.

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," requires 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 2003 (September 30, 2003). Like the 2003 report, this chapter uses a 10-year look-back: estimates are based on the major regulations reviewed by OMB from October 1, 1993 to September 30, 2003. This means that 32 rules reviewed from October 1, 1992 to September 30, 1993, 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.

A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB[1]

Table 1 presents estimates by agency of the benefits and costs[2] of major rules[3] reviewed by OMB over the past year (October 1, 2002 to September 30, 2003). OMB reviewed 37 final major rules during that period.[4] They represent approximately 11 percent of the 349 final rules reviewed by OMB during this 12-month period, and less than 1 percent of the 4,312 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.

Of the 37 rules, 25 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 12 regulations were "social regulations," which may require substantial additional private expenditures as well as provide new social benefits.

Of the 12 "social regulations," we are able to present estimates of both monetized costs and benefits for 6 rules. OMB used agency estimates where available. If an agency quantified but did not monetize estimates, we used standard assumptions to monetize them, as explained in Appendix A. The 6 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 4.

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[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 will take effect in 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 4.

[4] This Report does not contain information on EPA's Prevention of Significant Deterioration and Nonattainment New Source Review: Routine Maintenance and Repair Final Rule (68 FR 61247). OMB completed review of this rule on August 27, 2003 and EPA published the rule on October 27, 2003. On December 24, 2003, however, the Court of Appeals for the District of Columbia Circuit stayed the effective date of the rule. As a result, the rule did not become effective on December 26, 2003, as originally intended by the Agency.

Table 1: Estimates of the Annual Benefits and Costs of Major Federal Rules October 01, 2002 to September 30, 2003 (millions of 2001 dollars)		
Agency	**Benefits**	**Costs**
Agriculture	43-152	17
Health and Human Services	457-3,065	19-35
Transportation	945	1,538
Environmental Protection Agency	204-355	360
Total	**1,649-4,517**	**1,933-1,950**

Table 2 presents an estimate of the total costs and benefits of 85 regulations reviewed by OMB over the ten-year period from October 1, 1993 to September 30, 2003 that met two conditions. Each rule generated costs or benefits of at least $100 million annually, 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 the 2003 Report, 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, 1993 to September 30, 2003 are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866.

Table 2: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1993 to September 30, 2003 (millions of 2001 dollars)		
Agency	**Benefits**	**Costs**
Agriculture	2,933-6,123	1,634-1,656
Education	655-813	361-610
Energy	5,224-5,292	2,968
Health &Human Services	8,742-12,138	3,025-3,121
Dept. of Homeland Security*	62	899
Housing & Urban Development	190	150
Labor	1,264-3,645	806
Transportation	6,608-9,386	3,815-5,855
Environmental Protection Agency	37,652-131,698	21,654-24,050
Total	**63,330-169,347**	**35,312-40,115**
*The Homeland Security column includes only Coast Guard rules, formerly part of Transportation		

The aggregate benefits reported in Table 2 are substantially smaller than the aggregate benefits presented in the 2003 Report. This is due to one EPA rule implementing the sulfur dioxide limits of the acid rain provisions in the 1990 Amendments to the Clean Air Act. This rule fell in the time period of 1992 to 1993 and therefore is not included in this report's totals. This rule's estimated benefits of nearly $80 billion per year represented roughly one-third to one-half of the total benefits from the 10-year aggregation. Regardless, 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 3 provides additional information on aggregate benefits and costs for specific agency programs. In order for a program to be included in Table 3, the program needed to have finalized 3 or more rules in the last 10 years with monetized costs and benefits. This criterion accounts for the major difference between Table 3 in the 2003 report and Table 3 of the 2004 report: the Coast Guard is no longer included as a program, since one of their Vessel Response Plans fell out of the 10-year range. OMB did review three major Coast Guard rules this year (see Table 4), but the benefits of a reduced risk of terrorism 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.

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 $2.2 billion to positive $5.7 billion per year.

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 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. OMB has not made any changes to monetized agency estimates other than converting them to annual equivalents. 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 4 of this Report.

Table 3: Estimates of Annual Benefits and Costs of Major Federal Rules: Selected Programs and Agencies October 1, 1993-September 30, 2003 (millions of 2001 dollars)		
Agency	**Benefits**	**Costs**
Energy		
Energy Efficiency and Renewable Energy	5,224-5,292	2,968
Health & Human Services		
Food and Drug Administration	1,911-4,754	283-301
Labor		
Occupational Safety and Health Administration	1,264-3,645	806
Transportation		
National Highway Traffic Safety Administration	4,227-7,005	2,300-4,340
Environmental Protection Agency		
Office of Air	34,601-115,509	15,796-17,647
Office of Water	1,095-8,431	2,778-3,291

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. EPA has two recent, major rulemakings —a recent final rule to reduce emissions from off-road diesel engines and a new proposed rule to reduce interstate transport of pollution from coal-fired power plants— which should achieve substantial, additional benefits in the reduction of fine particles.

As Table 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 SO_2 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.[5]

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

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

In this section, we examine in detail the benefits and costs of each major rule, as required by section 624(a)(1)(C), for which OMB concluded review during the 12-month period beginning October 1, 2002, and ending September 30, 2003.

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 similar statutory definitions in the Unfunded Mandates Reform Act and subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996: Congressional Review of Agency Rulemaking. Given these varying definitions, we interpreted section 624(a)(1)(C) broadly to include 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) (Congressional Review Act); and
- Rules designated as meeting the threshold under Title II of the Unfunded Mandates Reform Act (2 U.S.C. ' 1531 - 1538)

Social Regulation

Of the 37 economically significant rules reviewed by OMB, Table 4 lists 12 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: the Department of Homeland Security's (DHS) United States Coast Guard (USCG), 3 rules; the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), 2 rules; the Department of the Interior (DOI), 2 rules; and 1 rule each for the Environmental Protection Agency (EPA), the HHS Center for Medicare and Medicaid Services (CMS), the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), and the Department of Transportation's (DOT) National Highway Traffic Safety Administration (NHTSA), and Federal Motor Carrier Safety Administration (FMCSA).

The Table also includes 2 rules that were considered major under the Congressional Review Act (CRA) that were not otherwise included: a USDA Agricultural Marketing Service (AMS) rule, exempt from E.O. 12866 review, revising milk product-price formulas applicable to all Federal milk-marketing orders, and an EPA rule revising regional haze requirements for nine western states and eligible Indian tribes, which was not economically significant but was classified as a major rule under CRA.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Early-Season Migratory Bird Hunting Regulations	DOI	See "Other Information"	$50 million to $192 million per year	Not Estimated	DOI finalized a total of three Early Season regulations, the Final Framework (68 FR 51658), the Bag and Possession Limits (68 FR 51832), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (68 FR 51919). The analysis, which jointly estimated the impact of all Early and Late Season Regulations, was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses in 2003. The listed benefits represent estimated consumer surplus.
Late-Season Migratory Bird Hunting Regulations	DOI	See "Other Information"	$50 million to $192 million per year	Not Estimated	DOI finalized a total of three Late Season regulations, the Final Frameworks (68 FR 55784), the Bag and Possession Limits (68 FR 56048), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (68 FR 56102). The analysis, which jointly estimated the impact of all Early and Late Season Regulations, was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses in 2003. The listed benefits represent estimated consumer surplus.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Area Maritime Security	DHS/USCG	68 FR 39284	Reduced risk from a transportation security incident	$477 million (present value) for the period 2003 to 2012	The Coast Guard published a series of six temporary Interim Final Rules, three of which were economically significant and are listed here, 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. This unusual rulemaking procedure was necessitated by specific language contained in the MTSA, which stated the Secretary shall issue an interim final rule implementing these security requirements as soon as practicable after the date of enactment of the law. The MTSA further stated any of the temporary regulations that are not superseded by final regulations shall expire not later than 1 year after the date of enactment, or November 25, 2003. A final rule superseding the area maritime security interim rule was published on October 22, 2003 (68 FR 60472). The impact analysis accompanying these rules assumed they would be in place for the foreseeable future. Costs include committee meetings, travel, and security drilling (68 FR 39287). 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).

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Vessel Security	DHS/USCG	68 FR 39292	Reduced risk from a transportation security incident	$1.368 billion (present value) for the period 2003 to 2012	See first USCG Table entry for an explanation of the rulemaking process. A final rule superseding the vessel security interim rule was published on October 22, 2003 (68 FR 60483). 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 (68 FR 29298). 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).
Facility Security	DHS/USCG	68 FR 39315	Reduced risk from a transportation security incident	$5.399 billion (present value) for the period 2003 to 2012	See first USCG Table entry for an explanation of the rulemaking process. A final rule superseding the facility security interim rule was published on October 22, 2003 (68 FR 60515). 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 (68 FR 39319). 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).

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Truck Driver Hours of Service	DOT/FMCSA	68 FR 22456	$671 million per year (status quo baseline) $228 million per year (full compliance baseline)	$1,282 million per year (status quo baseline) Negative $905 million (full compliance baseline)	Because of widespread noncompliance with the current regulations, FMCSA estimated benefits and costs against two baselines: full compliance with current rules, and the status quo. Note that negative cost means a net cost-savings.
Light Truck CAFE for Model Years 2005-2007	DOT/NHTSA	68 FR 16867	$218 million (05) $645 million (06) $955 million (07)	$170 million (05) $537 million (06) $862 million (07)	The benefits are derived mainly from fuel savings over the lifetime of the vehicle, although they include other effects such as emissions reductions. Costs estimates are based on the specific technologies that manufacturers would need to apply to improve fuel economy up to the level of the final rule. All cost and benefit figures are net present values over the lifetime of each model year. The benefit and cost estimates are estimated from a baseline of each manufacturer's production plans for a single model year. It is likely that CAFE standards for prior model years (or anticipation of more stringent future standards) cause a given year's production plans to incorporate greater fuel economy than they otherwise would. NHTSA did not attempt to factor this effect into its baseline estimates, as this exercise would become increasingly speculative. To the extent that this is the case, the "true" baseline fuel economy is lower than that reflected in the product plans and, as estimated by NHTSA, both the cost and benefit estimates of a given standard will be underestimated.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Revisions to Regional Haze Regulations for Nine Western States and Eligible Indian Tribes	EPA	68 FR 33764	Not Estimated	$72 million per year	EPA performed a cost-benefit analysis in connection with the Regional Haze Regulations that it published as a final rule on July 1, 1999 (64 FR 35714). EPA finds that the costs and benefits associated with the Western Regional Air Partnership's program have been captured in the 1999 analysis. That analysis concluded that the planning, analysis, and Best Available Retrofit Technology control elements would result in $72 million in incremental annualized costs. If States all choose to establish the same illustrative progress goal, the incremental costs range from $1 billion to $4 billion with associated benefits of $1 billion to $19 billion.

Table 4. Summary of Agency Estimates for Final Rules
October 1, 2002 to September 30, 2003
(As of Date of Completion of OMB Review)

Rule	Agency	FR Cite	Benefits	Costs	Other Information
National Pollutant Discharge Permits and Standards for Concentrated Animal Feeding Operations (CAFOs)	EPA	68 FR 7175	$204 million to $355 million per year.	$360 million per year.	Monetized benefits are based on both health and environmental impacts. The rule also identifies several benefit categories that have not been monetized. These include reduced eutrophication and pathogen contamination of coastal and estuarine waters, reduced pathogen contamination of groundwater, reduced human and ecological risks from antibiotics, hormones, metals and salts, improved soil properties, and reduced costs of commercial fertilizers for non-CAFO operations. Only the first of these would likely significantly affect the benefits estimates if monetized. Costs are based on CAFO compliance costs and State and Federal government implementation costs. CAFO compliance costs are primarily associated with new restrictions on land application of manure, and coverage of dry poultry operations that were not previously covered by the regulations. Costs for land application include preparation of a Nutrient Management Plan, and transportation costs for sale or disposal of excess manure that can no longer be applied to the facility's own fields. Costs for dry poultry include, in addition to land application, capital and operation and maintenance costs for new technology. Note that the benefit and cost estimates are not directly comparable. The benefits estimate is for large CAFOs only (greater than 1000 animal units); EPA was unable to complete the benefits analysis for small CAFOs because of data and time constraints. The cost estimate is for both small and large CAFOs. The cost estimate for large CAFOs only is $304 million per year.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Health Insurance Reform: Security Standards Implementing HIPAA	HHS/CMS	68 FR 8333	Not Estimated	Not Estimated	This final rule adopts standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses, and certain health care providers. CMS stated that, although they could not determine the specific economic impact of the standards in this final rule (and individually each standard may not have a significant impact), the overall impact analysis makes clear that, collectively, all the standards will have a significant impact of over $100 million on the economy.
Trans fat Labeling	HHS/FDA	68 FR 41433	$234 million to $2,884 million per year.	$139 million to $275 million incurred in the first two years after rule finalized.	FDA estimates the benefits of this rule using two approaches that reflect different methods. First, it calculates benefits as the value of life-years gained from preventing a fatal case of heart disease, plus the value of quality adjusted life years (QALYs) gained from preventing a non-fatal case of heart disease. Its second calculation values reductions in mortality risk as the number of statistical deaths prevented multiplied by the willingness to pay to reduce the risk of death, and values reductions in morbidity risk as simply the medical cost savings. The range of benefits is also based on two different estimates of the effect of trans fat on CHD risk (one method leads to approximately twice the impact as the other method); adopting different valuations for QALYs, life years and lives saved; and applying the 3% and 7% discount rates. Cost estimates include direct labeling and other compliance costs, and reformulation costs and subsequent market impacts for firms that choose to reformulate. The range of costs is derived from the 3% and 7% discount rates, and model uncertainties in the labeling cost estimate.

Table 4. Summary of Agency Estimates for Final Rules
October 1, 2002 to September 30, 2003
(As of Date of Completion of OMB Review)

Rule	Agency	FR Cite	Benefits	Costs	Other Information
Patent Listing Requirements and Application of 30 Month Stays of Abbreviated New Drug Applications (Generics)	HHS/FDA	68 FR 36675	$230 million per year	Less than $10 million per year.	FDA estimates the largest impact will be a transfer of resources from current patent holders to generic drug manufacturers and consumers. FDA estimates patent holders will suffer approximately a $4.8 billion revenue loss per year. Consumers will save approximately $3.3 billion per year, and generic manufacturers will gain approximately $1.8 billion per year. The benefit is the efficiency gain from this market entry. Direct costs are derived from the increase in burden of additional applications and modifications to analytical requirements. In addition, because this rule lowers the profitability of new drugs, FDA explored the possibility that the rule would have an impact on innovation. FDA concluded any impact on innovation would be minimal. The benefits and costs are annualized at a 7% discount rate over 10 years.
Milk in the Northeast and Other Marketing Areas	USDA/AMS*	68 FR 7063	Not Estimated	Not Estimated	The Agricultural Marketing Service performed a cost analysis and summarized the average of the price changes from a model baseline using a 5-year period (2003-2007). The formula changes increase the protein prices and reduce the prices for butterfat and nonfat solids. The results are higher Class III prices, lower Class IV and Class II prices, and lower Class I prices. The advanced Class I base price is the higher of the Class III or Class IV advance pricing factors. The Class I base price is the Class IV price in all years of the analytical period for the baseline, while Class III becomes the Class I price in 2003 through 2005 under this decision. The Class I price falls in 2003, 2006, and 2007. The resulting increases in Class I and Class II demand for nonfat and fat solids sufficiently absorbs production increases to very slightly increase cheese and butter prices and only slightly decrease nonfat dry milk prices.

Table 4. Summary of Agency Estimates for Final Rules
October 1, 2002 to September 30, 2003
(As of Date of Completion of OMB Review)

Rule	Agency	FR Cite	Benefits	Costs	Other Information
Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products	USDA/FSIS	68 FR 34207	$44 million per year to $154 million per year	$16.6 million per year	The benefits are derived from avoided illnesses and death. Estimated costs are implementation costs. USDA also presents a range of benefits estimates, based on model uncertainty and statistical variability, and presents an alternative benefits estimate, based on a reduction in effectiveness, which is approximately 50% lower than the benefits presented here. Both benefits and costs are annualized at a 7% discount rate over 10 years, the assumed useful life of the necessary firm investments.

*OMB is statutorily prohibited from reviewing marketing orders. Information presented in this table is based on the GAO report.

Regulations Implementing Federal Budgetary Programs

Of the 37 economically significant rules reviewed by OMB, Table 5 lists the 25 that implement Federal budgetary programs. The budget outlays associated with these rules are "transfers" from taxpayers to program beneficiaries, therefore in past reports OMB has referred to these rules as "transfer" rules. The totals are: HHS/CMS, 11 rules; USDA, 6 rules; the Department of Veterans Affairs (VA), 2 rules; the Department of Labor (DOL), 1 rule; DOT, 1 rule; DOI, 1 rule; the DHS Federal Emergency Management Agency (FEMA), 1 rule; the Office of Personnel Management (OPM), 1 rule; and the Small Business Administration (SBA), 1 rule.

Here, we highlight two of the rules presented below. First, OPM issued a rule to allow Federal employees to pay for their health benefits with pre-tax dollars. This change is estimated to save Federal employees $848 million in taxes in fiscal year 2003. Unlike other rules listed here, this rule does not implement any particular spending program. This rule, however, has almost an identical effect as rules that implement other spending programs; by lowering the total taxes taken in, the effect is to transfer general tax revenue to a specific group.

Second, DOT's NHTSA issued a rule implementing a statute which requires the withholding of fiscal year 2004 Federal-aid highway funds from any State that has not enacted a driving while intoxicated law that provides for a blood or breath alcohol (BAC) limit of 0.08 percent. Although a major impact of this rule would be to Federal budgetary programs, the clear goal is to inspire State-level laws and regulations with public health and safety goals similar to the Federal rules reported in the other sections of this chapter.

Table 5: Agency Rules Implementing Federal Budgetary Programs (October 1, 2002 to September 30, 2003)
Department of Agriculture (USDA)
2002 Farm Bill: Cooperatives, Cotton, Dairy and Honey Price Support; Dairy and Apple Market Loss
2002 Farm Bill: Loans and Deficiency Payments for Peanuts, Pulse Crops, Wheat, Feed Grains, and Minor Oilseeds
2002 Farm Bill: Direct and Counter Cyclical Payments and Peanut Quota Buy-Out
2002 Farm Bill: Conservation Reserve Program
2003 Agricultural Assistance Act: Crop Disaster Program, Livestock Assistance Program, and Weather-Related Losses
Environmental Quality Incentives Program
Department of Health and Human Services (HHS)
Changes to the Hospital Outpatient Prospective Payment System and CY 2003 Payment Rates
Medicare Program: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2003
Medicare Program: Application of Inherent Reasonableness of All Medicare Part B Services Other than Physician Services
Medicare Program: Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2003
Medicare Program: Physician Fee Schedule Update for CY 2003.
Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations

Medicare Program: Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program
Medicare Program: Change in Methodology for Determining Extraordinarily High (Outlier) Payment in Acute Care and Long-Term Care Hospitals
Medicare Program: Changes to the Inpatient Rehabilitation Facility Prospective Payment System and FY 2004 Rates
Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates
Medicare Program: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities Update for FY 2004.
Veterans Administration
Payment or Reimbursement for Emergency Treatment Furnished at Non-VA Facilities
Enrollment; Provision of Hospital and Outpatient Care to Veterans; Subpriorities of Priority Categories 7 and 8 Annual Enrollment
Department of Labor
Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act of 2000
Department of the Interior
Bureau of Indian Affairs: Distribution of Fiscal Year 2003 Indian Reservation Roads Funds
Department of Transportation
Operation of Motor Vehicles by Intoxicated Persons
Federal Emergency Management Administration
Assistance to Firefighters Grant Program
Office of Personnel Management
Health Insurance Premium Conversion
Small Business Administration
Small Business Size Regulations: Government Contracting Programs; HUBZone Program

Major Rules for Independent Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) 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 "independent" agencies)[6]. We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2002 to September 30, 2003. GAO reported that 3 independent agencies issued 7 major rules during this period[7]. Two agencies, the Federal Reserve System and the Nuclear Regulatory Commission (NRC), did not conduct benefit-cost analyses, although the NRC did calculate the expected dollar amount of fee recovery from their program, which can be considered a cost of the rulemaking. One agency, the Securities and Exchange Commission (SEC), did consider the benefits and costs of its rules. OMB lists

[6] An exception to this is rules promulgated by the Federal Communications Commission (FCC) under the authority of the Telecommunications Act of 1996, which are exempt from GAO reporting.

[7] This list does not include 2 rules promulgated by FCC during this time period under the Telecommunications Act. On July 2, 2003, FCC released a rule modifying the broadcast ownership regulations. On July 24, 2004, however, the Court of Appeals for the 3rd Circuit blocked much of the rule. In addition, on August 21, 2003, FCC released a rule setting standards for the unbundling of telecommunications services. On March 2, 2004, however, the Court of Appeals for the District of Columbia circuit vacated and remanded much of the rule.

the agencies and the type of information provided by them (as summarized by GAO) in Table 6.

In comparison to the agencies subject to E.O. 12866, the independent agencies provided in their analyses relatively little quantitative information on the benefits of major rules; half of the economically significant rules reviewed by OMB reported monetized benefits, whereas only 1 of the 7 rules finalized by independent agencies reported monetized benefits. As Table 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 the independent agencies are similar to those of the analyses performed by agencies subject to the Executive Order, since OMB does not review rules from independent agencies.

Table 6: Rules for Independent Agencies
(October 1, 2002 to September 30, 2003)

Agency	Rule	FR Cite	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Reserve	Transactions Between Member Banks and Their Affiliates	67 FR 76560	No	No	No
NRC	Revision of Fee Schedules; Fee Recovery for FY 2003	68 FR 36714	Yes	No	Yes
SEC	Disclosure in Management's Discussion and Analysis About Off-Balance Sheet Arrangements and Aggregate Contractual Obligations, GAO-03-463R, February 19, 2003 IND	68 FR 5982	Yes	No	Yes
SEC	Strengthening the Commission's Requirements Regarding Auditor Independence	68 FR 6006	Yes	No	No
SEC	Disclosure of Proxy Voting Policies and Proxy Voting Records by Registered Management Investment Companies	68 FR 6564	Yes	No	Yes
SEC	Management's Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports	68 FR 36636	Yes	No	Yes

Table 6: Rules for Independent Agencies (October 1, 2002 to September 30, 2003)					
Agency	**Rule**	**FR Cite**	**Information on Benefits or Costs**	**Monetized Benefits**	**Monetized Costs**
SEC	Certain Research and Development Companies	68 FR 37046	Yes	Yes	Yes

C. Response to Public Comments on the Accounting Statement

Many commenters supported OMB's approach to the regulatory accounting statement. Several commenters (5, 31, 37, A and D) stated that the accounting statement is a useful tool for informing the public and policymakers on the scope and impact of the federal regulatory system. Other comments expressed support for OMB's oversight of the regulatory process (16, 24, and 37), and other OMB activities that they felt worked together with the accounting statement, specifically the Information Quality Guidelines and the new OMB Circular A-4, to improve the regulatory process (19, 27, 37, 39, and 40).

Comments on Scope/Coverage

Many commenters (2, 5, 8, 9, 19, 24, 37, 39, and 40) and peer reviewer A questioned OMB's decision to include only major rules in our benefit and cost totals. Most of these commenters questioned whether this practice led OMB to neglect reporting the impact of many important rules and therefore to underestimate the total costs and benefits of federal rulemaking. Two commenters (37 and 40) suggested that we should expand the scope to total regulatory costs and benefits, including all rules ever put in place, either through a literature review or through a greatly expanded summary of agency-prepared Regulatory Impact Analyses.

In the Draft Report, we stated that we included only information on the benefits and costs of major rules because we believe that these costs and benefits capture the vast majority of the total costs and benefits of all rules subject to OMB review. A comprehensive reassessment of every significant rulemaking is beyond the scope of this Report. Dues to the concerns raised by the commenters and a peer reviewer, however, we have reassessed the relative contribution of major and non-major rules for a selected group of agencies: OSHA, FDA, and NHTSA. These agencies were chosen, based on our reviewing experience, because they are more likely to have estimated quantified costs and benefits for non-major rules. For the purposes of this look-back, as a proxy for the impact of non-major rules, we examined significant rules reviewed by OMB. It is possible, but unlikely, that we are missing rules put in place by these agencies that were not considered significant enough for OMB review but have relatively large impacts.

First, we reviewed all significant final rules put in place by FDA from October 1, 2002 through September 30, 2003. In that time period, OMB concluded review on 4 significant FDA final rules and 2 economically significant FDA final rules. One of the rules was withdrawn by FDA. For the other 3 rules, FDA estimated costs of approximately $2.6 million per year and benefits of approximately $10-16 million per year. They also discussed but did not quantify other modest benefits of these rules. For the two economically significant final rules in this time period, FDA estimated costs of approximately $19 to $36 million per year and benefits of approximately $500 million to $3.1 billion per year. The benefits of the economically significant rules are far higher than the benefits from the significant rules. In addition, even though the estimated costs

for the economically significant rules are unusually small, they still are approximately 10 times the estimated cost attributable to the significant rules.

Next, we reviewed 8 significant final rules and 1 economically significant rule put in place by NHTSA from October 1, 2002 through September 30, 2003. In instances where NHTSA presented quantified but not monetized morbidity and mortality information, we monetized the estimates using techniques similar to those used to monetize results for the accounting statement (see Appendix B). For 3 of the 8 significant rules, NHTSA estimated costs of approximately $13 to $43 million per year. NHTSA also quantified the reduction in benefits from delaying the effective date of their advanced airbag requirements, which we monetized at roughly $2.5 to $3 million per year. The other rules did not quantify costs but stated they were minimal. With regard to benefits, NHTSA estimated mortality and morbidity benefits of approximately $5 to $22 million per year for the final rule establishing the Motor Vehicle Tire Safety Standards. No other significant final rule quantified benefits, although most stated that they considered benefits relatively small. An exception to this may be the New Information Program enhancing the presentation of rollover resistance information, which may have the potential to significantly affect consumer behavior if it were more effective than the previous program. The midpoint of the cost estimates is approximately 13%, and the midpoint of the benefit estimates is approximately 5%, of the costs and benefits of NHTSA's CAFE rule described above[8].

Finally, based on an analysis of the costs of both major and non-major rules issued by the Occupational Safety and Health Administration from 1976 to 2002, 87% of the $10.1 billion in costs were due to the 17 rules (out of a total of 59 rules) with costs at the time of issuance of over $100 million[9]. We also examined in greater detail the time period from October 1, 2002 through September 30, 2003. In that time, OMB concluded review on 5 significant OSHA final rules, but no economically significant OSHA final rules. In total, these rulemakings had a very small impact: two rules finalized delays in recordkeeping provisions, thus they generated no costs or benefits, 1 rule simply rewrote for clarity an existing regulation and generated no marginal impact, and 2 rules put in place agency procedures to handle discrimination complaints, leading to small OSHA administrative expenditures.

Two commenters (19 and 40) also stated that since federal agencies themselves determine which rules are major, using that screen for including rules in our report is questionable. This characterization of the process is not correct. Under E.O. 12866, Section 6, the agencies must submit a list of planned regulatory actions to OIRA, and the

[8] NHTSA also put in place an economically significant rule, discussed above and in Table 5, requiring that fiscal year 2004 Federal-aid highway funds be withheld from any State that has not enacted a driving while intoxicated law that provides for a blood or breath alcohol (BAC) limit of 0.08 percent. The primary impact of this rule is to the Federal budget; however, it was also substantially larger than the total of the significant rulemakings discussed here.

[9] Based on calculations from data in Fred Siskind, "A Critique of Published Estimates of the Overall Costs Imposed by OSHA Standards and Regulations" (Working Paper dated 9/17/03). The original data were provided by OSHA's Office of Regulatory Impact Analysis.

agencies and OIRA jointly determine which of these actions are economically significant and major.

Other commenters (2, 15, 29, 37, and 40) criticized the limitation of our accounting statement to final rules put in place over the previous 10 years. Some of these comments also stated that this principle was not consistently applied in other parts of the report. Some of these comments (2, 15, and 29) also criticized this 10-year window since it specifically caused the 1992 EPA Acid Rain regulations to fall out of the accounting statement.

We continue to believe that the 10-year window is the appropriate time period for which to limit this accounting statement, since we do not believe that the estimates of the costs and benefits of rules issued over ten years ago are very reliable or useful for informing current policy decisions. We will continue, however, to document the estimated costs and benefits of rules outside of this time period in appendices and other analyses where we believe appropriate. For example, in Appendix C we present information on all final rules, including the 1992 Acid Rain regulations, which we reported in Chapter I of the 2003 Report as part of the 10-year totals of costs and benefits, but are not included in Chapter I of the 2004 Report. In addition, in Chapter II, we present an analysis of the new yearly regulatory burden imposed by several administrations over the past 17 years. Although this analysis by necessity depends on rules promulgated outside of the 10-year window, we believe it is a very useful study of the different burden administrations were willing to impose on the private sector to realize regulatory benefits.

Several commenters (5, 8, 24, 39, 40, A, and B) criticized our less detailed presentation of information on Federal Communications Commission (FCC) and other independent agency rulemakings in our report, and that we do not include them in the accounting statement. One peer reviewer (B) suggested that we ask the independent agencies directly to provide us with annual assessments of the costs and benefits of their regulations. Another peer reviewer (A) pointed out that our reliance on GAO to develop our list of independent agency major rules caused an omission of rules promulgated under authority of the Telecommunications Act of 1996, since they are excluded from the GAO database by statute. As a result, at least two additional FCC major final rules – the modification of media ownership rules and its revision of local telephone access rules – were excluded in fiscal 2003, and rules may have been excluded in previous years.

OMB agrees that it is important to assess the benefits and costs of independent agency regulatory actions. Currently, OMB relies on GAO reports as the primary data source to do so. If the FCC rules mentioned by the peer reviewer were implemented, we would have added them to the list of independent agency rules; however, both of these rules have been at least partially blocked by Court actions. As with other rules blocked by the Court, we will not add these to the totals but will summarize the rules and the Court actions in a footnote. OMB encourages independent agencies to conduct benefit-cost analyses that conform to our regulatory analysis guidance, and to submit those analyses of major rules to OMB.

Two comments (2 and 29) claimed the OMB arbitrarily excluded deregulatory action from review. OMB does not arbitrarily or inappropriately exclude deregulatory actions from review or from this Report. This Report includes all final major rules reviewed by OMB over a ten-year period from October 1, 1993 to September 30, 2003, whether or not they are regulatory or deregulatory. Comment 2 included a list of rules they classify as deregulatory; however, these rules do not meet the criteria that would qualify them for inclusion in this Report. For example, their list included "deregulatory" actions from the Department of Labor, which consisted of an MSHA rule and two OSHA rules that were not major; one OSHA rule published after this Report's cutoff of September 30, 2003 that terminated a proposed rule that was never finalized; and one Wage and Hour major final rule implementing exemptions from minimum wage and overtime pay under the Fair Labor Standards Act, which was published two months after the publication of the 2004 Draft Report.

A few comments (9, 29, 40, C, and E) criticized our exclusion of rules that implemented federal budgetary programs from the cost and benefit totals. Peer reviewers C and E stated that rules that transfer Federal dollars will have opportunity costs and benefits if they cause behavioral responses.

We agree that rules that transfer federal budgetary programs often have opportunity costs or benefits in addition to the budgetary dollars spent. Several commenters, however, seem to have confused our less detailed presentation of Federal budget rules in this Report with less stringent analytical and review requirements. In fact, agencies thoroughly analyze and OMB thoroughly reviews all significant Federal budget rules under E.O. 12866. If economically significant, these rules must be accompanied by regulatory impact analyses that comply with OMB Circular A-4. As we mentioned in the 2003 Report, OMB does see merit in providing more information about these rules, and we are considering feasible ways of providing this information. We believe, however, that our approach of separately identifying budgetary rules has merit. Many of these rules - for example, CMS payment system regulations - are yearly updates that put in place changes that are relatively small when compared to the overall programs. This is in contrast to major social regulations, almost none of which have to be renewed on a yearly basis. Moreover, including budget programs in the overall totals would overwhelm the incremental new regulatory impacts identified by this Report, and would confuse the distinction between on-budget and off-budget government activity.

Other comments (27, 39 and 40) suggested that we should also quantify the costs and benefits of Federal Regulation on small businesses, perhaps by using agency-prepared Regulatory Flexibility Analyses, which accompany the Regulatory Impact Analyses on almost all major rulemakings. We see merit in the consideration of including more information on the impact of regulations on small businesses. We plan to explore this issue in more detail with the Office of Advocacy of the Small Business Administration.

Comments on the Overall Quality of Analysis

Many comments (5, 15, 16, 19, 37, A, B, C, and D) stated that costs and benefits of different regulations are difficult or impossible to compare due to methodological differences across agency analyses. One peer reviewer (C) also stated that since programs have interaction effects, it is wrong to add the separately calculated effects of different programs. This peer reviewer also mentioned that the division of effects into costs and benefits is somewhat arbitrary, since costs can always be classified as negative benefits, and vice versa.

To address these issues, two commenters (5 and 9) suggest that we stress the limited nature of the statistics in the executive summary as well as throughout the Report. OMB agrees. Two peer reviewers (A and B) suggested that OMB use our in-house expertise to modify and standardize regulatory impact analyses. These peer reviewers also suggested that OMB include a scorecard that summarizes agency compliance with OMB guidance. One peer reviewer (A) suggested that OMB include information on other credible studies that present alternative estimates of the impact of regulation. Other commenters (2, 15, 29, and E) stated that they believed the methodologies so unsound that any attempt to add the results together in an accounting statement was inherently misleading.

OMB acknowledged in the Draft Report that an aggregated accounting statement involves the assemblage of benefit and cost estimates that are not strictly comparable because of difference in methodologies; however, we do not believe that agency methodologies are so different that comparison across agencies is useless. For example, almost all agencies report results with a 7% discount rate, long required by OMB. Almost all agencies use similar methodologies for valuing fatalities avoided due to health and safety regulations. In addition, where benefits are primarily due to gains in economic efficiency, such as in FDA's final rule modifying Patent Listing Requirements and Application of 30 Month Stays of Abbreviated New Drug Applications (ANDAs, commonly known as generic drugs), the market analysis that leads to an estimate of efficiency gains is fairly standardized.

We further note that in limited cases, as explained in the draft Report, OMB does adjust agency cost and benefit estimates to help ensure consistency in the context of this annual Report. First, all values were adjusted to 2001 dollars; next, quantified but non-monetized estimates were monetized; and finally, estimates of net present values were annualized to provide a yearly stream of benefits and costs. Nevertheless, OMB agrees with the goal of further standardization of agency analyses, and believes the best way to promote this is through the application of the new OMB Circular A-4, which was designed to promote consistent analytical approaches. OMB has not yet considered putting out a scorecard to judge agency compliance with applicable guidance; however, we will be monitoring the impact of Circular A-4 as it is fully implemented.

OMB agrees with peer reviewer C that interaction effects between rulemakings must be taken into account; otherwise, the aggregation of costs and benefits may not be accurate. OMB regulatory impact guidance, however, has long directed agencies to take

these interactions into account in their estimates of benefits and costs. Specifically, our guidance directs agencies to consider a "pre-policy" baseline that includes any current regulations each rule interacts with. For example, in USDA's final rule putting place controls to prevent Listeria monocytogenes (or *Lm*, a food-borne illness) in some ready-to-eat products, many of the regulated facilities are already subject to food safety plan (Hazard Analysis and Critical Control Point) regulations. Therefore, Table 4 of the Report presents the incremental costs and benefits of adding the new *Lm* controls to existing food safety plans, not the total cost and benefits of all regulations these facilities are subject to. In cases of this type, it is legitimate to add the costs and benefits of the original safety plan and this rulemaking together, as we do in the accounting statement.

OMB also agrees with peer reviewer C's statement that in standard benefit-cost analysis, the attribution of effects to costs or benefits is not always clear, and that net benefits are not affected by the attribution of impacts to either costs or benefits. We also agree in part with the concerns expressed in one of the examples cited in support of this statement. In practice, however, our guidelines discourage the netting of costs and benefits before their presentation in this Report, due to OMB's rule designation process. A rule is significant based on the estimate of total costs, benefits, or transfers, not on any net value of impact. The two examples provided by the peer reviewer do not support the contention that costs and benefits are arbitrarily assigned in the rules summarized in this Report: the Truck Driver Hours of Service Rule presented costs and benefits relative to two different baselines; it is not an arbitrary choice to present costs as negative, but rather this reflects the burden reduction of the rule relative to the full compliance baseline. Furthermore, FDA's generic drug rule did not substantially net out any costs or benefits, as the peer reviewer suggests. The majority of these effects are market transfers, which are separately identified since the size of the transfers may determine whether or not to include a rule in this Report. OMB agrees, however, that the summary of this rule in Table 4 did not include all of the costs and benefits that may have been expected from this type of rule. Specifically, the analysis summary discussed the impact on total revenue due to the rulemaking, but did not discuss the possible impact of the rule on investment patterns, either in generic drugs or branded drugs, which would be considered changes to costs and benefits. FDA did consider these potential impacts and concluded they were minimal. In Table 4, we expanded and clarified the explanation of the transfers, costs, and benefits due to this rule.

Commenters (8, 9, 19, 24, 32, 37, and 40) suggested that the data and methodologies grossly underestimate the real cost to the economy of the regulatory state. Many of these commenters quoted literature citing a much higher overall impact of regulations. Other commenters (2, 15, 29, and E) suggested that regulatory impact analyses grossly overestimate the real cost to the economy and systematically underestimate the benefits of regulation, and also quoted literature to that effect. This second group contended that cost-benefit analysis is inherently biased against regulation. Two commenters (9 and 19) stated that OMB should require agencies to perform selective or general retrospective analyses to explore the extent to which pre-regulation estimates were accurate.

OMB does not agree that cost-benefit analysis or cost-effectiveness analysis are inherently biased for or against regulation. Estimates are inherently uncertain, and we are aware of retrospective analyses that have found both *ex-ante* costs and benefits to be both under and over estimated[10]. OMB agrees that it is useful to compare actual with predicted estimates, and encourages such efforts.

Several commenters made more specific criticisms of particular methodologies. Two commenters and a peer reviewer (15, 29, and E) make a now standard criticism of discounting. OMB has explained this practice at length in previous reports and in OMB Circular A-4.

One commenter (29) stated that the report overstates the cost of EPA's final rule on Concentrated Animal Feeding Operations (CAFOs) relative to the benefits, since benefits were quantified for only large CAFOs whereas costs were quantified for all CAFOs. OMB agrees that the monetized costs of this rule were monetized for all CAFOs, while the benefits were only monetized for large CAFOs. Like many rules included in this Report, the portion of the benefits that were not monetized are described in the qualitative discussion section of Table 4. We have modified and clarified that discussion.

One commenter (2) suggested that these analytical requirements necessarily delay regulation, which carries a cost not accounted for by OMB. OMB notes in Circular A-4 that regulatory delay may entail a cost, but also may entail benefits, if the delay is used to conduct further analysis which improves rulemaking. This "real options" approach to regulatory costs and benefits is discussed in more detail in Circular A-4; however, OMB is unaware of any agency that has explored this emerging analytical technique.

[10] For example, Harrington et al (2000), in an analysis of a sample of EPA and OSHA regulatory impact analyses, found that *ex-ante* per-unit abatement costs were overestimated about as often as underestimated. They also found that *ex-ante* total abatement costs were more likely to be overestimated than underestimated. Overestimation of total costs was primarily due to errors in estimating the quantity of benefits achieved by the rule, which suggests that the benefits of these rulemakings were overestimated as well, and to unanticipated technological change. We have added a more detailed summary of this paper to the manufacturing Chapter II.

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

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

Impacts on State, Local, and Tribal Governments

Over the past 8 years, 7 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).[11] The Environmental Protection Agency issued all 7 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)

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

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 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 $140 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.

- *EPA's Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category* (2002): This rule proposed three options to address storm water discharges from construction sites. Option two proposed technology-based effluent limitation guidelines and standards (ELGs) for storm water discharges from construction sites required to obtain National Pollutant Discharge Elimination System (NPDES) permits. Option three proposed not to establish ELGs for storm water discharges from those sites, but to allow technology-based permit requirements to continue to be established based upon the best professional judgment of the permit authority. Option one would establish inspection and certification requirements that would be incorporated into the storm water permits issued by EPA and States, with other permit requirements based on the best professional judgment of the permit authority. EPA is considering all options, and did not state a preferred option in the proposed rule. Options one and two would impose a mandate on the States, local, or Tribal governments, in the aggregate, or private sector that would exceed $100 million per year. Option three would not impose a mandate with costs that exceed $100 million per year for the public or private sectors.

Although these 7 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." This is largely attributable to fixed costs—costs that all firms must bear regardless of size. 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 are spread over a larger revenue and employee base resulting in lower unit costs.

The Office of Advocacy of the Small Business Administration (Advocacy) recently sponsored a study (Crain and Hopkins 2001) that estimated the burden of regulation on small businesses. 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. These findings are based on their overall estimate of the cost of Federal regulation for 2000 of $843 billion.

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). Under the RFA, whenever an agency comes to the conclusion that a particular regulation will have a significant 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 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.

Advocacy recently released two studies (CONSAD 2002, Advocacy 2004) exploring how well agencies work with Advocacy and OMB in estimating small business impacts and considering regulatory relief. The CONSAD report found that some agencies made significant improvements in determining small business impacts in their rulemaking, while others continued noncompliance. The study concluded that in 1995 about 39 percent of final rule notices did not certify or explain the small business economic impacts of the regulation; by 1999, the rate of RFA noncompliance fell to 32 percent.

The Advocacy 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. 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 the Advocacy. This section also shows breakdowns of 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 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 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."[12]

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.[13] 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

[12]From Ehrenberg and Smith's *Modern Labor Economics*, p. 279.
[13]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).

come at a cost in inefficiency from reduced competition, a cost which consumers must bear. Moreover, growth in real wages, which are limited generally by productivity increases, will not grow as fast without the stimulation of outside competition.[14]

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

Economic Growth and Related Macroeconomic Indicators

The strongest evidence of the impact of smart regulation on economic growth is the differences in per capita income growth and other indicators of well being experienced by countries under different regulatory systems. A well-known example is the comparison of the growth experience of the formerly 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.[15]

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.[16] 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

[14] 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.

[15] 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.

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

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.[17] The rank of the top ten economies is Hong Kong (1), Singapore (2), New Zealand, Switzerland, the United Kingdom, and the United States (3), Australia and Canada (7), and Ireland and Luxembourg (9). The index, which is based on 38 variables, many of them from surveys published by other institutions, measures five major concepts: size of government, legal structure and security of property rights, access to sound money, freedom of exchange with foreigners, and regulation of credit, labor, and business. The latest report finds that the index is highly correlated not just with per capita income and economic growth, but with other measures of well being, including life expectancy, the income level of the poorest 10%, 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. The second volume (*Doing Business in 2005, Removing Obstacles to Growth)* updates these measures and adds data about registering property and protecting investors. 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

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

- Rich countries regulate business in a consistent manner. Poor countries do not.[18]

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. [19]

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 French, German, and socialist origins. The top ten countries ranked on the ease of doing 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.[20]

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:

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[18] World Bank. *Doing Business in 2004: Understanding Regulation*. Oxford Press. Washington, DC.
[19] World Bank. *Doing Business in 2005: Removing Obstacles to Growth*. Oxford Press. Washington, DC.
[20] 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.

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.[21]

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 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."[22]

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.[23] 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

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[21] 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.

[22] 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).

[23] 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.

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.[24] 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."[25] Thus, countries with good records on entry regulation (which they point out includes some environmental regulation) also have good records on labor regulation.[26]

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 enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase state influence.[27]

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.[28] 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.[29] 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

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[24] *Ibid.*

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

[26] *Ibid.*

[27] 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.

[28] 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.

[29] 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.

greater benefits to society at less cost than regulation that is not.[30] 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.

[30] 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.

Response to Public Comments on Economic Growth and Related Macroeconomic Indicators

Commenters both welcomed and criticized the new discussion of the international evidence linking the quality of regulation with economic and social performance indicators. Those that welcomed the discussion thought that it made sense and was quite useful (14, 37, A, B, and D). In particular, several commenters agreed that the reports "general conclusion -- that the burden of regulation is on the whole inversely related to economic growth – seems well supported" (A) and U.S. policymakers should heed the results of the studies that examine the relationship between the degree of regulation and economic growth (37). Another (B) suggested that it could be useful for the United States to learn from the experience of other countries, and other countries to learn from the United States' experience, but was not sure that this report was the best place to provide this information. Another commenter, supportive of the section (D), said that a better job of distinguishing between social regulation and economic regulation would be useful since some have suggested that social regulation (that is, health, safety, and environmental regulation) can positively impact economic growth.

Those that criticized the discussion (15, 29, E) made several points. First, one commenter states that the report's description of the economic theory of regulation "is breathtaking" and calls into question OIRA's "role in regulatory affairs" (15). The report stated that "These results are also consistent with economic theory, which predicts that economic growth is enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase state influence." The commenter took offence to the phrase: "rather than to increase state influence." However, this is a statement of the "enforcement theory" of regulation recently set forth by Professor Andrei Shleifer and colleagues who served as the academic advisors to the World Bank study, *Doing Business*, which was one of the main studies discussed by OMB in this section. The theory posits that optimal regulation entails considering a trade off between two social costs: the costs of private injury brought about by market failures and the cost of state intervention, which refers to the ability of government to expropriate private agents through bureaucratic hassle and or the confiscation of private property.[31] The theory is a reconciliation of the two conflicting views of regulation: the public interest theory that holds that all regulation corrects market failures and George Stigler's capture theory of regulation that holds that the private interest of the regulators motivates regulatory behavior (and for which he was awarded the Noble Prize in Economics). As pointed out before, OMB sees its role not as an advocate of deregulation or of regulation, but as a proponent of better quality regulation.

A second line of criticism suggests that the report misuses the studies that found a relationship between regulation and economic growth (29, E). The two commenters

[31] See Doing Business, pages 90 – 92 and Simeon Djankov et al, "The New Comparative Economics" *The Journal of Comparative Economics* (2003) Vol. 31.4, pp 595-619.

focused on the World Bank study, *Doing Business in 2004: Understanding Regulation*[32], despite the fact that three other studies were also discussed. One commenter (E) suggests that it is not less regulation in countries such as Denmark, Sweden, and Norway that account for their economic performance but their "use of heavy taxes on industrial practices disfavored by government." No evidence is presented for this proposition. The same commenter also states that "OMB appears to assume, without citing any persuasive evidence, the rewards of 'economic freedom' accrue equally at every stage of deregulation. This is highly doubtful". The commenter then argued that the US, unlike Bolivia, is "economically free" and thus little can be said about the benefits of smarter regulation for the US. We did not mean to imply that the benefits of better regulation are equal for both developed and developing countries. But a survey of the literature does show that programs of smarter regulation are beneficial, even for high-income, relatively-free countries. In fact the report states:

> "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 Organization for Economic Cooperation and Development (OECD)"[33]

The revised section clarifies this point and provides additional evidence.

A third point offered by two commenters (29, E) is that the World Bank study was not concerned with "the types of regulation that OMB is most concerned about." That is incorrect. OMB is concerned with improving all types of regulation.[34] Moreover, the Regulatory Right to Know Act requires OMB to report on the impacts of *all* types of federal regulations on economic growth. The World Bank study and the other studies reviewed in this section, taken as a whole, provide evidence on the impact of all types of regulation on economic growth. Regulations cannot be neatly classified into those that have economic effects and those that affect health, safety, or the environment, as these commenters appear to believe. For example, labor market regulation, a major focus of the World Bank study as well as the others, has both economic aspects and health and safety aspects. Regulations that limit hours of work or allow family leave are often seen as a trade off between labor market flexibility and worker or family health.

A final point these same commenters make is that "the Report mistakes wealth and well-being" (E) and "OMB also errs by equating wealth and well being" (29). The

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[32] One commenter (E) characterized the World Bank study as "preliminary". This is not correct. It is the first volume in a series of annual reports that will examine scope and manner of regulations for over 130 countries. The second volume was recently released and is discussed in the final report.

[33] The report cites an OECD paper by Nicoletti that shows that among the high income OECD countries regulatory reforms have positive effects. It does not state that reforms have equal effects to those implemented in developing countries.

[34] Under EO 12866 issued in 1993, OMB is required to review all regulations except certain regulations that pertain to a military of foreign affairs function of the US and rules issued by the independent agencies. The independent agencies include both health and safety agencies such as the CPSC and the NRC and economic agencies such as the SEC and the FCC. The executive branch agencies also issue regulations that include a similar or wider range of diversity.

commenters point to measures of well being to support their point. On inspection, the measures of well being cited actually show a very high correlation between income and well being. As contrary evidence, one comment (E) states that several countries in Europe have higher life expectancies and lower infant mortality than the US. The implication is that wealth and well being are not related. Another comment (29) is that The Human Development Index, created by the United Nations Development Program to address this point, shows that countries with the highest income do not always have the highest well being. The commenters are correct that these correlations are not perfect and there are exceptions. Yet the weight of the evidence supports the relationship between income and well being. The draft report cites the strong associations found between the Fraser Institute's 2003 Index of World Freedom and both per capita, economic growth, and life expectancy in a study by Gwartney and Lawson. The final report cites additional evidence by Gwartney and Lawson using the 2004 Index of Economic Freedom: the index is associated positively with several other indicators of well being including the distribution of income, infant mortality, adult literacy, lack of corruption and fewer young children in the labor force.[35] In addition, the World Bank study *Doing Business in 2005; Removing Obstacles to Growth* presents a graph showing the very strong relationship between the ease of doing business index and the UN Human Development Index. The World Bank report concludes:

> "Economic growth is only one benefit of better business regulation and property protection. Human development indicators are higher as well. Government can use revenues to improve their health and education systems, rather than support an overblown bureaucracy" … (and) "businesses spend less time and money on dealing with regulations and chasing after scarce sources of finance." [36]

These two commenters (29, E) also take exception with the observation that the US program of "Smarter Regulation" outlined in this and previous reports corresponds fairly closely to the characteristics that the World Bank concludes are well-performing approaches to regulation. The commenters suggest that OMB's central oversight role that relies on cost benefit analysis, peer review, and "an expanded bureaucratic staff" is "at odds" (E) or "in tension" (29) with the World Bank recommendations for better regulation. It is not clear how these commenters arrived at this logic. OECD has found that it is difficult for regulation to be improved without strong interest from the center of government and without subjecting regulations to benefit-cost analysis and independent peer review. Indeed, the World Bank cites benefit-cost analysis and regulatory impact analysis as important tools in a better regulation program and also suggests that a successful reform program must be continuous and supported by political will.[37] The OMB program fits those characteristics.

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[35] See James Gwartney and Robert Lawson, *Economic Freedom of the World 2004 Annual Report*, Fraser Institute, Vancouver, BC, (2004).

[36] See *Doing Business in 2005; Removing Obstacles to Growth*, World Bank and Oxford University Press, (2005) p. 5.

[37] *Doing Business in 2004* (p. 94) and *Doing Business in 2005* (P.5)

CHAPTER II: Regulations and Manufacturing

Introduction

Streamlining regulation is a key plank in the President's economic program. The cumulative regulatory burdens on the manufacturing sector, however, are larger than the costs imposed on other sectors of the economy -- and disproportionately large for small and medium-sized manufacturers. Manufacturing is a substantial and vital sector of the U.S. economy, accounting for about 14% of Gross Domestic Product in 2002 (Yuskavage and Strassner 2003). Since U.S. manufacturers compete with firms from both developed and developing countries in an increasingly global economy, it is critical that any unnecessary costs are removed.

In light of these large regulatory burdens and the importance to the economy of a vibrant manufacturing sector, OMB initiated in the Draft Report a call for public nominations of promising regulatory reforms of the US manufacturing sector. In order to assist commenters, we also summarized the extensive literature on the many ways in which regulation may impact the manufacturing sector.

Regulatory reform of the manufacturing sector needs to be approached with analytic care because many rules governing this sector may produce substantial benefits for workers, consumers and the environment. For example, this and previous OMB Reports have discussed the billions of dollars of public health benefits associated with selected rules adopted pursuant to the 1990 Amendments to the Clean Air Act, and some of these rules cover the manufacturing sector. Even where the benefits of particular rules are substantial, it makes sense to search for more cost-effective ways of achieving those benefits (e.g., market-based policy instruments). Moreover, the cumulative regulatory burden is enormous and may pose barriers to economic productivity that were unanticipated when regulations were first put in place, especially for small businesses and others trying to create new jobs.

Section A of this Chapter updates our review of trends in Federal regulatory activity and the burden of regulation on the manufacturing sector. Section B summarizes the results of our call for manufacturing reform nominations and offers a detailed list of those nominations. Section C responds to public and peer review comments on the review and the reform initiative.

A. Trends in Federal Regulatory Activity and Review of Manufacturing

Definition of the Manufacturing Sector

The U.S. Census Bureau (2003) defines manufacturers as "establishments engaged in the mechanical, physical, or chemical transformation of materials, substances, or components into new products." This includes such activities as electronic equipment, transportation equipment, printing and publishing, rubber and plastic products, and textile mills. The indirect effects of impacts to this sector can be more widespread, including impacts to consumers or suppliers in the form of higher or lower prices, and impacts to employment trends to the extent that manufacturing employment experiences relative productivity gains when compared to other sectors (Economic Report of the President 2004).

This review provides background on two questions. What is the overall burden of regulatory requirements on manufacturers, and what could be the direct and indirect effects of this burden on the economy?

Regulatory analysts have developed a variety of ways to measure the growth of Federal regulatory burden over time: the number of new Federal rules, the number of pages in the Federal Register devoted to new Federal rules, the number of new "economically significant" rules and the number of full-time equivalent staff at regulatory agencies. Although each of these measures offers some insight, they share the important limitation that they do not measure a key quantity of interest: the overall economic cost to society of new Federal rules. In order to develop such a measure, OIRA has assembled for this Report a time series of new Federal regulatory costs for the 1987-2003 period.

Each year since 1987 OIRA has collected estimates of the new regulatory costs imposed on the economy due to actions by Cabinet agencies and EPA that were reviewed by OIRA (under E.O. 12291 prior to September 1993 and under E.O. 12866 after 1993). These actions are primarily "social regulations" which expend capital and labor resources in an effort to improve public health, safety, and the environment. A substantial number of these rules affect the manufacturing sector, particularly labor and environmental rules. During this period there were few new "economic regulations" reviewed by OIRA. The analysis reported below excludes the economic impacts of new rules that are included in the Federal budget, since most of these rules represent transfers from one group in society to another and thus do not necessarily incur societal cost. Cost estimates for each of the new rules are based on agency estimates prepared in the pre-regulation period, prior to the promulgation of the rule.

Over this 17-year period, these new rules added a total of $104 billion in regulatory cost burden, which amounts to an average incremental burden of $5.6 billion per year. The additional costs of new regulation are not spread evenly over the 17-year period. The added costs were largest in the early part of the period, plus the large increase in the last year of the Clinton Administration. During the first 32 months of this Administration, the average annual increase in regulatory costs has been about $1.6

billion, approximately 75% smaller than the average for the previous 14 years. Table 7 summarizes the results of this study.

Table 7: The Economic Burdens of New Major Rules 1987-2003, All Sectors of the Economy

Year	Annualized Cost (in billions of 2001 dollars)	Number of rules over $1 billion
1987	3.6	N/A
1988	12.5	N/A
1989	4.1	N/A
1990	3.8	0
1991	9.7	2
1992	16.3	7
1993	5.1	2
1994	8.7	2
1995	3.5	0
1996	2.6	1
1997	2.4	0
1998	5.4	1
1999	8.4	3
2000	13.1	4
2001	0	0
2002	1.9	0
2003	2.5	1
Total	**103.6**	**23**

Notes: The incremental costs presented in this table include only unfunded mandate rules, not rules put in place enabling Federal budget spending. From 1997 to 2000, costs are on a regulatory year basis with April 1 of the year as the starting date. Starting in 2002, costs are on a Fiscal Year basis with Oct 1, 2001 as the starting date. (There were no costs April thru Sept 30, 2001).

An even better measure of new regulatory performance would be net benefits (new benefits to society minus new costs to society), a measure of overall economic efficiency. We do not yet have comparable measures of new regulatory benefits for the 1987-2003 period; however, we are looking into the feasibility of a similar benefits analysis. That analysis would necessarily be incomplete, since many rules that impose significant cost do not have any corresponding numeric estimate of benefit.

With regard to the quality of regulatory cost information, we highlight here some of the important technical limitations of the available estimates. First, these cost estimates are generated by the regulatory agency prior to a rule's promulgation and have not been validated by post-regulation cost measurement. Although many of these cost estimates may be accurate, the regulatory analysis literature suggests, based on limited validation studies, that the actual costs of rules can be significantly different -- larger or smaller -- than the pre-regulation estimates of costs. We discuss this issue of *ex-ante*

versus *ex-post* regulatory cost in the next section below. Second, these cost estimates typically address only the direct costs of rules (e.g., compliance expenditures made by regulated businesses). However, the full social cost of regulation would include any declines in product quality or price-induced changes in consumption that are caused by regulation. The magnitude of the resulting error in regulatory cost estimation is unknown but could be significant. Third, there are intangible costs of rules -- for example, losses of freedom, privacy, and innovation -- that are difficult to measure in monetary terms. Thus, the intangible costs of regulation need to be considered in conjunction with the tangible resource costs. Finally, the estimates reported here are only for "economically significant" Federal rules that impose unfunded mandates on the private sector, which account for a small percentage of the total number of Federal rulemaking actions. However, OIRA believes that these "economically significant" actions, because they have impacts greater than $100 million per year, are likely to account for the vast majority of new regulatory costs. We discussed the basis for this belief in more detail in Chapter I.

The Regulatory Burden on Manufacturing.

Among the more recent and comprehensive sources of estimates of the overall burden of regulation on specific economic sectors is the Crain and Hopkins 2001 study performed for the SBA Office of Advocacy. Crain and Hopkins estimated the impact of four types of regulations —social regulation, which they separate into environmental and workplace rules; economic regulation; and tax compliance— on different sectors of the economy. These sectors are manufacturing, trade, services, and "other",[38] and the study used three metrics of regulatory burden: the overall burden per sector, the burden per firm in each sector, and the burden per employee in each sector. The study found that manufacturing firms face a regulatory burden approximately 6 times greater than the average firm, and when adjusted for the number of employees, manufacturing firms face a regulatory burden per employee approximately 2 times greater than the average firm. According to the study, environmental regulations are the highest source of burden on manufacturing, followed by economic regulations, tax compliance, and workplace rules, which include categories such as employee benefits, occupational safety and health rules, and labor standards.

Several studies have focused on whether traditional measures of the cost of regulatory activity in manufacturing systematically under or overestimate the true burden of regulation.[39] Two issues dominate this line of literature. The first is whether *ex-ante* estimates of regulatory burden (the estimates agencies produce as part of a regulatory impact analysis before a rule is finalized) are an accurate estimate of the burden regulations actually impose after they are put in place. The second is whether survey instruments that purport to measure the cost of regulation actually imposed on businesses, such as the Pollution Abatement Costs and Expenditures (PACE) surveys, accurately

[38] These sectors are defined using codes from the U.S. Census Bureau's "Statistics of U.S. Businesses." The trade sector includes both wholesale and retail trade. The "other" sector consists of the residual of businesses in this dataset that do not fall under the other three categories.

[39] Studies have also found that benefits can be under or overestimated.

measure the true burden. Most of this literature focuses on environmental regulation, the largest component of manufacturing regulatory burden.

Ex-ante estimates compared to ex-post measurements of burden. Most advocates in this debate claim that *ex-ante* costs are either systematically over or understated. For example, many public comments to the Draft Report (see Chapter I response to comments) assert that the true cost of regulation is much greater than agencies estimate before the rules are put in place. The most common reason cited is that agencies typically estimate compliance costs only, and fail to consider more widespread changes to business practices that regulation inspires.

Literature cited to support this claim includes the Crain and Hopkins study described above, and James (1998). The James analysis is based on an examination of the regulatory compliance cost estimates of 25 new rules published by OSHA after 1980, which the author adjusted upwards based on various estimated multipliers of regulatory activity. James concludes that reported compliance costs substantially underestimate the burden of OSHA regulations. Specifically, the total annual cost of OSHA regulations in 1993 are estimated at approximately $33 billion. This cost estimate is approximately three times the highest figure estimated in previous studies of OSHA.

In perhaps the most global estimate of the impact to the economy of regulations, Jorgenson and Wilcoxen (1990) simulate the growth of the U.S. economy with and without the regulatory burden associated with environmental regulation, in contrast to other estimates that tend to be based on static compliance costs. Note that this is a relatively old study that does not include the rules issued over the period from 1992 to 2003 that are covered in this Report. They conclude that the annual growth rate of the economy between 1973 and 1985 fell by .191% due to environmental regulations. This result implies that Gross National Product (GNP) in 1985 was approximately $140 billion (1996$) lower than it would have been in the absence of environmental regulation; this is several times the reduction in growth estimated in previous studies.

The second line of commentary on our Draft Report asserts exactly the opposite, that *ex-ante* cost estimates prepared by agencies systematically overstate the impact of regulations on the economy. The most common reason cited is that such analyses do not anticipate technological or efficiency gains in the regulated industries, which allow businesses to more creatively and efficiently adjust to regulatory constraints. Literature cited to support this claim includes McGarity and Ruttenberg (2002), which concludes that prospective (and even retrospective) cost studies are biased upward, primarily because of this technological change and because of a tendency for agencies to use conservative assumptions.

At least partly in response to these contradictory assertions, Harrington et al (2000) studied a sample of EPA and OSHA regulations in order to compare *ex-ante* with *ex-post* cost estimates. The authors point out that they only study whether the components of cost estimated during the regulatory process contain systematic errors, not whether the agency analyses have exhaustively identified all the important cost

components. Their review found that *ex-ante* estimates of total cost have tended to exceed *ex-post* costs: 14 of the 28 rules studied overestimated actual costs, whereas only 3 underestimated actual costs. On the other hand, their review found that per-unit abatement costs are about as likely to be overestimated as underestimated. They also found that rulemakings in their sample contained more accurate cost estimates after 1981, which is when President Reagan introduced OMB regulatory review.

The authors believe their findings are driven by many factors. For example, the authors claim that many rulemaking cost estimates do not change appreciably from the proposed rule stage, while the rules themselves tend to be relaxed between the proposed and final stages; this may lead to cost overestimation. The authors also believe a primary cost-reducing factor is unanticipated technological change that firms are able to put in place because of flexible rules. Eight rules in their dataset incorporate market-based incentives, which likely allow firms to reduce costs through new techniques or innovative compliance strategies. This is supported by Carlson et al (2000) in a study of the compliance costs of Title IV of the 1990 Clean Air Act Amendments, which established the market for transferable sulfur dioxide emissions. EPA's *ex-ante* abatement cost estimates, according to this study, were substantially overestimated due to unanticipated drops in low sulfur coal prices and unanticipated technology improvements which lowered the cost of fuel switching.

Survey-based estimates compared to the true burden. Researchers necessarily depend on less than perfectly precise measures, even when estimating *ex-post* regulatory costs. This imprecision may arise due to many different factors. Morgenstern, Pizer, and Shih (2001) frame the issue well in their study of the accuracy of the (PACE) surveys, the primary source of environmental burden estimates. Most researchers agree that this data is the best available source for environmental expenditures by industry; however, theory suggests several reasons why these expenditures may over or understate the true burden of regulation. Costs could be understated because 1) environmental investments crowd out other productive investment, 2) many rules contain a new source bias that may discourage investment in new more efficient facilities, or 3) pollution control may reduce operational flexibility. Costs could be overstated because 1) complementarities in production may exist, or the cost of jointly producing output and an environmental "good" may be less expensive than producing each one separately, 2) the direct value of effluents that rules may require firms to recycle may not be counted as an offset to expenditures, or 3) firms may be able to coordinate the timing of other efficiency-enhancing investments with required environmental investments in order to lower their cost. For example, if a firm must shut down a line to install environmental equipment, they could use that opportunity to also install other equipment and avoid another line shutdown.

Porter and Van de Linde (1995) make a more provocative claim: well designed environmental regulations can actually improve competitiveness. By stimulating innovation and causing more productive use of resources, regulations can actually yield net cost savings to industries. The authors rightfully point out that most economists are

resistant to this idea, since it implies that firms are not pursuing profitable activities without the help of government intervention.

Gray and Shadbegian (1998) used Census data to study individual paper mills, and found evidence for several of the characteristics of abatement costs summarized above. For example, they found that abatement and productive investments tended to be scheduled together, which is evidence for harvesting. They also found, however, that plants with high abatement costs over their studied time period had significantly less productive investment, which is evidence that the regulation is crowding out private investment.

Other studies have come to mixed conclusions on this point. Some studies suggest that costs, if reported as expenditures, substantially underestimate regulatory burden. Joshi, Krishnan, and Lave (2001) used plant level data from steel mills to conclude, in that industry, that a $1 increase in environmental compliance costs is associated with $9 - $10, at the margin, in additional costs. These costs are in areas such as labor, materials, and energy, and arise primarily due to increased constraints introduced into the production process that are not captured in direct compliance cost measurements.

The Morgenstern, Pizer, and Shih (2001) study tested for both systematic under and overstatement, and did include a direct test of the Porter hypothesis, using plant level data from pulp and paper, plastics, petroleum, and steel. They found no evidence of understatement of costs, and some evidence of overstatement. The paper also found no empirical support for the claim that environmental regulation is overall cost saving.

These two papers used substantially similar PACE data from the U.S. Census Bureau to reach somewhat different results. This is due to two factors. First, Joshi et al estimate the marginal cost of new regulations, whereas Morgenstern et al estimate the average cost of regulations. Joshi et al do point out that the average total cost of environmental regulations is probably less than 10 times the average direct cost. It should be relatively easy to reduce emissions as controls are first introduced, but as stringency increases, the marginal cost of further reductions is likely non-linear and rising. They state their result may be more applicable to newly-introduced regulations that impose costs over and above existing regulatory requirements. Second, the two papers employ different modeling techniques that may contribute to their differing results. Briefly, Joshi et al use a "pooled model," that does not contain a term to measure unobservable plant level differences, while Morgenstern et al use a "fixed effects" model that is the same as the pooled model but does contain terms to measure plant level differences. Although they point out that both modeling choices have shortcomings, Morgenstern et al do include a discussion of the technical reasons for why they believe the fixed effects model is a more accurate description of the true relationship.

Trade and Competitiveness Implications

As regulation changes the incentives and constraints a firm faces, firms react to regulation in sometimes unpredictable ways. This is often a good thing; for example, regulations employing flexible, market-based instruments such as the Sulfur Dioxide trading regulation described above often allow firms to creatively achieve or exceed the regulatory goals of society at substantially lower cost than the agency assumed. Other times, however, the optimal firm response to regulation may carry a substantial hidden cost. This section discusses two of those potential costs: the possibility that regulations may disproportionately burden smaller firms, which often are important drivers of innovation and job growth; and the possibility that regulations may inspire firms to simply move their operations to areas of less regulation, which may limit or eliminate the intended benefit of the regulatory intervention. It is incumbent upon agencies to understand and consider these possibilities when designing regulations.

Large Versus Small Firms. Some studies conclude that regulatory burdens favor large firms relative to small firms. Since most new firms start as small firms, a regulatory burden favoring large firms can be considered a barrier to entry. Crain and Hopkins (2001) estimated that firms employing fewer than 20 employees face an annual regulatory burden per employee nearly 60 percent above that facing a firm with over 500 employees. Dean, Brown, and Stango (2000) estimate the effects of environmental regulations on the formation of small manufacturing establishments. By estimating the effect of size and environmental regulatory burden on new firm formation across manufacturing industries, they conclude that environmental regulation appears to be a barrier to entry for small manufacturing firms, while the regulation appears not to have deterred market entry by large manufacturing firms. They found this effect persistent across the study time period of 1977, 1982, and 1987.

Millimet (2003) also finds that increasing regulatory stringency may increase firm size, but only in a specific situation. This study measured the impact on firm size due to increasing state-level regulatory activity, and found that if firms are already experiencing relatively high industry-specific abatement costs, an increase in state level stringency is associated with an increase in firm size. The study also found, however, that the opposite is true in industries experiencing relatively low industry-specific abatement costs. The author hypothesizes that in the former case, an optimal reaction to increasing state stringency may be for firms to get larger in order to meet the standards of what they may perceive to be a permanent change. In the latter case, an optimal reaction for firms not already investing in much environmental abatement may be to use smaller establishments that may be able to avoid inspections during a perceived transitory increase in state stringency.

Plant Location Decisions. Much literature is dedicated to the "pollution haven" hypothesis, where industries in countries with less stringent regulation out-compete industries in countries with stringent regulation, therefore causing manufacturing to shift to low standard countries. Much of this literature also concentrates on factory location decisions within the United States. Among the first studies to explore this question was Walter (1982). A related concept is the "race to the bottom" hypothesis, where competition to lure and keep manufacturers affects environmental standards. Seminal

work in this area includes studies collected in Anderson and Blackhurst (1992) and Bhagwati and Hudec (1996). Almost all studies of this type concentrate on the question of environmental regulation; however, nothing in theory restricts this effect to environmental rules. Other imposed regulatory burdens on the manufacturing process will adversely affect firms in a similar way.

Studies within the United States have found that differing environmental stringency across areas affects firm investment and location decisions, though that finding is not universal. Becker and Henderson (2000) use county level air quality attainment status and plant-level panel data from 1963-1992, and find a substantial relocation of polluting industries from more to less polluted areas to avoid stricter regulation, a relative proliferation of small-scale enterprises (which enjoy less strict regulation in this case), and a substantial effect on the timing of new plant investments (polluted area plants start off significantly larger, with more up front investment). Greenstone (2002) also uses county level attainment status data for four different air pollutants and concludes that non-attainment (and therefore regulatory stringency) is associated with modest decreases in employment, investment, and production among manufacturing enterprises. McConnell and Schwab (1990) studied the location decisions of motor vehicle plants based on air pollution regulation. In their more refined measure of the degree to which counties were out of attainment, they found that firms were deterred from locating plants in the most polluted non-attainment areas. On the other hand, Levinson (1996a) examines the effect of differences in state environmental regulations on location choice, and finds no evidence that environmental regulations systematically affect location choices in most manufacturing industries. This study looked at a broad range of manufacturing industries; however, because it used state-level measures of activity, as opposed to county-level activity measures used in the other mentioned studies, this study may not capture the effect of regulatory stringency on location decisions. This may also be evidence that differences in regulatory stringency may only be a secondary factor affecting location decisions within a state.

The other major theme of this literature is the impact of differences in international regulatory regimes on trade and competitiveness. These studies depend on complicated trade flow models, which are well summarized in Van Beers and Van Den Bergh (1996), which focuses on environmental regulatory impact; and Brown, Deardorff, and Stern (1996), which concentrates on labor standards and other workplace regulation.

Jaffe et al. (1995) characterize the concerns well: if international regulatory differences lead to a decrease in net exports, this impact could manifest itself in several ways. In the short run, a reduction in net exports in manufacturing would raise the current account deficit, which would eventually require a decline in the value of the dollar to return toward balance in the long run. Under such an effect, imported goods would become more expensive, thus reducing U.S. living standards. Second, if industries most affected by regulation employ less flexible workers, those workers displaced may have an especially hard time finding new jobs at comparable wages. Third, a diminishing U.S. share of world capacity in particular industries, such as steel, petroleum refining, and autos, may endanger economic security. Finally, the rearrangement toward other

non-pollution intensive industries may create a broader set of social costs associated with a transitioning economy.

Most early empirical studies did not find that the relative stringency of environmental requirements gave rise to international pollution havens or had an impact on trade flows. Several reviews (Dean 1992, Jaffee et al 1995 and Levinson 1996b) have summarized literature on this issue. Dean (1992) concludes that the many empirical studies developed to test the hypothesis have failed to show any evidence in support of it. Levinson (1996b) comes to much the same conclusion, stating that "the literature surveyed is almost unanimous in its conclusion that environmental regulations have not affected interjurisdictional trade or the location decisions of manufacturers." Jaffee et al (1995) report pollution abatement and control expenditures as a percent of GDP for several OECD countries, and show that the U.S. is roughly comparable up to 1990.

Studies that have also come to this conclusion include the seminal work of Walter (1982), which looked at aggregate foreign investment flows and surveys of international firms. While a significant amount of production by pollution-intensive, multi-national firms occurred in developing countries, the study found little evidence that these investments were seriously influenced by environmental considerations. Xu (1999) uses a later time series accounting for almost 80% of world exports of environmentally sensitive goods from 1965-1995, and finds that the pattern of export performance for these goods did not undergo systematic changes between the 1960s and 1990s, a period when significantly more stringent environmental standards in most developed countries were introduced.

Some recent research, however, has begun to find a significant effect of regulation on trade and investment. Brunnermeier and Levinson (2004) summarize much of this recent research. This may be due to several factors. First, much of the early research used cross-section data from one time period; with this type of data it is difficult to control for unobserved influences on both regulation and production. This is in contrast to most of the literature that found an impact within the United States using panel data from multiple years. For example, a country could have an unobserved comparative advantage in the production of a pollution intensive good, which causes it to simultaneously export that good, generate much pollution, and impose strict pollution regulations.

Second, just as regulatory stringency can impact trade, trade can impact regulatory stringency, which confounds the relationship in simple models. Papers controlling for both of these confounding factors include Copeland and Taylor (2003), Ederington and Minier (2003), and Ederington, Levinson, and Minier (2003). All of these studies found a positive relationship between abatement costs and net imports within specific industries; in other words, as abatement costs increased in an industry, so did net imports, which lends empirical support to the notion that regulatory stringency can influence trade flows.

With a few exceptions, these reviews generally cover the period before many large regulations covered in Chapter I became effective. There are also regulatory-reform efforts underway in the European Union that are designed to improve the competitiveness of European industry. More research is needed to further elucidate how the changing US and foreign regulatory regimes are impacting trade and production.

B. Regulatory Reform Recommendations

In the Draft Report, OMB requested nominations of specific regulations, guidance documents or paperwork requirements that, if reformed, would result in substantive reductions in regulatory burden and result in true savings by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty and increasing flexibility. OMB expressed particular interest in reforms that address burdens on small and medium-sized manufacturers. Commenters, in developing nominations, were asked to consider (1) whether a benefit-cost case can be made for the reform, (2) whether agencies have the statutory authority to implement the suggested reform, (3) whether the reform gives due consideration to fair and open trade policy objectives, and (4) whether the rule or program is important. The reforms may include modifying, extending or rescinding rules, guidance documents, or paperwork requirements. Commenters were provided 90 days, until May 20, 2004, to prepare their nominations and submit them electronically to OMB. We are pleased that 41 commenters have submitted 189 regulatory reform nominations relevant to the U.S. manufacturing sector. In this final Report, OMB has organized and summarized these 189 reform nominations (see Table 8)

Upon release of this blueprint, the regulatory reform process will proceed as follows. First, federal agencies are expected to review the merits of each of the 189 reform nominations and prepare a response for OMB by January 24, 2005. The response should include a determination as to whether reform action is appropriate and, if so, a proposed time line for action and a plan for public participation. After agencies have performed their evaluations, OMB will work with the agencies to identify the Administration's regulatory reform priorities, which we will announce in February, 2005. OMB has also asked the Office of Advocacy in the Small Business Administration to review the reform nominations and identify for agencies those that it thought offered the potential to reduce unjustified regulatory burdens on small manufacturers. Agencies should utilize Advocacy's expertise and assistance with their review of these nominations. OMB has also asked the Department of Commerce's Office of the Assistant Secretary for Manufacturing and Services to review and evaluate these nominations.

Table 8 summarizes the 189 reform nominations, sorted alphabetically by Agency. Each summary includes a title of the reform, a list of the commenter or commenters who proposed the nomination, a short summary paragraph, and a reference number. Readers interested in learning more about one or more of the items on the list should consult OMB's web site at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html, where each of the comments is available for review.

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
All	Small Business Liaisons	National Association of Manufacturers (9)	Agency Small Business Liaisons should regularly inform small businesses of reporting or regulatory obligations.	1
All	Privatize Government Regulatory Activities	Deere & Company (1)	Competition through the private market can lower costs in most activities. This should apply to the development and enforcement of regulations as well.	2
CEQ	National Environmental Policy Act Implementation Process	National Association of Manufacturers (9); U.S. Chamber of Commerce (19)	The NEPA process has become entangled with State, local, and private interests, which in turn has created confusion for manufacturers. Lack of federal staffing and funding has caused delays in the NEPA implementation process. A review of NEPA is needed because it is adversely affecting site permitting, project development, and industrial activity.	3
Commerce/ NOAA	Coastal Zone Management Act (CZMA) Federal Consistency Regulations	National Association of Manufacturers (9)	Under the CZMA, a State has an opportunity to review Federal permitting actions to ensure consistency with its Federally-approved management plan. These reviews however have become mired in controversy. DOC should go further than its recent proposed rule and significantly reduce the time required for Federal and State review and eliminate the open-ended information and analysis requirements that are used to delay approval indefinitely. Process modifications are needed to meet the goals of Executive Orders 13211 and 13212 regarding expediting energy project permitting and reducing burdens on energy supplies.	4
CPSC	Consumer Complaints	Gas Appliance Manufacturers Association (21)	CPSC is not required to evaluate consumer complaints before making them public. Without proper evaluation, such information could negatively and unfairly impact sales. Commenter supports third-party substantiation of claims before complaint information is released.	5

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
DHS/CBP	NAFTA Certificates of Origin	Motor & Equipment Manufacturers Association (41); Recreational Vehicle Industry Association (25)	Importers must possess these certificates to prove that goods qualify as originating under NAFTA and thus qualify for preferential tariff treatment. The paperwork associated with these certificates is time consuming for automotive parts companies. Moreover, the detailed information required creates difficulties among suppliers and vehicle manufacturers, given its sensitivity. Commenter recommends simplification of the certificate.	6
DHS/USCG	Maritime Security	American Shipbuilding Association (44)	Shipyards that are subject to more stringent DoD security plan requirements should be exempted from redundant, conflicting, and burdensome USCG maritime security rules on vessels and facilities.	7
DOE	Appliance Efficiency Test Procedures and Compliance Requirements	Gas Appliance Manufacturers Association (21)	DOE is lagging significantly behind its statutory and published schedules for the issuance of test procedures manufacturers must use to evaluate their products for regulatory compliance. This leads to regulatory uncertainty and makes design and planning decisions difficult. DOE must meet its statutory deadlines and published schedules for these requirements.	8
DOE & FTC	Reporting Requirements for Water Usage	Delta Faucet Company (6)	Manufacturers demonstrate compliance with Federal, State, and local regulations and codes governing water usage by listing their products with third-party certification bodies. The Federal government should accept these third-party certifications in lieu of direct reporting.	9
DOE, EPA & FTC	Eliminate Duplicative or Superfluous Energy Labels	Gas Appliance Manufacturers Association (21)	The EPA and DOE Energy Star programs and the FTC EnergyGuide regulations create duplicative labels for certain appliance categories. The resulting labels are costly to manufacturers without producing a clear benefit to consumers, who may actually be confused by multiple labels. The relevant agencies should work with the industry to streamline duplicative energy labels.	10
DOT/FAA	Air Carrier Supplier Rule	National Association of Manufacturers (9)	FAA currently requires that employees of any supplier to an air carrier must have a drug and alcohol testing program. The commenter notes that this rule puts U.S. companies at a disadvantage when supplying items to air carriers, since the standard is not applied to foreign counterparts.	11

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
DOT/FMCSA	Motor Vehicle Brakes	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	Outdated "brake" rules need to be amended to permit the limited lawful use of "surge brakes" on small-to-medium sized trailer and tow-vehicle combinations since they meet the federal regulatory requirements for stopping distance and holding on a 20 percent grade and have a record of safety. Trailers with surge brakes can be used by consumers but not for commercial uses (such as where a marina owner would transport a boat for a boat owner for repair). The mandated electric brakes are not workable in conditions where the trailer would be submerged in water such as in a boat trailer.	12
DOT/FMCSA	Hazardous Materials Rules	Gas Appliance Manufacturers Association (21)	Regulatory protections against transportation security risks should be tailored appropriately, particularly the requirement for comprehensive security plans for quantities of hazmat requiring placards. FMCSA should review transportation security regulations to determine their costs and benefits. Manufacturers bear the cost of the labor and administration to comply with procedures such as personnel screening and training, facility access, and trip security.	13
DOT/FMCSA	Hours of Service	SBA Office of Advocacy (39)	Current rules set maximum on-duty hours per 24-hour period and per work week for commercial truck drivers; also set minimum number of hours between days of work and between weeks. Drivers may only work 11 hours before taking a 10 hour break; the rule allows one day per week on which drivers may be working up to 16 hours. Drivers may work up to 70 hours within an eight-day period but must take a break of at least 34 hours before beginning a new eight-day period. For businesses that deliver products locally, redefining on-duty hours to allow deliveries to be made beyond the 11-hour maximum will save costs for businesses whose primary business is not trucking.	14

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
DOT/NHTSA	Early Warning Reporting	National Association of Manufacturers (9)	NHTSA collects information from manufacturers of motor vehicles and motor vehicle equipment that would give NHTSA "early warning" of safety-related defects. The early warning information includes defect-related claims, notices of death and serious injury, property damage data, consumer complaints, and information on incidents involving fatalities or serious injuries from possible defects in the U.S. or in identical or similar vehicles or equipment in foreign countries. NHTSA should increase the number of units manufactured for coverage from 500 to a more significant amount, such as 5,000, and it should review the applicability of the rule to off-road vehicles.	15
DOT/NHTSA	Lighting & Reflective Devices	National Association of Manufacturers (9); Motor & Equipment Manufacturers Association (41)	This rule, which sets forth minimum safety standards for automotive lighting equipment, has been amended frequently during the past 30 years and is now difficult to understand and comply with. The standard should be revised to make it more clear and concise, which will decrease confusion about NHTSA's enforcement of the imported non-compliance product clause.	16
DOT/NHTSA	Airbag Sensors	National Association of Manufacturers (9)	New amendments to crash performance standards require equipping front seats with extra sensors, which react to an occupant's weight and disable the airbag if it is below a certain threshold. These sensors are costly. Increased usage of smart airbags (which deploy according to crash severity) would reduce sensor costs.	17
DOT/NHTSA	Occupant Ejection Safety Standard	Public Citizen (2)	Address window glazing, side curtain and side impact airbags and increase strength of door locks and latches.	18
DOT/NHTSA	Regulation of 15-Passenger Vans	Public Citizen (2)	Subject vans to light truck safety standards and the New Car Assessment Program (NCAP), which provides vehicle safety information, primarily front and side crash test results and rollover ratings.	19
DOT/NHTSA	Rollover Crashworthiness Safety Standard	Public Citizen (2)	Include dynamic roof strength standard that requires improved seat structure and safety belt design.	20

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
DOT/NHTSA	Rollover Prevention Safety Standard	Public Citizen (2)	Increase vehicle resistance to rollover.	21
DOT/NHTSA	Vehicle Compatibility Standard	Public Citizen (2)	Include standard metric rating to evaluate vehicle mismatch; establish compatible bumper heights; mitigate harm done by "aggressive" design.	22
DOT/NHTSA	Early Warning Reporting/Trailers	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	NHTSA collects information from manufacturers of motor vehicles and motor vehicle equipment that would give NHTSA "early warning" of safety-related defects. The early warning information includes defect-related claims, notices of death and serious injury, property damage data, consumer complaints, and information on incidents involving fatalities or serious injuries from possible defects in the U.S. or in identical or similar vehicles or equipment in foreign countries. Commenter believes the 500-unit threshold for exempting small entities provides no meaningful exemption, and recommends that NHTSA re-evaluate EWR burdens for manufacturers of small-to-medium trailers under 26,000 lbs.	23
DOT/RSPA	Hazardous Materials Rules	DGAC (22)	RSPA currently manages a large regulatory program for the safe transportation of hazardous materials. The commenter would like regulatory changes to the hazardous materials regulations to be issued in a more-timely manner. The commenter notes that OMB's significance determination slows issuance of these rules.	24
DOT/RSPA	Hazardous Materials Rules (HM-223)	HM-223 Coalition (13)	Historically, DOT has regulated the loading, unloading and temporary storage of hazardous materials. However, DOT recently reduced their jurisdiction in this area by publishing a final rule in October 2003 (effective in 2004) that excluded unloading and temporary storage unless performed in the presence of or by carrier personnel. The commenter argues that this regulatory void will be filled by more onerous EPA and OSHA regulations and possibly other state and local regulations. The commenter recommends that OMB intervene and prevent this regulatory mistake.	25

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EEOC	Employer Information Report (EEO-1)	U.S. Chamber of Commerce (19)	Employers with greater than 100 employees are required to file an employer information report (EEO-1) annually regarding employees and their demographics. The commenter seeks to ensure that the form minimizes burden, and asks that reporting on occupational categories be aggregated to the extent possible.	26
EPA	"Whole Effluent Toxicity" (WET) Methods	Inter-Industry Analytic Group (14); American Public Power Association (11)	WET test methods use living organisms to test water samples for toxicity. Since there is inherent variability in using living organisms for testing, appropriate precautions should be taken when using WET methods for regulatory decisions, such as whether a wastewater discharge has the "reasonable potential" to cause or contribute to an exceedance of a water quality standard. EPA needs to adopt rigorous and clear standards for when and how WET methods should be used in regulatory contexts.	27
EPA	AP-42: "Coke Production" Emission Factors	American Coke and Coal Chemicals Institute (3)	An improved process is needed for updating Section 12.2 of AP-42 (Coke Production) in collaboration with the industry. This guidance document contains critical emission factors, has been under revision for nearly 10 years, and is posted in draft form on an agency web site. However, the agency has no realistic plan for finalization. The updating process should include industry test data and greater stakeholder involvement to resolve issues.	28
EPA	AP-42: Haul Road Vehicle Emissions Information	American Iron and Steel Institute (34)	The agency's AP-42 document contains an emissions factor for haul road vehicles that over-predicts real-world emissions, does not account for vehicle size, and does not include a reasonable precipitation allowance for dust suppression. The document should be revised to take these issues into account.	29

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	AP-42: Science and Site-Specific Conditions	National Association of Manufacturers (9)	The agency's AP-42 document contains emission factor information that is not sufficient. AP-42 should be improved by stating more clearly that site-specific data are preferable to category-wide averages for use in applicability and permitting determinations, using updated test results, and assisting state and local regulatory agencies in interpreting AP-42 data consistently and accurately.	30
EPA	CAP 2000	Alliance of Automobile Manufacturers (23)	The information required for CAP 2000 application should be further streamlined to move to a real self-certification process and allow in-use experience and results to demonstrate the reliability of a manufacturer's processes. In addition, the interim Part 1 and Part 2 submissions should be eliminated to reduce burden.	31
EPA	Chemical Inventory Update Rule	National Paint and Coatings Association (18)	The agency's 2003 final inventory update rule will affect manufacturers and downstream users of chemicals beginning in calendar year 2005. This rule will impose substantial additional paperwork on chemical manufacturers and users. However, the agency has yet to identify how the new data will be used to advance the agency's mission of environmental protection. The agency has also not quantified the effects of the new rule on downstream users of chemicals. The agency should reconsider the costs and benefits of this final rule.	32
EPA	Clean Up Standards for PCBs	Motor and Equipment Manufacturers Association (41)	Clean up of PCBs at member companies have imposed substantial costs without consideration of the actual risk posed by the PCB. EPA should allow risk-based screening of sites to assure that clean up is necessary.	33
EPA	Common Company Identification Number in EPA Databases	Deere & Company (1)	Different EPA programs, each of which deals with different environmental media (air, water, and so forth), may use a different identification number for the same manufacturing facility/company. Confusion about the identity of facilities would be reduced if a common identification number were used.	34

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	ECHO Website	American Iron and Steel Institute (34)	The agency's ECHO web site provides inaccurate information to the public about the environmental performance of facilities. The agency should correct current errors and establish a process for updating the site on a timely basis.	35
EPA	Electronic Formats for Agency Forms	National Association of Manufacturers (9)	Some forms used by manufacturers are being made available in only one format (e.g., Word Perfect) while many manufacturers use a different format (e.g., Microsoft Word). Making forms available in multiple electronic formats would reduce conversion burdens on manufacturers.	36
EPA	Exempt the Utility Industry from Restrictions on the Storage of PCB-Containing Equipment	Utility Solid Waste Activities Group (7)	EPA should rescind its storage for re-use rule, which imposes recordkeeping requirements and disposal obligations on entities storing electrical equipment for re-use. Four years ago a federal court remanded this rule to EPA for further consideration because the agency had not justified its application to the utility sector. The lack of an exemption is imposing paperwork and other burdens on the utility industry without corresponding environmental benefit. The agency should grant the suggested exemption in a prompt rulemaking.	37
EPA	Expand the Comparable Fuels Exclusion (CFE) under the Resource Conservation and Recovery Act	National Association of Manufacturers (9); American Chemistry Council (31)	The CFE excludes from hazardous waste regulation those wastes that can be and are burned as fuels, and that are not more hazardous than the fossil fuels that facilities would otherwise use. The agency should enhance this exclusion by reducing the analytical requirements, including enactment of a flexible demonstration for non-halogenated organic constituents that can be shown to be destroyed in a well-operated, efficient combustion system.	38
EPA	Export Notification Requirements	National Association of Manufacturers (9); American Chemistry Council (31)	Companies are required to notify EPA when exporting substances or products that contain chemicals listed on the Export Notification 12(b) list under the Toxic Substances Control Act. Since current rules do not have a low-level cutoff, many minor substances or product ingredients trigger large amounts of paperwork. To reduce this burden, a low-level cutoff should be added to 12(b).	39

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	General Permits	Deere & Company (1)	The use of General Permits should be expanded (e.g., general permit for discharges associated with boiler water blowdown and general air permit for smaller gas-fired boilers with provisions to ensure that the doctrine of prevention of significant deterioration of air quality is avoided). The use of general permits could save time and money for both the agency and the regulated companies.	40
EPA	Groundwater Cleanup Goals	Alliance of Automobile Manufacturers (23)	The agency has a longstanding and unrealistic goal of cleaning up all groundwater to its highest quality use (usually drinking water), without regard to risk, the likely use of the groundwater, or the availability of effective cleanup technology. The agency needs to establish an open, peer-reviewed, weight-of-evidence approach to establishing acceptable risks and cleanup goals for groundwater under the Corrective Action program.	41
EPA	Hazardous Waste Rules Should Be Amended to Encourage Recycling	National Association of Manufacturers (9); American Petroleum Institute (12); Synthetic Organic Chemical Manufacturers Association (17); National Paint and Coatings Association (18); U.S. Chamber of Commerce (19); Alliance of Automobile Manufacturers (23); Specialty Graphic Imaging Association (27); American Chemistry Council (31); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	Under current rules under the Resource Conservation and Recovery Act, certain waste streams are regulated as hazardous wastes, even when they are being recycled. The agency should clarify that a material that is being sent for recycling is not subject to regulation as a hazardous waste because it is not being "discarded". This reform would increase recycling rates while reducing the costs of managing hazardous wastes.	42

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Lead Reporting Burdens Under the Toxic Release Inventory Program	National Federal of Independent Business (8); National Association of Manufacturers (9); Synthetic Organic Chemical Manufacturers Association (17); National Paint and Coatings Association (18); The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); The Copper and Brass Fabricators Council (45)	The 2001 rule adding lead and lead compounds to the list of persistent, bioaccumulative and toxic chemicals caused a lowering in the annual reporting threshold for lead from 10,000 to 100 pounds of use per year. The result has been that thousands of small businesses must file Form R to the federal government, even though their emissions of lead into the environment are minor or even zero. EPA should reexamine the justification for lowering the reporting threshold and the 2001 rule should be amended to reduce the substantial paperwork burden on small lead emitters.	43
EPA	MACT Standard for Chromium Emissions	The Policy Group (28)	In 2002 the agency proposed revisions to the MACT standard governing chromium emissions from metal finishing operations. The proposal provides more flexibility for new sources, more flexibility in the legal treatment of technical violations, and more compliance flexibility (e.g., use of other technologies). The proposal should be finalized to allow facilities to take advantage of these provisions.	44
EPA	PCB Remediation Wastes	Utility Solid Waste Activities Group (7)	The agency should clarify that all PCB remediation waste containing small amounts of PCBs can be disposed, on its as-found concentration, in a municipal solid waste landfill. This clarification will reduce the costs of disposal without causing environmental harm.	45
EPA	Permit Use of New Technology to Monitor Leaks of Volatile Air Pollutants	National Association of Manufacturers (9); U.S. Chamber of Commerce (19)	Current rules for monitoring leaks and fugitive emissions, specified in Method 21, require an operator to visit and screen each regulated component to determine if it is leaking. This process is labor intensive, expensive, and not particularly accurate. Method 21 should be replaced with a more technologically-advanced approach to emissions monitoring such as the use of optical imaging devices.	46

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Pretreatment Streamlining Rule Under the Clean Water Act	The Policy Group (28); SBA Office of Advocacy (39); Motor and Equipment Manufacturers Association (41)	In 1999 the agency proposed a rule to streamline pretreatment requirements to remove unnecessary burdens on POTWs, industry and agencies. The proposal provides flexibility to POTWs to set either mass-based or concentration-based limits, exempts Categorical Industrial Users if their discharges are below thresholds, and revises noncompliance criteria for extenuating circumstances that cause delay in paperwork filings. This rule should be finalized because it reduces burdens on POTWs without negatively impacting the environment.	47
EPA	Provide More Flexibility in the Management of Wastewater Treatment Sludge to Encourage Recycling	The Policy Group (28); IPC - The Association Connecting Electronics Industries (32); SBA Office of Advocacy (39)	Under the Resource Conservation and Recovery Act, metal precipitate sludge is considered an F006 listed hazardous waste when a manufacturing facility ships it off site for metals recovery. This determination discourages reuse, recycling and reclamation by increasing the cost of recycling these valuable materials. The agency should exempt recycled electroplating sludge from hazardous waste management requirements to reduce management costs while protecting the environment.	48
EPA	Regulation of Air Toxics from Area Sources	National Paint and Coatings Association (18)	The agency is moving forward on a plan to regulate smaller, diffuse ("area") sources of air toxics, many of which are small businesses. In order to make sure this plan proceeds in a cost-effective manner, the agency should convene SBA advisory panels to ensure any subsequent rules are technically sound and respond to the concerns of the small business community.	49
EPA	Regulation of Air Toxics from Area Sources	National Paint and Coatings Association (18); Specialty Graphic Imaging Association (27); SBA Office of Advocacy (39)	EPA currently adds new industries to its list of categories to be regulated under air toxics standards, which will have a significant impact on costs imposed on manufacturers. EPA should amend its list only after providing public notice and an opportunity for comment.	50

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Remove Regulatory Disincentive to Recycle Spent Hydrotreating and Hydrorefining Catalysts	American Petroleum Institute (12)	A conditional exclusion from hazardous-waste rules should be provided for the recycling of spent hydrotreating and hydrorefining catalysts. By encouraging recycling, this exclusion would improve environmental quality while reducing the costs of managing wastes.	51
EPA	Reporting and Paperwork Burden in the Toxic Release Inventory Program	Deere & Company (1); National Association of Manufacturers (9); American Petroleum Institute (12); National Small Business Association (24); Specialty Graphic Imaging Association (27); Society of Glass and Ceramic Decorators (33); SBA Office of Advocacy (39)	The required TRI database contains thousands of reports that show little or no release of toxic chemicals, an indication that expensive and time-consuming reports are required with little environmental benefit. Burden-reduction reforms are needed such as raising the reporting thresholds on the amount of material that can be used without triggering a report.	52
EPA	Small Business Relief from MACT Rule for Brick Manufacturing	SBA Office of Advocacy (39)	This rule requires maximum achievable control technology to reduce hydrogen chloride and particles from brick manufacturing plants. The rule impacts about 80 small businesses in an industry of 100 firms. The production-based threshold for covering plants should be replaced or supplemented by a low-risk exemption as was used in the plywood and industrial boiler MACTs.	53
EPA	Spill Prevention Control and Countermeasures (SPCC) Rule	American Furniture Manufacturers Association (35)	This rule is extremely costly for manufacturers. The rule should be modified to allow tank owners and operators the flexibility to periodically inspect and repair tanks on their own without reliance on outside inspections. EPA should also extend the time period that a company can store spent solvent on-site in order to encourage recycling.	54
EPA	Spill Prevention Control and Countermeasures (SPCC) Rule	National Paint and Coatings Association (18)	The 2002 SPCC rule requires expensive and burdensome integrity testing on small storage tanks. EPA should allow a professional engineer to certify that certain systems are "environmentally equivalent" to the mandatory integrity testing.	55

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Spill Prevention Control and Countermeasures (SPCC) Rule	SBA Office of Advocacy (39), Copper and Brass Fabricators Council (45)	The rule requires facilities that store oil above certain threshold levels and that are located near waterways to prepare and implement spill prevention, control, and countermeasure plans. The plans must be certified by a professional engineer. EPA should eliminate the applicability of the professional engineer requirements for small facilities, reduce the stringency of some requirements, especially for smaller tanks, and more narrowly define whether a spill would have the possibility of "reaching a waterway".	56
EPA	Spill Prevention Control and Countermeasures (SPCC) Rule	Synthetic Organic Chemical Manufacturers Association (17)	EPA's 2002 rulemaking has numerous problems that are causing confusion and unnecessarily imposing additional costs on regulated entities. In addition to additional guidance and more time to comply, commenters suggest a number of changes to the rule that they believe would provide additional flexibility without compromising environmental protection, such as accommodating advanced optical inspection technology, allowing owners to inspect and repair tanks without requiring outside engineers, and providing more regulatory safe harbors.	57
EPA	Spill Prevention Control and Countermeasures (SPCC) Rule	Utility Solid Waste Activities Group (7); National Association of Manufacturers (9); General Electronic Company (26); American Public Power Association (42)	The agency's current oil spill and response regulations currently do not have a separate section for oil-filled electrical equipment, even though such equipment is widely used with low risk of environmental harm. The result is costly and burdensome requirements for the utility sector with little environmental benefit.	58
EPA	Water Permit Rules	National Association of Manufacturers (9); American Chemistry Council (31)	The current rule sets mass-based effluent limits into water by multiplying average process wastewater flow by the regulated concentrations. If a company implements a water conservation project, it will be penalized when the permit is renewed. Permittees should be permitted to retain mass limits when permits are renewed if process wastewater flows have been reduced for purposes of water conservation. If process wastewater flows are decreased for other reasons, the mass-based emission limits can be adjusted per the current rule.	59

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	"Permit-By-Rule" (PBR)	Deere & Company (1)	Under PBR, the applicant would provide notice and comment to the regulator that it intends to be covered by PBR and would certify that it meets the relevant criteria. This approach would save both time and money for the agency and regulatory companies.	60
EPA	Annual Reporting of Pesticide Information	National Association of Manufacturers (9)	Current pesticide reporting forms impose extraneous administrative costs because they require reporting of how many pesticide devices and filters are produced and they define pesticide devices in an overly broad manner. The agency should reconsider the estimates of burden and whether such information is needed.	61
EPA	Attainment of Ozone and Fine-Particle Standards	National Association of Manufacturers (9)	Many states will face non-attainment challenges under the new primary air quality standards for ozone and fine particles and will have to adopt additional controls on many of the same sources and pollutants that have already been heavily regulated. However, the attainment deadlines for the two pollutants have not been harmonized, and the attainment deadlines have not been set to provide states the maximum beneficial impact of the cleaner engines, fuels and power plants resulting from recent federal rules. The attainment deadlines for ozone and fine particles should be reset in a realistic and harmonized manner.	62
EPA	Cap Distillation Index on Fuels	Alliance of Automobile Manufacturers (23)	EPA should act on the Alliance Petition for a cap of 1200 on the distillation index.	63
EPA	Clean Fuel Fleet Program.	Alliance of Automobile Manufacturers (23)	The Clean Fuel Fleet Program requires significant additional emissions testing even though its standards are less strict than the current Tier 2 emission standards. Therefore, the requirements of this program are obsolete.	64
EPA	Clear Skies Initiative	National Association of Manufacturers (9)	The Clear Skies Initiative should continue to pursue its vision of eventually replacing existing patchwork of confusing and conflicting rules.	65

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Compliance Certificates	American Furniture Manufacturers Association (35)	EPA should consolidate semi-annual certifications concerning Title V air permits, limits on certain volatile organic compound (VOC) emissions, and requirements under wood furniture MACT into an annual certification. Modify the method of calculating VOCs to allow for inherent business cycles.	66
EPA	Controls on Inorganic Mercury Discharges Into Water as Method to Reduce Organic Mercury in Fish	National Association of Manufacturers (9); Motor and Equipment Manufacturers Association (41)	Under the Great Lakes Initiative, EPA is attempting to reduce levels of organic mercury in fish by regulating the amount of inorganic mercury discharges into water bodies. Substantial discharge-reduction efforts by industry and POTWs over several years have achieved no demonstrable benefit in reducing levels of mercury in fish. The agency should re-evaluate its policy, since there may be no constant relationship between inorganic mercury in the water column and organic mercury in fish.	67
EPA	Cooling Water Intake Structures, Phase III	American Public Power Association (42)	EPA is developing a rule to reduce impingement and entrainment of aquatic organisms at the cooling water intake structures for manufacturing facilities and smaller electric utility generating plants (<50 mdg). These standards are unlikely to yield net benefits and no further Federal action is necessary with respect to these facilities.	68
EPA	Detergents in Gasoline: 211(1) Rule	Alliance of Automobile Manufacturers (23)	The 1995 211(1) rule on detergents in gasoline was based on 1986 vehicle technology and need to be reconsidered to reflect current and near-term vehicle technology. A modernized rule may need to be mo re stringent to assure that fuel systems are operating for the full vehicle life.	69
EPA	Develop All Rules in Conjunction with Business and Industry Coalitions	Deere & Company (1)	Developing rules in collaboration with the affected businesses and industry associations reduces the risk of costly legal challenges and negotiations, with savings for both the agency and the regulated community.	70

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Dry Cooling Tower Rule	National Association of Manufacturers (9)	The current rule requires utilities to build dry cooling towers in an effort to reduce the amount of water needed for cooling. The water conservation rationale for this rule may make sense in more arid regions, such as the Southwest, but may make less sense in water abundant areas, such as the Great Lakes. This rule should be reviewed to determine whether requirements should vary for different ecological regions.	71
EPA	Durability Rule	Alliance of Automobile Manufacturers (23)	EPA's proposed requirements in the Durability NPRM are overly prescriptive and will inhibit manufacturers' ability to use good engineering judgment. Manufacturers should be allowed to carryover already-approved durability bench processes used in certify-test/durability groups with aged components.	72
EPA	Durability Rule	Alliance of Automobile Manufacturers (23)	EPA should not finalize its Durability NPRM with an effective date earlier than the 2008 model year because development of the 2007 model year is already under way.	73
EPA	Duration of Air and Water Permits	Deere & Company (1)	EPA should expand the duration of environmental permits. Extending the duration of environmental permits would reduce the expenditure of resources by both the regulator and the regulated companies.	74
EPA	Electronic Filing by Manufacturing Firms	American Furniture Manufacturers Association (35)	The agency, in collaboration with state regulators who administer federal air quality rules, should develop and implement user-friendly, multi-media electronic filing systems as a means of reducing paperwork burden on manufacturers. Encouraging commonality of forms and electronic filing procedures, coupled with use of compatible software between state and federal regulators, is essential to burden reduction.	75
EPA	Eliminate the Requirement that Additional Monitoring Must be Reported to the Regulator	Deere & Company (1)	Analytic data are useful for process control and detecting pending upset conditions that could increase emissions. However, there is currently a requirement in the General Conditions section of many permits that says if a facility does additional monitoring, beyond what is required by law, the data must be reported to the agency. This requirement should be removed because it has a chilling effect on the incentive to generate additional monitoring data.	76

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	EPA and State Oversight	Deere & Company (1)	Dual EPA and state oversight of manufacturing facilities leads to duplication of effort, second guessing, and slowness in final decisions. One agency, rather than two, should review permits and make regulatory decisions.	77
EPA	Establish Federal Uniformity in How Best Available Control Technology is Defined	American Iron and Steel Institute (34)	When implementing the federal environmental requirements, states are inconsistent in how they define Best Available Control Technology, with varying numbers and sometimes no caps at all. A uniform, federal requirement should be established that specifies numbers in terms of specific amounts of pollution removed.	78
EPA	Estrogenic Effects on Human Health Impacts	People for the Ethical Treatment of Animals (36)	Without statutory authority, the agency has broadened its estrogenic testing program under the Food Quality and Protection Act to endocrine effects on wildlife as well as humans. The screening program should be restricted to validated tests indicating effects that may result in humans, as required by law.	79
EPA	Harmonize Federal and State Regulations	Deere & Company (1)	Dual sets of state and federal rules lead to confusion and increased risk of non-compliance. Harmonization around federal rules would reduce burden on facilities.	80
EPA	HPV Program: Test Validation Standards	People for the Ethical Treatment of Animals (36)	The HPV program uses the Screening Information Data Set (SIDS) endpoints established by the OECD. A number of the SIDS endpoints entail animal-based testing protocols that have never been validated. The agency should apply the same validation standards to *in vivo* testing assays as it applies to *in vitro* assays.	81
EPA	Include Animal Protection Community on EPA FACA Committees	People for the Ethical Treatment of Animals (36)	In order to ensure that agency FACA committees are balanced, as required by law, the agency should include PETA on relevant as a representative of the animal protection community. A concrete example where this needs to be fixed is the National Pollution Prevention and Toxics Advisory Committee.	82

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Leak-Detection and Repair Regulatory Programs	National Association of Manufacturers (9)	The same manufacturing facility often faces multiple leak-detection and repair programs under different EPA rules. The paperwork associated with these programs is burdensome. EPA should amend existing rules so that only one leak-detection and repair program is required for any given plant.	83
EPA	Maximum Achievable Control Technology (MACT) Rules of Pharmaceutical Industry	National Association of Manufacturers (9)	Confusion exists as to whether a condenser is part of the manufacturing process or part of an air pollution control system. Current MACT rules are interpreted differently, even by EPA enforcement officers. The result is more administrative costs from confusing recordkeeping and reporting. The condenser should be interpreted as part of the manufacturing process because it is integrated into the process of making pharmaceuticals.	84
EPA	Mercury Rulemaking	U.S. Chamber of Commerce (19)	Before moving forward to finalize the proposal to regulate mercury emissions from power plants, the agency should immediately address a potential conflict issue regarding a former senior official at the agency, update its 2000 determination based on updated mercury science, and revise its proposal to fully account for the reductions in mercury emissions that will accrue as a co-benefit from regulation and use of nationwide emission trading.	85
EPA	Method of Detection Limit/Minimum Level (MDL/ML) Procedure under the Clean Water Act	National Association of Manufacturers (9); Inter-Industry Analytic Group (14); Alliance of Automobile Manufacturers (23)	The agency's MDL/ML procedure used for establishing low-level detection of chemical constituents results in a high rate of false positives. When used for compliance purposes, this data may inaccurately characterize a discharger's effluent as being non-compliant. Although the agency's Technical Support document confirms that the MDL/ML approach is unsuitable for compliance determinations, it appears this approach is being used for compliance and may continue to be used for compliance. This practice should halt.	86

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Operating Permits Under the Clean Air Act	National Association of Manufacturers (9)	All major and some minor stationary sources must file for operating permits under Title V of the Clean Air Act. The growing number of requirements under Title V, coupled with the growth of state permit programs, has created confusion and additional burden. The Title V permitting process should be reviewed and amended to clarify language, make permit language more concise, and reduce costs to firms seeking permits.	87
EPA	Potential to Emit (PTE) Test	Deere & Company (1); Motor and Equipment Manufacturers Association (41)	Use of the PTE test in implementing the Clean Air Act treats sources with real-world emissions below the statutory threshold as "major sources" subject to the full extent of major source regulations. EPA should eliminate the “potential to emit” test because it does not reflect real world emissions.	88
EPA	Preemption Exemptions for States-Formulation and Labeling Requirements	Motor and Equipment Manufacturers Association (41)	The Federal government has given preemption exemption from environmental requirements. This has allowed States to adopt varying label requirements for consumer products, utilizing different formulations and standards, and thus placing unnecessary costs on the manufacture of consumer products.	89
EPA	Prohibit Use of Mercury in Automobile Manufacturing	American Iron and Steel Institute (34)	The agency should move to prohibit the use of mercury in automobile manufacturing to minimize environmental impact of mercury to facilitate recycling.	90
EPA	Prohibit Use of MMT unleaded gasoline	Alliance of Automobile Manufacturers (23)	The use of the fuel additive MMT should be prohibited because it adversely affects the performance of vehicle emission control systems.	91
EPA	Raise the Inspection Frequency from Weekly to Monthly for Selected RCRA Facilities	Deere & Company (1)	EPA should reduce the frequency of inspections of RCRA large quantity generator accumulation areas. The risk to the environment from a release from a well-engineered Large Quantity Generator Accumulation Area is less than previously thought. Thus, burden reduction could be achieved under the Resource Conservation and Recovery Act if the inspection frequency for these facilities was reduced from weekly to monthly.	92

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Regulation of Fuels Should Be Modernized	Alliance of Automobile Manufacturers (23)	The oxygenated fuel requirement, coupled with the proliferation of boutique fuels, is contributing to volatility in the supply and price of gasoline. Yet the emissions benefits of oxygenates need to be reconsidered in light of modern vehicle emissions controls. EPA should issue a national fuel specification. This would relieve the supply issues associated with these "boutique" fuels and promote cost effective emissions reductions.	93
EPA	Replace "Command-and-Control" Rules with Pollution Prevention	Deere & Company (1)	Current command-and-control regulations should be substituted with regulatory incentives for companies to adopt formal pollution prevention programs. The result will be a more efficient use of chemicals by industry and cost savings for the regulated community.	94
EPA	Replace F-Listing of Hazardous Wastes with Analytic Testing to Determine Hazardousness	Deere & Company (1)	The F-Listing scheme under Resource Conservation and Recovery Act establishes a presumption of hazard for the covered wastes. EPA should replace the F-List with a hazard determination based on analytic testing and analysis. This would remove the need for costly delisting petitions.	95
EPA	Replace Visual Determinations with Property Line Measures When Regulating Sources of Particles	National Stone, Sand & Gravel Association (20)	The aggregates industry is required to use a visual emissions test to determine opacity of its emissions (Method 9). This method should not be used because it is (1) subjective and often inaccurate and (2) based on a measure of opacity even though opacity exhibits a poor relationship to particulate matter concentrations that are the subject of National Ambient Air Quality Standards. Instead of an opacity test, compliance should be based on ambient air concentration measurements taken at the property line.	96
EPA	Reportable Quantity (RQ) Threshold for Nitrogen Oxide and Dioxide at Combustion Sources	National Association of Manufacturers (9); American Chemistry Council (31)	The current rule sets the RQ for nitrogen emissions too low for combustion sources (e.g., the flares used to control emissions of volatile organic compounds), triggering reporting burdens on owners/operators of combustion facilities and administrative burden on the NRC and state and local reporting entities. The RQ should be raised.	97

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Respect Early Action Compact on Ozone Attainment	American Furniture Manufacturers Association (35)	The furniture-producing Triad region of North Carolina has established an Early Action Compact with US EPA to develop strategies aimed at reducing emissions that contribute to ozone formation. A transportation emissions control plan is also being developed as part of the EAC. EPA should await the results of this pact before making a designation of the Triad area with respect to attainment. If a premature nonattainment designation is made, the resulting permit restrictions could adversely impact manufacturing production in the Triad region.	98
EPA	Rulemaking to Limit Mercury Emissions from Electric Utilities	American Public Power Association (42)	EPA is currently developing a rule to limit mercury emissions from electric utilities. Costs for smaller plants using currently available continuous monitoring methods will impose considerable capital and operating and maintenance costs. EPA should allow smaller utility systems to work with States to adopt the most practical and reliable monitoring methods at the lowest cost.	99
EPA	SARA 311 Reporting	American Furniture Manufacturers Association (35)	Facilities that need to report material safety data sheets for chemicals stored on site under EPCRA section 311 also must report an annual inventory to state and local emergency response and planning authorities. These requirements should be streamlined to ensure consistency between Federal, state, and local requirements and to provide for a single electronic means of submitting this information.	100
EPA	Sulfur and Nitrogen Monitoring at Stationary Gas-Fired Turbines	National Association of Manufacturers (9)	The current New Source Performance Standards require monitoring of sulfur and nitrogen content of fuel being fired in gas turbines. However, there is negligible sulfur and little nitrogen in natural gas. The requirements should be rescinded, which would reduce the need to submit paperwork showing no emissions. For facilities with Title V permits, if there are excess emissions, they would be reported under the Title V deviation reports and thus there is no need for a separate NSPS report.	101

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Superfund Alternative Program (SAP)	National Association of Manufacturers (9)	Current agency guidance encourages Regional Offices to evade the requirements of the National Priorities List (NPL) and pursue cleanup of sites without regard to risk or a company's accountability for the site. The program should be terminated.	102
EPA	Systematic Program for Developing and Validating Analytic Methods	Inter-Industry Analytic Group (14); American Public Power Association (42)	The agency's process for deciding what analytic methods to develop and to approve is not transparent to the public. Costly and time-consuming disputes among regulated entities have been spawned over how to develop analytic methods and how to use them when making compliance decisions. The agency should, first, develop a systematic process for determining what analytic methods should be developed for regulatory use and, second, develop formal criteria for validating and adopting analytic methods.	103
EPA	TSCA Test Guidelines	People for the Ethical Treatment of Animals (36)	In 2000 the agency issued Test Guidelines under the Toxic Substances Control Act without undertaking a notice-and-comment rulemaking under the Administrative Procedure Act. The guidelines also need to be reconsidered because they were not scientifically validated based on considerations of reliability, reproducibility, and relevance, as set forth by international consensus.	104
EPA	Two-Part Test for all Rules	Deere & Company (1)	Eliminate all regulations that fail either of two tests: (1) Does it do anything to protect public health or the environment; (2) Is it redundant? Applying this two-part test will eliminate busywork for both agencies and regulated companies.	105
EPA	Establish a Federal Prohibition Against the Use of Fees By States for Unrelated Programs	Deere & Company (1)	A federal rule is needed to prohibit states from establishing environmental fees that are used to support a state's General Revenue Fund, though such fees should be permissible for the intended environmental program. The result would be cost savings to regulated businesses.	106

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	High Production Volume (HPV) Chemical Test Program	People for the Ethical Treatment of Animals (36)	The agency's HPV testing program was developed without public comment opportunity as defined in the Administrative Procedure Act. It was never noticed in the Federal Register until after its implementation. The HPV program should be reconsidered in rulemaking.	107
EPA	Deferral of Duplicative Federal Permitting	The Policy Group (28)	Currently, metal finishing facilities comply with federal air emission standards that are implemented through state and local permits. However, if action is not taken, in late 2004 duplicative federal permitting requirements would automatically be added, with no environmental benefit. The agency should develop a rule that permanently exempts metal finishing facilities from cumbersome federal permitting requirements, saving time and money for both the agency and the regulated industry.	108
EPA	Reporting of Coincidental Manufactured Compounds under the Toxic Release Inventory Program	The Policy Group (28)	Through informal procedures and guidance, the agency has compelled facilities to count numerous chemical reactions in plating booths as coincidental manufacturing of metal compounds when determining thresholds for reporting facility emissions under the TRI program. These actions have had the effect of subjecting more small businesses to the TRI reporting requirements while the confusion over the interpretation creates enforcement traps for facilities that are making good faith efforts to comply with the confusing requirements. The agency should reconsider how manufactured metal compounds are treated under TRI through a notice-and-comment rulemaking.	109
EPA	SARA Title 312 and 313 Programs	American Iron and Steel Institute (34)	The SARA 312 and 313 programs are misleading to the public and burdensome to manufacturers. The agency should initiate rulemaking to make reporting biennial (313 one year, 312 due the next), eliminate reports of chemicals managed at landfills and through deep well injection, and focus reporting on toxic (rather than criteria) air pollutants.	110

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	SARA Title III Reporting Requirements	Motor and Equipment Manufacturers Association (41)	EPA imposes significant paperwork burdens on enforcement targets and current penalties for minor reporting errors are excessive. EPA also requires excessive paperwork for reporting an omission. EPA should revise its enforcement provisions to reward voluntary reports of non-compliance and to moderate penalties for minor clerical errors.	111
EPA	Vapor Recovery at Gasoline Stations	American Petroleum Institute (12)	Emissions may occur in the gap between the station's nozzle and the vehicle fill pipe during the re-fueling of vehicles of service stations. Two redundant systems have been required for controlling these emissions: one on the vehicle, the Onboard Vapor Recovery System, and one at the station, Stage II Vapor Recovery Systems. As more vehicles are produced with onboard vapor recovery systems, the regulations on the service stations should be phased out to reduce unnecessary burdens (e.g., the cost of maintaining, inspecting and managing the paperwork for the vapor recovery systems).	112
EPA	Waiver Process for States under the Clean Air Act	Alliance of Automobile Manufacturers (23)	The agency has allowed states such as California to enforce regulations without obtaining proper waivers from EPA under the Clean Air Act. For example, the agency is allowing states to adopt California zero-emission and on-board diagnostic standards without first evaluating the case for granting a waiver for California's regulations. The agency should enforce its waiver authority as intended by the Clean Air Act. In addition, the requirements and process for granting fuel waivers are vague and need to be clarified.	113
EPA	Paper and Other Web Coating MACT	National Association of Manufacturers (9)	The current MACT rule covering paper and web coating requires case-by-case agency approval for the use of any air pollution control device other than a Sulfur Recovery Unit or oxidizer. These case-by-case approvals can be time consuming and burdensome. The agency should allow companies the flexibility of using any method that achieves greater than 95% control of hazardous air pollutants, instead of imposing a requirement for case-by-case approval.	114

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Stormwater Regulations	Copper and Brass Fabricators Council (45)	Current Phase I stormwater regulations require certain categories of dischargers associated with industrial activity to obtain authorization to discharge storm water under permit. As part of the permit, dischargers are required to develop and submit Storm Water Pollution Prevention Plans. When promulgated, the controls necessary to meet permit requirements were expected to be low-cost and not technology intensive; however, satisfactory SWPPPs now frequently include major construction expenses for capturing and treating stormwater, probably incurring major expenses for minimal reductions in pollutant discharges in most cases.	115
EPA	Publicly Owned Treatment Work (POTW) removal credits	Copper and Brass Fabricators Council (45)	Under the national pre-treatment program, industrial facilities that discharge to POTWs must meet pretreatment standards that generally include concentration limits on specific pollutants. The CWA provides that if a particular pollutant can be removed by the treatment processes at the POTW, the POTW may grant a "removal credit" to the facility that reduces the level of treatment required at the facility to account for the treatment that will occur anyway at the POTW. Before a POTW can grant removal credits to its industrial dischargers, however, it must obtain "removal credit authority" from EPA. The commenter states that the procedures established in 40 CFR 403.7 companies must follow to get authority for removal credits are unreasonable and extremely difficult to obtain. Recommends revisions to more accurately reflect the total removal by the POTW, and modifications to facilitate the granting of authority when justified.	116
EPA	Categorical Wastewater Sampling and Testing	Copper and Brass Fabricators Council (45)	40 CFR 403-471 requires dischargers to sample and test for certain categorical pollutants. Under EPA interpretations, some dischargers must test for elements they don't use. For example, some copper forming dischargers must test for chromium and lead, but do not use those chemicals. Categorical dischargers should not be required to test for all pollutant in the category when it can be independently shown that no possibility exists for certain pollutants to be in the discharge.	117

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA	Definition of Volatile Organic Compound	Copper and Brass Fabricators Council (45)	The definition of volatile organic compound (VOC) as found in 40 CFR 51.100(s) has no volatility element and therefore disregards whether a compound is even volatile at all. The rule defines VOCs very broadly as any carbon compound, but appropriately narrows the definition somewhat by limiting VOCs to those carbon compounds that "participate in atmospheric photochemical reactions." Of particular concern are ozone precursors; photochemical activity is one measure of an organic compound's ability to be an ozone precursor, but it is not the only measure. As applied by EPA, all organic compounds are assumed to be participants in atmospheric photochemical reactions. The comment suggests including a vapor pressure threshold (such as 0.1 mm Hg in the VOC Emissions Standards for Consumer Products Rule, 1996) below which a carbon compound would not be considered volatile and would not meet the definition of VOC.	118
EPA	Thermal Treatment of Hazardous Waste Guidance	Copper and Brass Fabricators Council (45)	Under current guidance, hazardous waste generators are allowed to treat without permit if the treatment is conducted in compliance with standards applicable to "tanks and containers." EPA,however, no longer allows "thermal treatment" of hazardous waste in this instance. EPA included evaporation of water under this thermal treatment prohibition, primarily because direct-fired units were being used by some for incineration and combustion. The commenter stated that the prohibition of incineration and combustion is reasonable; however, the overbroad interpretation now prevents other reasonable methods, such as evaporation, that reduces the volume of hazardous waste. If allowed, evaporation could reduce the volume of hazardous waste generated and transported by as much as 95% and allow the remainder to be shipped offsite for conventional treament. The reduced shipping volume would not only reduce cost, but also reduce risk to the environment.	119

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
EPA & DOD/Army Corps	Regulation of Intrastate Waters and Streams under the Clean Water Act	National Federal of Independent Business (8)	Due to a 2001 decision of the US Supreme Court, rulemaking would clarify the proper regulation of isolated wetlands in the United States. A regulatory clarification will better ensure that small businesses are not incurring unnecessary costs acquiring federal permits for activities near intrastate streams.	120
FCC	"Do Not Fax" Rule	National Federal of Independent Business (8); National Association of Manufacturers (9); U.S. Chamber of Commerce (19); National Small Business Association (24); SBA Office of Advocacy (39)	The "Do Not Fax" rule prevents businesses from using one of their most effective means of advertisement by requiring prior written consent, a stronger standard than that for telemarketers. The rule should be withdrawn or the standard should be changed from requiring "written consent" to allowing faxes in cases of "previous existing business relationships."	121
FCC	Broadband	Heritage Foundation (5)	FCC has pending proceedings concerning the regulatory treatment of broadband - one to determine whether broadband is a "telecommunications service" or "information service," another on whether telephone companies providing broadband should be regulated as "dominant" providers . These should be decided expeditiously in a way that reduces or eliminates regulation.	122
FCC	Broadband Ruling	Heritage Foundation (5)	The D.C. Court of appeals ruled on FCC rulemaking decisions overturning portions that required the Bells' to continue sharing their local voice telephone elements of their networks with competitors, but upholding portions that freed Bells from sharing their new broadband fiber networks. A Supreme Court cert on this issue could possibly include the broadband portion of the decision, and not just the local telephone issue. Administration should not request Supreme Court review of D.C. Circuit court ruling affirming FCC's deregulation of broadband providers.	123

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
HHS	Privacy of Individually Identifiable Health Information	National Federation of Independent Business (8)	The privacy rules, which HHS published pursuant to HIPAA, significantly increased costs. Small businesses need further clarification about the business-associated provisions. These provisions should be refined. Additionally, HHS should publish a compliance guide for small entities as required under SBREFA.	124
HHS/CMS	HIPAA	Motor & Equipment Manufacturers Association (41)	HIPAA amended the Internal Revenue Code to improve portability and continuity of health insurance coverage in the group and individual markets, and to simp lify the administration of health insurance. Implementation of HIPAA has been problematic because companies have had to deal with multiple effective dates and the need to reengineer existing processes to eliminate or reduce exposure. Considerable time and money have been spent trying to comply with these complex requirements. The compliance burden should be reduced.	125
HHS/CMS	Medicare Secondary Payment Law	National Association of Manufacturers (9)	To collect Medicare overpayments, as required by Medicare Secondary Payer policies, consumer credit collection agencies are used. Medicare should only use such agencies that deal professionally with the former employers of those from whom payment is being sought. Additionally, a time limit of one year should be imposed on such collections to alleviate burden on employers.	126
HHS/FDA	Use of Term "Fresh" for Baked Goods	National Federation of Independent Business (8); American Bakers Association (10); SBA Office of Advocacy (39)	Currently, FDA restricts the use of the term "fresh" in connection with food labeling such that thermally processed (i.e., baked) food cannot use the term. The commenter recommends that FDA allow bakery products to use the term "fresh".	127
HHS/FDA	BSE/Feed Ban	Public Citizen (2)	Currently, FDA restricts only the ingredients in ruminant feed as a safety measure to reduce the risk of spreading BSE infection. The commenter recommends that the FDA ban feeding of "mammalian parts to other animals or poultry".	128

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
HHS/FDA	Compounded Drugs	Public Citizen (2)	Compounded drugs, products created by pharmacists through mixing drugs and other ingredients, can currently be sold without FDA approval. The commenter recommends that FDA should have the authority to treat compounded drugs as unapproved new drugs and mandate reporting by pharmacists of adverse effects from compounded drugs.	129
HHS/FDA	Dietary Supplements	Public Citizen (2)	Dietary supplements can generally be sold without pre-market approval by FDA. The commenter recommends that FDA should mandate pre-market studies and post-market adverse reports for dietary supplements.	130
HHS/FDA	Off-Label Promotion	Public Citizen (2)	Currently, FDA does not pre-approve the promotion of off-label use of drugs. The commenter recommends that FDA should have the authority to regulate off-label promotions.	131
Interior/FWS	Listing of Species as Threatened or Endangered	National Association of Manufacturers (9)	ESA permits citizens to nominate additions to the threatened and endangered list without requiring scientific data or analysis. This has hindered land management planning and permitting, making it difficult for and even inhibiting industry to conduct business. FWS should hold public hearings on all listings and should develop specific scientific criteria to determine which species should be listed. In addition, FWS needs to work with Congress to tighten the statute so that it must use mainstream science to evaluate species for listing.	132
Justice	Administration of Federal Prison Industries (FPI)--Guidance	U.S. Chamber of Commerce (19)	FPI ignore statutory prohibition on the sale of prison commodities in the private commercial market. Comment recommends rescinding DOJ guidance memos allowing FPI to compete with the private sector. Doing so would reduce competition for manufacturing firms and thereby help create jobs.	133

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor	FMLA/Intermittent Leave	FMLA Technical Corrections Coalition (4); Heritage Foundation (5); National Federation of Independent Business (8); National Association of Manufacturers (9); U.S. Chamber of Commerce (19)	Current regulations allow employees to report intermittent leave used in increments as small as six minutes, creating substantial administrative burden for employers. Conversely, excessively large increments force employees to use more time than needed and increase the likelihood they will exhaust annual FMLA limits. A good balance would be struck with implementation of a one hour bound with room for employer interpretation.	134
Labor	FMLA/Perfect Attendance Awards	FMLA Technical Corrections Coalition (4); U.S. Chamber of Commerce (19)	As fringe benefits may not be denied to employees taking FMLA leave, large FMLA absentee periods may not count against employees in the distribution of employer-sponsored perfect attendance awards. Resulting resentment undermines staff morale and the value of the awards and hurts employers' ability and incentive to provide such benefits and therefore encourage high attendance. Commenters request that employers be able to count FMLA leave as an absence.	135
Labor	FMLA/Request for Leave	FMLA Technical Corrections Coalition (4); National Federation of Independent Business (8); U.S. Chamber of Commerce (19)	Employers must verify and designate leave as FMLA within two days of notification by the employee, while the burden on the employee to report FMLA leave or assist in employer verification is ambiguous. Five days is more appropriate to employer requirements. Employee responsibilities should be clarified to limit the amount of leave that can be used prior to employer notification.	136

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor	FMLA/Serious Health Condition	FMLA Technical Corrections Coalition (4); Heritage Foundation (5); National Association of Manufacturers (9); U.S. Chamber of Commerce (19); American Furniture Manufacturers Association (35); Motor & Equipment Manufacturers Association (41); Society for Human Resource Managment (46)	The original legislative and statutory definition has been expanded by Department of Labor guidance documents to include minor illnesses such as the flu and common cold. Not only is such expansion contrary to legislative intent, it increases the potential for fraudulent claims, creates a disincentive for employer leave policies, and threatens office morale. Guidance should be rescinded.	137
Labor	H-1B Visas	U.S. Chamber of Commerce (19)	The commenter states that DOL's current processing of H-1B labor applications for high-skilled immigrant labor is overly burdensome to employers. It recommends that the Department streamline its processing of such applications and provide more conformity with current business practices.	138
Labor	Conflicting Standards: Training	American Furniture Manufacturers Association (35)	Commenters noted privacy provisions in FMLA, HIPAA, and ADA are in conflict, making it difficult to determine whether employees are eligible for FMLA leave. It is likely workers compensation laws are also problematic. Department of Labor should research the need for and burden of harmonization of these four areas.	139
Labor	FMLA/Arbitration	National Federation of Independent Business (8)	FMLA carries a high legal cost, with many lawsuits resulting from poorly defined communication around leave designations FMLA - eligible intermittent absences. The commenter reports many employers have been forced to carry higher liability insurance policies due to increases in legal action from FMLA. Labor should investigate the possibility of mandating arbitration prior to legal action and capping damages at lost salary and expenses for wrongful termination suits.	140

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor	FMLA/Health Care Provider Certification	FMLA Technical Corrections Coalition (4); National Association of Manufacturers (9); U.S. Chamber of Commerce (19); American Furniture Manufacturers Association (35); Motor & Equipment Manufacturers Association (41)	Employers are currently prohibited from contacting providers to verify an employees' claim of an FMLA -eligible serious health condition or clarify the activities the employee is unable to perform and the appropriate period of leave. Forced to go through third party providers, employers bear unnecessary burden and cost and are often unable to access desired information in the limited period of time available. Increased access must be balanced by patients' privacy concems.	141
Labor	FMLA/Penalty Provisions	FMLA Technical Corrections Coalition (4)	A Supreme Court (Ragsdale v. Wolverine) case struck down one penalty provisions with the implication that other similar provisions are also legal. The Department of Labor should investigate the breadth and validity of these implications and take action accordingly.	142
Labor	FMLA/Substitution of Paid Leave	FMLA Technical Corrections Coalition (4)	Current interpretation permits employees to consecutively use employer-provided and FMLA leave, lengthening available leave periods and creating disincentives for employers to provide paid leave. Guidance should clarify interaction between employer and FMLA leave.	143
Labor	FMLA/Unable to Perform	FMLA Technical Corrections Coalition (4); U.S. Chamber of Commerce (19)	Currently, employees are entitled to FMLA leave if a serious medical condition renders them unable to perform one essential function of their position. Employers would like the ability to reassign the employee to other "light duty;" benefiting employees by providing a venue to continue to work and receive pay. New or revised provisions should limit the scope of "light duty" to tasks related to the employee's current position.	144
Labor	Permanent Labor Certification	U.S. Chamber of Commerce (19)	The commenter recommends that the new labor certification application process to bring permanent alien workers into the US be finalized and streamlined to reduce burden on employers. Specifically, the commenter would like DOL to implement a pilot program tested in the 1990s that allows for particular types of labor market tests, to minimize administrative burden on employers.	145

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor/MSHA	Diesel PM Exposure	National Stone, & Gravel Association (20); SBA Office of Advocacy (39)	MSHA currently bans worker rotation as an option to minimize miners' exposure to diesel particulate matter and plans to reduce the Permissible Exposure Limit (PEL) from an interim level of 308 micrograms to 160 micrograms in 2006. MSHA should revise its policies to allow for worker rotation and should not lower the PEL as planned.	146
Labor/MSHA	Driver Training	National Association of Manufacturers (9)	The definition of what constitutes "mining" is too expansive for purposes of driver training requirements. The standard treats both shallow and deep surface mining the same. Shallow surface mining (such as clay and shale) should not be subject to the same training requirements for deep surface mining.	147
Labor/OFCCP	Affirmative Action Plans and EEO Surveys	U.S. Chamber of Commerce (19)	Federal contractors are required to maintain affirmative action plans and submit information to DOL regarding the hiring, firing, and promotion of individuals of different race/ethnic backgrounds and gender. The commenter seeks a streamlined reporting and recordkeeping requirement to ease administrative burden on employers.	148
Labor/OFCCP	Compliance Surveys	National Association of Manufacturers (9)	DOL currently requires that employers, when entering into a federal contract, provide a company profile each time a new contract is signed. The commenter recommends that DOL provide the employer with a contractor code that can be used for subsequent contracts, to obviate providing redundant information.	149
Labor/OFCCP	Definition of "Applicant"--Guidance	U.S. Chamber of Commerce (19)	DOL and EEOC have proposed a redefinition of the term "applicant" for the purposes of recordkeeping and recording the demographics of applicants for a particular job, in light of electronic (i.e. Internet) means for job hiring. The commenter recommends finalizing this new definition of "applicant" and ensuring that job hiring through various electronic means, in addition to the Internet, are covered under this new definition.	150

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor/OSHA	Annual Training Requirements for Separate Standards	American Furniture Manufacturers Association (35)	Both EPA and OSHA require annual employee training for specific standards related to a variety of requirements. The cost of training is a major annual expense and not always productive. A single, integrated program should be developed.	151
Labor/OSHA	Coke Oven Emissions	American Coke and Coal Chemicals Institute (3); American Iron and Steel Institute (34)	The OSHA standard that applies to the control of employee exposure to coke oven emissions is in need of major revision to account for the development of new technology, the obsolescence of antiquated technology and the results of 25 years of exposure monitoring data. Additionally, the personnel monitoring of lead/cadmium should be reduced. Updating the standard would allow the industry to more effectively utilize its resources.	152
Labor/OSHA	Flammable Liquids	National Association of Manufacturers (9); National Marine Manufacturers Association (38)	The current rule cites the National Fire Protection Association standards set in 1969 for spray application of flammable and combustible liquids and should be updated to reflect current technology.	153
Labor/OSHA	Hazard Communication	National Federation of Independent Business (8); National Stone, & Gravel Association (20); Specialty Graphic Imaging Association (27); SBA Office of Advocacy (39)	Current OSHA practice requires chemical manufacturers to adhere to certain guidelines established by nongovernmental organizations. Because these standards are not subject to notice and comment, the regulated community does not have a voice in these decisions. OSHA should modify its procedures, as MSHA has, to provide for notice and comment.	154
Labor/OSHA	Hazard Communication Training	National Association of Manufacturers (9)	The current format and detail of the information in this program is overwhelming for small business. Some of the recommended procedures in this guidance document are too complicated for small businesses with limited resources. OSHA should develop a simplified approach with more information on how to obtain referenced source material.	155

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor/OSHA	Hazard Communication/MSDSs	Deere & Company (1); National Association of Manufacturers (9); American Furniture Manufacturers Association (35)	Material Safety Data Sheets should be prepared in a consistent format by chemical suppliers throughout the U.S. A consistent format would allow the regulated community to find information on MSDS's more quickly and therefore save time and money. Additionally, quality of the information provided should be improved to reduce the risk of unintended employee exposure.	156
Labor/OSHA	Hexavalent Chromium	The Policy Group (28); SBA Office of Advocacy (39)	OSHA is required by court order to propose a new standard with regard to worker exposure to hexa valent chromium. Consistent with its obligations under SBREFA, OSHA should make efforts to minimize the impact of the new standard on small business. It should consider scientific data, costs, and economic impact.	157
Labor/OSHA	Lead, Bloodborne Pathogens, Retraining Requirements	National Association of Manufacturers (9)	While the initial training requirement should be retained, the annual retraining requirements should be revis ed to be more performance-based. Employees who demonstrate sufficient knowledge by passing a test on the relevant subject matter should be exempt from the training requirement. Making every employee go through retraining causes losses in productivity and is costly.	158
Labor/OSHA	Sling Standard	U.S. Chamber of Commerce (19); Associated Wire Rope Fabricators (42)	Companies in the lifting, rigging and loading industry typically use slings made of wire rope to lift objects by crane. The current OSHA standard is 30 years old and is outmoded when compared to the consensus standard promulgated by the American Society of Mechanical Engineers (ASME). The standard should be updated to reflect the ASME consensus.	159
Labor/OSHA	Guardrails Around Stacks of Steel	American Iron and Steel Institute (34)	Employers are required to provide either guardrails or tie-off protection to workers who must perform their duties 48 inches or greater above the ground. These requirements are infeasible for operations that exist in steel and steel products companies where individuals need to stand on "stacks" of product to rig bundles for crane lifts. The rules should provide employers with some flexibility by adding the term "where practical" to the standard.	160

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor/OSHA	Threshold Limit Values	American Bakers Association (10)	Decisions reached by consensus organizations with close ties to the regulating agency should not be relied upon as the foundation for Permissible Exposure Limits and should not be used by OSHA to issue citations under its "general duty clause" unless their conclusions are supported by sound science.	161
Labor/OSHA	Beryllium	Public Citizen (2)	A revised beryllium standard is needed that is adequate to protect workers, together with medical surveillance and engineering controls to reduce exposure.	162
Labor/OSHA	Ergonomics	Public Citizen (2)	A regulation should be developed to prevent ergonomic injuries.	163
Labor/OSHA	Ergonomics Guidance	U.S. Chamber of Commerce (19)	The current voluntary guidelines do not adequately reflect the uncertainty surrounding the science of ergonomics. The guidelines should be revised to acknowledge the lack of consensus within the scientific and medical communities on the nature and causes of musculoskeletal disorders.	164
Labor/OSHA	Metal Working Fluids	Public Citizen (2)	A regulation is needed to protect workers who handle metalworking fluids.	165
Labor/OSHA	Personal Protection Equipment	Public Citizen (2)	A requirement that employers pay for all required personal protective equipment should be instituted to increase workplace safety.	166
Labor/OSHA	Process Safety Management	Public Citizen (2)	The Process Safety Management Standards should be amended to achieve more comprehensive control of reactive hazards.	167
Labor/OSHA	Tuberculosis	Public Citizen (2)	A rule is needed to protect workers who are at risk of exposure to tuberculosis infection.	168

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Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Labor/OSHA	Walking and Working Surfaces	Copper and Brass Fabricators Coucil (45)	Under some circumstances, 29 CFR 1910.24 requires the use of fixed ladders when spiral stairways or ship stairs would be safer. The regulations define requirements for stairs in certain circumstances, while permitting an exception for fixed ladders where they are commonly used. No allowance, however, is made for the use of ship stairs (shallow stairs with handles separated from the tread) or spiral stairs, unless they are wrapped around a structure with at least a five foot diameter. OSHA previously proposed to allow ship stairs; however, it was never promulgated.	169
Labor/OSHA & EPA	Modernize and Harmonize Asbestos Rules and Guidance Documents	Deere & Company (1)	Rules governing asbestos at EPA and OSHA are old and not well coordinated. For example, the requirement of advance notification of demolition for any load-supporting member -- even when there is no asbestos present -- causes unnecessary costs for both agencies and the regulated community. Updated rules and guidance on asbestos need to be harmonized.	170
OMB	Administration of Federal Prison Industries (FPI)--Guidance	U.S. Chamber of Commerce (19)	Current law grants preferential status to FPI in the government procurement process, forcing Federal agencies to buy from FPI instead of using a competitive process. This preferential status costs jobs, reduces government efficiency, and increases taxpayer costs. Sec. 637 of the 2004 Consolidated Appropriations Act (PL 108-199) contained a one-year provision ending the FPI's favored status by allowing agencies to meet procurement needs by examining the existing marketplace. Commenter recommends making the applicable FAR implementing rules permanent.	171
OMB/OIRA	Oversight of Non-Government Setting Bodies	American Furniture Manufacturers Association (35)	The commenter is concerned about the de facto regulatory role being played by non-governmental standard-setting bodies (e.g., International Agency for the Research of Cancer). Specific concerns include the lack of transparency in their deliberations and the absence of requirements for balance among panel participants. OIRA should engage in appropriate scrutiny of the influence of these bodies on agencies to ensure high standards for procedural fairness and risk-based decision making.	172

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
State	International Traffic in Arms Regulation (ITAR)	National Association of Manufacturers (9)	ITAR requires U.S. companies to (1) obtain a license for the permanent export of defense articles and (2) have a Technical Assistance Agreement before discussing technical details with foreign companies or non-US.- citizen employees of international operations. Once a license is approved a company should not have to resubmit paperwork for each additional purchase for the same part. Foreign counterparts do not have the same regulations and are better able to compete in the global marketplace. This regulation is particularly time consuming and costly to small business, as they tend not to have export control departments.	173
Treasury/ Customs	Customs Valuation	National Association of Manufacturers (9)	This rule requires computing of "value for duty" for imports. It involves accounting procedures that neither resemble nor are applicable to other accounting areas of a company, thereby adding complexity to the process and requiring a separate recordkeeping system. The commenter proposes that the value for duty calculations be aligned with GAAP standards and based on values that are already required for inventory purposes, greatly reducing the administrative costs for manufacturers.	174
Treasury/ Customs	Duty Drawback	National Association of Manufacturers (9)	Drawback is the refund of Customs duties and other taxes and fees paid to U.S. Customs at the time of importation. The refund is administered after the exportation or destruction of either the imported product or the article that has been manufactured from the imported product. The Duty Drawback paperwork is so time consuming that some member companies forego the refund because the process costs are higher than the amount they can claim. Commenter recommends that the recordkeeping requirements be standardized, saving manufacturers significant amounts of money and time.	175

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Treasury/IRS	"Statutory Employees"--Bakery Drivers	American Bakers Association (10)	Since 1991 the IRS has treated commissioned delivery drivers for bakeries as "statutory employees," resulting in administrative cost associated with withholding taxes, associated accounting, and quarterly reporting. The commenter requests reversion to the pre-1991 interpretation of the Internal Revenue Code in order to reduce costs to the baking industry.	176
Treasury/IRS	Communications Distance Sensitivity	SBA Office of Advocacy (39)	An excise tax is imposed on amounts paid for certain communication services including local and "toll" telephone service. IRS has proposed changing the definition of 'toll" telephone service from the existing requirement that it be distance price sensitive to encompass current industry practice of a flat fee structure. The commenter requests that IRS withdraw the proposed rule and not impose the excise tax flat fee non-local telephone service. This would eliminate the potential 3% excise tax.	177
Treasury/IRS	Election to Expense Certain Depreciable Business Assets	SBA Office of Advocacy (39)	Businesses can currently "expense" up to $100,000 in equipment in any given year under section 179 of the Internal Revenue Code. This allows a reduction in recordkeeping and significant capital cost recovery benefits as well as cash flow assistance. Under current law the limit is scheduled to revert to $25,000 for 2005 and thereafter. The commenter requests OMB support for legislation to have the "expensing" limits (enacted in 2003) made permanent.	178
Treasury/IRS	"Statutory Employees"--Bakery Drivers	SBA Office of Advocacy (39)	Since 1991 the IRS has treated commissioned delivery drivers for bakeries as "statutory employees," resulting in administrative cost associated with withholding taxes, associated accounting, and quarterly reporting. The commenter requests a small business exception from this requirement benefiting retail and commercial bakeries which constitute over 95% of the firms in the industry.	179

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
Treasury/IRS	Bonus Depreciation	SBA Office of Advocacy (39)	The 2003 Jobs and Growth Tax Relief Reconciliation Act allows certain depreciable property placed in use before 2005 to qualify for additional depreciation in its first year of use. This "bonus" depreciation of 50% verses 30% under prior law will expire after 2004. The commenter recommends that OMB support legislation to make the 50% "bonus" depreciation permanent.	180
Treasury/IRS	Mobile Machinery Exemption	SBA Office of Advocacy (39)	IRS has proposed a rule to effectively eliminate an excise tax exemption in place since 1956 by taxing "mobile machinery" vehicles as highway vehicles. This would impose a 12% Federal excise tax on these trucks and on fuel they consume on highways. Redefining these vehicles affects the mining industry as well as firms in the oil drilling, water drilling, commercial construction and timber harvesting industries. The commenter requests that the current definition not be changed.	181
USDA/FSIS	BSE	Public Citizen (2)	The commenter believes that the potential effects of Bovine Spongiform Encephalopathy are devastating, yet USDA has failed to mandate additional safety measures to protect against human exposure. USDA should implement a total ban on the use of Advanced Meat Recovery, a ban on all brains, spinal cords, and other significant risk materials from cows of any age, a testing program that ensures that appropriate animals are tested at an adequate rate and includes testing of all non-ambulatory, disabled animals, and testing of all cattle 20 months or older. USDA should also continue to bar the importation of both live animals and meat products from Canada.	182
USDA/FSIS	HACCP Regulations: Microbial Tests for Salmonella	Public Citizen (2)	Many of the largest ground beef plants in the United States have been allowed to continue to send ground beef stamped USDA-approved to market after tests repeatedly showed the presence of Salmonella. USDA should require daily microbial tests for Salmonella and take appropriate action as soon as plants fail the tests.	183

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
USDA/FSIS	Mandatory Recalls of Meat and Poultry	Public Citizen (2)	USDA lacks the authority to require the recall of meats and poultry. This prevents the agency from removing from public distribution products that may be tainted. USDA should have this authority in order to protect the nation's food supply.	184
USDA/FSIS	Microbial Performance Standards and Sanitation Standards	Public Citizen (2)	Due to recent court cases, USDA may not be able to force remedial action on a producer that fails to comply with sanitation standards or has products that fail microbial testing. USDA should have this authority in order to ensure unsafe products are not distributed to the public.	185
USDA/FSIS	Zero Tolerance for Fecal Contamination on Meat and Poultry	Public Citizen (2)	Petitioner argues that USDA has issued directives that constrain their inspectors' ability to implement the "zero tolerance" policy for fecal contamination. USDA should withdraw such directives and ensure enforcement of "zero tolerance" for fecal contamination under any and all circumstances.	186
USDA/FSIS	Irradiated Meat for the School Lunch Program	Public Citizen (2)	No long term studies have been done on the effect of eating irradiated food. Petitioner argues that irradiation produces new chemical compounds that have been found to cause cellular damage. USDA should not allow irradiated meat in the School Lunch Program.	187
USDA/FSIS	Ready to Eat Meat Establishments to Control for Listeria Monocytogenes	National Association of Manufacturers (9); SBA Office of Advocacy (39); William Russell & Associates, Inc. (30)	The rule requiring ready to eat meat manufacturers to control for Listeria monocytogenes within their establishments is proving to be more costly than USDA estimated, causing substantial harm to small manufacturers. In addition, the benefits were overestimated. The rule should be rescinded and a new rulemaking should be undertaken to consider less burdensome alternatives to both the rule and the HACCP system with a return to the pre-HACCP regulatory regime. As a less preferred alternatively, the Listeria rule should be amended to replace the current regulatory requirements for small and very small processor with a pre-HACCP regulatory environment.	188

Table 8: Manufacturing Reform Nominations				
Agency	**Rule/Guidance**	**Commenter(s) (No.*)**	**Summary of Comment**	**Ref. Number**
USDA/RUS	Guarantees for Bonds and Notes Issued for Electrification or Telephone Purposes (Proposal)	U.S. Chamber of Commerce (19)	The proposed rule does not provide appropriate safeguards to ensure the security of a government guarantee for a bond or note issued under this new Federal credit program. RUS lacks the ability to oversee this program, and USDA failed to comply with numerous regulatory process requirements in developing the proposed rule. In addition, the proposed rule does not provide for adequate collateral, nor does it provide for oversight from a qualified banking regulator. USDA/RUS should withdraw its proposed rule and issue a revised proposed rule.	189

C. Response to Public and Peer Review Comments

Introduction, General Comments, and Call for Reforms

Many commenters (9, 23, 32, 33, 35, 37, 38, and 40) and peer reviewers A and B expressed support for analyzing the impact of regulation on the manufacturing sector and requesting specific reforms to regulations, guidance documents, and paperwork requirements that would improve manufacturing regulation. Two commenters (9 and 37) stated that their own research supports OMB's focus on manufacturers, and one peer reviewer (A) stated that focusing the analysis of regulatory impact on the manufacturing sector is worthwhile, while also suggesting OMB should explore the impact of regulations on other sectors. OMB does see merit in this request and will consider other sectors that may be the subject of useful focus in future Reports.

One peer reviewer (B) stated that the chapter presented a good survey of the many potential effects that regulations may have on manufacturing. Many commenters and peer reviewers C and D also suggested further literature to add to the survey. OMB has added summaries of much of the literature suggested by commenters, as well as other literature we felt could inform the discussion of the impact of regulations on manufacturing.

Other commenters (2, 15, and 29) and peer reviewer E stated OMB had not made the case that focusing regulatory reform on the manufacturing sector is warranted. These comments stated that merely showing that regulatory burden on manufacturing is large does not provide a basis for a regulatory reform initiative. These comments also state that the Report does not mention the benefits of regulation on the manufacturing sector, and therefore focusing only on cost is meaningless. OMB disagrees. We believe regulatory reform should be pursued where it may have the most potential impact; while it is impossible to predict with certainty which sector may particularly benefit from regulatory reform, the relatively large burden imposed on the manufacturing sector certainly does provide a basis for believing manufacturing regulatory reform may have a relatively large impact. OMB also disagrees that we are ignoring the benefits of these regulations. In fact, the Draft Report clearly stated that regulatory reform of the manufacturing sector must be approached with care because many rules governing this sector may produce substantial benefits. The Draft Report also stated that the first criteria commenters should consider for their reform nominations is whether a *benefit-cost* case can be made for the reform.

Definition of the Manufacturing Sector

One commenter (29) and peer reviewer E stated that OMB's definition of the manufacturing sector is vague and overly broad. OMB clearly noted in the Draft Report that this is a standard definition of manufacturing developed by the U.S. Census Bureau. Since this generally accepted definition is the basis for the majority of manufacturing statistics, it would be misleading to adopt a different definition solely for the purpose of regulatory reform. In addition, the Census Bureau defines exactly which North American

Industry Classification System (NAICS) codes constitute the manufacturing sector. A relatively new classification system, NAICS was jointly developed by the U.S., Canada, and Mexico to provide enhanced comparability in statistics about business activity across North America.

The Regulatory Burden on Manufacturing

Several comments (2, 15, and 29) stated that we relied too heavily on the Crain and Hopkins study of overall regulatory impact. One commenter suggested that OMB's previous testimony regarding this study is inconsistent with our current reliance on this study in the 2004 Draft Report. OMB disagrees. Comment 2 referred to congressional testimony by the OIRA Administrator that offered a critical analysis of this study. That testimony, however, did state OIRA's belief that the Crain and Hopkins study "is the best available for its purpose." In the 2004 Draft Report, OMB characterizes the study as "among the more recent and comprehensive sources of estimates of the overall burden of regulation on specific economic sectors." These statements are not contradictory. In one respect, however, OMB did modify the discussion of the Crain and Hopkins results. As mentioned in the 2003 testimony --and presented in more detail in statements at a February, 25, 2004 hearing before the Subcommittee on Energy Policy, Natural Resources, And Regulatory Affairs, United States House of Representatives-- we believe that the Crain and Hopkins study is more useful as a relative indicator of regulatory activity rather than as an absolute indicator of the overall burden of regulation. Although our conclusion from the Crain and Hopkins study --that manufacturing enterprises face a relatively high regulatory burden-- is sound, we have removed references to the absolute burden imposed by regulation mentioned in the Draft Report.

Several comments (2, 15, and 29) stated that OMB mischaracterized and mistakenly rejected the Porter Hypothesis. OMB believes that it correctly characterized the Porter Hypothesis as the idea that environmental regulation, by stimulating innovation and efficient investments, could be costless or even lead to higher profits in the industries being regulated. OMB also correctly described the empirical test carried out by Morgenstern et al (2001), which the authors themselves characterized as an empirical test of the Porter Hypothesis. The Draft Report does mention the many ways in which actual costs imposed by regulation may be higher or lower than the compliance costs typically estimated in Regulatory Impact Analyses and PACE surveys. We believe, however, that almost all evidence, including the extensive literature on regulatory burden and the almost 100 impact studies summarized in the accounting statement of this Report, clearly shows that regulation, while often leading to substantial benefits, does impose substantial burdens on industry.

Peer reviewer D states that OMB's characterization of two studies (Morgenstern et al 2001, and Joshi et al, 2001) is potentially misleading. OMB disagrees that the Chapter drew misleading conclusions from these studies, but agrees that we did not explain in detail the origin of different estimates of regulatory impact derived in the two studies, which are due primarily to the modeling choices of the authors. In the Final

Report, OMB has presented enough information on these studies to allow the reader to make an informed judgment about the issue of model choice.

Comment 15 included a lengthy critique of the James (1998) estimate of OSHA compliance costs. As in the studies mentioned above, OMB has provided enough information of this study's methods to allow the reader to make an informed judgment. OMB disagrees with the claim made by the commenter that this study necessarily overestimates the impact of regulations because it relies on consistently exaggerated *ex-ante* regulatory cost estimates. As mentioned in more detail in the Chapter I response to comments and the revised Chapter II, OMB disagrees that *ex-ante* costs are consistently overestimated, and is aware of retrospective analyses that have found both costs and benefits to be both under and overestimated.

Trade and Competitiveness Implications

Peer reviewer C stated that since the studies cited in this section use cross-section data, they likely will not be able to correct for unobserved characteristics which may influence both the propensity for a geographic area to regulate and the propensity for the area to attract or discourage firms for other reasons. The peer reviewer suggests a further set of papers that attempt to correct for this bias. OMB agrees that cross-sectional analyses of plant location decisions may have this potential shortcoming, and has included a summary of the literature suggested by the peer reviewer.

Comment 29 suggests that the conclusion of this section, that the literature does not consistently show evidence for the existence of international "pollution havens," or areas that have derived a competitive advantage due to lax environmental controls, implies that the case has not been made for manufacturing regulatory reform. OMB disagrees: the existence of international pollution havens is not a necessary condition for a manufacturing regulatory reform initiative. The purpose of this section was to inform readers, through a comprehensive discussion of the literature, of the many ways in which regulations may impact the manufacturing sector. Many commenters and peer reviewers found this discussion informative. In addition, peer reviewer C suggested that a series of new studies has begun to uncover evidence that regulations in fact may have a significant impact on net trade flows.

CHAPTER III: Regulatory Reform, 2001-2005: Progress and Additional Steps

The Bush Administration has put Federal agencies to work modernizing the sea of existing federal regulatory programs and paperwork requirements. This Chapter describes 103 specific reforms that Federal agencies have finalized or have underway due to actions taken during the 2001-2004 period. The reforms include both regulatory and deregulatory actions as well as reductions in unnecessary reporting, paperwork, and recordkeeping requirements. The Chapter also requests that Federal agencies undertake some reforms of programs that were not adequately addressed in 2001-2004.

In preparing this chapter, we included reforms suggested by the public through solicitations published in our annual Report to Congress on the Costs and Benefits of Federal Regulations, reforms initiated within the agencies, reforms suggested by OIRA through "prompt" letters sent to federal agencies, and significant reductions in paperwork burden accomplished by federal agencies and highlighted in our annual Information Collection Budget. The specific reforms, which follow below, are organized by issue area (education, environment, financial, health and safety, health care, homeland security, labor, land management, procurement, social policy, and transportation) and agency.

As used in this chapter, the term "regulatory reform" is defined as a modification of an existing regulatory program, an initiation of a new regulatory program, or a deregulatory action. Actions highlighted in this chapter exemplify the Administration's "smart-regulation" agenda, as defined in OMB's 2002 Annual Report to Congress on the Costs and Benefits of Regulation. A "regulatory" reform is defined broadly to include changes to agency guidance and paperwork burdens as well as rules.

Table 9 lists 75 regulatory reform accomplishments during the 2001-2004 period. Each entry in the table is a final regulatory reform, classified by issue area and agency, including a brief narrative description of each reform. In order to appear in Table 9, the regulatory reform must be a final action -- usually a final rule, guidance, or information collection --adopted by a Cabinet agency or EPA. Some of these reforms were proposed in the previous Administration while others were both proposed and finalized during the Bush Administration. Although the listing of reforms is diverse and extensive, the listing is intended to be illustrative rather than exhaustive or comprehensive. Most of the reforms were discretionary administrative actions, although some were responsive to specific legislative directions from the Congress or were byproducts of regulatory litigation.

Table 10 lists an additional 28 promising regulatory-reform proposals. In order to appear in Table 10, the reform must have been formally proposed by the agency, usually in the form of an advanced notice of proposed rulemaking or a notice of proposed rulemaking. Again, this listing is intended to be illustrative rather than exhaustive. Since OMB has judged these specific reforms to be "promising", OMB is asking the relevant agencies to supply OMB with a blueprint, including procedural steps and dated milestones, for finalizing these reforms by January 24, 2005.

Table 11 lists another 12 topics where OMB has determined that agencies should consider proposing regulatory reforms. For the most part, these items are "unfinished business" that was previously discussed by OMB and the agencies during the previous four years. Often these items reflect promising reform nominations made to OMB by the public in 2001 and/or 2002 that have not yet been the subject of a formal agency proposal. In some cases, these reform ideas have simply evolved from interagency discussions. For each of these 12 topics, OMB is asking the relevant agencies to supply OMB a blueprint, including procedural steps and dated milestones, for proposing and finalizing reforms by January 24, 2005. If an agency should determine that reform is not necessary or not a priority, they should supply an explicit rationale to OMB for that determination.

The items in Tables 10 and 11, where OMB soon expects a blueprint from agencies, supplement the regulatory reform nominations that agencies will be considering as part of the Administration's manufacturing initiative (see Chapter 2). In future editions of this report, OMB plans to report on additional progress on this "smart-regulation" agenda.

Table 9: Regulatory Reform Accomplishments

Issue Area	Agency/Rule	Summary/Status
Education	ED: Federal Family Education Loan Program and Financial Aid Regulations	The Department of Education published on November 1, 2002 the final regulation for Federal Student Aid Programs. The rule reduces administrative burden for program participants and provides participants with greater flexibility to serve students and borrowers. The new regulations eliminate the "12-hour rule" that restricted financial aid for students enrolled in distance education and other non-traditional term programs. In addition, colleges and universities will no longer be required to coordinate a borrower's monthly payments unless the borrower has initiated a request.
Environment	USDA: Environmental Quality Incentives Program for Farmers (EQIP)	USDA issued a final EQIP rule in May 2003, implementing new provisions contained in the 2002 Farm Bill. This rule includes national priorities that guide application-funding decisions at the state and local level. These national priorities give a preference to applications that address water quality concerns in impaired watersheds, air quality concerns in non-attainment areas, at-risk species concerns, and protection of high-value wetlands. The use of national priorities is expected to increase the environmental benefits generated by the program by focusing on the most pressing natural resource concerns.
Environment	EPA: Reducing Emissions from Recreational, Off-Road Vehicles	In November 2002, EPA adopted new standards to reduce pollutants for the first time from several groups of non-road engines, including large industrial engines, snowmobiles, and all-terrain vehicles. When fully implemented, these standards will remove more than 2 million tons of pollution each year – the equivalent of removing the pollution from more than 32 million cars every year. Much of this reduction in emissions results from the control requirements for engines used in industrial settings. The health benefits of this action are significant, including annually avoiding approximately 1,000 premature deaths. EPA estimates the long-term fuel savings of this action will be approximately 800 million gallons per year, at a savings of $770 million annually. EPA estimates the rule will cost about $190 million annually.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Environment	DOI and Army Corps of Engineers: Everglades Restoration Project	These final regulations guide the $8 billion joint Federal-State restoration of the Everglades and provide a strong foundation for implementation of the long term restoration plan and its 68 separate project components, including interim hydrologic and ecological goals, use of sound science, peer review, adaptive management, and broad stakeholder participation at every step in the process. These regulations, which were developed by the Corps of Engineers in close consultation with the Department of the Interior and the State of Florida, will help ensure that the long term goals of the Comprehensive Everglades Restoration Plan are achieved.
Environment	EPA: Effluent Guidelines for Metals Products and Machinery	In December 2000, EPA proposed a rule under the Clean Water Act establishing new discharge standards for facilities that manufacture metal products and machinery. The proposed rule would have cost $2 billion annually and affected over 50,000 facilities in 18 different industry sub-sectors. After the proposed rule was published, EPA received detailed analyses indicating that the benefits analysis was flawed because most of the sources covered by the proposal were already controlling discharges under the existing regulatory requirements. Once the analysis was corrected, it became clear that the costs of the proposal greatly exceeded the benefits and that most affected facilities already were using appropriate pollution control technology. In May 2003, EPA issued a substantially scaled back final rule, which imposed tailored requirements costing about $14 million per year, a savings of almost $2 billion per year.
Environment	EPA: Effluent Guidelines for Stormwater Runoff from Construction Sites	In the Spring of 2002, EPA submitted to OMB a draft proposed rule under the Clean Water Act to set national standards for stormwater runoff from construction sites. The draft proposal included post-construction standards that would have significantly increased federal involvement in State and local land-use decisions. During interagency review, concerns were raised that this proposal could have raised the average cost of new homes by $1000 to $2200, preclude 135,000 to 325,000 low-income families from owning a new home, eliminate up to 18,000 jobs, shut down as many as 800 construction firms, unduly burden about 150,000 small businesses, and impede highway construction. Because of these concerns, and because the adverse ecological impacts to streams from stormwater are largely local in nature, EPA ultimately decided to work with State and local governments on implementing the existing stormwater program rather than issuing burdensome new Federal regulations. This approach will be more effective, better tailored to local needs and resources, and will yield cost savings of over $4.1 billion per year.
Environment	EPA: Brownfields Program	On January 11, 2002, President Bush signed into law the Small Business Liability Relief and Brownfields Revitalization Act. This landmark legislation will help hundreds of American communities turn thousands of environmental eyesores into productive community assets. This law expands EPA's Brownfields program, boosts funding for assessment and cleanup, enhances roles for State and Tribal response programs, and clarifies Superfund liability. By promoting the cleanup and redevelopment of contaminated industrial sites, this law will improve the environment, protect public health, create jobs, and revitalize communities. As required by the Act, EPA issued a proposed rule in August of 2004 to clarify the Superfund liability provisions. EPA is also providing a substantial amount of support for this program to fund grants for states, tribes, and local communities.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Environment	EPA: General Reforms of the New Source Review Program	The New Source Review (NSR) program requires major sources that modify their production operations in a way that increases emissions to undergo a rigorous review to assure that the source is well-controlled and that the projected increase in emissions will not adversely affect air quality. This rule makes five changes to the NSR program including: (1) an updated method for establishing an actual emissions baseline; (2) a method for calculating emissions changes to determine the applicability of the NSR program; (3) provisions for setting facility-wide emissions caps, known as Plantwide Applicability Limits; (4) a Clean Unit exclusion; and (5) a streamlined approach to adopt Pollution Control Projects. These changes to the NSR program will provide sources with more flexibility to respond to rapidly changing markets and to undertake pollution control and prevention projects.
Environment	EPA: Reform of the New Source Review Program: Routine Maintenance, Repair, and Replacement Activities	This rule clarifies what component replacement activities are "routine maintenance, repair, and replacement" and therefore exempt from NSR requirements. The rule exempts from cumbersome case-by-case review certain "identical" or "like-kind" component replacements costing less than 20% of the affected process unit. This will promote routine component replacements and facility upgrades. To help ensure that adverse environmental effects will not occur, the rule contains safeguards, including the cutoff for equipment replacements costing more than 20% of the affected process unit, a requirement that the basic design parameters of the unit cannot be changed, and a bar on exceeding applicable emissions limitations. In addition, the full panoply of Clean Air programs that are the primary means for achieving emissions reductions from existing sources will continue to protect and improve the nation's air quality.
Environment	EPA: Conserving Water through the Submetering of Water Systems	On December 16, 2003, EPA issued a final policy memorandum revising EPA's interpretation of Safe Drinking Water Act (SDWA) applicability to submetered properties. This revised interpretation will promote water conservation by allowing building managers to meter and bill tenants separately for water without triggering a host of duplicative SDWA requirements. This revised interpretation only applies when a building obtains its water from a regulated water system that already provides SDWA compliant water. EPA is currently studying whether additional water conservation benefits could be obtained by expanding the policy to buildings that bill but do not separately meter residents for water (again, provided that they obtain water from a regulated water system meeting all SDWA requirements).
Environment	EPA: Reducing Emissions from Non-Road Diesel Engines	EPA in collaboration with OMB/OIRA, developed the Non-Road Diesel rule to reduce by 90% the amount of SO_2, NO_x and PM exhaust from off-road engines used in mining, agriculture and construction. These gains can only be accomplished through a dramatic reduction in the sulfur content of diesel fuel and installation of new control equipment on engines. EPA estimates that the benefits will far outweigh the costs: the present value of benefits over the period from 2004 to 2036 is estimated to be $805 billion using a 3% discount rate and $350 billion using a 7% discount rate, while the present value of costs over the same period is estimated to be $27.1 billion using a 3% discount rate and $13.8 billion using a 7% discount rate.. The rule is expected to prevent 6,400 premature deaths in 2020 and 12,000 in 2030.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Environment	EPA: Effluent Guidelines for Concentrated Animal Feedlots	In December 2000, EPA published a proposed rule expanding the Clean Water Act permitting requirements for concentrated animal feeding operations (CAFOs) and strengthening the effluent guidelines for those facilities. The proposed rule would have affected 35,000 farms, including many smaller farms, and cost about $900 million annually. In February 2003, EPA published the final rule on CAFOs. The final rule focuses on 15,000 large farms that account for most of the pollution from this sector. For the first time, these large farms will be required to control runoff of manure from their fields. Smaller farms are generally addressed through a voluntary USDA program that provides grants and technical assistance to address runoff and other environmental concerns. However, they may be subject to regulatory controls in cases where their runoff is linked to specific water quality problems. EPA estimated the cost of the final rule at $360 million annually, of which about $300 million would fall on large CAFOs. Fresh water benefits from reduced runoff at large CAFOs were estimated in the range of $200 to $350 million annually. Additional non-monetized benefits include reduced runoff from small and medium CAFOs and reduced impacts on marine waters.
Environment	EPA: Watershed Rule (Total Maximum Daily Load – TMDL)	The July 2000 Watershed Rule revised the existing requirements for States to prepare lists of impaired waters and to develop total maximum daily loads (TMDLs) for the waters on these lists. The most significant change was to require that implementation plans be developed for each TMDL and approved by EPA. Commenters argued that the prescriptive, procedural approach adopted in the 2000 rule undermined the benefits of a watershed approach to addressing water quality. In particular, the requirement for up-front EPA approval of implementation plans was thought to limit State flexibility, impede adaptive management, and unduly interfere in State water pollution control programs. The rule was withdrawn by EPA in March 2003, following public notice and comment.
Financial	Treasury/IRS: Domestic Relations Tax Reform Act Rules – Burden Reduction	This action regards a family's use of a corporate redemption or corporate dividend to divide a family business on the occasion of an owner's divorce. Treasury published a final regulation on January 13, 2003 permitting taxpayers relief under the regulation if the taxpayers enter into an agreement to specify the tax treatment agreed to by the spouses. The agreement must have been in effect on the date of the final regulation. This remedy is intended to resolve a situation resulting in conflicting court opinions regarding the prior regulation.
Financial	Treasury/IRS: 2002 Form 1040A and Schedules, U.S. Individual Income Return – Burden Reduction	This form is used by individual taxpayers to report their taxable income and calculate their correct liability. Changes made by Treasury include the deletion of two worksheets, as well as further revisions to the number of lines, Code references, and the size of worksheets. These changes were made throughout Form 1040A, instructions, and schedules, reducing paperwork burden on taxpayers by over 5 million hours. Form 1040A is used by taxpayers who do not itemize and have less than $50,000 in taxable income.
Financial	Treasury/IRS: U.S. Individual Income Tax Return, 2002 Form 1040 – Burden Reduction	This form is used by individual taxpayers to report their taxable income and calculate their correct tax liability. Treasury decided to increase the threshold for filing Schedule B (Form 1040 – used to itemize interest and ordinary dividends) to $1,500, so that fewer taxpayers will be required to file it. This reduced burden on the public by over 12 million hours.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Financial	Treasury/IRS: U. S. Corporation Income Tax Return, 2002 Form 1120 and 1120-A and Schedules – Burden Reduction	Forms 1120 and 1120-A are used by corporations to compute their taxable income and tax liability and verify that it has been correctly computed. Corporations with total receipts and assets of less than $250,000 are no longer required to complete Schedules L, M-1 and M-2 of the 1120. These same corporations are no longer required to complete Parts III and IV of the 1120-A. Furthermore, Code references were revised throughout the form and instructions to clarify and reduce burden. Changes made throughout Form 1120, schedules, and instructions by adding lines, and adding 1 form attachment further clarified how to complete the forms. These changes reduced burden by over 36 million hours.
Financial	Treasury/IRS: U.S. Income Tax Return for an S Corporation, 2002 Form 1120S and Schedules – Burden Reduction	Form 1120S and its schedules are used by S corporations, generally small businesses, to figure their tax liability and report their income and other tax-related information. IRS uses the information to determine the correct tax for S corporations and their shareholders. Under the IRS Burden Reduction Initiative, corporations with total receipts and assets of less than $250,000 are no longer required to complete Schedules L and M-1. This will reduce burden by over 14 million hours.
Financial	Treasury/IRS: Research Tax Credit – Burden Reduction	Final Treasury regulations issued in December 2002 provide rules for determining which research activities are eligible for the research credit. These final regulations were issues after an extensive public comment process and replaced earlier regulations issued in January 2001 that had been criticized as being too subjective and narrow. The new final rules provide more objective guidance for determining credit eligibility and further the purpose of encouraging research activities in the U.S.
Financial	Treasury/IRS: Consumer-Directed Health Plans	In an effort to increase employee involvement in health care decision-making and consequently reduce the increase in health care costs, many employers are establishing more consumer-directed health plans. In addition, Congress, as part of the Medicare Prescription Drug Improvement and Modernization Act of 2003, allowed Health Savings Accounts (HSAs) as a way for consumers to have more health choices. The IRS and Treasury have facilitated the establishment of these types of arrangements by providing a series of guidance measures, which addressed outstanding issues in the establishment and operation of HSAs. In addition, the IRS and Treasury provided guidance that detailed how employers could establish Health Reimbursement Arrangements, an employer-provided "account," which could be used by an employee solely to pay for qualified medical expenses. In addition, to facilitate these account-based medical plans (including flexible spending arrangements), guidance was issued that detailed how debit card technology could be used in conjunction with these arrangements.
Financial	Treasury/IRS: Employer-Based Retirement Savings Plans	The IRS and Treasury have issued multiple pieces of regulatory guidance that provided updated rules for employers to use in operating employer-based retirement savings plans, such as the 401(k) plans, 403(b) plans and 457 plans. These updated rules reflect legislative changes over the last 15 years and provide needed simplification in the administration of these plans. Final regulations were provided to set out the rules for the provision in the Economic Growth and Tax Relief Reconciliation Act of 2001 for catch-up contributions for participants over age 50 that participate in these employer-based savings plans and the minimum distribution requirements that apply to these plans and IRAs and to update the rules regarding 457 plans. Proposed regulations have been issued to update the rules for 401(k) plans and 403(b) plans.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Financial	Treasury/IRS: Mortgage Revenue Bond Purchase Price Limits	States may issue mortgage revenue bonds to provide below-market rate mortgages to certain first-time home buyers. The home prices are limited to no more than 90% of the average purchase price for homes with the area in which the home is located. Prior to 2004, the purchase price limits had not been adjusted since 1994. In 2004 IRS and Treasury updated the limits to reflect recent market conditions. This change resulted in more homes purchased by first-time buyers being eligible for the below market rate mortgages.
Financial	Treasury/OCC: Bank Activities and Operations: Real Estate Lending and Appraisals	Treasury's Office of the Comptroller of the Currency (OCC) issued a final rule addressing the applicability of certain types of state laws to national banks' deposit-taking and lending activities. The rule lists particular types of state laws that it preempts. This rule preempts without the need for further analysis, those types of state laws for which substantial precedent existed prior to the adoption of the rule - recognizing the interference they pose to the ability of Federally chartered institutions to operate under uniform standards. This rule preempts state laws that impermissibly affect national bank deposit-taking and lending powers and contains a new uniform standard to combat predatory lending. It prohibits a bank from making any loan based predominantly on the foreclosure value of the borrower's collateral, without regard to ability to repay. Further in making a loan, a national bank shall not engage in unfair or deceptive practices.
Financial	Treasury/OCC: Fair Credit Reporting Rules	Treasury issued two regulations addressing consumer protection provisions of the Fair and Accurate Transactions Act of 2003 (FACT Act). (1) On March 28, 2004, OCC issued a proposed rule that would implement provisions of the FACT Act restricting the circumstances in which consumer reporting agencies may furnish consumer reports containing medical information. The FACT Act prohibits creditors from obtaining or using medical information pertaining to a consumer in connection with any determination of eligibility for credit, and restricts the sharing of medical information and related lists or descriptions among affiliates. (2) On July 15, 2004, the OCC published for comment, a proposed regulation to implement the affiliate marketing provisions in section 214 of the FACT Act. The proposal generally prohibits an institution from using certain information about a consumer it receives from an affiliate to make a solicitation to them unless the consumer has been given the opportunity to opt out of the solicitation. An institution that has a pre-existing business relationship with the consumer would not be subject to this marketing limitation.
Health and Safety	USDA: Reducing *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products	*Listeria monocytogenes* is a pathogen that can cause listeriosis, an uncommon but potentially fatal disease in immunocompromised persons. Listeriosis is also a major concern in pregnant women because the illness can cause fetal death. Listeriosis outbreaks have been traced to both contaminated hot dogs and lunch meats. On June 6, 2003, USDA published an interim final rule, "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products," that requires establishments that produce ready-to-eat meat and poultry products to establish controls that prevent products from *Listeria monocytogenes* contamination. According to USDA, the rule imposed costs on firms of approximately $16.6 million per year, while the rule generated benefits, in the form of fewer cases of listeriosis, of approximately $44 million to $154 million per year.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Health and Safety	USDA: Bovine Spongiform Encephalopathy (BSE or "Mad Cow Disease")	On December 23, 2003, BSE was confirmed in a cow in Washington State. BSE has been linked to variant Creutzfeldt-Jakob Disease (vCJD), a disease that can destroy the human nervous system. On January 12, 2004, USDA adopted a number of additional measures to address BSE: • An Interim final rule, "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle", that banned "specified risk materials" (SRMs) -- e.g., the vertebral column from cattle 30 months and older, all non-ambulatory disabled cattle ("downers"), and mechanically separated meat from the food supply. • An Interim final rule, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems", that prohibited the use of SRMs in AMR systems and imposed quality control criteria to ensure that the products of AMR systems meet the definition of meat. • An Interim final rule "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter", that prohibited the use of air-injection stunning for slaughter. In addition, USDA has undertaken an intensive animal health testing program designed as a one-time effort that will provide a snapshot of whether BSE is present in the U.S. This program is designed to test over 200,000 cattle, and will be able to detect BSE in the cattle population even if the true rate is as low as 1 in 10 million. In July 2004, USDA and HHS also published a joint Advanced Notice of Proposed rulemaking (ANPRM) to request comment on additional measures that may be taken to address BSE. FDA also issued an interim final rule, "Use of Materials Derived from Bovine and Ovine Animals in FDA-Regulated Products," that banned, consistent with USDA's restrictions, SRMs, all non-ambulatory disabled cattle, and mechanically separated meat from FDA-regulated human food (including dietary supplements) and cosmetics.
Health and Safety	HHS/FDA: Consumer Food Labeling for Trans-Fat Content	Based on the strong scientific link between the consumption of *trans* fat and coronary heart disease, on July 11, 2003 FDA issued a final rule requiring the disclosure of *trans* fat content on nutrition labels. Information on the amount of *trans* fat in food products will allow consumers to consider the amount of *trans* fat in their food purchasing decisions, and the attention to *trans* fat content will provide an incentive for food manufacturers to reduce the amount of *trans* fat in their products. The rule is expected to produce billions of dollars in health benefits by preventing thousands of fatal and non-fatal heart attacks. FDA estimates the final rule's ratio of benefits to costs to be about 100 to 1.
Health and Safety	HHS/FDA: Bar Code Rule to Reduce Medication Errors	FDA issued a final rule on February 26, 2004 to require certain human drug and biological product labels to have bar codes. The rule will help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. The rule also requires the use of machine-readable information on blood and blood component container labels to help reduce medication errors. The rule is expected to prevent 25,000 adverse events and blood transfusion errors annually over the next 20 years. FDA estimated this rule's benefits about $5.2 billion per year and costs of about $670 million per year.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Health and Safety	HHS/FDA: Qualified Health Claims for Omega-3 Fatty Acids	The FDA will now allow producers the opportunity to make a qualified health claim for reduced risk of coronary heart disease (CHD) on conventional foods that contain eiscosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids. Typically, EPA and DHA omega-3 fatty acids are contained in oily fish, such as salmon, lake trout, tuna and herring. These fatty acids are not essential to the diet; however, scientific evidence indicates that these fatty acids may be beneficial in reducing CHD. The new qualified health claim for omega-3 fatty acids should help consumers make healthier and more informed decisions by enabling them to identify foods that contain Omega-3 fatty acids. A qualified health claim on a conventional food must be supported by credible scientific evidence.
Health and Safety	HHS/FDA: Generic Drug Rule	New regulations streamlined the process for making safe, effective generic drugs available to consumers by limiting a drug company to only one 30-month "stay" of a generic drug's entry into the market for resolution of a patent challenge. The rule also established changes in the FDA's review procedures, intended to help improve the speed and reduce the cost of determining that a new generic drug is safe and effective. The changes in the regulations were estimated to result in savings to consumers of an estimated $35 billion over 10 years, by making generic alternatives to certain more costly brand-name drugs available more quickly by avoiding time-consuming legal delays. The improvements in the efficiency of review procedures, which will require changes by both FDA and generic manufacturers, are expected to save consumers billions more, by reducing the time for determining that most new generic drugs are safe and effective, and therefore can be made available to patients.
Health and Safety	HHS/FDA: Prohibition on the Sale of Dietary Supplements Containing Ephedra	FDA issued a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra) because such supplements present an unreasonable risk of illness or injury. This FDA rule reflects what the scientific evidence shows – that ephedra poses an unreasonable risk to those who use it. Under the Dietary Supplement Health and Education Act of 1994, FDA may remove a dietary supplement from the market if it presents a significant or unreasonable risk of illness or injury when used according to its labeling or under ordinary conditions of use. FDA's final regulation presents a framework for applying this unique statutory standard. Given FDA's assumptions regarding the underreporting rate of ephedra-related health effects, they estimate the rule will lead to approximately 40-50 fewer illnesses and 7-12 fewer deaths per year tied to ephedra use, at a cost of between $7 and 90 million per year.
Health and Safety	DOL/OSHA and HHS/FDA: Promotion of Automated External Defibrillators	In July 2001 OMB suggested that OSHA consider steps to promote the use of automated external defibrillators (AEDs) in the workplace. AEDs are a proven lifesaving technology that, when used promptly and properly, increases the rate of survival after cardiac arrest. In response to OMB's request, OSHA initiated a three-pronged educational effort: an informative Technical Information Bulletin, a more detailed AED Safety and Health Topics Web page providing comprehensive information on how employers can design and implement AED programs, and a brochure entitled "Saving Sudden Cardiac Arrest Victims in the Workplace." OSHA's alliance program is promoting AED use in collaboration with the American Heart Association and the National Safety Council. OSHA has also contracted with Eastern Research Group to quantify the extent of AED use in the workplace and identify barriers to the widespread dissemination of this lifesaving technology. Additionally, FDA recently approved AEDs for use by the general public without a prescription.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Health and Safety	Treasury: Health Claims in Alcohol Labeling and Advertising	On March 3, 2003 Treasury's Alcohol and Tobacco Tax and Trade Bureau issued a final rule on the use of health claims and other health-related statements in the labeling and advertising of alcohol beverages. The rule allows the use of truthful and non-misleading health claims and health-related statements in the labeling and advertising of alcohol beverages. Health claims must be adequately substantiated by scientific evidence and properly detailed and qualified. Also the claims must disclose the health risks associated with alcohol consumption. This will enable consumers to make healthier, more informed choices with regard to consumption of alcoholic beverages.
Health Care	HHS/CMS: Medicare Prescription Drug Discount Card	This interim final regulation is designed to help people who are covered by Medicare with the cost of prescription drugs. The regulation outlining the new drug discount card program was the first action resulting from the Medicare Prescription Drug Improvement and Modernization Act of 2003. The program provides Medicare beneficiaries with discounts on the cost of their prescription drugs and is an interim benefit available to seniors until January 2006 when Medicare begins covering prescription drugs.
Health Care	HHS/CMS: Streamlining Skilled Nursing Facilities Reporting Burden	Skilled nursing facilities (SNFs) are required to submit resident assessment data in order to administer the appropriate payment rate methodology. The burden associated with this is the SNF staff time required to complete the Minimum Data Set (MDS), encode the information, and transmit the data. The new resident assessment tool takes half the time to use as the old one. This will reduce burden by over 3 million hours.
Health Care	HHS/CMS: Emergency Medical Treatment and Labor Act	On August 29, 2003, HHS issued a final rule clarifying hospital obligations to patients who request treatment for emergency medical conditions under the Emergency Medical Treatment and Labor Act (EMTALA). The rule is designed to ensure that people will receive appropriate screening and emergency treatment, regardless of ability to pay, while removing barriers to the efficient operation of hospital emergency departments. For example, the rule clarified that the EMTALA requirements do not apply to off-campus locations that are not Emergency Departments, and do not apply to admitted patients.
Health Care	HHS/CMS: Streamlining the Outcome and Assessment Information Set for Home Health Agencies	The Outcome and Assessment Information Set (OASIS) is a system used by home health agencies to submit treatment information required for Medicare reimbursement. CMS streamlined the assessment instrument and submission requirements, resulting in a reduction in the number of required items by nearly 30 % and reducing the amount of time required to complete the instrument by over 25%. Additionally, CMS has implemented clear instructions that remove the requirement that Home Health Agencies collect OASIS information on non-Medicare/Medicaid paid patients. Home Health Agencies are, however, allowed to continue to use the OASIS tool to collect data on these patients if their business processes make this desirable. These changes reduced reporting burden over 2,400,000 hours per year.
Health Care	HHS/CMS: State Discretion about Anesthesia Services	The rule, finalized on November 15, 2001, permits States to determine which professionals are permitted to administer anesthesia services and the level of supervision required. The additional flexibility provided to States allows for better access to care, particularly in rural areas, by making it easier for licensed health professionals, such as Certified Nurse Anesthetists to practice.
Health Care	HHS/CMS: Reducing Burdens under the Medicare Secondary Payer Provision	The Medicare Secondary Payer (MSP) provision specifies the conditions under which parties other than the Medicare program have primary responsibility to pay for health care services. On March 29, 2004, in compliance with the Medicare Modernization Act, CMS issued an instruction package, which relieved hospital laboratories of the burden of collecting MSP information for reference laboratory services. These changes save an additional 255,000 hours of paperwork burden.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Homeland Security	HHS/FDA: Bioterrorism Act Rules	HHS issued two regulations under the Bioterrorism Preparedness and Response Act of 2002 to bolster the safety and security of America's food supply. The new regulations enable better-targeted efforts to monitor and inspect imported foods. The rules allow quick identification and notification of food processing companies and other establishments involved in any deliberate or accidental contamination of food. These requirements represented the latest steps in ongoing efforts to respond to bioterrorism threats. (1)Registration of Food Facilities – this regulation required domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the US to register with FDA by December 12, 2003. Registration is one of several tools that would enable FDA to act quickly in responding to a threatened or actual attack on the US food supply. In the even of an outbreak of foodborne illness, such information would help FDA and other authorities determine the source and cause of the event. (2) Prior Notice of Imported Food – this regulation requires the submission to FDA of prior notice of food, including animal feed that is imported or offered for import into the US. The information must be submitted and confirmed electronically as facially complete by FDA for review no more than 5 days and no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival.
Homeland Security	DHS: Student Exchange Visitor Information System	DHS published a final rule on December 11, 2002 implementing the Student Exchange Visitor Information System (SEVIS). SEVIS is an internet-based system that provides users with access to accurate and current information on nonimmigrant foreign students, exchange visitors, and their dependents. SEVIS enables schools and sponsors to transmit electronic information and event notifications, via the Internet, to DHS, the Bureau of Immigration and Custom Enforcement (ICE) and the Department of State (DOS) throughout a student's or exchange visitor's stay in the United States. The rule reduces the public burden associated with reporting and retaining paper-based forms and streamlines the process for collecting information on nonimmigrant foreign students, exchange visitors and their dependents.
Homeland Security	HHS/CDC: Requirements for Select Agents	HHS established requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States of select agents and toxins. This includes requirements concerning registration security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. The interim final rule, implementing provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, provides protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the US homeland, such as terrorist acts involving anthrax. In response to public comments the final rule streamlines reporting requirements, clarifies inspection criteria, and provides performance based standards for securing select agents.
Homeland Security	DHS: Procedures for Handling Critical Infrastructure Information	This rulemaking establishes the procedures necessary to fulfill the provisions of the Critical Infrastructure Information (CII) Act of 2002. It establishes uniform procedures for the receipt, care and storage of CII voluntarily submitted to the Federal government. These procedures apply to all Federal agencies that receive, care for or store CII.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Homeland Security	DHS: United States Visitor and Immigrant Status Indicator Technology (US VISIT) Program	DHS published two interim final rules for the US VISIT Program, an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities, and authenticates aliens' travel documents through comparison biometrics, The first rule established US VISIT for arrivals at air and sea ports of entry and authorized a limited number of pilot exit programs. The second rule expanded US VISIT to the 50 busiest land ports of entry and expanded coverage to include travelers from Visa Waiver Program countries
Homeland Security	DHS: Designating Aliens for Expedited Removal, and Border Crossing Card Initiative	The Expedited Removal notice authorized the DHS to place in expedited removal proceedings any or all members of the following class of aliens: aliens determined to be inadmissible who are present in the US without having been admitted or paroled following inspection by an immigration officer at a designated port-of-entry, who are encountered by an immigration officer within 100 air miles of the US international land border and who have been physically present in the US continuously for the 14-day period immediately prior to the date of the encounter. The Border Crossing Card interim final rule extended the period of time which Mexican Border Crossing Card (BCC) holders can remain in the United States without obtaining additional immigration documents. The rule expanded this time from 72 hours to 30 days to help expand cross-border commerce.
Homeland Security	DHS: Implementation of National Security Maritime Initiatives	The maritime security requirements published by the Coast Guard in a final rule on Oct. 22, 2003 replace temporary rules originally issued in July 2003. The final rules effect significant changes in security practices within all segments of the maritime industry, including cruise ships, container ships, and offshore oil platforms. Designed to protect the nation's ports and waterways from a terrorist attack, the requirements require the development and implementation of security plans for vessels and facilities that have a higher risk of involvement in a transportation security incident.
Homeland Security	Treasury: Terrorism Risk Insurance Program	The Terrorism Risk Insurance Program (TRIP) has created a temporary Federal program that establishes a system of shared public and private compensation for insured losses resulting from certain types of terrorist acts. • Interim Guidance Notices – To provide necessary guidance to the insurance industry in complying with TRIA before formal regulations could be developed, Treasury issued a series of 3 interim guidance notices immediately following TRIA's November 22, 2002 effective date. Among other things, they provided clarifications to TRIA's disclosure and "make available" requirements, the insurance entities eligible to participate in the Program, and the timing and method of issuing required disclosures. • Interim Final Rules – While the interim guidance process was being pursued, Treasury simultaneously began formal rulemaking to incorporate and supercede the interim guidance notices. The rules set forth the purpose and scope of the Program, key definitions, requirements for disclosures insurers must make to policyholders and their "make available" obligation under TRIA.
Homeland Security	DOT/FAA: Cockpit Doors and Related Security Rules	The FAA implemented several rules to enhance flight and airport security in the aftermath of September 11th. These security improvements included strengthened doors on airplanes, improved baggage and cargo screening, airspace restrictions, photo identification requirements for pilots, additional background checks for baggage screeners, and the establishment of a general aviation security program.
Homeland Security	Treasury/IRS: Post September 11th Administrative Relief	As part of the federal government's rapid reaction to the events of September 11th, beginning as early as September 12, 2001, Treasury issued 20 items of guidance providing administrative relief to alleviate the tax burden on individuals and businesses affected by the attacks.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Housing	OFHEO: Public Disclosure of Financial and Other Information	On May 29, 2002, OMB sent a letter prompting OFHEO to consider rulemaking to strengthen the corporate governance of Fannie and Freddie and require certain public disclosures. OFHEO issued a final rule on April 2, 2003 to ensure the safety and soundness of the Fannie Mae and Freddie Mac. The rule also implements an agreement reached in July 2002 between OFHEO and the Securities. Under OFHEO's final rule, Fannie and Freddie would satisfy OFHEO's disclosure requirements by complying with the SEC's disclosure requirements under the Securities Exchange Act of 1934. These disclosures include reports to shareholders, proxy statements, and monthly earnings and business summaries.
Housing	OFHEO: Risk Based Capital Standards	On July 19, 2001, the Office of Federal Housing Enterprise Oversight issued a rule establishing capital standards for Fannie Mae and Freddie Mac pursuant to the Federal Housing Enterprise Safety and Soundness Act of 1992. The rule was amended and fine tuned on February 13, 2003. The two Federally chartered enterprises provide liquidity and support to the secondary mortgage markets. The rule models the portfolios and balance sheets of the two enterprises and sets up a stress test based on extreme interest rate environments and economic conditions to determine what level of capital they would need to weather such financial conditions. Thus the rule increases the financial safety and soundness of our mortgage markets and financial system
Housing	HUD: Housing Goals for Government-Sponsored Entities	By law HUD sets housing goals for the two Government-Sponsored Enterprises (GSEs) that are mortgage intermediaries: Fannie Mae and Freddie Mac. A final rule published on November 2, 2004 affects GSEs starting January 1st. The final rule helps make homeownership more affordable for persons of low or moderate incomes and those in areas that are "underserved" with affordable housing. Congress expects these federally-chartered GSEs to lead the rest of the mortgage market in making housing affordable. In fact, the GSEs have usually lagged the market. The goals are minimum performance standards. For each type of homeowner, tenant, or community that the GSEs were chartered to help, the final rule sets the minimum shares of each GSE's business that serves these housing goals. The GSEs would keep up with market forecasts, with no risk to their finances. A pre-rule published at the same time asks for public comment on how to resolve a difficult detail. Low-income homeowners are slower than others to refinance their fixed-rate mortgages when rates drop. Consequently, periods of extensive refinancing, like 2003, have relatively few affordable mortgages and so make it more difficult for the GSEs to meet their goals. Although HUD has the authority to deal with such circumstances all parties wanted HUD to propose a mathematical procedure for these times. The pre-rule solicits suggestions for developing an acceptable procedure.
Labor	DOL: Birth and Adoption Unemployment Compensation	The Department of Labor removed regulations allowing States to provide partial wage replacement through unemployment compensation, for parents taking approved leave to care for a newborn or newly adopted child. This rule, issued on October 9, 2003, will protect the availability of already scarce unemployment trust funds for the involuntarily unemployed by preventing their use by individuals on voluntary leave.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Labor	DHS: Forms I-140 and I-485	DHS published an interim final rule on July 31, 2002 allowing concurrent filing of forms I-140 and I-485. The previous rules only allowed for an immigrant worker to file the Application To Register Permanent Residence or Adjust Status, Form I-485, after the alien's underlying Immigrant Petition for Alien Worker, Form I-140, had been approved. Due to these requirements, there were growing delays and backlogs from the time the Form I-140 was filed with the legacy INS until the alien worker was able to file Form I-485 and obtain interim benefits such as permission to travel and an Employment Authorization Document. Concurrent filing eliminates the delay that took place between approval of the Form I-140 worker petition and the subsequent filing of the Form I-485 adjustment application.
Labor	DOL: White Collar Exemption (541 Overtime)	The final rule implements the exemption from minimum wage and overtime pay for executive, administrative, professional, outside sales and computer employees. These exemptions are often referred to as the FLSA's "white collar" exemptions. To be considered exempt, employees must meet certain minimum tests related to their primary job duties, and in most cases must be paid on a salary basis at not less than minimum amounts specified in these regulations. The final rule simplifies complex "duty" tests, raises the exempt salary thresholds in the salary level test, allows for deductions from pay for disciplinary suspensions, and creates a "safe harbor" for employers who make improper salary deductions that are isolated or inadvertent. The final rule strengthens overtime protections of 6.7 million workers earning $23,660 or less, including 1.3 million salaried "white collar" workers newly eligible for overtime who will gain approximately $375 million in additional earnings every year. The final rule ensures that employees can understand their rights to overtime pay, employers can readily determine their legal obligations, and DOL can more vigorously enforce the law.
Labor	DOL: Labor Organization Annual Financial Report (LM-2)	This final rule revises the Form LM-2, which is used by the largest labor organizations to file annual financial reports. The purpose of this reform is to improve the transparency and accountability of labor organizations to their members, to increase the information available to members of labor organizations, and to make the data disclosed in such reports more understandable and accessible. The rule requires Form LM-2 filers to file reports that identify "major" receipts and disbursements, and to allocate disbursements among the categories provided in the form (e.g., contract negotiation and administration, organizing, political activity, lobbying, etc.). It also requires covered labor organizations to report the assets, receipts, liabilities, and disbursements of organizations that meet the statutory definition of a "trust in which a labor organization is interested."
Land Management	USDA: Conservation Security Program for Farmers	USDA issued a final rule implementing the Conservation Security Program (CSP), a newly created program supporting the conservation efforts of agricultural producers. CSP is unique in that it provides payments to agricultural producers who meet the eligibility requirements for their existing conservation efforts, as well as for new conservation practices and activities they undertake during their contracts. CSP rewards producers that have addressed soil and water quality concerns, and encourages them to address additional resources.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Land Management	DOI/MMS: Deep Gas Royalty Relief	In January 2004, the Department of Interior's Minerals Management Service (MMS) issued a final rule creating new incentives for natural gas development in hard-to-reach areas of the Gulf of Mexico. The accelerated production expected to result from these incentives will help to meet expected increases in demand and ease price volatility until additional supplies become available. The rule will save American consumers an estimated $570 million a year and help to ensure the nation's energy security by boosting domestic production. Although most of the gains to consumers will be offset by losses to producers, the agency did find that this rule will result in a net social gain of approximately $30 million per year. Because this rule would only apply to those operators who have current active leases and existing infrastructure, it is not expected to have significant adverse environmental effects.
Land Management	DOI, USDA, Commerce: Healthy Forest Initiative	The three Departments have promulgated several regulations to promote the implementation of healthy forest projects. The USDA Forest Service amended its rule limiting project appeals by the public to the early stages of the decision-making process, to expedite project decisions and allow faster implementation. The DOI's Bureau of Land Management (BLM) promulgated a final rule which allows wildland fire management decisions to be effective immediately when public lands are at substantial risk from wildfires. Additionally, the DOI's Office of Hearings and Appeals amended its rules to expedite its review of wildland fire management decisions. The Departments of the Interior and Commerce also issued joint Endangered Species Act (ESA) counterpart regulations that accelerate ESA reviews for projects that support the National Fire Plan on federal lands.
Procurement	DOD: Defense Federal Acquisition Regulation Supplement	In December 2002, DOD completed a burden reduction initiative that will reduce annual paperwork burden on its contractors and contract applicants by over 14 million hours. The requirements for contract solicitations are Defense's second largest information collection and many Defense Department contracts are targeted to and awarded to small businesses. This burden is to apply for benefits and for contracts to provide goods and services under the Defense Federal Acquisition Regulation Supplement (DFARS), a supplement to the Federal Acquisition Regulation. The higher burden for collection of information increased costs and delays.
Procurement	DOD: Acquisition Management Systems and Data Requirements Control List	This list is used in contracts for supplies, services, hardware, and software, necessary to support design, testing, manufacture, training, and the operation and maintenance of procured items. DOD implemented new business processes and improved policies that reduced information requirements. Enabling electronic transmittal of required information further reduced the burden on contractors. The initiative reduced burden by over 26 million hours.
Procurement	DOD: Information Collection in Support of the DoD Acquisition Process (Solicitation Requirements).	An offeror must submit to DoD a variety of procurement-related information in response to DoD solicitations. As a result of business process re-engineering and improved acquisition policies, information requirements were reduced. Enabling electronic transmittal of required information further reduced the burden on contractors. This reduced burden by over 14 million hours.
Procurement	DOD: Contract Bundling	Contract Bundling is the practice of grouping a number of different contract requirements into a single large contract. This practice can lead to reduced small business participation in Federal contracting by making the contracts too large for them to handle. Prompted by the President's Small Business Agenda, the Small Business Administration and Federal Acquisition Regulation Council published a final rule amending the Prime Contracting Assistance regulations on October 20, 2003, that restricted contract bundling, ensuring increased opportunities for small businesses to participate in Federal contracts.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Social Services	Faith Based Initiative	The Faith-Based Initiative has been active in implementing the principles of the Executive Order 13279 through regulations. Faith-Based Organizations have for many years been an integral part of social services and safety net programs in this country. To a large extent, these regulations seek to ensure Faith-Based Organizations the opportunity to compete on equal footing for Federal funding and to eliminate unequal burdens on grantees that are Faith-Based in nature. Faith-Based centers at seven agencies (Ed., HHS, HUD, DOJ, DOL, USDA, and USAID) have promulgated thirteen final rules, including general rules that cover the funding delivered by six agencies, three regulations implementing Charitable Choice statutes, a DOL regulation implementing the amendment of EO 11246, and three regulations changing discriminatory language in specific HUD, VA, and DOL programs. Two additional rules have been proposed and are yet to be finalized, one of which is a general regulation covering a seventh agency.
Social Services	HHS: Language-Assistance Services for Limited English Proficient Individuals	On August 8, 2003 HHS issued revised LEP guidelines, which explain when and how providers should make appropriate interpretation and translation services available for people who need this help. The guidelines are based on a framework developed by DOJ, with modifications designed to reduce regulatory burden on health care providers, such as by allowing LEP individuals to use family and friends as translators.
Social Services	USDA: Food Stamp – Social Security Combined Application Project	The Food and Nutrition Service and the Social Security Administration have signed a memorandum of understanding to approve state agencies to operate Combined Application Project (CAP) demonstrations. These projects simplify enrollment procedures for both caseworkers and the elderly and disabled recipients by relying on technology, standardized benefits and streamlined application procedures for providing food stamp benefits to one-person households eligible for both Food Stamps and Social Security Income. To date, 3 CAP projects (MS, WA, and NY) have been implemented. Several other States are in the process of implementing the CAP project. Early evidence indicates that the CAP project increases participation and lowers administrative costs.
Transportation	DOT: Deregulation of Computer Reservations Systems	Computer reservations systems (CRSs) provide software to travel agents to allow them to book airfares 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. DOT's January 2004 final rule eliminated the CRS rules. Industry estimates that the elimination of these rules will save consumers $1.9 billion per year.
Transportation	DOT/NHTSA: Modernized Hours of Service For Truck Drivers (HOS)	The new HOS rules allow truck drivers to drive 11 hours after 10 consecutive hours off-duty. Also, drivers may not drive beyond the 14th hour after coming on duty, following 10 hours off duty. The old HOS rules allowed 10 hours of driving within a 15-hour on-duty period, after 8 hours of off-duty time. Similar to existing rules, drivers may not drive after 60 hours on duty within a consecutive 7-day period or 70 hours on duty in a consecutive 8-day period. The new, science-based rule makes significant strides in providing commercial drivers a 24-hour work/rest schedule in line with the body's circadian rhythm. The longer off-duty time allows drivers to have more regular schedules and increases the opportunity for quality sleep. This is consistent with fatigue- and sleep-related studies considered in development of the rule that indicate the amount and quality of sleep a person receives has a strong influence on alertness.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Transportation	DOT/FAA: Sport Pilot Certification Rule	This FAA final rule enables the safe development of a new area of aviation by establishing new certification requirements for light-sport aircraft (small, single-engine, and low performance aircraft designed for one or two passengers). The rule also establishes requirements for light-sport plane pilots and repairmen. The lower costs associated with the production and development of light-sport aircraft are expected to foster growth in general aviation and the current pilot population.
Transportation	DOT/FWHA: Highway Work Zone Safety	On November 20, 2003, the FHWA published a final rule including provisions for greater use of high-visibility clothing and barricade devices to improve safety for highway construction workers. It also contained a new section on fluorescent pink signs to alert drivers to traffic incidents and increased letter size on street signs and turn-path pavement markings at intersections meant to help older drivers. For pedestrians, the FHWA has included "animated eyes," "countdown signals" and "in-street" pedestrian signs. Additionally, there are new provisions to help pedestrians with disabilities such as the use of barriers to assist in safe navigation of walkways and audible devices to communicate sign information will assist visually impaired individuals. Other items to improve safety are longer stopping distances, more warning signs, sequential chevron panels, nighttime lighting requirements and flashing lights on STOP/SLOW paddles.
Transportation	DOT/FRA: Electronic Submission; Hours of Service Regulations	The Department of Transportation has undertaken a number of initiatives to reduce paperwork burden through the use of automation and electronic reporting. For example, the Hours of Duty records, used by railroads to account for the time that covered employees spend on the job were converted from a paper to an electronic format. To date, both time and cost burdens have been substantially reduced. The conversion from a paper to an electronic format reduced the burden on railroads by over 772,000 hours.
Transportation	DOT/FRA: Whistle Bans on Highway-Rail Grade Crossings	This FRA rule requires locomotive engineers to continue to sound horns at highway crossings unless communities create "quiet zones" by installing new crossing safety equipment or prove that the risk is low for accidents at a crossing that has gates and flashing lights. In all cases, an engineer can sound a horn whenever he believes there is an emergency. In addition, horns would be sounded no more than 15 to 20 seconds before reaching a crossing, rather than in accordance with the current quarter-mile rule. The rule also set new standards for the minimum sound level and, for the first time, the maximum sound level that can emanate from a locomotive horn. The rule effectively balances the safety of motorists with the desire of communities near railroad tracks to get some sleep at night.
Transportation	DOT/NHTSA: Corporate Average Fuel Economy (CAFE) Standards	In April 2003 NHTSA published a final rule raising light-truck, fuel-economy standards for the first time in a decade. NHTSA estimates that the fuel savings for consumers who purchase 2005-2007 vehicles will more than pay for the compliance costs of this rule. The rule will reduce oil consumption by 3.6 billion gallons over the life of these vehicles.
Transportation	DOT/NHTSA: Fuel System Safety Standard B Vehicle Fires	In December 2003, NHTSA published a final rule upgrading its fuel system integrity standard. This upgrade increases the test speed for rear crashes from 30 mph to 50 mph and increases the test speed for side crashes from 20 mph to 33.5 mph. The upgrade also uses a heavier barrier with a more aggressive face to better replicate a crash with another vehicle. This upgrade will ensure that people who survive high-speed crashes will not die in a fire caused by a fuel leak from the crash. The new rear impact requirements will be phased-in, beginning September 1, 2006, with compliance of all new vehicles required by September 1, 2008. All new vehicles will be required to comply with the new side impact requirements beginning September 1, 2004.

Table 9: Regulatory Reform Accomplishments		
Issue Area	**Agency/Rule**	**Summary/Status**
Transportation	DOT/NHTSA: Collection of Annual Registration Fees	In its final rule issued on January 9, 2003, RSPA reduced the hazmat registration fee for all persons who transport or offer for transportation certain categories and quantities of hazmat. For large businesses the fee used to be $1975 annually. It was reduced to $275. For small businesses it was $275 and now is $125.

Table 10: Promising Regulatory Reform Proposals		
Issue Area	**Agency/Rule**	**Summary/Status**
Education	ED: Title IX and Single-Sex Schools	The Department is changing the regulations implementing Title IX of the Education Amendments of 1972, which prohibits sex discrimination in federally assisted education programs. A proposed rule, published on March 9, 2004, would expand flexibility for recipients that may be interested in providing single-sex schools or classes.
Environment	EPA: Stormwater Permits for Small Oil and Gas Drilling Operations	In this final action, EPA delayed for two years – until March 1, 2005 -- its requirement that small oil and gas drilling operations obtain permits for stormwater runoff during construction of the site. The impacts on these operations were not analyzed when EPA established the original permit requirement because EPA believed most such operations would be eligible for an exemption as sites less than 1 acre in size. However, new information showed that this assumption was incorrect. Following President Bush's Executive Order 13211 requiring energy impacts analysis, EPA decided to gather additional data to determine if imposing permitting requirements on these operations would result in a significant energy impact. EPA also decided to evaluate the applicability of the statutory exemption for oil and gas exploration to these facilities. Based on current information, environmental impacts from such operations appear to be minimal. There should be at least $55 million in annual cost savings to the affected 30,000 drilling starts each year.
Environment	EPA: Integrated Risk Information System (IRIS)	IRIS is a database containing information on human health effects that may result from exposure to various substances found in the environment. IRIS was initially developed for EPA staff in response to a growing demand for consistent information on chemical substances for use in risk assessments, decision-making and regulatory activities. IRIS is now broadly used by all sectors of society. Comments from the public have included the suggestions that the IRIS process be more transparent and better documented. There are also concerns that it contains outdated information. EPA has expanded the IRIS staff and revised the internal review processes used to review database submissions. EPA is continuing to work on ensuring compliance with the pre-dissemination standards in the OMB and EPA Information Quality Guidelines.

Table 10: Promising Regulatory Reform Proposals		
Issue Area	**Agency/Rule**	**Summary/Status**
Environment	EPA: Cancer Risk Assessment Guidelines	The Guidelines for Carcinogen Risk Assessment are designed to provide EPA staff and decision makers with guidance for developing and using carcinogen risk assessments, as well as transparency for interested parties with respect to EPA's assessment methods. Final guidelines were last published in 1986. The agency requested comment on updated in drafts in 1996, 1999, and 2003. The 1999 draft is currently designated as the interim guidance. In conjunction with the 2003 draft, EPA released the first draft of its "Supplemental Guidance for Assessing Cancer Susceptibility from Early Life Exposures to Carcinogens." This supplemental guidance was reviewed by the Agency's Science Advisory Board (SAB) in March of 2004. EPA is in the final stages of preparing guidance that will replace the 1986 (and the 1999 draft interim) guidelines. The document, which includes the Agency's response to public comments and concerns raised by the SAB, is designed to ensure compliance with the pre-dissemination standards in the OMB and EPA Information Quality Guidelines. These updated Guidelines will be submitted for interagency review shortly.
Environment	EPA: Utility Mercury Reductions Rule	On December 15, 2003, EPA issued a proposal to substantially cut mercury emissions from coal-fired power plants. The rule would permanently cap emissions from coal-fired power plants and provide companies with flexibility to achieve early reductions of mercury. This is the first time EPA has proposed to regulate mercury from coal-fired power plants; when it is fully implemented, the rule will cut mercury emissions by nearly 70 percent.
Environment	EPA: Metals Assessment Framework	In response to widespread concerns from stakeholders, EPA has been working for the past three years on a new framework for assessing the environmental hazards of metals. This effort reflects a growing consensus within the scientific community that the "persistent, bioaccumulative toxic" (PBT) approach has limited usefulness for inorganic metals for several reasons, including 1) bioaccumulation appears to be inversely related to ambient concentration in many cases, 2) the PBT framework does not adequately account for fate and transport, 3) trace amounts of metals are essential for many organisms, and 4) because elemental metals are naturally occurring, many organisms have developed mechanisms for sequestering them (e.g. in bone) that may not correlate well with hazard. EPA is about to launch a Science Advisory Board review of the current draft of the framework, which will ultimately serve as the basis for hazard assessment for metals across EPA program areas.
Environment	EPA: Beach Act Pathogen Standards	In July of 2004, EPA issued a proposed regulation to improve standards for water quality monitoring at our nation's beaches. The new rule will ensure that more protective, health-based standards for infections pathogens are in place in all coastal recreational waters nationwide, including both coastal and Great Lakes beaches. This will support improved beach monitoring programs, tougher permitting to prevent wet weather sewage overflows, and reduced transmission of waterborne diseases.
Environment	EPA: Paperwork Burden Reduction Initiative under the Resource Conservation and Recovery Act	A proposed rule was published in 2002 that would significantly reduce the paperwork burden imposed under the Resource Conservation and Recovery Act (RCRA). The rule establishes higher chemical use thresholds for small businesses (facilities below these thresholds would not have to report). EPA wants to ensure that only the information actually needed to run the RCRA program is collected. EPA estimates that the initiative will reduce burden by 929,000 hours and save $120 million annually.

Table 10: Promising Regulatory Reform Proposals		
Issue Area	**Agency/Rule**	**Summary/Status**
Environment	EPA: Definition of Solid Waste	EPA published a proposed rule on October 28, 2003, that would revise the definition of "solid waste" under the Resource Conservation and Recovery Act (RCRA). This rule would expand the universe of industrial wastes, including various spent solvents, sludge and other wastes that would be eligible for the recycling exemption under RCRA. Successfully expanding recycling of industrial wastes would be environmentally beneficial and yield large cost savings by reducing disposal costs. EPA also proposed an option that would allow a wider use of recycling. EPA estimated its primary option could save about $200-$300 million annually compared with current regulations.
Environment	EPA: Best Available Retrofit Technology	The Clean Air Act addresses visibility in national parks and wilderness areas, in part, by requiring best available retrofit technology (BART) on certain major sources emitting pollutants that impair visibility. In 2001, EPA proposed BART guidelines to assist states in identifying BART-eligible sources, determining which sources may be anticipated to contribute to visibility impairment, and conducting a technical analysis of possible controls. EPA's 1999 regional haze rule allows States the option of implementing an emissions trading program or other alternative measure instead of requiring BART. In 2004, in response to a court ruling, EPA re-proposed its BART guidelines to provide states with greater flexibility in determining which sources may be anticipated to impair visibility, and to require states to consider visibility improvement when making a BART determination. EPA also stated that it expects the final Clean Air Interstate Rule (CAIR) to satisfy the BART requirements for affected electrical generating units (EGUs) that are covered pursuant to the final CAIR. EPA believes that such an approach will increase net benefits over source-specific BART.
Environment	EPA: Disinfection Byproducts Rule and Long Term Surface Water Treatment Rule	These rules, proposed on August 18, 2003, will reduce exposure to potentially harmful disinfection byproducts (DBPs) in drinking water, while at the same time maintaining and enhancing protection against pathogens, particularly cryptosporidium. Under the new rules, drinking water systems will be required to monitor for cryptosporidium in their source water, and depending on results, increase their removal rate by up to 300 fold. They will also have to ensure that customers in all parts of the distribution system receive water that meets standards for DBPs, rather than only ensuring that water meets the standards on average, as is currently the case. This is important because harmful DBPs can form disproportionately in parts of the distribution system, after water leaves the treatment plant. The rules reflect consensus recommendations of a broad range of drinking water stakeholders including environmental groups, consumer advocates, drinking water utilities, and State and local governments.
Environment	EPA: Interstate Clean Air Rule: Reducing Pollution from Coal-Fired Powerplants	In December 2003, EPA proposed the largest air pollution reductions since the passage of the Clean Air Act Amendments of 1990. The proposed rule would reduce the interstate transport of pollutants that contribute to unhealthy levels of particulate matter and ozone. The proposed rule would establish a modern trading system to cut power plant emissions of SO_2 by 70% and NOX by 65% in 30 states (mostly located East of the Mississippi River.) EPA estimates that the final CAIR rule will yield benefits of $80 billion per year – with reductions of 13,000 premature deaths, 18,000 non fatal heart attacks – and impose costs on the electric utility sector of $2.5 to $4 billion per year.

Table 10: Promising Regulatory Reform Proposals		
Issue Area	**Agency/Rule**	**Summary/Status**
Environment	EPA: Paperwork Burden Reduction in the Toxic Release Inventory Program	EPA has undertaken several initiatives to streamline and strengthen the TRI reporting program. These include an enhanced version of its award winning TRI Made Easy (TRI-ME) software; a white paper soliciting comment on various burden reduction approaches, including enhanced use of Form A, higher reporting thresholds for some classes of chemicals and facilities, and "no significant change" certification in lieu of comprehensive annual reporting; and revisions to its instruction, guidance and Q&A documents.
Environment	EPA: Spill Prevention Plans	EPA finalized a Spill Prevention, Control, and Countermeasures (SPCC) rule in July 2002. This rule was designed to prevent discharges of oil into navigable waters of the United States, and to contain those spills after they occur. Facilities subject to the rule must prepare and implement plans to prevent such discharges and respond to spills. Regulated entities believe that the cost of compliance with SPCC requirements could be reduced by hundreds of millions of dollars without diminishing the environmental benefits. In 2004, EPA published a list of clarifications to the rule, developed by the Agency during the course of settlement proceedings. EPA also extended, by one year, the deadline for facilities to amend and implement their SPCC plans. EPA recently announced its intention to consider specific changes to the SPCC rule.
Environment	DOE: Greenhouse Gas Guidelines	As part of the Administration's effort to encourage proactive, voluntary reductions of greenhouse gas emissions, DOE's Guidelines for Voluntary Greenhouse Gas Reporting will strengthen the process for entities to assess, calculate and report greenhouse gas reductions to DOE. DOE will then process and disseminate the data in a publicly available database. A proposed rule, published on December 5, 2003, increases the requirements that the voluntary participants must meet with respect to data quality, and thereby strengthens the credibility of the emission reduction claims.
Health and Safety	USDA: Animal Identification	Currently the U.S. does not have a comprehensive system that can quickly and effectively identify individual animals or groups; the premises where they are located; and the date of entry to that premise. Such information enhances disease preparedness by allowing the U.S. to identify and locate any animals exposed to disease and will facilitate stopping the spread of that disease. On Dec. 30, 2003 the USDA announced that they would expedite the implementation of a national animal identification system for all species after the discovery of a BSE positive cow in Washington State. On April 27, 2004, USDA announced the framework for implementation and initiated phase I of their plan for a National Animal Identification System (NAIS). In July 2004, USDA and FDA published a joint ANPRM seeking further comment on the implementation of a national animal ID system. Implementation of the system is prioritized to address cattle first, then moving to other types of livestock. While much has been done, more remains.
Health and Safety	HHS/FDA: Consumer Food Labeling for Trans-Fat Content	On July 11, 2003, FDA published a final rule that requires manufacturers to list the amount of *trans* fat on nutrition labels on food packaging. However, the final rule left some issues unresolved such as establishing definitions of specific content claims for *trans* fat (e.g., *trans* fat free), qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids. Under the Nutrition Labeling and Education Act food producers may not use nutrient content claims or health claims that are not explicitly defined by FDA in a regulation. In addition, FDA did not provide recommendations on the consumption of *trans* fat. To address these issues, FDA published an advance notice of proposed rulemaking along with the final rule to solicit information and data that could be used to develop new nutrient content claims and health claims about *trans* fat as well as other information on food labels to help consumers in maintain healthy dietary practices.

Table 10: Promising Regulatory Reform Proposals		
Issue Area	**Agency/Rule**	**Summary/Status**
Health and Safety	DOL/OSHA: Ergonomics Guidelines for Industry	In November 2000, OSHA issued an "ergonomics" regulation designed to address musculo-skeletal disorders (MSDs) such as carpal tunnel syndrome, bad backs and tendonitis. The rule would have required employers with an employee who reported experiencing an MSD to implement a wide-ranging ergonomics program. OSHA estimated that the cost of the rule would have been over $4 billion annually. Industry estimated that the costs of the rule were $90 billion annually. In March of 2001, Congress passed a historic and bipartisan joint resolution overturning the ergonomics regulation under the Congressional Review Act. President Bush signed the joint resolution. In this Administration, OSHA is developing targeted, non-binding guidelines to reduce MSDs rather than issue cumbersome rules. So far, OSHA has published final Guidelines for Retail Grocery Stores. OSHA expects to publish similar guidelines shipyards and poultry processing and to select additional industry or task-specific guidelines.
Health and Safety	DOL/OSHA: Reducing Occupational Exposure to Hexavalent Chromium	With this rule, OSHA proposed to amend its existing standard for employee exposure to hexavalent chromium (Cr(VI)) based upon a determination that employees exposed to Cr(VI) face a significant risk to their health at the current permissible exposure limits and that the proposed standard could significantly reduce that risk. The rule proposes to change the current permissible exposure limit from 52 micrograms of Cr(VI) per cubic meter of air to 1 microgram per cubic meter of air. OSHA also proposes ancillary provisions for employee protection such as preferred methods for controlling exposure, respiratory protection, protective work clothing, hygiene practices, and medical surveillance.
Health and Safety	HHS and USDA: Update of the Dietary Guidelines for Americans and the Food Guide Pyramid	*Dietary Guidelines for Americans* provide science-based advice to promote health and to reduce risk for major chronic diseases through diet and physical activity. By law, the Secretaries of the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) issue a report at least every 5 years that "shall contain nutritional and dietary information and guidelines for the general public." Every 5 years, an expert Dietary Guidelines Advisory Committee is appointed to make recommendations to the Secretaries concerning revision of *Dietary Guidelines for Americans*. The 2005 Dietary Guidelines Advisory Committee report includes recommendations on reducing consumption of foods high in trans fatty acids and increasing consumption of foods rich in omega-3 fatty acid. On May 23 2003, OMB sent a prompt letter to HHS and USDA concerning trans fat and omega-3.
Health Care	HHS: HIPAA - Standards for Protecting the Privacy of Individually Identifiable Information (Medical Privacy Rule)	This regulation initially issued in 2000 and subsequently revised and simplified by HHS in 2002, put in place a large number of requirements intended to protect the privacy of individual medical records. However, implementation has been confusing and burdensome for the medical community and additional reform may be required. Commenters recommend that the rule should be refined and clarified to reduce administrative and compliance costs.
Homeland Security	DHS: Support Anti-Terrorism by Fostering Effective Technology (SAFETY Act)	DHS published an interim final rule with request for comments implementing the SAFETY Act provision of the Homeland Security Act of 2002. Through this rule, DHS provides critical incentives for the development and deployment of antiterrorism technologies by providing liability protections for sellers of "qualified antiterrorism technologies" and others. The final rule revised and simplifies the Safety Act application kit.

Table 10: Promising Regulatory Reform Proposals		
Issue Area	**Agency/Rule**	**Summary/Status**
Labor	DOL/Vets: Uniformed Services Employment Reemployment Rights Act (USERRA)	This rule would set forth regulations for the USERRA program, in operation since 1994 through technical assistance and operating guidance. Under USERRA, eligible service members who leave their civilian jobs for military service are entitled to return to their jobs with the seniority, status, and rate of pay they would have attained had they not been on duty. USERRA also assures they will not suffer discrimination in employment because of military service or obligations. This is a rule that should ease the transition home for service members currently in the field. It should be received neutrally by employers, who should already be aware of its obligations and have been seeking clarification to the current implementation framework.
Land Management	USDA: Roadless Rule	On July 16, 2004, USDA issued a proposed rule governing the management of inventoried roadless areas in the National Forest Service lands in the lower 48 states. This rule will replace the 2001 Roadless rule which prohibited, with certain exemptions, all road construction and reconstruction in National Forests. The proposed rule allows state governors to petition USDA to issue state-specific rules addressing roadless area management. This rule responds to criticism that USDA failed to consider states' concerns when it promulgated the 2001 rule – in particular, the difficulty of tailoring a national rule to address unique local conditions. The rule also takes steps that will lead to more sustainable forest management.
Land Management	USDA/NFS: Forest Planning	Commentor recommended the 2000 Forest Planning rule be revised to avoid polarizing the public and wasting agency resources. The Forest Service issued a new proposed planning rule in December 2002 and is working to finalize it based on public comments. The new rule will focus on adaptive management and monitoring to streamline the planning process and result in more timely agency actions.
Transportation	DOT/NHTSA: Reform of Corporate Average Fuel Economy (CAFE) Standards	The Administration earlier had asked Congress to provide broader authority to reform and improve the CAFE program. In the absence of Congressional action, NHTSA has focused its efforts on reforms that can be achieved with existing authority and has used as guidance the recommendations of a National Academy of Science report. NHTSA published in December 2003 an ANPRM seeking comment on possible ways to improve CAFE. For model years 2008 and beyond, NHTSA is considering reforms of the CAFE program that will facilitate even greater fuel savings, without risk to passenger safety or jobs in vehicle manufacturing. The ANPRM discusses several options for restructuring the program for light trucks (i.e., SUVs, vans, and pickup trucks).
Transportation	DOT/NHTSA: On-Board Crash Recorders	In June 2004, NHTSA published a proposed rule to establish defined protocols to be used in the incorporation of Event Data Recorders (EDRs) into motor vehicles. These devices provide critical crash information that aid investigations of the causes of crashes and injuries, and make it possible to better define safety problems and develop more effective future safety initiatives. Among the proposals are ones to (1) require that the EDRs voluntarily installed in light vehicles record a minimum set of specified data elements useful for crash investigations, analysis of the performance of safety equipment, and automatic collision notification systems; (2) specify requirements for data format; (3) increase the survivability of the EDRs and their data.

Table 10: Promising Regulatory Reform Proposals		
Issue Area	**Agency/Rule**	**Summary/Status**
Transportation	DOT/NHTSA: Side-Impact Protection	In May 2004, NHTSA published a proposed rule to upgrade the federal motor vehicle safety standard established to protect vehicle occupants in side impact crashes. First, it would upgrade the standard by requiring that all light passenger vehicles protect front-seat occupants against head, thoracic, abdominal and pelvic injuries in a vehicle-to-pole test simulating a vehicle's crashing sideways into narrow fixed objects like telephone poles and trees. Second, this proposed rule would upgrade the standard's existing vehicle-to-vehicle test that requires protection of front- and rear-seat occupants against thoracic and pelvic injuries in a test that uses a moving deformable barrier to simulate a moving vehicle's being struck in the side by another moving vehicle. When fully implemented, the proposed upgrade is estimated to save 700 to 1000 lives and prevent 900 to 1000 serious injuries over the life of each year's new vehicle fleet, at a cost of $1.6 billion to $3.6 billion per year.

Table 11: Unfinished Business: Additional Regulatory Reforms		
Issue Area	**Agency/Rule**	**Summary/Status**
Environment	EPA: New Source Review (NSR)	New Source Review (NSR) is a Clean Air Act program that requires major stationary sources to install state-of-the art air pollution controls whenever an owner or operator of such a source undertakes a major modification that would result in a significant increase in one or more of the criteria pollutants. Commenters argued that the regulations are too vague and complex, making it difficult to determine when a facility triggers the NSR permitting process. EPA has already published two rules to address some of the problems with the NSR program, including the final Equipment Replacement rule (see descriptions above in Table 9). EPA is continuing to work on changes to the NSR program to simplify and clarify the requirements of the program. These additional changes include a proposal to address questions concerning the treatment of "de-bottlenecking" projects and the procedures for "aggregation" of multiple projects.
Environment	DOI and DOC: Definition for Listing and Critical Habitat	The Ninth Circuit has recently ruled that DOI and DOC's definitions for the standards applied to endangered and threatened species and critical habitat consultations under Section 7 of the ESA are improper. Currently, the standard used to determine if a species will be "jeopardized" by a proposed action and that used to determine if a designated critical habitat will be "adversely modified" are so similar as to render the designation of critical habitat meaningless. The Departments' regulations will need to be revised to address this concern.
Environment	EPA: Sanitary Sewer Overflows	Currently, all discharges from a Publicly Owned Treatment Works are required to achieve effluent limitations based upon secondary treatment. EPA has interpreted this to include any discharge from the collection system (sewers). In practice, however, most sewer systems experience occasional discharges due to a variety factors. All such discharges (called "sanitary sewer overflows") are currently treated as violations of the Clean Water Act, regardless of whether they are beyond the reasonable control of the operator. EPA is currently developing a rule, with stakeholder input, that would clarify appropriate operation, maintenance and planning practices for good sewer system operation, while recognizing that municipalities which follow these practices should not be penalized for overflows that are beyond their reasonable control.
Environment	EPA: Drinking Water Affordability	Under the Safe Drinking Water Act, EPA may authorize States to grant variances to small drinking water systems for specific regulatory requirements, but only if EPA first determines, based on a national level analysis, that the requirements are not affordable for small systems, and that granting the variances will not endanger public health. EPA's current threshold for determining that a standard is not affordable is that the average incremental cost of achieving the standard at small systems should not exceed $500 per household per year. This is based on specific assumptions about income, baseline water bills, and compliance costs that may be valid on a national average basis, but do not reflect the situation of economically disadvantaged systems. As a result, no drinking water standard has ever been identified by EPA as "unaffordable" at a national level, and small systems variances have never been authorized, even though several recently promulgated standards have imposed very high per household costs on some small systems. EPA should revise its affordability approach to allow States an opportunity to judge the economic circumstances of individual systems and grant variances where compliance with standards is not affordable.

Table 11: Unfinished Business: Additional Regulatory Reforms		
Issue Area	**Agency/Rule**	**Summary/Status**
Health and Safety	USDA/FNS: Meal Requirements for Child Nutrition Programs to Prevent Obesity	The regulations set forth requirements for school breakfasts and school lunches. The guidelines were designed so that meals given through the program would provide a sufficient proportion of the Recommended Daily Allowance of calories and nutrients. The commenter believed that the minimum calorie level required in the regulations contributes to childhood obesity and type-2 diabetes. Recent research has indicated that the energy expenditure needs of children were overestimated.
Health and Safety	Labeling of Food Allergens for Consumers	Though many food producers voluntarily label common food allergens following industry standards, FDA currently does not require the labeling of food allergens. As described in previous Unified Agenda entries, FDA has been actively engaged in development of a proposed rule to revise the agency's labeling regulations to require that foods that contain ingredients derived from the most common allergens include information on the label in plain English terms that clearly identifies the allergenic source of these ingredients. Furthermore, Public Law No. 108-282, signed by the President on August 2, 2004, requires food labels to clearly state whether a food product contains milk, eggs, peanuts, tree nuts, fish, shell fish, soy and wheat (the most common food allergens) starting Jan. 1, 2006.
Health and Safety	NHTSA – High-Speed Frontal Offset Crash Test	In response to a 2001 prompt letter from OMB, the National Highway Traffic Safety Administration has established offset frontal crash protection as one of its highest rulemaking priorities. Such a rule has substantial potential for cost-effective improvements in highway safety. About 3,000 people are killed and 400,000 injured annually in these types of crashes. In February, 2004, NHTSA published a request for comments on this issue. NHTSA is now in the process of developing a notice of proposed rulemaking, which it plans to publish sometime in 2005.
Health Care	HHS/CMS: Medicare & Medicaid Conditions of Participation – One Hour Restraint Rule	This interim final rule contains standards for the use of patient restraint and seclusion in hospitals. The one-hour provision referenced by the commenter requires that a physician examine, in-person, any patient for which restraint or seclusion is ordered within one hour of the issuance of that order. The commenter believed that the one-hour restriction is particularly burdensome for small and rural hospitals and the agency did not adequately analyze the impact of the one-hour provision or possible alternatives. HHS has met with affected industry groups and professional associations to devise a patient standard that would balance the need for both quality patient care and adequate provider resources. However, the agency has not yet moved forward with a more appropriate standard.
Health Care	HHS/CMS: Medicare – Physician Certification for Non-Emergency Ambulance Services	This requires ambulance providers to obtain physician certification for non-emergency trips in order to bill Medicare. According to the commenter, the requirement has proven to be ineffective and burdensome for both physicians and ambulance providers.

Table 11: Unfinished Business: Additional Regulatory Reforms		
Issue Area	**Agency/Rule**	**Summary/Status**
Health Care	HHS/CMS: Revisions to the Physician Fee Schedule	This regulation adjusts the fee schedule for services provided primarily by physicians; however, various non-physician groups, such as portable x-ray and EKG providers are also included. Commenters believed that the regulation adopts a one-size-fits-all approach that affects small providers disproportionately. Further, the commenter believes that the agency failed to assess adequately the true operating costs of portable x-ray and EKG provider industry in its consideration of the regulatory flexibility analysis, which could result in economic hardship for portable x-ray and EKG providers. HHS/CMS is working with medical associations such as the American College of Radiology and the American College of Cardiology to develop a permanent solution to the payment of non-physician services in the physician fee schedule. Changes will be proposed in upcoming updates to the physician fee schedule.
Housing	HUD: Streamlining the Predatory Lending Rules	The existing predatory lending rules have been implemented to protect consumers from predatory lending practices by unscrupulous brokers offering services at higher cost or higher interest rates than the buyer can qualify for. However, commenters believed that the rules are burdensome and confusing for both brokers and consumers and should be streamlined.
Transportation	DOT/FAA: Design and Construction Standards	The rules prohibit airplanes from having "design features or details that experience has shown to be hazardous or unreliable." Commenters believed that FAA should go through notice and comment rulemaking to amend these regulations, which they felt have been applied inconsistently.

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, 1993 and September 30, 2003. 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 7 in this appendix presents the newly added rules from October 1, 2002 to September 30, 2003. 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).

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. All inflation adjustments are performed using the latest CPI-U numbers from the Bureau of Labor Statistics. 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 will take effect in January 1, 2005, for final rules. The guidance recommends what OMB considers to be "best practice" in regulatory analysis, with a goal of strengthening the role of science, engineering, and economics in rulemaking. The overall goal of this guidance is a more competent and credible regulatory process and a more consistent regulatory environment. OMB expects that as more agencies adopt our recommended best practices, the costs and benefits we present in future reports will become more comparable across agencies and programs. OMB will work with the agencies to ensure that their impact analyses follow the new guidance.

Table 12. Estimates of Annual Benefits and Costs of 6 Major Rules
October 1, 2002 to September 30, 2003
(millions of 2001 dollars per year)

Rule	Agency	Benefits	Costs	Explanation
Truck Driver Hours of Service	DOT	690	1,318	Impacts are relative to the status quo baseline. Year 2000 wages are the basis of analysis, so we inflated estimates to 2001 dollars.
Light Truck CAFE for Model Years 2005-2007	DOT	255	220	We amortized the sum of all three model years of the agency's present value estimates over 10 years, the assumed lifespan of a vehicle.
National Pollutant Discharge Permits and Standards for Concentrated Animal Feeding Operations (CAFOs)	EPA	204-355	360	
Patent Listing Requirements and Application of 30 Month Stays of Abbreviated New Drug Applications (Generics)	FDA	226	10	
Trans fat Labeling	FDA	230-2839	9-26	
Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products	USDA	43-152	17	
Total		**1,649-4,517**	**1,933-1,950**	

APPENDIX B: Valuation Estimates for Regulatory Consequences[40]

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.[41] 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 article (Brown and Savage, "The Economics of Double-Hulled Tankers," *Maritime Policy and Management*, Volume 23(2), 1996, pages 167-175.)
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):	$400 to $2,500 per ton
Nitrogen Oxide (mobile):	$1,400 to $8,800 per ton
Sulfur Dioxide:	$2,100 to $14,000 per ton
Particulate Matter:	$10,000 to $100,000 per ton

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

[41] National Highway Traffic Safety Administration, The Economic Cost of Motor Vehicle Crashes, 1994, Table A-1. http://www.nhtsa.dot.gov/people/economic/econvc1994.html

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).

OMB has revised the estimates for reductions in NO_x emissions to reflect a range of estimates from recent EPA analyses for several rules and for proposed legislation. In particular, OMB has adopted different benefit transfer estimates for NO_x reductions from stationary sources (e.g., electric utilities) and from mobile sources. EPA believes that there are a number of reasons to expect that reductions in NO_x emissions from utility sources achieve different air quality improvements relative to reductions from ground-level mobile sources. For example, mobile source tailpipe emissions are located in urban areas at ground level (with limited dispersal) while electric utilities emit NO_x from "tall stacks" located in rural (remote) locations with substantial geographic dispersal (Letter to Don Arbuckle, Deputy Administrator, OIRA from Tom Gibson, Associate Administrator, Office of Policy, Economics and Innovation, EPA, May 16, 2002). There remain considerable uncertainties with the development of these estimates. The discussion below outlines the various EPA analyses serving as the basis for the NO_x benefit transfer values presented above and discusses the uncertainties that attend these estimates.

Analysis of recent EPA rules yield several estimates for the NO_x benefits per ton from electric utility sources. (See the Regulatory Impact Analyses for the "NO_x SIP Call" and the Section 126 rules, available on the web at http://www.epa.gov/ttn/ecas/econguid.html. In addition, see Memo to NSR Docket from Bryan Hubbell, Senior Economist, Innovative Strategies and Economics Group, EPA.) Based on these studies, EPA estimates the mortality-based benefits of NO_x reductions from stationary sources (electric utilities) is $1,300 (1999$) per ton.

For mobile sources, EPA recently published the final Tier II/Gasoline Sulfur rule RIA (EPA, 1999), which affects light-duty vehicles. In this rule, NO_x reductions account for around 90 percent of PM precursor emissions and 86 percent of ozone precursor emissions. Based on the final Tier 2/Gasoline Sulfur RIA, EPA estimates that NO_x reductions will yield benefits of $4,900 (1999$) per ton. NOx benefit estimates are difficult to transfer to other applications, however. The location of reductions, reductions in other PM precursors, air chemistry, meteorology, emission release heights, baseline conditions, etc. can have dramatic effects on the relationship between NOx emission reductions and ambient PM concentrations. Further, the understanding of the atmospheric chemistry characterizing PM formation, and photochemical air quality modeling are rapidly evolving. To value mobile NOx emissions, we use estimates from the Tier II rule RIA, while recognizing that the Tier II analysis was based on an air quality fate and transport model that had limited treatment of atmospheric chemistry. New results based on EPA's ongoing analyses supporting the suite of Clean Air Rules (including the Clean

Air Interstate Rule, Clean Air Visibility Rule, and Clean Air Mercury Rule) may provide better estimates for future reports[42].

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.[43] Because of the importance of this endpoint and the considerable uncertainty among economists and policymakers as to the appropriate way to value reductions in mortality risk, OMB has adjusted these benefits per ton estimates to reflect the substantial range in the estimated values (VSL) for reductions in mortality risk. In its recent rulemakings setting SO_2, NO_x and mercury emissions standards for electric utilities, EPA adopted a confidence interval for VSL estimates ranging from $1 million to $10 million based on two meta-analyses of the wage-risk VSL literature. The $1 million lower end estimate represents the lower end of the interquartile range from the Mrozek and Taylor (2002) meta-analysis. The $10 million upper end estimate represents the upper end of the interquartile range from the Viscusi and Aldy (2003) meta-analysis. Using this VSL range, the estimated benefits for reductions in NO_x emissions range from $400 to $2,500 per ton and for mobile sources range from $1,400 to $8,800 per ton.

EPA also developed estimates for the benefits associated with reductions in SO_2 from electric utilities. Based on an analysis outlined in a June 20, 2001 EPA memo to the file, "Benefits Associated with Electricity Generating Emissions Reductions Realized Under the NSR program," we used $7,300 per ton. Using the VSL range, the estimated benefits for reductions in SO_2 range from $2,100 to $14,000 per ton.

As mentioned above, OMB only monetized benefits estimates for rules that were not otherwise monetized by the agencies. Therefore, these per ton benefits estimates

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[42] Additional details on the Tier II benefits analysis are available in the Tier II/Sulfur Final Rulemaking RIA, available on the web at http://www.epa.gov/oms/fuels.htm.

[43] 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 SO_2 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.

were only applied to EPA rules in which emission impacts were quantified but not monetized by EPA.

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); and Steam Generating Units (1998-1999).

B. 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.[44]

C. 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,

[44] The adjustment to reflect the range in VSL estimates was developed as follows: The mortality-related benefits associated with NO_x reductions typically account for 90 percent or more of total monetized benefits. Starting with the estimate of $1,300 per ton for the mortality-related benefits associated with a reduction in NO_x emissions, and assuming that this represents 90 percent of total benefits, a reduction in NOx emission would yield total benefits of $1,450 per ton - $1,300 per ton in mortality-related benefits and $150 per ton in other monetized benefits. Since the mortality-related benefits are proportional to VSL and the $1,300 per ton is based on a VSL of $6 million, the VSL range of $1 to $10 million yields mortality-related benefits of $217 to $2,167 per ton (1999$) and total benefits of $400 to $2,300 per ton for reductions in NO_x emissions from stationary sources. A similar calculation yields a total benefits estimate for reductions in NO_x emissions from mobile sources ranging from $1,238 to $7,965 per ton (1997$).

these analyses may adopt different baselines in terms of the regulations and controls already in place. In addition, the analyses for these rules may well treat uncertainty in different ways. In some cases, agencies may have developed alternative estimates reflecting upper- and lower-bound estimates. In other cases, the agencies may offer a midpoint estimate of benefits and costs. In still other cases the agency estimates may reflect only upper-bound estimates of the likely benefits and costs. While OMB has relied in many instances on agency practices in monetizing costs and benefits, citation of, or reliance on, agency data in this report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates.

APPENDIX C: The Benefits and Costs of 1992-1993 Major Rules

Tables 13 and 14 list the rules that were reported in Chapter 1 of the 2003 report as part of the 10-year totals of costs and benefits, but are not included in Chapter 1 of the 2004 report. Table 13 presents only the rules that had annualized, monetized costs and benefits used for the purposes of calculating the totals in previous reports. Table 14 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. FDA published a single analysis as a basis for the costs and benefits of 23 individual rules regarding food labeling. If considered separate rulemakings in this accounting, the total number of rules that drop out of the analysis is 32. If considered one rulemaking, the total number of rules that drop out of the analysis is 10.

Table 13. Estimate of Annual Benefits and Costs of 10 Major Rules October 1, 1992 to March September 30, 1993
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Nutrition Labeling of Meat and Poultry Products	USDA/FSIS	205	25-32	We amortized the agency's present value estimates over 20 years.
Food Labeling (combined analysis of 23 individual rules)	HHS/FDA	438-2,637	159-249	We amortized the agency's present value estimates over 20 years.
Real Estate Settlement Procedures	HUD	258-332	135	
Manufactured Housing Wind Standards	HUD	103	63	
Permit Required Confined Spaces	DOL/OSHA	540	250	We valued each fatality at $5 million and each lost-workday injury at $50,000. We did not value non-lost-workday injuries.
Vessel Response Plans	DHS/USCG	9	295	We amortized the agency's present value estimates over 30 years. We valued each barrel of oil not spilled at $2,000.
Acid Rain Permits Regulations	EPA	78,454-78,806	1,109-1,871	We valued SO_2 reductions at $7,800 per ton.
Vehicle Inspection and Maintenance (I/M)	EPA	247-1,120	671	We used the estimates of cost and emission reductions of the new I/M program compared to the baseline of no I/M program. We valued VOC reductions at $600-$2,700 per ton. We did not assign a value to CO reductions.

Table 13. Estimate of Annual Benefits and Costs of 10 Major Rules October 1, 1992 to March September 30, 1993 (millions of 2001 dollars per year)				
REGULATION	**AGENCY**	**BENEFITS**	**COSTS**	**EXPLANATION**
Evaporative Emissions from Light-Duty Vehicles, Light-Duty Trucks, and Heavy-Duty Vehicles.	EPA	274-1,246	161-248	We assumed the VOC emission reductions began in 1995 and rise linearly until 2020, after which point they remain at the 2020 level. Annualizing this stream results in an average of 468,000 tons per year. We valued these tons at $600-$2,700 per ton.
Onboard Diagnostic Systems	EPA	702-3,423	226	We amortized the agency's emission reduction and cost estimates over 15 years. We valued VOC reductions at $600-$2,700 per ton and NO_x reductions at $1,100-$5,500 per ton.

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Nutrition labeling of meat and poultry products	USDA/ FSIS	$1.75 billion (NPV)	$218-272 million (NPV)	NPV of benefits and costs discounted over 20 years at 7%
Food Labeling (combined analysis of 23 individual rules)	HHS/FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by 23 HHS-FDA rules put in place as a result of the Nutrition Labeling and Education Act.
Real Estate Settlement Procedures Act (Regulation X), FR-1942	HUD	$119,014,950 annually in greater competition in title insurance business $89.1-148.5 million net benefit annually in reducing transaction costs by packaging services with affiliated services	Cost of duplicate good-faith-estimates: $56,824,627 per year Cost of new disclosure for controlled business arrangements: $48,147,000 per year Cost of computerized loan originations: $3,607,890 per year Cost of two additional years for storage (discount rate=6%): 24,305	
Manufactured Housing Construction and Safety Standards	HUD	$103 million	$63 million	

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Final frameworks for early-season migratory bird hunting regulations	DOI	Not Estimated	Not Estimated	
Migratory bird hunting, final frameworks for late-season migratory bird hunting regulations	DOI	Not Estimated	Not Estimated	
The Family and Medical Leave Act of 1993	DOL/ESA	Not Estimated	$674 million annually	Estimate provided by U.S. General Accounting Office (Parental Leave: Estimated Costs of H.R. 925, the Family and Medical Leave Act of 1987—GAO/HRD-88-34, Nov. 10, 1987)
Permit Required Confined Spaces	DOL/OSHA	Reduced annually: 54 fatalities; 5,931 lost-workday injury and illness cases; 5,908 non-lost-workday cases	$202.4 million annually	"OSHA anticipates that improved worker productivity as a result of the standard will help to lower production costs and contribute to higher quality output. Although OSHA did not quantify these cost offsets, the Agency believes they will be substantial" (RIA, pp. I-10, I-13). "OSHA anticipates that greater use of mechanical ventilation to reduce atmospheric hazard in permit spaces may result in additional release of hazardous substances to the air. Incremental release quantities related to the permit space standard are not determinable at present, but are expected to be minor relative to current overall releases" (RIA, pp. I-17 – I-18).

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Lead Exposure in Construction	DOL/OSHA	Near-term avoided annual health effects Reduced nerve conduction velocity: 16,199-22,831 cases; Reduced blood ALA-D levels: 130,056-164,044 cases; Increased urinary ALA: 60,389-78,676 cases; Gastrointestinal disturbances: 1,135-4,413 cases; Detected blood-lead levels above MRP trigger: 24,262-35,163 cases Long-term avoided health effects over 10 years Fatal/nonfatal infractions: 2,164-2,322 cases; Fatal/nonfatal stroke: 644-698 cases; Renal disease: 1,258-2,157 cases	$365-445 million annually plus one-time start-up costs of $150-$183 million.	

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Response Plans for Marine Transportation-Related Facilities	DHS/USCG	58,838 barrels of oil not spilled (NPV)	$176,105,666 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; $1996
Vessel Response Plans	DHS/USCG	50,312 barrels of oil not spilled (NPV)	$3,245,869,985 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; $1996
Light Truck Average Fuel Economy Standard for Model Year 1995	DOT/NHTSA	Not Estimated	Not Estimated	

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Water quality standards regulation: Compliance with CWA Section 303(C)(2)(B) Amendments	EPA	Not Estimated	Not Estimated	"The analysis performed was limited to assessing only the potential reduction in cancer risk; no assessment of potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects was conducted. However, given the number of pollutants, there could be: (1) Decreased incidence of systemic toxicity to vital organs such as liver and kidney; (2) decreased extent of learning disability and intellectual impairment due to the exposure to such pollutants as lead; and (3) decreased risk of adverse reproductive effects and genotoxicity." (57 FR 60848-) "The ecological benefits that can be expected from today's rule include protection of both fresh and salt water organisms, as well as wildlife that consume aquatic organisms…In addition, the rule would result in the propagation and productivity of fish and other organisms, maintaining fisheries for both commercial and recreational purposes. Recreational activities such as boating, water skiing, and swimming would also be preserved along with he maintenance of an aesthetically pleasing environment" (57 FR 60848-) "EPA acknowledges that there will be a cost to some dischargers for complying with new water quality standards as those standards are translated into specific NPDES permit limits…Revised wasteload allocations may result in adjustments to individual NPDES permit limits for point source dischargers, and these adjustments could result in increased wastewater treatment costs or other pollution control activities such as recycling or process changes. The magnitude of these costs depends on the types of treatment or other pollution control, the number and type of pollutants being treated, and the level of control that can be achieved by technology-based effluent limits for each industry. Similar sources of costs and the variables affecting costs may also apply to indirect industrial dischargers to the extent that the industrial discharger is a source of toxic pollutants discharged by the POTW…Nonpoint sources of toxic pollutants may also incur increased costs to the extent that best management practices need to be modified or applied to more sources to reflect the revised water quality standards. Although there is no Federal permit program for nonpoint sources comparable to that for point sources, there are State regulatory programs to control nonpoint source discharges. Monitoring programs are another source of potential incremental costs to dischargers and States." (57 FR 60848-)

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Coastal nonpoint pollution control program development and approval guidance (EPA, NOAA), guidance specifying management measures for sources of nonpoint… Section 6217	EPA	Not estimated	$389,940,000-$590,640,000 (annualized)	The RIA identified generally the types of "off-site benefits" that could be related to water quality improvements, including 4 use benefits (in-stream, near stream, option value, and diversionary) and 3 non-use (intrinsic) benefits (aesthetic, bequest, and existence).
Oil and Gas Extraction Point Source Category, Offershore Subcategory, Effluent Limitations Guidelines and New Source Performance Standards (Final Rule)	EPA	$28.2-103.9 million per year	Total annualized BAT and NSPS costs: 1st year=$122 million, 15th year=$32 million	"Other benefits that are quantified, to the extent possible, but not monetized due to lack of appropriate data, include: (1) Human health risk reductions associated with systemics other than lead, pH-dependent leach rates, carcinogens for which there are no risk factors available, exposure to pollutants via sediment or food chair; (2) ecological risk reductions; (3) fishery benefits; and (4) intrinsic benefits…The non-quantified, non-monetized benefits assessed in this RIA include increased recreational fishing, increased commercial fishing, improved aesthetic quality of waters near the platform, and benefits to threatened or endangered species [the Kemp's Ridley Turtle and the Brown Pelican] in the Gulf of Mexico." (58 FR 12454-)

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Acid Rain Permits, Allowance System, Emissions Monitoring, Excess Emissions and Appeals Regulations Under Title IV of the Clean Air Act Amendments of 1990	EPA	10 million tons/year reduction in SO_2 emission (mandated by Title IV) Cost savings: $689-973 million (annualized)	$894-1,509 million (annualized)	SO_2 emission reductions are expected to : (1) reduce acidification of surface waters, thereby increasing the presence an diversity of aquatic species; (2) improve visibility by reducing haze; (3) may improve human health as lower SO_2 emissions reduce air concentrations of acid sulfate aerosols and thus acute and chronic exposure to the acid aerosols that adversely affect human health may even affect even mortality; (4) eliminate damage to forest soils and foliage, especially of high-elevation spruce trees in the eastern U.S. and allow recovery of previously damaged tree populations; (5) may reduce damage to auto paint, reduce soiling of buildings and monuments, and thus the life of some materials and structures may be extended and the costs of maintenance or repair reduced (RIA, pp. 1-5 to 1-6, and 6-1 to 6-3) Engineering costs associated with CEM retrofit were not analyzed (RIA, pp. 4-18) "The annualized costs of the implementation regulations are estimated to increase the annual costs of generating electricity by 0.5 to 1.2 percent." (58 FR 3590-)

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Vehicle Inspection and Maintenance Requirements for State Implementation Plan (Final Rule)	EPA	Emission reductions from continuing current I/M program unchanged (baseline=no I/M program)in 2000: 116016 tons VOC, 1566395 tons CO (annual tons in 2000) Emission reductions from new I/M program in 2000 (baseline=no I/M program): 420415 tons VOC, 2845754 tons CO (annual tons in 2000)	Continuing current I/M program: NET COST=$894 million ($2000) New I/M program: NET COST=$541 million ($2000)	"These repairs have been found to produce fuel economy benefits that will at least partially offset the cost of repairs. Fuel economy improvements of 6.1% for repair of pressure test failures and 5.7% for repair of purge test failures were observed. Vehicles that failed the transient short test at the established cutpoints were found to enjoy a fuel economy improvement of 12.6% as a result of repairs." (57 FR 52950-) "In conclusion, today's action may cause significant shifts in business opportunities. Small businesses that currently do both inspections and repairs in decentralized I/M programs may have to choose between the two. Significant new opportunities will exist in these areas for small businesses to continue to participate in the inspection and repair industry. This will mean shifts in jobs but an overall increase in jobs in the repair sector and a small to potentially large increase in the inspection sector, depending on state choices." (57 FR 52950-)
Evaporative emission regulations for gasoline-fueled and methanol-fueled light duty vehicles, light-duty trucks, and heavy-duty vehicles —SAN 2969	EPA	Total VOC Reduction in 2020: 1,120,000 metric tons	Annual total program cost without fuel savings: $130-200 million ($1992, NPV to the year of the sale)	"[Emission] projections are made for the year 2020 in order to provide benefit predictions for a fully turned-over fleet and to factor in other known trends, such as the effects of other new Clean Air Act programs. These new programs include high-technology inspection and maintenance and reformulated gasoline. Reformulated gasoline achieving a 25 percent overall VOC emission reduction standard is assumed to be used in 40 percent of the nation." (58 FR 16002) "[The cost] estimate does not include the offsetting fuel savings." EPA estimated that the fuel savings almost completely offset the quantified costs (58 FR 16015)

Table 14. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Control of air pollution from new motor vehicles and new motor vehicle engines, regulations requiring on-board diagnostic systems on 1994 and later model year light-duty vehicles	EPA	4.0 million tons HC, 30.8 million tons CO, 2.5 million tons NO_x (NPV)	$16.6 billion (NPV) ($1993)	Discount rate: 7% (58 FR 9468-) Timeline: 2005-2020 (58 FR 9468-) "EPA has not been able to adequately quantify some potential cost savings not included in these estimates. Potential cost savings can accrue due to early repairs of malfunction which, if left undetected and unrepaired, could result in the need for even more costly repairs in the future. Also, improved repair effectiveness should reduce the potential for a part to be unnecessarily replaced in attempting to fix a problem. Repair facilities should also benefit from the availability of generic tools for accessing and using the OBD system in problem diagnosis and repair. These service facility benefits could be passed along to the consumer in the form of lower repair costs." (58 FR 9468-)

APPENDIX D: Status Report on the 2001 and 2002 Reform Nominations

In our 2001, 2002 and 2004 draft Reports to Congress on the Costs and Benefits of Federal Regulation, OMB requested public nominations of regulatory reforms. This appendix updates the status of the 2001 and 2002 reform nominations. The 2004 manufacturing initiative is discusses in more detail in Chapter 2 of this Report. Additional details on the 2001 and 2002 regulatory reform nomination process can be found in the 2003 final Report, which is available on our website at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

Summary of Reform Nominations

The following table summarizes the number of reform nominations, by agency, received through our nomination process in 2001 and 2002.[45] Please note that OMB did not receive updates from the following agencies in time for inclusion in this Report: the Federal Reserve, FCC, CFTC, NARA, U.S Army Corps, and USPS.

Table 15: Summary of Reform Nominations

Agency	2001	2002 Regulations	2002 Guidance Documents	Total
Agriculture	3	16	1	20
Commerce	0	1	0	1
Education	1	3	0	4
Energy	2	2	0	4
HHS	2	32	8	42
HUD	0	2	0	2
Interior	2	11	1	14
Justice	1	7	1	9
DOL	16	30	5	51
State	0	1	0	1
DOT	2	53	2	57
Treasury	2	11	1	14
Access Board	0	0	1	1
EEOC	2	3	1	6
EPA	24	43	22	89
FERC	1	1	0	2
Federal Reserve	3	8	0	11

[45] The total in Table 15 for the 2001 reform nominations differs from the number of entries in the 2001 summary Table 16. This is because some regulations involve multiple agencies; for example, the nomination regarding the Privacy of Consumer Financial Information.

Table 15: Summary of Reform Nominations				
Agency	**2001**	**2002 Regulations**	**2002 Guidance Documents**	**Total**
FDIC	3	0	0	3
OTS	2	0	0	1
FCC	0	24	0	24
FTC	0	4	1	5
CFTC	2	0	0	2
NARA	0	1	0	1
OMB	0	0	3	3
OPM	0	1	0	1
SBA	0	1	1	2
SEC	7	9	0	16
U.S. Army Corps	1	2	1	4
U.S. Postal Service	1	1	0	2
Total	76	267	49	392

2001 Regulatory Reform Nominations

In the draft version of the 2001 annual report, OMB asked for suggestions from the public about specific regulations that should be modified in order to increase net benefits to the public. We received suggestions regarding 71 regulations. In an initial review of the comments, OMB placed the suggestions into three categories: high priority, medium priority, and low priority. The following table summarizes the status of these reform nominations as of December 10, 2004.[46] A detailed description of each reform candidate can be found in Appendix A of our 2001 Report, which is available on our website at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

[46] In their response to the OMB data call to agencies requesting an updated status of all reform nominations, EPA classified regulations according to the following criteria: "Response Complete" - those nominations for which the Agency took the comments raised by nominations into consideration when taking action, those for which the Agency had previously addressed/considered the commenter's suggestions, and those where the Agency seriously considered the comment, but nevertheless disagreed with the commenter's recommendation. "Initiated Reform" - actions are underway via notice-and-comment rulemaking, peer review, and other Agency processes designed to ensure the final product is based on high quality and timely information. "Continuous Improvement" - these actions are part of ongoing Agency programs that are continually improved. "Under Consideration" - the Agency is still considering the best approach to address outstanding issues related to the action. In order to be consistent with EPA's classification scheme, we have preserved these descriptors in the "status" column of each table in this update.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
Agriculture/ Forest Service	Forest Service Planning	High	Proposed rule published 12/6/2002 (67 FR 72770). Final rule publication expected 2005.
Agriculture/ Forest Service	Roadless Area Conservation and EIS Notice	High	Proposed rule published July 16, 2004 (69 FR 42636) Proposed rule would replace existing rule with a petitioning process that would provide Governors an opportunity to seek establishment of management requirements for National Forest System inventoried roadless areas within their State. Applicability to National Forest System Lands in Alaska - Proposed rule published 7/15/2003 (68 FR 41864). Final Rule expected April 2005. Applicability to the Tongass National Forest, Alaska: Final Rule published 12/30/03 (68 FR 75136). This was nominated for reform again in 2002.
Education	Financial Aid (Title IV)	High	These Financial Aid regulations are the subject of annual regulatory negotiations. In 2002, the Department of Education developed a list of proposed regulatory changes to improve the Title IV student assistance program, specifically including the Federal Family Education Loan Program. This particular regulation was one of the 109 Reform Nominations of 2002 already under consideration by agencies. The Department took action to reform both the Institutional Eligibility section of the Higher Education Act and the Federal Family Education Loan Program regulations in 2002. The Department issued two notices of proposed rulemaking in August 2002 (67 FR 51036; 67 FR 51718) and final regulations in November 2002 (67 FR 67048). The final regulations combined the proposed amendments from the two notices of proposed rulemaking. These amendments reduce administrative burden for program participants and provide them with greater flexibility to serve students and borrowers.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
Energy	Central Air Conditioning and Heat Pump Energy Conservation Standards	High	On January 22, 2001, DOE promulgated a regulation that would have raised the energy efficiency of new central air conditioners by 30 percent. On May 23, 2002, DOE withdrew this rule and issued a final rule raising the minimum energy efficiency levels by 20 percent. The latter action was the subject of a litigation that concluded in 2004, with the court holding that DOE must implement the regulation promulgated on January 22, 2001. On August 17, 2004, DOE published revisions to the Code of Federal Regulations that reflect the energy efficiency increase of 30 percent that will take effect in 2006 (69 FR 50997). This was nominated for reform again in 2002.
HHS	Standards for Privacy of Individually Identifiable Health Information	High	On August 14, 2002 (67 FR 53182), HHS published final revisions to this rule clarifying some aspects and modifying others. The rule as amended goes into effect on April 12, 2003. This was nominated for reform again in 2002.
HHS/FDA	Food Labeling: Trans Fatty Acids in Nutrition Labeling	High	OIRA Administrator John D. Graham sent a prompt letter to FDA on September 18, 2001 urging the agency to finalize this rulemaking. Final Rule published 7/11/2003 (68 FR 41433).
Interior	National Park Service Snowmobile Regulations (Rocky Mountain)	High	The NPS published a final rule on September 2, 2004 (69 FR 53626) that eliminated three of four routes previously designated for snowmobile use, while maintaining the North Supply Access Trail to accommodate the interests of the town of Grand Lake, local businesses, nearby private landowners, and Arapaho National Forest. On each of the routes closed to snowmobile use, NPS will continue as in past years to plow the routes to provide vehicle access to these areas. This was nominated for reform again in 2002.
Interior	Hardrock Mining Operations (Section 3809)	High	Both the definition of "unnecessary and undue degradation" and the 2000 performance standards were amended in 2001. The BLM went through a rulemaking process in 2001 to make both changes which the commenter criticizes, and published a rule on October 30, 2001. Interior did so because the definition of unnecessary or undue degradation may well have exceeded BLM's authority and because the 2000 performance standards, in some cases, went beyond that which is necessary to allow environmentally safe exploration and development. While the October 30 rule solicited comments on other aspects of the "3809 rules" at this time the Department plans no additional changes.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
Labor	Certification of Employment- Based Immigration and Guest Worker Applications	High	ETA expects to issue final rules later this year regarding the permanent employment of aliens and H-2B reform.
Labor	"Helpers" on Davis - Bacon Act Projects	High	ESA is not contemplating any action. Prior efforts at rulemaking from 1979 to 2000 were litigated successfully by opponents of the rules and also resulted in Congressional appropriation holds.
Labor	Overtime Compensation Regulations Under the Fair Labor Standards Act: Bonuses	High	ESA is not contemplating any action; legislation would be required.
Labor	Recordkeeping and Notification Requirements Under the Family and Medical Leave Act	High	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations. Additional aspects of the FMLA rules were nominated for reform again in 2002.
Labor and EEOC	Affirmative Action and E.O. Survey.	High	Affirmative Action: OFCCP completed a directive addressing this issue in March, 2002. EO Survey: OFCCP has engaged an outside contractor to study the effectiveness of the survey in identifying noncompliant firms and expects to receive the study in 2005. This was nominated for reform again in 2002.
Transportation	Hours of Service of Drivers	High	DOT issued a final rule modifying the hours of service regulations on April 28, 2003. This was nominated for reform again in 2002.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
EEOC	Uniform Guidelines for Employee Selection Procedures	High	UGESP directs employers to analyze their hiring procedures to determine if they use selection standards that disproportionately exclude minority applicants for reasons unrelated to the job or the business. UGESP calls for employers to keep data about the race, ethnicity and gender of actual "applicants" for this analysis. In July, 2000, OMB directed the EEOC and the three other agencies responsible for UGESP, to evaluate whether new guidance was needed on the meaning of "applicant" to guide data collection in the Internet age. Federal government contractors nominated this guidance for regulatory reform because they wanted the new guidance to account for the burden of collecting and analyzing race, ethnic and gender data when there are large numbers of electronic applicants. The EEOC published a notice soliciting public comment on guidance about the UGESP definition of "applicant" for purposes of the Internet and related electronic technologies on March 4, 2004 (69 Fed. Reg. 10152). Public comments were received, and the UGESP agencies are considering these comments and preparing a final notice. There is not a firm date for final completion.
EPA	"Mixture and Derived From" Rule	High	Issued a proposed rule to revise these regulations on April 8, 2003. No update on expected date of final rule.
EPA	Total Maximum Daily Load	High	Continuous Improvement. The July 2000 Watershed Rule revised the existing requirements for States to prepare lists of impaired waters and to develop total maximum daily loads (TMDLs) for the waters on these lists. The most significant change was to require that implementation plans be developed for each TMDL and approved by EPA. Commenters argued that the prescriptive, procedural approach adopted in the 2000 rule undermined the benefits of a watershed approach to addressing water quality. In particular, the requirement for up-front EPA approval of implementation plans was thought to limit State flexibility, impede adaptive management, and unduly interfere in State water pollution control programs. The rule was withdrawn by EPA in March 2003, following public notice and comment. This was nominated for reform again in 2002.
EPA	Drinking Water Regulations: Cost Benefit Analyses	High	OMB addressed these issues in its revised analytic guidance Circular A-4. This guidance was nominated for reform by the public in 2002.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
EPA	Economic Incentive Program Guidance	High	Response Complete. EPA issued guidance on January 19, 2001, and the States are now using the guidance in developing economic incentive programs.
EPA	New Source Review	High	Response Complete. Final rules published on November 7, 2003 and October 27, 2003. Stay granted December 24, 2003.
EPA	Concentrated Animal Feeding Operations	High	Response Complete. Final rule published February 12, 2003. Guidance published November 3, 2003. Nominated in 2002.
EPA	Arsenic in Drinking Water	High	Response Complete. The arsenic final rule was issued on January 22, 2001, and became effective on May 22, 2001. EPA has decided not to modify this final rule. This was nominated for reform again in 2002.
EPA	Notice of Substantial Risk: TSCA Section 8(e)	High	Initiated Reform. EPA has established a new TSCA 8(e) web page that contains guidance, previous 8(e) submissions, and new submissions posted within two weeks of receipt. EPA is also working on a package that would make policy clarifications.
Labor	Affirmative Action Plans (60-2)	Medium	OFCCP completed a directive addressing this issue in March, 2002.
Labor	Scheduling Letter requesting compensation data	Medium	OFCCP solicited public comment on this collection burden earlier this year. The Information Collection Request (ICR) regarding the Paperwork Reduction Act (PRA) clearance was approved without change by OMB until November 30, 2005.
Labor/OSHA	Consultation Program	Medium	OSHA is not contemplating any action; legislation would be required.
Labor	Defining and delimiting "Any employee employed in a bona fide executive, administrative, or professional capacity or in the capacity of outside salesman"	Medium	ESA issued a final rule on April 23, 2004 (69 FR 22122). The rule revised regulations protecting overtime payments under the Fair Labor Standards Act. This was nominated for reform again in 2002.
Labor	Definition of "Serious Health Condition" under FMLA	Medium	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations. Additional aspects of the FMLA rules were nominated for reform in 2002.
Labor	Limits on how employers may take intermittent leave under FMLA	Medium	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations. Additional aspects of the FMLA rules were nominated for reform in 2002.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
Labor	Information needed for Employer to Designate Leave under FMLA	Medium	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations. Additional aspects of the FMLA rules were nominated for reform in 2002.
Labor	Wage Determination Process for Service Contractors	Medium	ESA plans to streamline the process for obtaining wage determinations and to update the occupational index. The NPRM regarding the Wage Determinations OnLine is expected later this year, and the occupational index update is expected in December, 2005.
Transportation	Advanced Air Bags	Medium	The agency responded in November 2003 and August 2004 to the requests raised by the submitters for reconsideration of an earlier final rule on advanced air bags. NHTSA does not consider this issue suitable for further review or reform at this time.
EPA	Definition of "solid waste"	Medium	Response Complete. Proposed Rule published on October 28, 2003.
EPA	Toxic Release Inventory: lowering reporting thresholds for, Persistent, Bioaccumulative, Toxics	Medium	Response Complete. No action necessary.
EPA	High Production Volume (HPV) Chemical-Testing Program Voluntary Children's Chemical Evaluation Program Endocrine Disruptor Screening Program (EDSP)	Medium	Response Complete. No action necessary.
EPA and Customs	Importation Rules for Special Classes of Merchandise	Medium	Response Complete. No action necessary.
EPA	Export Notification Requirements, TSCA Section 12(b) Issue 1	Medium	Under consideration. Legislation is still pending. Will revisit status of legislation with the renewal of the ICR in 2006, which actually begins in early 2005.
EPA	Export Notification Requirements, TSCA Section 12(b) Issue 2	Medium	Under consideration. Legislation is still pending. Will revisit status of legislation with the renewal of the ICR in 2006, which actually begins in early 2005.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
EPA	Control of Greenhouse Gas Emissions from New and In-Use Highway Vehicles and Engines	Medium	Response Complete. EPA Published a Notice of Denial of Petition on September 8, 2003. In October 1999, 19 groups petitioned EPA to regulate mobile source emissions of four greenhouse gases – CO2, methane, nitrous oxide, and hydroflourocarbon – to reduce the risk of climate change. EPA published a request for public comment on the petition in January 2001.
OCC/FDIC/ OTS Federal Reserve	Second Consultative Package on the New Basel Capital Accord	Medium	The federal banking regulators jointly published an ANPR in August, 2003 (68 FR 45900). The text for the framework of the revised Basel Accord was issued in June, 2004. The FDIC stated that they well aware that the concerns raised by the reform comment on the new Accord have been expressed, both formally and informally, by a number of observers throughout the Basel II development process. The U.S. agencies are taking these issues seriously as they develop a proposed rule for the implementation of Basel II, expected to be published for public comment in the Federal Register in 2005. Comments received in response to that proposed rule will be carefully considered before a decision is made to implement an operational risk capital requirement.
CFTC	Multilateral Transaction Execution Facilities, Intermediaries and Clearing Organizations; Exemption for Bilateral Transactions	Medium	
CFTC	Fast-track Designation and Rule Approval Procedures	Medium	
FDIC	Minimum Security Devices, and Procedures and Bank Secrecy Act Compliance	Medium	FDIC had already withdrawn this proposed rule, 12 CFR Part 326, as the commenter suggested, on March 29, 1999 (64 FR 14845). Other approaches more appropriately protect banks' safety and soundness and guard against criminal activity.
FERC	Regulation of Short-Term and Long-Term Gas Transportation	Medium	On February 9, 2000, FERC amended its regulations to improve the efficiency of the natural gas market and provide captive customers with the opportunity to reduce their cost of holding long-term pipeline capacity while continuing to protect against the exercise of market power. FERC did not adopt the requirement for mandatory auctions but did encourage their extensive use for the wide range of benefits they can provide to the industry. (65 FR 10156, February 25, 2000).

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
OCC/FDIC Federal Reserve OTS	Privacy of Consumer Financial Information	Medium	The content of the banking regulators' privacy rules (12 CFR 40, 216, 332, and 573) is dictated in significant part by the Gramm-Leach-Bliley Act (P.L. 106-102). The agencies are currently exploring the development of a "short form" privacy notice that would be simpler and easier for consumers to use. The banking regulators issued a joint ANPR regarding the short form privacy notices in December, 2003 (68 FR 75164).
SEC	Nasdaq Integrated Order Delivery and Execution System	Medium	This relates to a proposed rule change submitted to the SEC by the National Association of Securities Dealers (NASD). The summary of the nomination describes it as contending that several operational components of the NASD's rule proposal would "likely reduce market transparency." The SEC published the NASD's rule proposal for public comment on March 4, 1998. The NASD withdrew its rule proposal on March 16, 2000.
SEC	Concept Release on Regulation of Market Information, Fees and Revenues	Medium	This nomination relates to an SEC concept release on the regulation of market information, fees and revenues. OMB describes the nomination as contending that the cost-based approach for setting market data fees set forth in the concept release is unworkable and that the SEC should focus on promoting competition in the provision of market information. The Commission issued this concept release on December 9, 1999. The concept release did not immediately result in rulemaking. However, this year, the Commission proposed Regulation NMS, part of which would address market information, fees and revenues. Regulation NMS, 69 FR 11126 (March 9, 2004). The Commission announced on November 30, 2004 that it will consider on December 15, 2004 a staff recommendation to publish for public comment revisions to the rule proposal.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
SEC	Request for Comment on Issues Relating to Market Fragmentation	Medium	This nomination relates to an SEC concept release on issues relating to market fragmentation. OMB describes the nomination as contending that there is little evidence that market fragmentation is significant and that solutions discussed in the concept release would create cumbersome disclosure systems. In 1999, the New York Stock Exchange (NYSE) submitted to the Commission a proposal to rescind its restrictions on off-board trading. The Commission requested public comment on the NYSE's proposed rule change and simultaneously issued a concept release requesting comment on attendant issues of market fragmentation. The Commission approved the NYSE's proposed rule change in May 2000. Based in part on the information obtained pursuant to the concept release, the Commission earlier this year proposed Regulation NMS, which, if adopted, would address issues relating to market fragmentation. Regulation NMS, 69 FR 11126 (March 9, 2004). The Commission announced on November 30, 2004 that it will consider on December 15, 2004 a staff recommendation to publish for public comment revisions to the rule proposal. This was nominated for reform again in 2002.
SEC	Disclosure of Mutual Fund After-Tax Returns	Medium	This nomination relates to an SEC rule proposal on the disclosure of mutual fund after-tax returns. OMB describes the nomination as contending that the SEC proposal likely would not generate net benefits. At the time that the Commission was considering this proposal, Congress also was considering legislation to mandate mutual fund disclosure of after-tax returns. Indeed, by the time the Commission adopted this rule, the House of Representatives had passed such legislation. In its final rule, adopted January 18, 2001, the Commission reduced the scope of information it had proposed to require and exempted funds whose shares are offered exclusively as investment options for defined contribution plans and similar arrangements, for which the disclosure would be irrelevant. It concluded that shareholders would have an improved understanding of the effects of taxes on their investments, while the cost of the one-time change in mutual fund reporting would total around $16 million. Disclosure of Mutual Fund After-Tax Returns, 66 FR 9001 (February 5, 2001). This was nominated for reform again in 2002.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
SEC	Disclosure of Order Routing and Execution Practices	Medium	This nomination relates to an SEC rule proposal on the disclosure of order routing and execution practices. OMB describes the nomination as contending that there is no market failure that justifies the proposal. The Commission adopted two rules to improve public disclosure of order routing and execution practices on November 17, 2000. Disclosure of Order Routing and Execution Practices, 65 FR 75415 (December 1, 2000). This was nominated for reform again in 2002.
SEC	Self-Regulatory Organizations	Medium	This nomination relates to a Commission rule proposal to change its procedures to speed up the filing and effectiveness of SRO rule changes. OMB describes the nomination as contending that it is unlikely that significant innovations will result from the proposed rule change since fundamental structural changes are excluded from expedited consideration under the proposed new procedures. On March 30, 2004, the Commission published a new rule proposal that dealt with some of the same issues as in the earlier proposal. On October 4, 2004, the Commission adopted a form and rules, which: • require SROs to file proposed rule changes electronically with the Commission, rather than in paper form; • require SROs to post all proposed rule changes, as well as current and complete sets of their rules, on their Web sites; and require all participants in National Market System Plans to arrange for posting on a designated Web site a current and complete version of the NMS Plan. Proposed Rule Changes of Self-Regulatory Organizations, 69 FR 60287 (October 8, 2004). This was nominated for reform again in 2002.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
SEC	Registration of Broker-Dealers Pursuant to Section 15(b)(11)	Medium	This nomination relates to an SEC rule proposal on the registration of broker-dealers pursuant to Section 15(b)(11) of the Securities Exchange Act of 1934. OMB describes the nomination as contending that the SEC's proposed registration format would result in duplication of registration procedures for futures commission merchants and introducing brokers already registered with the CFTC. Section 15(b)(11) was added to the Securities Exchange Act in 2000 as part of legislation to permit the trading of security futures products. On August 21, 2001, the Commission adopted a registration mechanism that requires an entity that is required to register as a broker-dealer solely because it trades security futures products to file a brief statement with the Commission affirming that it meets the statutory conditions for registration. Registration of Broker-Dealers Pursuant to Section 15(b)(11) of the Securities Exchange Act of 1934, 66 FR 45138 (Aug. 27, 2001). This was nominated for reform again in 2002.
Army Corps	Discharge of Dredge or Fill Material Permits	Low	
Energy	Clothes Washer Energy Conservation Standards	Low	On January 12, 2001, DOE published new energy conservation standards for clothes washers that would raise the energy efficiency of new clothes washers by 22 percent beginning on January 1, 2004, and by 35 percent beginning on January 1, 2007. The effective date of the rule was delayed pending completion of review in accordance with the President's regulatory review initiative. On April 17, 2001, DOE published a notice stating that it had completed its review of the rule and allowed the rule to take effect (66 FR 19714). No further action is planned. This was nominated for reform again in 2002.
Labor	Annual Report For Federal Contractors on Veterans	Low	VETS completed the rulemaking on October 11, 2001 (66 FR 51997). The rulemaking made the changes to the Federal contractor reporting requirements that were necessitated by the by the Veterans Employment Opportunity Act of 1998 amendments.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
Labor/OSHA	Occupational Injury and Illness Record Keeping and Reporting	Low	OSHA issued final rules on July 1, 2002 (67 FR 4403), and June 30, 2003 (68 FR 38601). OSHA modified the recordkeeping and reporting requirements to revise criteria related to hearing loss, as well as to change requirements related to reporting musculoskeletal disorders. This was nominated for reform again in 2002.
Labor	Accrual of compensatory time and provision of more flexible schedules.	Low	ESA is not contemplating any action; legislation would be required.
EPA	National Ambient Air Quality Standard for Particulate Matter	Low	Initiated Reform. Final Rule for PM2.5 Implementation expect June 2005.
EPA	Heavy-Duty Engine and Diesel Rule	Low	Response Complete. Final rule published on January 18, 2001.
EPA and Justice	Worst Case Scenario Proposal	Low	The final rule "Accidental Release Prevention Requirements; Risk Management Programs; Distribution of Off-site Consequence Analysis Information" (a.k.a., "Worst Case Scenario rule") was published in the Federal Register by EPA and Justice on August 4, 2000 (65 FR 48107.) The Department believes that the rule properly balanced security and public access to information. The Department is not contemplating amendments to this rule. This was nominated for reform again in 2002.
EPA	National Ambient Air Quality Standard for Ozone	Low	Initiated Reform. Final Rule Phase II expected December 2004. Final Rule for PM2.5 Implementation expect June 2005. Regarding the Ozone NAAQS rule, EPA responded to remand on potential health benefits and issued a final rule on January 6, 2003. This was nominated for reform again in 2002.
EPA	Finding of Significant Contribution and Rulemaking for certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone;	Low	Agency decided not to pursue
EPA	Environmental Enforcement and Compliance Assistance Activities	Low	Agency decided not to pursue
EPA	Tier 2 Standards for Vehicle Emissions and Gasoline Sulfur Content	Low	Response Complete. Final rule was published February 10, 2000.

Table 16: 2001 Regulatory Reform Nominations			
Agency	**Title of Reform**	**OMB Priority**	**Status**
EPA	Filter Backwash Recycling	Low	Response Complete. No action necessary.
EPA	Ground Water	Low	Initiated Reform. Final rule expected April 2005
EEOC	EEO1 form	Low	The EEO-1 employer report is a government form submitted to the EEOC and the OFCCP annually by many employers and all federal contractors to enumerate employees by job category and by ethnicity and race. The EEOC and the OFCCP started updating the EEO-1 report in response to OMB's 1997 guidelines to all agencies to collect ethnic and racial data in greater detail, in light of the increasing diversity of the U.S. population. Government contractors and employers nominated the EEO-1 report for regulatory reform because they want the EEOC and the OFCCP to minimize employer reporting burdens in this revision. The EEOC published a request for comment on proposed revisions to the EEO-1 report on June 11, 2003. (68 Fed. Reg. 34965). Public comments were submitted, and a public hearing was held on October 29, 2003. The agencies are evaluating this input and preparing a final revised EEO-1 report for formal submission to OMB. There is not a firm date for completion.
Federal Reserve	Revision to Regulation B	Low	
USPS	Delivery of Mail to a Commercial Mail Receiving Agency	Low	

2002 Regulatory Reform Nominations

As discussed in more detail in our 2003 final Report, OMB determined which of the 316 reform nominations we received in 2002 were already under active consideration at the agencies and which of the nominations should be referred to the Independent and Cabinet agencies. Table 17 below updates the status of the 2002 reform nominations as of December 10, 2004. Also included in this table is a reference number to the detailed nomination descriptions available on our website at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

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Table 17A: 2002 Regulatory Reform Nomination Status

Agency	Title of Reform	Status	Ref. Number
Agriculture	Child Nutrition Program	USDA decided not to pursue	1
Agriculture	Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems	On May 23, 2003, FSIS issued FSIS Directive 5000.1. This directive was issued as FSIS Handbook, "Verifying an Establishment's Food Safety System." This handbook provided comprehensive direction to FSIS field personnel on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations. The directive addressed concerns raised about the FSIS program and instructions to the field force. Since its publication, FSIS has provided extensive training to its field force regarding this directive. FSIS is continuing to ensure that all issuances to the field are based on the concepts in this directive and training material.	2
Agriculture	Animal Identification	Published Interim Rule 11/08/2004 (69 FR 64644). To recognize additional numbering systems to identify animals in interstate commerce. This will be a key element in developing a national animal identification system, which is presently on a voluntary basis.	3
Agriculture	Post Mortem Inspection: Extent and Time of Post Mortem Inspection - Staffing Standards	FSIS is testing a new HACCP-based system of inspection in volunteer plants. The new system is intended to accommodate new technologies and allow increased operational efficiencies. If the results of the testing justify a new system, FSIS will consider appropriate amendments to its regulations.	4

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Agriculture	Zero Tolerance for *Listeria monocytogenes* and Performance Standards	Interim Final Rule Published June 6, 2003 (68 FR 34207). Official establishments that produce ready-to-eat meat and poultry products that are exposed to the environment after lethality treatments and that support the growth of L. monocytogenes will be required to have, in their hazard analysis and critical control point (HACCP) plans, or in their sanitation standard operating procedures or other prerequisite programs, controls that prevent product adulteration by L. monocytogenes. On 12/01/04, FSIS issued a report outlining the impact of the interim final rule and making recommendations for possible future action. FSIS extended the comment period on the interim final rule to 01/31/2005 (69 FR 70051) to coincide with the comment period of the report.	5
Agriculture	Salmonella Performance Standards	FSIS published a Notice in 2003 (68 FR 18593) asking for comments on suggested changes in reporting and posting Salmonella sample results. A Notice and Response to Comments announcing the chosen policy is being prepared and should be published in 2005.	6
Agriculture	National Organic Program	USDA decided not to pursue	7
Agriculture	Nutrition Labeling of Ground or Chopped Meat and Poultry Products	On January 18, 2001, FSIS published a proposed rule (66 FR 4970) to require nutrition information either on labels or at the point-of purchase for the major cuts of single ingredient, raw meat and poultry products and to require nutrition labels on all ground or chopped meat and poultry products unless an exemption applies. Comments are being evaluated for final rule.	8
Agriculture	Plant Pest Regulations	The issue identified by the commenter regarding restrictions on butterflies was part of a proposed rule. APHIS intends to address comments on the proposed rule in the final rule.	9
Agriculture	Badge as Identification of Inspectors	USDA decided not to pursue	10

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Agriculture	Mad Cow Disease	In January 2004, FSIS published three interim final rules to prevent the agent of bovine spongiform encephalopathy (BSE) from entering the human food supply (69 FR 1861; 69 FR 1874; 69 FR 1885). FSIS took this action in response to the confirmation of BSE in a cow in Washington State. The animal had been imported from Canada. In addition, FSIS issued a Federal Register Notice in January 2004 that announced that the Agency would no longer pass and apply the mark of inspection to carcasses and parts of cattle selected for BSE testing by APHIS until the sample is determined to be negative. In August 2004, FSIS, along with the USDA's Animal and Plant Health Inspection Service (APHIS) and the Food and Drug Administration (FDA) published a joint Advance Notice of Proposed Rulemaking (ANPR) (69 FR 42287) that describes additional Federal measures that the agencies are considering to further mitigate the risk of BSE. FSIS is evaluating the comments received in response to the interim final rules and the ANPR to determine whether FSIS should revise any of the measures it has implemented, or implement additional measures, to prevent human exposure to the BSE agent.	11
Agriculture	Phytosanitary Certificates for Seeds	APHIS will propose to amend the nursery stock regulations by allowing the importation of small lots of seed under an import permit with specific conditions, instead of requiring a phytosanitary certificate from the government of the exporting country. Draft final review under agency review. Expected publication date: 2/2005.	12
Agriculture	Swine Production Contract Library	Final Rule Published August 11, 2003 (68 FR 47802). The Grain Inspection, Packers and Stockyards Administration published a final rule to implement a swine contract library.	13
Agriculture	National Forests Land Use: Special Uses	USDA decided not to pursue	14
Agriculture	Roadless Area Conservation	Proposed rule published July 16, 2004 (69 FR 42636) Proposed rule would replace existing rule with a petitioning process that would provide Governors an opportunity to seek establishment of management requirements for National Forest System inventoried roadless areas within their State. Applicability to National Forest System Lands in Alaska - Proposed rule published 7/15/2003 (68 FR 41864). Final Rule expected April 2005. Applicability to the Tongass National Forest, Alaska: Final Rule published 12/30/03 (68 FR 75136).	15
Agriculture	Low Cost Timber Sales and Grazing Fees	USDA decided not to pursue	16

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Commerce	Annual Capital Expenditures Survey	During OMB's review of this survey under the Paperwork Reduction Act, OMB confirmed that the information collected on this survey cannot be obtained from IRS.	17
Education	Title IX and Collegiate Sports Participation	The Department of Education has taken no action related to this particular regulation.	18
Education	Title IX and Single-Sex Schools	The Department of Education published a Notice of Proposed Rulemaking in the Federal Register on March 9, 2004 (69 FR 11276), to amend the regulations implementing Title IX of the Education Amendments of 1972 (Title IX), which prohibits sex discrimination in federally assisted education programs. These proposed amendments would clarify and modify Title IX regulatory requirements pertaining to the provision of single-sex schools and classes in elementary and secondary schools. The proposed amendments would expand flexibility for recipients that may be interested in providing single-sex schools or classes, and they would explain how single-sex schools or classes may be provided consistent with the requirements of Title IX. Comments in this rulemaking were due by April 23, 2004. The Department is currently reviewing these comments and working toward preparation of final regulations.	19
Education	Federal Family Education Loan Program	The Department took action to reform both the Institutional Eligibility section of the Higher Education Act and the Federal Family Education Loan Program regulations in 2002. The Department issued two notices of proposed rulemaking in August 2002 (67 FR 51036; 67 FR 51718) and final regulations in November 2002 (67 FR 67048). The final regulations combined the proposed amendments from the two notices of proposed rulemaking. These amendments reduce administrative burden for program participants and provide them with greater flexibility to serve students and borrowers.	20
Energy	Energy Conservation Standards for Clothes Washers	On January 12, 2001, DOE published new energy conservation standards for clothes washers that would raise the energy efficiency of new clothes washers by 22 percent beginning on January 1, 2004, and by 35 percent beginning on January 1, 2007. The effective date of the rule was delayed pending completion of review in accordance with the President's regulatory review initiative. On April 17, 2001, DOE published a notice stating that it had completed its review of the rule and allowed the rule to take effect (66 FR 19714). No further action is planned.	21

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Energy	Energy Conservation Standards for Central Air Conditioners and Heat Pumps	On January 22, 2001, DOE promulgated a regulation that would have raised the energy efficiency of new central air conditioners by 30 percent. On May 23, 2002, DOE withdrew this rule and issued a final rule raising the minimum energy efficiency levels by 20 percent. The latter action was the subject of a litigation that concluded in 2004, with the court holding that DOE must implement the regulation promulgated on January 22, 2001. On August 17, 2004, DOE published revisions to the Code of Federal Regulations that reflect the energy efficiency increase of 30 percent that will take effect in 2006 (69 FR 50997).	22
HHS/CMS	Special Treatment: Direct Graduate Medical Education Payments	Decided not to pursue	23
HHS/CMS	Medicare Secondary Payer Provision	On Feb. 27, 2004, CMS issued an instruction implementing § 943 of the MMA, with the result that hospitals need not obtain "secondary payer" information from beneficiaries for laboratory services.	24
HHS/CMS	Physician Certification for Non-Emergency Ambulance Services	A review to ensure that there are no legal obstacles to the removal of this requirement was completed in 2003. CMS developed an internal task force to address this issue, but the issue is still under discussion with FBI and DOJ.	25
HHS/CMS	75% Rule	Language in FY'05 Appropriations bill constrains HHS from implementing final rule.	26
HHS/CMS	Converted Bed Rule	Under a 1999 statute, CMS contracted with RAND to study the impact on utilization and beneficiary access to services of the possible elimination of these rules; the study is largely completed, and CMS is examining the finding for IRF payment policy implications.	27
HHS/CMS	Exemption Date Rule	Under a 1999 statute, CMS contracted with RAND to study the impact on utilization and beneficiary access to services of the possible elimination of these rules; the study is largely completed, and CMS is examining the finding for IRF payment policy implications.	28
HHS/CMS	Medical Director Rule	Decided not to pursue	29
HHS/CMS	Minimum Staffing Standards for Nursing Homes	Decided not to pursue	30
HHS/CMS	One-Hour Restraint Rule	In October 2002, CMS convened a Town Hall Meeting with affected industry groups, professional organizations, and advocates to gain input regarding reducing burden while maintaining patient protections. The Fall Regulatory Agenda is projecting publication of an NPRM by April 2005.	31
HHS/CMS	Revisions to Medicare Payment Policies	Decided not to pursue	32

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
HHS/CMS	Certificates of Medical Necessity	Decided not to pursue	33
HHS	Medicare Program Prospective Payment System for Hospital Outpatient Services	Final rule published Sept. 9, 2003 (68 FR 53221)	34
HHS/CMS	Use of the OASIS for Home Health Agencies	CMS has streamlined the OASIS instrument. As a result of these changes, the number of items in the OASIS was reduced by 28%. The amount of time to complete the OASIS was reduced by 25%.	35
HHS/CMS	Clinical Laboratory Improvement Act Rules	Decided not to pursue	36
HHS	Health Insurance Portability and Accountability Act Claims Processing Standards	HHS does not agree that health plans must accept a HIPAA-compliant claim as a "clean claim" for purposes of contractual provisions with other entities under HIPAA, and for State and Federal prompt-pay requirements. HHS views the requirements of HIPAA statute and regulations as separate and distinct from various State and Federal "clean claim" requirements. The requirements of one do not necessarily fulfill the requirements of the other. Further action is therefore unlikely.	37
HHS/FDA	Standard of Chemical Quality – Arsenic	Proposed rule published 12/2/2004 (69 FR 70082).	38
HHS/FDA	Standard of Chemical Quality – Uranium	Final rule published on 3/3/2003 (68 FR 9873).	39
HHS/FDA	Standard of Microbiological Quality—Total Coliform	The 1993 proposal to establish standards for coliform was cited in an April 22, 2003 notice announcing FDA's intent to withdraw 84 regulatory proposals whose publications dates were five years ago or longer. This proposal was withdrawn on 11/26/2004 (69 FR 68831)	40
HHS/FDA	Labeling Genetically Modified Foods	Decided not to pursue	41
HHS/FDA	Hormones in the Food Supply	Decided not to pursue	42
HHS/FDA	Antibiotics in Food Supply	Decided not to pursue	43
HHS/FDA	Food Identity Standards	Decided not to pursue	44
HHS/FDA	Medical Drug and Device Regulations	Decided not to pursue	45
HHS/FDA	Premarket Notice for Bioengineered Foods	This rulemaking has been withdrawn, as announced in the Spring 2003 Regulatory Agenda.	46
HHS/FDA	Labeling of Carmine	Fall 2004 Unified Agenda projects rule in 9/2005.	47

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
HHS/FDA	Labeling of Sorbitol	Decided not to pursue	48
HHS/FDA	Labeling of Caffeine Content	Decided not to pursue	49
HHS/FDA	Labeling of Food Allergens	Undetermined. FDA is still considering how best to address this issue.	50
HHS/FDA	Investigational New Drug (IND) Regulations	Decided not to pursue	51
HHS/FDA	Pediatric Rule	The rule was overturned, as exceeding FDA's statutory authority, by court decision on October 17, 2002, and is no longer in effect.	52
HHS	Individually Identifiable Health Information	HHS is constantly issuing guidance on implementation of the privacy rules that went into effect on April 17, 2003. Changes in the codified text of the rules are, however, not currently contemplated.	53
HHS	Protection of Human Subjects	NPRM published July 6, 2004 (69 FR 40584). Final rule projected for May 2005 in fall Agenda. Thorough review underway by a new Secretary's Advisory Committee on Human Subjects Protections; see: http://www.hhs.gov/ohrp/sachrp/charter.htm	54
HUD	Predatory Lending	Rather than eliminate rules as the commenter recommended, our experience in combating predatory lending practices justified the need for rules to protect homebuyers and borrowers. We continue to believe that predatory lending is an important issue that needs to be addressed. Since the publication of the 2003 Report, HUD has promulgated three additional rules aimed at addressing predatory lending: 1. Prohibition of Property Flipping in HUD's Single Family Mortgage Insurance Programs (FR-4615-F-02), published May 1, 2003 (68 FR 23370). This rule provides that properties sold within six months after acquisition are not eligible for mortgage insurance. The rule does provide for the Secretary to make case-by-case exceptions. 2. Appraiser Qualifications for Placement on FHA Single Family Appraiser Roster (FR-4620-F-02), published May 16, 2003 (68 FR 26946). This rule requires that appraisers on the Appraiser Roster have the minimum professional credentials required by the Appraiser Qualifications Board of the Appraisal Foundation. 3. Lender Accountability for Appraisals (FR-4722-F-02) published July 20, 2004 (69 FR 43504). This rule makes the lender responsible for the quality and completeness of appraisals on property that will become the security for an FHA insured mortgage.	55

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
HUD	Insured Ten-Year Protection Plans	HUD declined to take action because, rather than adopt a "uniform warranty" and require FHA borrowers to purchase such plans as the commenter recommended, HUD believed that local building and occupancy permits adequately protected FHA borrowers at a lower cost. HUD does not anticipate any regulatory action to require FHA borrowers to purchase warranty plans.	56
Interior/ Agriculture	Digital Aircraft Radios	Being addressed as part of Presidential Spectrum Management Initiative.	57
Interior	Conservation Use in Grazing	The BLM published a proposed rule on December 8, 2003 (68 FR 68451-68474) that would remove this provision from its grazing regulations. While retaining most of the substantive changes made in 1995, the rule includes amendments designed to improve working relationships between BLM and grazing operators. For example, the rule provides for shared ownership of range improvements, directs BLM to document consideration of social, economic, and cultural effects of grazing changes, removes the 3-year limit on temporary non-use, and requires that decisions on developing and implementing management actions when rangelands do not meet land health standards and guidelines must be based on monitoring. The rule also increases administrative service charges for several types of BLM actions. BLM expects to publish a final rule in January 2005.	58
Interior	Surface Management of Mining Claims	Both the definition of "unnecessary and [sic] undue degradation" and the 2000 performance standards were amended in 2001. The BLM went through a rulemaking process in 2001 to make both changes which the commenter criticizes, and published a rule on October 30, 2001. Interior did so because the definition of unnecessary or undue degradation may well have exceeded BLM=s authority and because the 2000 performance standards, in some cases, went beyond that which is necessary to allow environmentally safe exploration and development. While the October 30 rule solicited comments on other aspects of the "3809 rules" at this time the Department plans no additional changes.	59
Interior	Endangered Species Act	This rule requires reform due to a recent 9th Circuit Court ruling which invalidated existing regulations defining adverse modification. FWS proposes to promulgate new regulations in the beginning of 2005.	60

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Interior	Endangered Species Act Delisting	The Department's Fish and Wildlife Service proposed the bald eagle for delisting in 1999 (64 FR 36454, July 6, 1999). We received a large amount of information and comments during the public comment period, and processing this information has resulted in a delay in issuing the final rule. Among these comments, the Service received numerous questions concerning the protections the bald eagle will continue to have under the Bald and Golden Eagle Protection Act (BGEPA) and the Migratory Bird Treaty Act (MBTA), once the species is delisted under the ESA. To address this issue, the Service is preparing clarification of the protections afforded to bald eagles under these laws following delisting. This information is needed to reduce the possibility of the public unintentionally violating the BGEPA or the MBTA after the bald eagle is delisted. The Service anticipates publishing these management guidelines, as well as a proposed regulatory definition of "disturb" under the BGEPA, early this winter; at the same time, the Service will re-open the comment period on the proposed rule to delist the bald eagle. On July 21, 2004 (69 FR 43663), the Service published a proposed rule to delist the Eastern Distinct Population Segment (DPS) of the gray wolf. The Eastern DPS includes the Great Lakes region. This DPS has achieved all of its recovery criteria, and the States of Minnesota, Wisconsin, and Michigan have plans in place to manage their respective wolf populations. The public comment period on the proposed rule closed on November 18, 2004, and the Service is currently reviewing public comments and processing the final rule.	61
Interior	National Landscape Conservation System	Decided not to pursue.	62
Interior	Possessory Interest Assets	The current regulations do not reference the term "book value" for determining the value of capital improvements by a concessioner. The current legislation implemented in 1998 provides for Leasehold Surrender Interest (LSI) for reimbursement of capital improvements. The NPS believes that using book value would be a clearer method of determining reimbursement value but is held to language included in the legislation. Nonetheless, the NPS has created an interdisciplinary workgroup to listen to concerns about LSI from the NPS Hospitality Association and others and try to resolve those concerns. The legislation provides that in 2007 the NPS will be able to readdress the issue of LSI with Congress and potentially modify how reimbursements for capital improvements are valued.	63

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Interior	Snowmobiles in Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr. Parkway	Regulations governing winter use snowmobiles and snow coaches in Yellowstone and Grand Teton National Parks and the John D. Rockefeller, Jr., Memorial Parkway were published by the Department in 2001 and 2003 but were vacated on NEPA and Administrative Procedure Act grounds in separate legal challenges brought in the District of Columbia and Wyoming. As a result of those court decisions, on November 10, 2004 NPS published in the Federal Register (69 FR 65348) new regulations governing snowmobile and snow coach use in these three park units for the next three winter seasons, while it continues long-term studies on the impacts of such use. Provisions of these new regulations require the use of the best commercially available snowmobile technology and commercial guides to protect park resources and minimize impacts on visitors. Although a legal challenge was immediately filed against these regulations, the omnibus appropriations act for FY 2005 directs that these regulations be used for the current winter use season.	64
Interior	Snowmobiles in the Rocky Mountain National Park	The NPS published a final rule on September 2, 2004 (69 FR 53626) that eliminated three of four routes previously designated for snowmobile use, while maintaining the North Supply Access Trail to accommodate the interests of the town of Grand Lake, local businesses, nearby private landowners, and Arapaho National Forest. On each of the routes closed to snowmobile use, NPS will continue as in past years to plow the routes to provide vehicle access to these areas.	65
Interior	Wild and Scenic Rivers—Water Resources Projects	The agency published proposed rules regarding water resource projects. The Wild and Scenic Rivers Act conveys authority to the Department of the Interior, and in some circumstances the USDA Forest Service, to make final determinations on Section 7 of the Act.	66
Interior	Cooperative Conservation Initiative	No agency action is needed.	67
Justice	Hemp Food Products	In 2002 the Drug Enforcement Administration (DEA) provided detailed written responses to SBA's comments regarding the October 2001 interpretive rule, proposed rule, and interim rule regarding THC and products containing THC (referred to by SBA as the "hemp food products" rules). While those comments thoroughly addressed SBA's stated concerns, please be advised of the following subsequent litigation. In Hemp Industries Association v. DEA (9th Cir. 2004), the Ninth Circuit issued an order which states that DEA is enjoined from enforcing the rules. DEA is now considering whether to initiate a formal procedure to add natural THC to the list of controlled substances.	68
Justice	List of Terrorist Organizations	The agency does not believe that reform of this rule is necessary.	69

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Justice/INS	Driver's Privacy Protection Act	The Department believes that no actions are advisable regarding this item.	70
Justice (now DHS)	Electronic Storage of I-9 Forms	A final rule is under development.	71
Justice (now DHS)	Admission Period for B-1/B-2 Visitors	Withdrawn by agency on June 3, 2002. No further action will be taken on this rule.	72
Justice (now DHS)	Forms I-140 and I-485	The agency published an interim final rule on July 31, 2002.	73
Justice (now DHS)	I-9 Employment Verification	The proposed rule was published on February 2, 1998. The final rule is pending at the agency.	74
Labor	Birth and Adoption Unemployment Compensation	ETA completed rulemaking on October 9, 2003 (68 FR 58540) to repeal the Birth and Adoption Unemployment Compensation rule.	75
Labor	Family and Medical Leave Act (FMLA) Regulations	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations.	76
Labor	Medical Certification	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations.	77
Labor	Computer Professional Exemption under FLSA	ESA issued a final rule on April 23, 2004 (69 FR 22122). The rule revised regulations protecting overtime payments under the Fair Labor Standards Act.	78
Labor	White Collar Exemption	ESA issued a final rule on April 23, 2004 (69 FR 22122). The rule revised regulations protecting overtime payments under the Fair Labor Standards Act.	79
Labor	FLSA Administrative Exception	ESA issued a final rule on April 23, 2004 (69 FR 22122). The rule revised regulations protecting overtime payments under the Fair Labor Standards Act.	80
Labor	Permanent Labor Certification	ETA expects to issue a final rule later this year.	81
Labor	SCA/Wage Determination Process/Wage Surveys	ESA plans to streamline the process for obtaining wage determinations and to update the occupational index. The NPRM regarding the Wage Determinations On Line is expected later this year, and the occupational index update is expected in December, 2005.	82
Labor	Davis Bacon Act/Service Contract Act B Inclusion of Pension and Benefit Plans	Current regulations already permit the inclusion of self-insured benefit programs. ESA is not contemplating any action to change the DBA/SCA thresholds; legislation would be required.	83
Labor	SCA Wage Increases and Benefit Improvements	ESA plans to streamline the process for obtaining wage determinations and to update the occupational index. The NPRM regarding the Wage Determinations OnLine is expected later this year, and the occupational index update is expected in December, 2005.	84
Labor	FLSA Medical Leave	ESA is not contemplating any action; legislation would be required.	85

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Labor	Across the Board Penalties	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations.	86
Labor	H-1B LCA	The "L-1 Visa and H-1B Visa Reform Act" included in the "Consolidated Appropriations Act, 2005," reinstitutes provisions regarding the H-1B LCA that had sunset on October 1, 2003, and ETA/ESA are reviewing the H-1B regulations.	87
Labor	Explosives	MSHA has determined not to take action on this issue because the current regulations have proven to be effective and there is no compelling safety and health reason for making revisions.	88
Labor and EEOC	Affirmative Action and EO Survey	Affirmative Action: OFCCP completed a directive addressing this issue in March, 2002. EO Survey: OFCCP has engaged an outside contractor to study the effectiveness of the survey in identifying noncompliant firms and expects to receive the study in 2005.	89
Labor/OSHA	Explosives and Process Safety Management	OSHA plans to revise, clarify, and update the existing explosives standard to reflect new technology and the current state-of-the-art while removing regulations that conflict jurisdictionally with those of ATF and DOT.	90
Labor/OSHA	Hexavalent Chromium	OSHA is conducting a rulemaking to address the hazards posed by exposure to hexavalent chromium, and issued an NPRM on October 4, 2004 (69 FR 59306). The NPRM addressed such issues as a permissible exposure limit, methods of compliance, exposure monitoring, medical surveillance, and training.	91
Labor/OSHA	Hazard Communication	OSHA is not contemplating any action because it already explicitly recognizes electronic availability of MSDSs as satisfying the requirement for employee access. OSHA's Web Site consolidates all available hazard communication information. Guidance documents on different aspects of the rule are in various stages of completion — public comments have been received on two of them. OSHA also entered into alliances that address hazard communication issues.	92
Labor/OSHA	Lead in Construction	OSHA notes that the provisions would not apply where no lead exists. OSHA will conduct a 610 review under the Regulatory Flexibility Act beginning in March 2005.	93
Labor/OSHA	Payment for Personal Protective Equipment	OSHA is conducting a rulemaking and recently re-opened the record to collect information on "tools of the trade." OSHA is evaluating these comments.	94
Labor/OSHA	Exposure to Crystalline Silica	OSHA completed a SBREFA review in 2004. The draft risk assessment is being prepared, and OSHA expects to peer review the risk assessment early next year.	95

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Labor/OSHA	Sling Standard	OSHA is updating all standards relating to voluntary consensus standards. The sling standard will be reviewed and updated as part of that project. The first phase of the project is currently at OMB for review. The sling standard will be addressed in a later phase. OSHA is preparing a guidance document regarding the use of slings in the workplace, which is expected in June, 2005.	96
Labor/OSHA	Tuberculosis (TB) Standard	OSHA withdrew its proposed rulemaking on December 31, 2003 (68 FR 75767)	97
Labor/OSHA	Walking/Working Surfaces	OSHA has been collecting information regarding the current state of the art with regard to fall protection and other issues, as well as updating its cost analysis. OSHA plans to re-open the record in January, 2005 to collect comments on the updated cost figures and information in other areas.	98
Labor/OSHA	Process Safety Management/Highly Hazardous Chemicals	OSHA has arranged to make available through its Web Site a new manual to provide assistance to employers, and has an active alliance with key parties regarding reactive chemicals.	99
Labor/OSHA	Bloodborne Pathogens Standard	OSHA solicited public comment on this collection burden. The ICR regarding the PRA clearance is pending at OMB.	100
Labor/OSHA	Metalworking Fluids	OSHA is not contemplating any regulatory action. OSHA has addressed the hazards of metalworking fluids by developing a best-practices guide and making it available on its Web Site in 2001.	101
Labor/OSHA	Recordkeeping for Work-Related Injuries, Illnesses and Fatalities	OSHA issued final rules on July 1, 2002 (67 FR 4403), and June 30, 2003 (68 FR 38601). OSHA modified the recordkeeping and reporting requirements to revise criteria related to hearing loss, as well as to change requirements related to reporting musculoskeletal disorders.	102
Labor/OSHA	Ergonomics Standard	OSHA is addressing this issue through the issuance of guidelines, enforcement, compliance assistance, and input from the National Advisory Committee on Ergonomics.	103
Labor/EBSA	Claims Procedures	EBSA completed rulemaking in November, 2000 (65 FR 70246, 66 FR 35886), and is not contemplating any further action.	104
State	Flight Simulators	Agency decided not to pursue	105
DOT	Disadvantaged Business Enterprise Program	Decided not to pursue	106
DOT/FAA	General Definitions of Major and Minor Repair	The FAA plans to charter an advisory committee this fiscal year to review the issue of "major vs. minor." The task will include examining the feasibility of harmonizing with other regulatory authorities.	107
DOT/FAA	Design and Construction	Decided not to pursue	108

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/FAA	Standards for Approval for High Altitude Operation of Subsonic Transport Airplanes	DOT/FAA is continuing to review this issue.	109
DOT/FAA	Seats, Berths, Safety Belts, and Harnesses	Decided not to pursue	110
DOT/FAA	Emergency Landing Dynamic Conditions	FAA anticipates no change in this area because it would have a negative effect on safety.	111
DOT/FAA	Improved Flammability Standards for Thermal/Acoustic Material	The final rule improving flammability standards was published July 31, 2003 (68 FR 45046), and became effective September 2, 2003.	112
DOT/FHWA	Contract Requirements for Minor Transportation Projects	FHWA has already published transportation enhancement program guidance. The guidance included several memoranda which exempt transportation enhancement (TE) projects from several highway requirements, and these are highlighted at www.fhwa.dot.gov/environment/te_meas.htm FHWA is exploring legislative options to streamline administrative procedures for TE activities.	113
DOT/FHWA	Historic Preservation Regulations	The issues raised by the commenter are actively under consideration as FHWA develops its legislative reauthorization proposal.	114
DOT/FHWA	Outdoor Advertising Control	DOT decided not to pursue	115
DOT/FHWA	Highway Design	DOT decided not to pursue	116
DOT/FHWA	Traffic Operations	The FHWA published a final rule on the 2003 edition of the Manual on Uniform Traffic Control Devices on November 20, 2003. Additionally, on October 22, 2004, the FHWA published a notice of proposed rulemaking (NPRM) proposing the minimum levels of sign retroreflectivity.	117
DOT/FHWA	Highway Work Zone Safety	The FHWA published a final rule to amend work zone safety regulations (23 CFR 630) on September 9, 2004. This regulation that governs traffic safety and mobility in highway and street work zones. The changes to the regulation will facilitate comprehensive consideration of the broader safety and mobility impacts of work zones across project development stages, and the adoption of additional strategies that help manage these impacts during project implementation. These provisions will help State Departments of Transportation (DOTs) meet current and future work zone safety and mobility challenges.	118

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/FHWA	Commercial Size and Weight	The FHWA considered the need to revise reporting requirements for State certification of their enforcement of Federal and State size and weight statutes and regulations and issued an NPRM in September 2000. Recommendations from the May 2002 National Research Council report have broadened the discussion of possible reform needed to both Federal and State truck size and weight programs. In light of recommendations in this report, the FHWA terminated the rulemaking proceeding.	119
DOT/FHWA and FTA	Transportation Planning and Environmental Review Procedures	Environmental streamlining is a priority for FHWA and FTA. The Department has taken a number of actions to help streamline the environmental review of highway and transit projects. On September 20, 2002, FHWA and FTA partially withdrew the proposed rulemaking amending requirements on State metropolitan planning. Both agencies jointly issued a final rule on January 23, 2003 that amended the planning regulations as it relates to consultation with non-metropolitan local officials in the transportation planning process.	120
DOT/FMCSA	Inspection, Repair, and Maintenance	DOT/FMCSA is continuing to review this issue	121
DOT	Background Checks for Truckers Hauling Hazardous Materials	DOT is continuing to review this issue.	122
DOT	Commercial Vehicle Cross-Border Safety	DOT is continuing to review this issue.	123
DOT/FMCSA	Hours of Service for Truckers	DOT issued a final rule modifying the hours of service regulations on April 28, 2003.	124
DOT/FTA	Buy America Pre-Award and Post Delivery Certification	DOT decided not to pursue	125
DOT/FTA	Set-Aside for Intercity Bus	DOT decided not to pursue	126
DOT/MARAD	Vessel Financing Assistance	DOT decided not to pursue	127

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/NHTSA	Corporate Average Fuel Economy (CAFE) Standards	On March 31, 2003, NHTSA issued a final rule setting new fuel economy standards for model year (MY) 2005-2007 light trucks. NHTSA has expressed its intent to consider reforms to the CAFE system, applicable to both passenger cars and light trucks, consistent with its statutory authority. On December 29, 2003, NHTSA published an Advanced Notice of Proposed Rulemaking (ANPRM) for the reform of the CAFE system. The notice described potential reforms NHTSA has the statutory authority to make, but did not advocate specific reforms. On April 23, 2004, the comment period closed for the ANPRM. Over 66,000 comments were received from the auto industry, special interest groups and the public. Possible higher levels and/or program restructuring for CAFE standards for future year rulemakings will be considered, based on these criteria and other statutory provisions, as well as the impact on safety and jobs.	128
DOT/NHTSA	Head Restraints	In January 2001, NHTSA published a proposal to upgrade FMVSS 202 for improved occupant protection in crashes. The final rule will be published on December 14, 2004.	129
DOT/NHTSA	Tire Pressure Monitoring Systems	A federal appellate court ruled in August 2003 that the statute mandating this rule requires a TPMS capable of detecting significant under-inflation in any tire up to a total of four tires. The court vacated the final rule, which permitted a TPMS that could detect only a single under-inflated tire. A new NPRM, in accordance with the court decision, was published on September 19, 2004. A final rule will be published in 2005.	130
DOT/NHTSA	Advanced Airbags	The agency responded in November 2003 and August 2004 to the requests raised by the submitters for reconsideration of an earlier final rule on advanced air bags. NHTSA does not consider this issue suitable for further review or reform at this time.	131
DOT/FHWA	Fuel System Safety Standard B Vehicle Fires	A final rule upgrading the standard was published in November 2003.	132

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/NHTSA	Occupant Crash Protection	NHTSA published a Request for Comment in 2004 on offset frontal rulemaking. This rulemaking was the subject of an OMB prompt letter sent to NHTSA in December 2001. NHTSA is developing and refining advanced dummies and associated injury criteria related to offset frontal crashes. On May 12, 2000, NHTSA published a final rule that amended FMVSS No. 208, "Occupant Crash Protection," to upgrade the maximum belted full-frontal rigid barrier crash test requirement up to 35 mph (56 km/h) for the 50th percentile adult male test dummy beginning with MY 2008 vehicles. At that time, NHTSA indicated that it intended to initiate rulemaking that would increase the maximum belted test speed for the 5th percentile adult female test dummy in time to have both dummies tested at the higher speed starting in 2007. NHTSA published an NPRM on August 6, 2003, to increase the 5th percentile adult female test speed required for frontal crash tests. NHTSA incorporated its resolution to initial and subsequent FMVSS No. 208 petitions for reconsideration in Final Rules in December 2001, January 2003 and November 2003, and will respond to additional petitions. NHTSA published on May 17, 2004, an NPRM to upgrade FMVSS No. 214, "Side impact protection," to provide greater head and chest side impact protection. The Agency's side impact upgrade proposal addresses the growing number of light trucks in the U.S. fleet and includes protection against collisions with narrow objects, such as poles.	133
DOT/NHTSA	Lower Interior Front Impact Protection	Decided not to pursue	134
DOT/NHTSA	Passenger Vehicle Compatibility	In June 2003, NHTSA issued a report on plans to address safety problems associated with vehicle incompatibility. The agency is conducting research aimed at informing regulatory and program decisions on measures to reduce these problems.	135
DOT/NHTSA	Rollover Protection	Rollover is one of NHTSA's five top priority areas for which Integrated Project Teams have been established. Per the requirements in the TREAD Act the agency began providing consumer information about vehicle rollover resistance for 2004 model year vehicles. Other actions to improve rollover protection include: research to support a regulatory decision on electronic stability control; a proposal (NPRM) for a global technical regulation for the performance of door, door retention components and door locks (publication expected in mid-December 2004); and a NPRM for improved roof crush protection in spring 2005.	136

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/NHTSA	Roof Crush	In October 2001, NHTSA issued a Request for Comment to assist in upgrading the requirements of FMVSS No. 216. The notice asked the public for its views and comments on what changes, if any, are needed to the roof crush resistance standard. Based on these comments and agency testing, NHTSA is developing an NPRM for a proposed upgrade to the standard. Publication of the NPRM is planned for spring 2005.	137
DOT/NHTSA	Passenger Vehicle Brakes	Agency decided not to pursue. Although the agency has upgraded this standard, it has not found sufficient benefits to warrant making the suggested changes. NHTSA is pursuing other initiatives to improve vehicle control and crash avoidance.	138
DOT/NHTSA	Door Locks	As a part of an international committee under the auspices of the United Nations/Economic Commission for Europe, NHTSA worked with other governments' experts to develop a global technical regulation for the performance of door, door retention components and door locks. This technical regulation was established in November 2004 as the first global technical regulation for vehicle safety. NHTSA has developed a NPRM based on that global technical regulation, and publication is expected soon.	139
DOT/NHTSA	Child Restraints	NHTSA is currently considering several regulatory solutions designed to address the risks experienced by children between the ages of four and ten. The agency soon will propose requirements for a new 10-year-old crash dummy and propose amending its child restraint standard to cover older and larger children.	140
DOT/NHTSA	Tire Safety	On June 26, 2003, NHTSA published a final rule to upgrade its tire performance requirements for light vehicles.	141
DOT/NHTSA	Glazing Materials and Crash Avoidance	NHTSA continues to monitor new technological developments to ensure that glazing is safe, both in terms of visibility and crashworthiness. Recent information on a new glazing product may eliminate the issue of surface scratching and the effects of aging. NHTSA will pursue independent evaluation of this technology.	142
DOT/NHTSA	Lamps, Reflective Devices and Associated Equipment	NHTSA completed a regulatory review assessment of its lighting standard in May 2004. The agency will continue to monitor new technologies as well as other issues such as glare.	143
DOT/NHTSA	Commercial Vehicle Operator Visibility	NHTSA published a Request for Comment on visibility technology and is working on a response to a petition for rulemaking on fender-mounted mirrors for trucks.	144

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/NHTSA and FMCSA	On-Board Crash Recorders	The FMCSA is addressing the issue of electronic on-board recorders (EOBRs) and is preliminarily considering whether to propose regulatory amendments concerning the use of EOBRs as a way to document compliance with the Federal hours-of-service rules. NHTSA published an ANPRM on September 1, 2004, in which the agency gathered information on issues to be considered in the development of improved performance specifications for these recording devices. NHTSA then published a NPRM on June 14, 2004, specifying uniform, minimum requirements for data elements, data format, and retrieval process for voluntarily installed EOBRs. A final rule is planned for 2005.	145
DOT/NHTSA	Driver Distractions	NHTSA has been conducting research for several years on driver distractions in general and specific distractions associated with in-vehicle displays and other technologies. This work has been funded in part by the Intelligent Vehicle Initiative program and involves use of the National Advanced Driver Simulator in some instances. Based on this research, NHTSA may ultimately decide to move forward with regulations designed to address driver distractions.	146
DOT/NHTSA	Pedestrian Crash Protection	NHTSA has agreed to work with the international community in developing a global technical regulation addressing pedestrian injuries. Data are being analyzed to determine whether or not the anticipated GTR would be a cost effective regulation for the U.S.	147
DOT/NHTSA	Bumper Strength	The last evaluation of the bumper standard is over 15 years old. Based on the length of time that has passed, NHTSA believes it may be appropriate to reevaluate the bumper standard. However, this may not be possible given the competing resource needs of important evaluations that relate to fatality and injury reduction measures.	148
DOT/NHTSA	Commercial Vehicle Brakes	An ANPRM will be published by early 2005 on stopping distance improvements for truck tractors. Research will continue. A regulatory decision is planned for 2006.	149
DOT/NHTSA	Consumer Information	NHTSA now provides consumer information on the dynamic rollover resistance of vehicles. NHTSA is considering potential changes to its frontal NCAP program as a result of increases in test speeds for some requirements under FMVSS No. 208, and to this end, has issued a Request for Comment. When revisions to FMVSS No. 214 become final, the agency will address any needed changes to the side NCAP program. NHTSA is currently exploring ways to incorporate the head injury data recorded during its side impact test into the side impact NCAP star rating. Work continues toward a decision on adding braking tests to NCAP.	150

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/FHWA and NHTSA	Commercial Vehicle Rollover	The FHWA and NHTSA studied current passenger vehicle rollover testing to discern whether the same principles could apply to commercial motor vehicles. NHTSA is examining the benefits and effectiveness of electronic stability control to prevent rollover.	151
DOT/NHTSA	Side-Impact Protection	A NPRM proposing enhanced head, chest, and abdominal protection in side impacts under FMVSS No. 214 was published on May 17, 2004. The agency will evaluate the comments received and conduct additional work, as needed, for the issuance of a final rule by the end of calendar year 2005.	152
DOT/NHTSA	.08 Alcohol Incentive Program	NHTSA believes the submitter is unaware of all the provisions of the applicable regulation. NHTSA has called the submitter to explain the scope of the relevant regulation. The submitter, Wisconsin Department of Transportation, stated that NHTSA appears to be applying the compliance criteria of the interim final rule rather than the regulatory text adopted in the subsequent final rule. It noted that the interim final rule states under the 5th compliance criteria that a State must establish a 0.08 BAC per se level under its criminal code. These criteria did not appear in the regulatory text adopted under the final rule. In a subsequent telephone call with agency personnel, the Wisconsin DOT acknowledged that its concerns had already been addressed by a letter sent to it by NHTSA in July 2002. The Wisconsin DOT has no further concerns on this issue, and NHTSA has confirmed they are not further pursuing.	153
DOT/FHWA and NHTSA	Emergency Response and Auto Crash Notification	NHTSA and FHWA are actively monitoring this technology. However, the agency does not believe regulatory review or reform is advisable at this time.	154
DOT/NHTSA	Commercial Vehicle Design Compatibility	We are monitoring crashes of commercial vehicles into light vehicles and have assisted the NTSB in evaluating the possible role of heavy truck compatibility in their investigations. However, we do not have any active research programs to address heavy truck aggressivity. Depending upon developments in the automotive industry on its compatibility commitments, there may be an opportunity to work with the trucking industry towards similar commitments (geometric alignment).	155

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
DOT/RSPA	Collection of Annual Registration Fees	On January 9, 2003, RSPA published a final rule reducing registration fees beginning July 1, 2003, to levels that should eliminate the unexpended balance in the Hazardous Materials Emergency Preparedness Grants Fund by 2006 and thereafter produce total receipts equivalent to the annual grants authorized by Congress. Thereafter, the 14 industry associations dismissed their lawsuit seeking an order to compel RSPA to reduce registration fees. RSPA understands that Congress may want to increase the total amount of annual emergency preparedness grants. If an increase is adopted, it may be necessary for RSPA to conduct a further rulemaking to raise registration fees in order to collect a higher total amount for grants.	156
DOT/RSPA	Emergency Preparedness Grants	RSPA completed and submitted to OMB an assessment of the Hazardous Materials Emergency Preparedness (HMEP) Grants program. RSPA has scheduled a Section 610 review of its regulations on the HMEP Grants program during 2006, as indicated in DOT's semi-annual Regulatory Agenda, published in the Federal Register on June 28, 2004.	157
DOT/RSPA	Hazardous Materials Training	RSPA published its final rule in DOT Docket No. RSPA-98-4952 (HM-223) on October 30, 2003, to clarify the applicability of RSPA's regulations to specific functions and activities, including hazardous materials loading, unloading, and storage. RSPA anticipates publishing a further final rule in early 2005 to address several administrative appeals to the HM-223 final rule (DOT is also defending a lawsuit in the Court of Appeals for judicial review of the HM-223 final rule). In coordination with the Department of Labor (DOL), DOT also proposed an amendment to Federal hazardous material transportation law to make explicit that RSPA's regulations do not preclude DOL from prescribing standards, regulations, or requirements regarding hazardous materials employee training. In DOT's letter on the Senate and House versions of the highway bill (which would reauthorize the hazardous material safety program), DOT emphasized the importance of this proposal.	158
Treasury	Currency and Foreign Financial Accounts	Decided not to pursue	159
Treasury	Alcohol Labeling	Final rule published on March 3, 2002.	160
Treasury/IRS	Employer Identification Numbers	Decided not to pursue	161

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Treasury/IRS	Flexible Spending Accounts	The Administration has proposed statutory modifications that would address concerns about unnecessary year-end purchases of medical care to avoid forfeiture. These proposals would allow (1) up to $500 in unused benefits in a FSA to be carried forward to the next year and (2) up to $500 in unused benefits in a FSA to be transferred to a 401(k), 403(b), 457(b) SARSEP, SIMPLE IRA, and/or MSA. Treasury is also studying whether it has the legal authority to provide some administrative flexibility in the operation of the "use it or lose it" rule contained in the regulations.	162
Treasury/IRS	Government Fleet Fuel Cards	This item will not be pursued because the American Jobs Creation Act changed the underlying statutory provision to provide that the ultimate vendor is the proper party to claim a refund of taxes in the case of a sale of gasoline to a state or local government for its exclusive use or to a nonprofit education organization for its exclusive use. See Internal Revenue Code section 6416(a)(4), as amended by section 865 of the American Jobs Creation Act of 2004.	163
Treasury/IRS	Interest Reporting Requirements	Treasury has issued two NPRMs on reporting on interest paid to non-resident aliens. The commenters expressed concern with these NPRMs. Treasury is still considering these and other public comments; however, the agency does not have an expected publication date for any final rules.	164
Treasury/IRS	Domestic Relations Tax Reform Act Rules	Treasury Decision 9035, January 13, 2003, finalized the regulation. The final regulation applies to redemptions of stock on or after January 13, 2003, that are pursuant to instruments in effect after January 13, 2003. The final regulation also applies to redemptions before January 13, 2003, or that are pursuant to instruments in effect before January 13, 2003, if the spouses or former spouses execute a written agreement on or after August 3, 2001, that satisfies the requirements of section 1.1041-2(c)(1) or (2) of the final regulations. The effective date provision in the final regulation permits taxpayers to avail themselves of the clarifying relief provided by the regulation if the taxpayers enter into an agreement as contemplated by the proposed and final regulation to specify the tax treatment agreed to by the spouses. Applying the provisions of the proposed and final regulations to taxpayers who have not entered into an agreement as contemplated by the regulations would not be consistent with sound tax administration and might result in adverse consequences to taxpayers.	165
Treasury/IRS	Monthly Tax Deposits	Decided not to pursue	166

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
Treasury/IRS	Mortgage Revenue Bond Purchase Price Limits	Under IRC section 143(e), States may issue mortgage revenue bonds to provide below market rate mortgages to certain first-time homebuyers. Home prices are limited to no more than 90% of the average purchase price for homes within the area in which the home is located. Prior to 2004, safe harbor purchase price limits had not been adjusted since the publication of a 1994 Revenue Procedure. On March 1, 2004, the IRS and Treasury Department updated the safe harbor limits with the publication of Revenue Procedure 2004-18 (2004-9 IRB 529). The 2004/2005 Priority Guidance Plan for the Office of Tax Policy and the Internal Revenue Service includes a project to update this Revenue Procedure.	167
Treasury/IRS	Partnership Investments in Small Business Stock	Decided not to pursue	168
Treasury/IRS	Business Use of Home	Decided not to pursue	169
EPA	Regulatory Reform for Handling Refrigerants	Initiated Reform. Administrator's signature on NPRM for "Split System" expected December 2004.	170
EPA	Chemical Plant Safety Standards	Response Complete. EPA plans to review the RMP database after RMP submissions and updates are received (ongoing) and will prepare findings in early 2005.	171
EPA	Risk Management Plans (Worst Case Scenario)	Response Complete. Final rule published August 04, 2000. EPA decided not to pursue any further action.	172
EPA	Definition of Solid Waste	Response Complete. Proposed Rule published on October 28, 2003.	173
EPA	RCRA Burden Reduction Initiative	Initiated Reform. Final rule expected August 2005.	174
EPA	RCRA Subtitle C Hazardous Waste Regulations	Response Complete. Conducted internal and external stakeholder meetings. Performance Track rule published April 14, 2004 focused on extension of hazardous waste accumulation time	175
EPA	Best Available Retrofit Technology	Initiated Reform. Revisions to the regional haze rule will address concerns raised by DC Circuit regarding best available retrofit technology. SNPRM published May 5, 2004. Final rule expected April 2005	176
EPA	1997 EPA Standards for Ozone and Particulate Matter	Initiated Reform. Final Rule Phase II expected December 2004. Final Rule for PM2.5 Implementation expected June 2005. Regarding the Ozone NAAQS rule, EPA responded to remand on potential health benefits and issued a final rule on January 6, 2003.	177
EPA	Protections for Farm Children from Pesticide Exposures	Response Complete. Litigation is ongoing but EPA considers response to comment complete.	178

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
EPA	Definition of Volatile Organic Compound	Under consideration. Administrator's signature on ANPRM expected December 2004.	179
EPA	Motor Vehicle Emission Standards for Greenhouse Gases	Response Complete. EPA Published a Notice of Denial of Petition on September 8, 2003. In October 1999, 19 groups petitioned EPA to regulate mobile source emissions of four greenhouse gases – CO2, methane, nitrous oxide, and hydroflourocarbon – to reduce the risk of climate change. EPA published a request for public comment on the petition in January 2001.	180
EPA	Heavy-Duty Engines and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements	Response Complete. Final rule was published January 18, 2001. No further action needed.	181
EPA	Protection from Pollution from Diesel Engines	Response Complete. Final rule was published January 18, 2001. No further action needed.	182
EPA	Proposed Tier 2 Motor Vehicle Emission Standards and Sulfur Gasoline Control Requirements	Response Complete. Final rule was published February 10, 2000. No further action needed.	183
EPA	Withdrawal of State Delegations	Response Complete. No action necessary	184
EPA	New Source Review	Response Complete. Final rules published on November 7, 2003 and October 27, 2003. Stay granted December 24, 2003.	185
EPA	Risk Assessment for Rodenticides	Response complete. Released preliminary comparative ecological assessment in January 2003. OPP schedules for REDs are posted on the internet.	186
EPA	Ban on Chromated Copper Arsenate (CCA)	Response complete. On March 17, 2003, EPA granted the cancellation and use termination requests affecting virtually all residential uses of CCA-treated wood and has issued the cancellation orders to the registrants for CCA. After December 30, 2003, CCA products cannot be used to treat lumber intended for most residential settings, including play structures, decks, picnic tables, landscaping timbers, residential fencing, patios and walkways/boardwalks. A Federal Register notice announcing the cancellation orders will be published in 2003.	187
EPA	TRI Alternate Reporting Threshold (Form A)	Initiated reform. Two part proposed rule under development; first (quick fixes) to be published December, 2004; second (more complex issues) August, 2005.	188
EPA	Collection of Health Screening Data	Response Complete. No action necessary	189

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
EPA	Export Notification Requirements	Under consideration. Legislation is still pending. Will revisit status of legislation with the renewal of the ICR in 2006, which actually begins in early 2005.	190
EPA	PCB Spill Cleanup Policy	Response Complete. Completed internal review, no further action planned	191
EPA	Storage for Reuse	Response Complete. FR notice published September 7, 2004.	192
EPA	RCRA Cement Kiln Dust (CKD)	Under Consideration. Considering publication of NODA by June 2005. Final rule expected October 2006.	193
EPA	Spill Prevention Plans	Response Complete. EPA issued a final rule in April 2003 extending compliance dates and outreach. EPA plans to conduct outreach.	194
EPA	NPDES and Sewage Sludge Monitoring Reports	Response Complete. No action necessary	195
EPA	Watershed Rule (Total Maximum Daily Load)	Continuous improvement. The July 2000 Watershed Rule revised the existing requirements for States to prepare lists of impaired waters and to develop total maximum daily loads (TMDLs) for the waters on these lists. The most significant change was to require that implementation plans be developed for each TMDL and approved by EPA. Commenters argued that the prescriptive, procedural approach adopted in the 2000 rule undermined the benefits of a watershed approach to addressing water quality. In particular, the requirement for up-front EPA approval of implementation plans was thought to limit State flexibility, impede adaptive management, and unduly interfere in State water pollution control programs. The rule was withdrawn by EPA in March 2003, following public notice and comment.	196
EPA	TRI Lead	Initiated Reform. This reform nomination would modify a final rule issued in January 2001. EPA is currently considering various burden reduction options for the TRI program and expects to issue a proposed rule in the summer of 2005.	197
EPA	Arsenic in Drinking Water	Response Complete. The arsenic final rule was issued on January 22, 2001, and became effective on May 22, 2001.	198
EPA	Concentrated Animal Feeding Operations	Response Complete. Final rule published February 12, 2003. Guidance published November 3, 2003.	199
EPA	Stormwater Construction General Permit	Response Complete. Final rule published July 1, 2003.	200
EPA	Stormwater Phase I	Response Complete. No action necessary	201
EPA	Stormwater Phase II	Response Complete. No action necessary	202
EPA	Removal Credits for POTWs	Under consideration. EPA developed an issue paper on options to remove perceived impediments to POTWs' use of removal credits. Further discussion required.	203

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
EPA	Sanitary Sewer Overflows	Continuous Improvement. Report to Congress signed August 6, 2004. Final rule expected November 2007.	204
EPA	Effluent Guidelines for Metal Products and Machinery	Response Complete. Final rule published May 15, 2003.	205
EPA	Drinking Water Standards for Emerging Contaminants	Response Complete. Final notice published July 18, 2003.	206
EPA	Drinking Water Standards for Radionuclides	Response Complete. No action necessary	207
EPA	Radon in Drinking Water	Under Consideration. EPA issued the proposed radon rule on November 2, 1999. Final rule expected December 2005.	208
EPA	TRI Form R Reporting	Initiated Reform. Changed Form R (for 2003) to break out on-site and off-site disposal. Additional Form R changes are being considered in Burden Reduction Initiative.	209
EPA	TRI: Lowering Reporting Thresholds for PBT Chemicals	Response Complete. No action necessary	210
EPA	Groundwater Rule	Initiated Reform. EPA issued the proposed rule on May 10, 2000. Final rule expected April 2005.	211
EPA	Disinfection Byproducts Rule	Initiated Reform. Final rule expected July 2005.	212
EEOC	Employer Information Report EEO-1	The EEO-1 employer report is a government form submitted to the EEOC and the OFCCP annually by many employers and all federal contractors to enumerate employees by job category and by ethnicity and race. The EEOC and the OFCCP started updating the EEO-1 report in response to OMB's 1997 guidelines to all agencies to collect ethnic and racial data in greater detail, in light of the increasing diversity of the U.S. population. Government contractors and employers nominated the EEO-1 report for regulatory reform because they want the EEOC and the OFCCP to minimize employer reporting burdens in this revision. The EEOC published a request for comment on proposed revisions to the EEO-1 report on June 11, 2003. (68 Fed. Reg. 34965). Public comments were submitted, and a public hearing was held on October 29, 2003. The agencies are evaluating this input and preparing a final revised EEO-1 report for formal submission to OMB. There is not a firm date for completion.	213

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
EEOC	Waivers Under Age Discrimination in Employment Act	Tender Back of Consideration. This December, 2000 regulation, promulgated by notice and comment rulemaking, established that individuals do not ratify an unlawful written agreement to waive their ADEA rights if they keep the money received in exchange for the waiver. (29 C.F.R. § 1625.23) The ADEA's specific statutory requirements for a valid written waiver always control, and individuals are not required to return the money in order to challenge age discrimination and an invalid waiver. Employers nominated this rule for revision because they want a rule that has firm assurances that funds spent on waivers will prevent ADEA lawsuits. The EEOC fully considered a range of employer arguments during the public comment period and addressed them when issuing the final rule in 2000. The EEOC is not revising this regulation.	214
EEOC and DOL	Affirmative Action and EO Survey/Definition of Applicant	DOL's OFCCP has engaged an outside contractor to study the effectiveness of the survey in identifying noncompliant firms, and expects to receive the study in 2005.	215
FCC	Ground Penetrating Radar and Other Ultrawide Band Devices		216
FCC	Telephone Number Portability		217
FCC	Broadband Access to the Internet Over Cable		218
FCC	Open Network Architecture Reporting		219
FCC	International Section 214 Authorizations		220
FCC	Complaints, Applications, Tariffs, and Reports		221
FCC	Content of Applications		222
FCC	Competitive Bidding Proceedings		223
FCC	Procedures Implementing NEPA		224
FCC	Access to Telecom Service		225

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
FCC	Construction, Marking, and Lighting of Antenna Structures		226
FCC	911 Services		227
FCC	Cellular Radiotelephone Service		228
FCC	Required New Capabilities Pursuant to CALEA		229
FCC	Personal Communications Services		230
FCC	Reports of Communications Common Carriers		231
FCC	Abbreviated Dialing Codes		232
FCC	Fees for Switching Long Distance Carriers		233
FCC	Remedying Interference to Public Safety Communications 800MHz		234
FCC	Mitigation of Orbital Debris		235
FCC	Customer Proprietary Network Information		236
FCC	Private Land Mobile Radio Services		237
FCC	Selection and Assignment of Frequencies		238
FCC	Competitive Bidding Procedures for 900 and 800 Mhz Service		239

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
FERC	Generator Interconnection Agreements	On July 24, 2003, FERC amended its regulations to require public utilities that own, control, or operate transmission facilities for transmitting electric energy in interstate commerce to file revised open access transmission tariffs containing standard interconnection procedures and a standard agreement, to provide interconnection service to generators having a capacity of more than 20 megawatts. FERC expects this rule to prevent undue discrimination, preserve reliability, increase energy supply, and lower wholesale prices for customers by increasing the number and variety of new generation that will compete in wholesale electricity markets. While FERC did not conduct a formal cost-benefit analysis for this rule, as it is not subject to the provisions of Executive Order 12866 for such an analysis, FERC did note that interconnection plays "a crucial role in bringing much-needed generation into the market to meet the growing needs of electricity consumers," and that the alternative "case-by-case approach is an inadequate and inefficient means to address interconnection issues." (68 FR 49846, August 19, 2003).	240
Federal Reserve	Regulation C: Annual Percentage Rate Reporting		241
Federal Reserve	Regulation D: Definition of Restricted and Unlimited Withdrawals		242
Federal Reserve	Monetary Policy Reserves, Regulation D		243
Federal Reserve	Electronic Account/Loan Applications		244
Federal Reserve	Truth in Lending/ RESPA		245
Federal Reserve	Definition of Electronic Address		246
Federal Reserve	Collection of Data and Race and Ethnicity		247
Federal Reserve	Regulation P: Privacy of Consumer Financial Information		248

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
FTC	Fair Packaging and Labeling Requirements	Staff understands that the rules implementing the Fair Packaging and Labeling Act (FPLA) also are listed because of Chairman Ose's suggestion that OMB review all ICB entries with 10 million burden hours or greater. While the current burden estimate for FPLA is 8,095,000 hours, that figure is an adjustment of the previous 12,000,000 figure, based on current information that fewer entities must comply with the FPLA than earlier thought. The reduced estimate was the predicate for OMB approval of the information collection requirements (primarily the rule's public disclosure requirements) for use through 2005. Neither of the public notices calling for comment on the paperwork burdens of the rule elicited any comment. The lack of interest in these burden estimates may stem from the fact that the FPLA rules were first promulgated in 1968. The rules implement the Act's requirements that packages of covered consumer commodities include a product identity statement; the identity of the manufacturer, packer, or distributor; and a declaration of the net quantity of product in the package. 33 FR 4718 (March 19, 1968); 16 C.F.R. Part 500. The rules have been modified occasionally in the ensuing 35 years to account for changes in the law (e.g., metrication) and in the marketplace, but their basic requirements have not changed. In 1994, in conjunction with consideration of statutorily required amendments, the Commission reviewed the FPLA rules its regulatory review program. The principal concern of the one comment from a small business was that businesses get sufficient time to transition to the use of new labels. Although the statute prescribed an effective date for compliance, the Commission issued an enforcement policy statement to ensure harmonization of its enforcement efforts with comparable state requirements. At present, it does not appear that the FPLA rules present an opportunity for further modernization to accomplish the goals noted in the "Smarter Regulations" Report. The FPLA rules are scheduled for another regulatory review during 2006. 67 Fed. Reg. 9630 (March 4, 2002).	249
FTC	Cooling Off Period for Sales Made at Home	The Federal Trade Commission issued its Cooling Off Rule in 1972. The Rule was created to protect consumers from problems associated with door-to-door sales, such as high-pressure sales tactics and misrepresentations as to the quality, price, or characteristics of goods. The Rule requires sellers, when selling consumer goods and services (costing $25 or more) at places other than the place of business of the seller, to inform buyers of their right to cancel the sale within three business days and receive a full refund. Specifically, the Rule requires	250

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
		sellers to furnish buyers with two copies of a notice of cancellation, which informs the buyer about: (1) the right to cancel; (2) the seller's obligation to return to the buyer any property traded in, payments made and any negotiable instruments executed by the buyer; and (3) the buyer's obligations with regard to the purchased product. On May 31, 2002, the Air Conditioning Contractors of America (ACCA) recommended that the Cooling-Off Rule be amended. The Cooling-Off Rule provides for certain exceptions to the three-day right to cancel. For example, the Rule does not apply when a buyer has asked the seller to visit the buyer's home to repair or perform maintenance on the buyer's personal property. This exception would apply if, for example, repair of a refrigerator is needed rather than replacement. Therefore, transactions involving repair and maintenance to most of the items in a person's home are not covered. Also, the Rule does not apply where a buyer waives the right to cancel to remedy a bona fide emergency. In an emergency, the Rule enables buyers to waive their cancellation right where: the buyer has initiated the contact, and the buyer gives the seller a handwritten statement, describing the emergency acknowledging and waiving the right to cancel. ACCA's comment expresses the concern that the Rule's requirements for emergency waivers are burdensome and impractical. In these situations, ACCA believes that buyers should be allowed to use a standard waiver form instead of the handwritten statement required by the Rule. ACCA also argues that the requirement that an effective waiver be signed by the buyer is impractical in many cases. For example, ACCA notes that, if the buyer is not present when the technician arrives to perform an emergency repair, no one else in the home (e.g., a teenage son or daughter, the maid) can waive the buyer's right to cancel. The Commission crafted a narrow waiver provision to ensure that form waivers would not be used by unscrupulous sellers to vitiate the Cooling-Off Rule's protections for consumers. The Commission considered and rejected the option of allowing sellers to give consumers a standard waiver form when it issued the Rule in 1972. Rather, the Commission patterned the Rule's emergency waiver requirements on those applicable in certain consumer credit transactions (waivers allowed if consumers give the lender a signed, handwritten statement describing the emergency and	

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
		waiving the right to rescind). Compare 12 C.F.R. § 226.15 (e). The FTC has not received evidence that the Cooling-Off Rule's requirement for handwritten waivers impedes consumers' ability to obtain emergency repairs. When the Commission sought comments on the Rule's costs and benefits during its regulatory review proceeding in 1995, none of the comments concerned the emergency waiver provision. In the staff's view, sellers can ensure that they obtain the appropriate waiver documents by telling potential customers about the waiver requirement before sending technicians to their homes. If the buyer will not be present when the technician arrives, a seller could arrange to have a handwritten waiver left at the home, if more than repairs or services are expected. Alternatively, a seller could ask the buyer to send the handwritten waiver by facsimile or by other electronic means (e.g., a document in .pdf format transmitted by electronic mail). Staff believes that a handwritten waiver document sent by facsimile or other electronic means would meet the Cooling-Off Rule's requirements for emergency waivers under Section 429.0(a)(3), if the document contains the buyer's handwritten signature and the other information, acknowledgments and statements required by the Rule. While the Commission has not formally adopted staff's views on the use of electronic transmissions to submit handwritten waivers, this view is consistent with statements the Commission made when it announced the results of the 1995 rule review proceeding. The Commission stated that a buyer's obligation to "mail or deliver" a signed and dated cancellation notice can be satisfied by sending a facsimile transmission. 60 FR 54180, 54185 (Oct. 20, 1995). Likewise, future technologies to transmit a waiver document electronically would be acceptable and consistent with the Commission's statement, provided that the document, like one transmitted by facsimile, is handwritten, contains the customer's handwritten signature and otherwise meets the Rule's requirements for a valid waiver. ACCA's comment also recommends that the Cooling-Off Rule be amended to exempt all transactions where the buyer initiates the first contact with the seller. Instead of a blanket exemption for sales initiated by consumers, the FTC chose a middle ground: a blanket exemption when maintenance or repairs of a buyer's personal property are involved and allowing consumers to waive their rights in cases of bona fide emergencies. A blanket exemption for sales initiated by consumers would not fully remedy	

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
		problems such as high-pressure sales tactics or misrepresentations that prompted the adoption of Rule. As noted by the FTC in 1972, for example, such a blanket exemption might "open the door for salesmen using all sorts of spuriously obtained invitations." (Statement of Basis and Purpose for the Cooling-Off Rule, 37 FR at 22946). Based on the previous regulatory review, the Commission concluded that the Cooling-Off Rule continued to provide significant protections to consumers. Considering the above analysis, staff thinks the Cooling-Off Rule is not a current candidate for reform. The Rule is scheduled to be reviewed again under the Commission's Regulatory Review program in 2007.	
FTC	Truth in Lending Requirements	Although the FTC enforces Regulation Z against creditors not regulated by another agency, and thus reports the paperwork burden imposed on those entities within its jurisdiction on its Information Collection Budget, the Federal Reserve Board, not the FTC, promulgates the regulation. The substantial burden estimate for Regulation Z that is attributed to the FTC is a function of the broad scope of its jurisdiction to enforce TILA. Regulation Z applies to all consumer credit advertisers and creditors. The FTC has residual enforcement jurisdiction under Section 108(c) of the TILA. 15 U.S.C. § 1607(c). The FTC's jurisdiction is the largest and most diverse of all the other federal agencies with TILA enforcement authority, covering most nondepository creditors, including mortgage lenders, finance companies, retailers, Internet companies, medical and dental service providers, and most nondepository credit advertisers. This burden estimate is based on FTC jurisdiction over more than one million entities. While the FTC does not promulgate Regulation Z, the agency has participated in various efforts to pare the burden of complying with TILA. For example, the Federal Reserve Board has issued interim final rules for use of electronic disclosures to comply with Regulation Z. See 66 FR 17329 (March 30, 2001) and 66 FR 41439 (August 8, 2001). The option for creditors to provide required disclosures electronically will likely reduce the burden of compliance with Regulation Z, provide greater flexibility, and reduce the paperwork burden for all entities covered by the regulation, including those under the FTC's jurisdiction. Although staff has no current recommendations, we stand ready to participate in further efforts to improve the effectiveness of Regulation Z's consumer credit disclosure requirements.	251

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
FTC	Retail Electricity Competition Plans	The nomination recommended restructuring the electricity market to allow retail competition and to provide numerous benefits to consumers. On several fronts, FTC staff has worked and continues to work with federal and state policymakers to ensure that consumers and businesses benefit from electric industry restructuring. Staff is monitoring federal and state legislation, offering policy guidance, when asked, on both competition and consumer protection issues, and engaging in outreach to the electric utility industry and its customers. Over the past 18 months, the Commission staff has filed comments on a number of FERC proposals to make wholesale electricity markets more competitive. In addition, the Commission released a staff study of the efforts of numerous states to deregulate the retail provision of electricity. The staff study followed up a July 2000 staff report examining two topics that bear directly on the FTC's expertise -- market power (e.g. evaluating and addressing horizontal market power concerns in generation) and consumer protection (e.g. disclosures by electric service providers of environmental attributes of power that they are selling). Staff continues to monitor developments in the industry and provide policy advice, when asked, at the state and federal levels.	252
NARA	Disposition of Federal Record	NARA, in partnership with stakeholders, will survey small businesses to assess their ability to meet the current standard to determine if amending the standard is necessary.	253
OPM	Federal Employees Health Benefits	Decided not to pursue	254
SEC	Regulation S-K: Environmental Liability Reporting	The nomination urges the SEC to expand its public company disclosure rules to require the disclosure of information regarding environmental performance. Item 103 of Regulation S-K currently requires public companies to disclose any administrative or judicial proceeding arising under any federal, state or local provisions regulating the discharge of materials into the environment or primarily for the purpose of protecting the environment if: the proceeding is material to the business or financial condition of the company; the claim for damages or potential monetary sanctions exceeds 10% of the company's assets; or a governmental authority is a party to the proceedings likely to result in a monetary sanction of $100,000 or more. The Rose Foundation for Communities and the Environment has submitted a rulemaking petition (SEC File No. 4-463) requesting the Commission to clarify the intent and application of its disclosure requirements with respect to "financially significant" environmental liabilities. This rulemaking petition is under consideration by members of the Commission staff.	255

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
SEC	Disclosure of Mutual Fund After-Tax Returns	This nomination relates to an SEC rule proposal on the disclosure of mutual fund after-tax returns. OMB describes the nomination as contending that the SEC proposal likely would not generate net benefits. At the time that the Commission was considering this proposal, Congress also was considering legislation to mandate mutual fund disclosure of after-tax returns. Indeed, by the time the Commission adopted this rule, the House of Representatives had passed such legislation. In its final rule, adopted January 18, 2001, the Commission reduced the scope of information it had proposed to require and exempted funds whose shares are offered exclusively as investment options for defined contribution plans and similar arrangements, for which the disclosure would be irrelevant. It concluded that shareholders would have an improved understanding of the effects of taxes on their investments, while the cost of the one-time change in mutual fund reporting would total around $16 million. Disclosure of Mutual Fund After-Tax Returns, 66 FR 9001 (February 5, 2001).	256
SEC	Disclosure of Order of Execution and Routing Practices	This nomination relates to an SEC rule proposal on the disclosure of order routing and execution practices. OMB describes the nomination as contending that there is no market failure that justifies the proposal. The Commission adopted two rules to improve public disclosure of order routing and execution practices on November 17, 2000. Disclosure of Order Routing and Execution Practices, 65 FR 75415 (December 1, 2000).	257
SEC	Registration of Broker-Dealers	This nomination relates to an SEC rule proposal on the registration of broker-dealers pursuant to Section 15(b)(11) of the Securities Exchange Act of 1934. OMB describes the nomination as contending that the SEC's proposed registration format would result in duplication of registration procedures for futures commission merchants and introducing brokers already registered with the CFTC. Section 15(b)(11) was added to the Securities Exchange Act in 2000 as part of legislation to permit the trading of security futures products. On August 21, 2001, the Commission adopted a registration mechanism that requires an entity that is required to register as a broker-dealer solely because it trades security futures products to file a brief statement with the Commission affirming that it meets the statutory conditions for registration. Registration of Broker-Dealers Pursuant to Section 15(b)(11) of the Securities Exchange Act of 1934, 66 FR 45138 (Aug. 27, 2001).	258

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
SEC	Self-Regulatory Organizations	This nomination relates to a Commission rule proposal to change its procedures to speed up the filing and effectiveness of SRO rule changes. OMB describes the nomination as contending that it is unlikely that significant innovations will result from the proposed rule change since fundamental structural changes are excluded from expedited consideration under the proposed new procedures. On March 30, 2004, the Commission published a new rule proposal that dealt with some of the same issues as in the earlier proposal. On October 4, 2004, the Commission adopted a form and rules, which: • require SROs to file proposed rule changes electronically with the Commission, rather than in paper form; • require SROs to post all proposed rule changes, as well as current and complete sets of their rules, on their Web sites; and require all participants in National Market System Plans to arrange for posting on a designated Web site a current and complete version of the NMS Plan. Proposed Rule Changes of Self-Regulatory Organizations, 69 FR 60287 (October 8, 2004).	259
SEC	Market Fragmentation	This nomination relates to an SEC concept release on issues relating to market fragmentation. OMB describes the nomination as contending that there is little evidence that market fragmentation is significant and that solutions discussed in the concept release would create cumbersome disclosure systems. In 1999, the New York Stock Exchange (NYSE) submitted to the Commission a proposal to rescind its restrictions on off-board trading. The Commission requested public comment on the NYSE's proposed rule change and simultaneously issued a concept release requesting comment on attendant issues of market fragmentation. The Commission approved the NYSE's proposed rule change in May 2000. Based in part on the information obtained pursuant to the concept release, the Commission earlier this year proposed Regulation NMS, which, if adopted, would address issues relating to market fragmentation. Regulation NMS, 69 FR 11126 (March 9, 2004). The Commission announced on November 30, 2004 that it will consider on December 15, 2004 a staff recommendation to publish for public comment revisions to the rule proposal.	260

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
SEC	Confirmations of Securities Transactions	This rule was nominated because the PRA burden associated with the rule is over 10 million hours, and the person making the nomination would like OMB to review all non-IRS rules that impose over 10 million burden hours annually. Most of the costs associated with the rule are the cost of mailing confirmations and the cost of developing computer systems to generate the confirmations. The SEC has not significantly modified the rule since the nomination. On September 6, 2002, however, in accordance with the Commodity Futures Modernization Act of 2000, the SEC adopted amendments to Rule 10b-10 to clarify the disclosures broker-dealers effecting transactions in security futures products in futures accounts must make in the confirmations sent to customers regarding those transactions. The amendments provide that broker-dealers effecting transactions in security futures products in futures accounts do not have to disclose all of the information required by Rule 10b-10, but rather require that the transaction confirmations for these accounts disclose specific information and notify customers that certain additional information will be available upon written request. Confirmation Requirements for Transactions of Security Futures Products Effected in Futures Accounts, 67 FR 58302 (September 13, 2002). On January 29, 2004, the SEC proposed new rules and rule amendments under the Securities Exchange Act of 1934 to enhance the information broker-dealers provide to their customers in connection with transactions in certain types of securities. Two proposed rules would require broker-dealers to provide their customers with targeted information, at the point of sale and in transaction confirmations, regarding the costs and conflicts of interest that arise from the distribution of mutual fund shares, unit investment trust interests (including insurance securities), and municipal fund securities used for education savings. The Commission also proposed amendments to Rule 10b-10 to provide investors with additional information about call features of debt securities and preferred stock. Confirmation Requirements and Point of Sale Disclosure Requirements for Transactions in Certain Mutual Funds and Other Securities, and Other Confirmation Requirement Amendments, and Amendments to the Registration Form for Mutual Funds, 69 FR 6438 (February 10, 2004).	261

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
SEC	Recordkeeping by Registered Investment Companies	Section 31 of the Investment Company Act of 1940 requires funds and other specified entities to maintain and preserve such records as the SEC by rule may prescribe as necessary or appropriate in the public interest or for the protection if investors, and the SEC has adopted Rule 31a-1 to implement this statutory provision. This rule was nominated because the PRA burden associated with the rule is over 10 million hours, and the person making the nomination would like OMB to review all non-IRS rules that impose over 10 million burden hours annually. SEC Rule 31a-1 requires funds, and every underwriter, broker, dealer, or investment adviser that is a majority-owned subsidiary of a fund, to maintain and keep current accounts, books, and other documents that constitute the record forming the basis for financial statements required to be filed under Section 30 of the Act, and of the auditor's certificates relating to the financial statements. The SEC has amended Rule 31a-1 since the nomination, but has not changed the basic requirement that funds make and keep specified records. Most of the records required to be maintained by the rule are of the type that generally would be maintained as a matter of good business practice and to prepare the fund's financial statements. The rule's recordkeeping requirements also are essential to the SEC's examination program.	262

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
SEC	Investment Advisor Registration Updates	Another nomination for reform relates to the requirement that investment advisers file annual updates to their registrations and register non-broker-representatives and complete a Form U-4 for each representative. OMB describes the nomination as contending that the registration process is cumbersome, filing Form U-4 is unnecessary, and the registration process yields little or no benefit. Investment advisers registered with the SEC are required to use the interactive web-based IARD system to file and update their registrations. The IARD system was built for the SEC and state securities administrators by NASD, which also operates the system as a vendor. An investment adviser trade group has reported that its members generally found the electronic system easy to use and that the amendment process has been greatly improved with electronic filing. Letter dated May 16, 2001 from Karen L. Barr, General Counsel, Investment Counsel Association of America to Paul F. Roye, Director, Division of Investment Management, U.S. Securities and Exchange Commission. The data submitted through the IARD system are used extensively by SEC staff in connection with rulemaking and industry analysis. The IARD data also form the basis of the Investment Adviser Public Disclosure system, a Congressionally-mandated database of information concerning investment advisers that is available free of charge to the public through the Internet. Requirements to register investment adviser representatives are state law requirements.	263
SBA/FAR	Contract Bundling	The final rule was published on October 20, 2003 at 68 FR 60006. The rule revises the definition of bundling to expressly include multiple award contract vehicles and task and delivery orders under such contracting vehicles; require procuring activities to coordinate with the Small Business Specialist (SBS) proposed acquisition strategies or plans contemplating award of a contract or order above specified dollar thresholds and require the SBS to notify the agency Office of Small and Disadvantaged Business Utilization (OSDBU) when those strategies include contract bundling that is unnecessary, unjustified, or not identified as such by the procuring activity; reduce the threshold and revise the documentation required for "substantial bundling;" require contracting officers to provide bundling justification documentation to the agency OSDBU when "substantial bundling" is involved; and require agency OSDBUs to perform certain oversight functions.	264
US Army Corps	Nationwide Permits	Decided not to pursue	265

Table 17A: 2002 Regulatory Reform Nomination Status			
Agency	**Title of Reform**	**Status**	**Ref. Number**
US Corps, EPA	Definition of Fill Material	Response Complete. No action necessary	266
USPS	Commercial Mail Receiving Agencies	Decided not to pursue	267

Table 17B: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Status**	**Ref. Number**
USDA	Policy on Beef Contaminated with *E. coli* O157:H7	On March 31, 2004, the Food Safety and Inspection Service (FSIS) issued a revised e. coli 0157:H7 testing directive for its inspectors. FSIS also issued compliance guidelines for industry on the FSIS e.coli 0157:H7 testing program. On May 17, 2004, the testing directive for inspectors was implemented. Between May 2004 and September 2004 workshops were held for industry.	1
HHS/CMS	Medicare Carrier Manual/Medicare Intermediary Manual	A review indicates that are no legal obstacles to the removal of this requirement. Unresolved as how to proceed.	2
HHS/CMS	Signature on File Requirement for Ambulance Services	Decided not to pursue	3
HHS/CMS	Payment to Health Care Delivery System	Decided not to pursue	4
HHS/CMS	Individual Health Insurance Rules	Decided not to pursue	5
HHS/CMS	Guidance to Surveyors – Long Term Care	Decided not to pursue	6
HHS	Discrimination Against Persons with LEP	To ensure that persons with limited English skills can effectively access critical health and social services, the HHS Office for Civil Rights (OCR) published policy guidance in 2003, which outlines the responsibilities under federal law of health and social services providers who receive Federal financial assistance from HHS to assist people with limited English skills. The guidance explains the basic legal requirements of Title VI of the Civil Rights Act of 1964 (Title VI) and explains what recipients of Federal financial assistance can do to comply with the law. The guidance contains information about best practices and explains how OCR handles complaints and enforces the law. You can print out a copy of the guidance from OCR's website at http://www.hhs.gov/ocr.	7
HHS/FDA	Nine-Compounds Monitoring	Decided not to pursue	8
HHS/FDA	Coverage of Personal Importations	Decided not to pursue	9
Interior	Endangered Species Act Survey Protocols	Decided not to pursue	10
Justice	Guidance on Federal Prison Industries	The Department still believes that no actions are advisable regarding this item.	11

Table 17B: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Status**	**Ref. Number**
Labor	Coordination of FMLA with other Leave Policies	ESA is reviewing its FMLA regulations, which includes an evaluation of its experience administering the rules and input from stakeholders, court decisions, and the public nominations.	12
DOL	Guidance on Equal Employment Opportunity	OFCCP's actions are consistent with the applicable 1997 guidance from OMB. OFCCP is currently working with OMB in connection with EEOC's revisions to the EEO-1 form.	13
DOL/OSHA	Inspection Procedures and Interpretive Guidance for Control of Hazardous Energy (Lockout/Tagout)	OSHA is developing a Directive, which is expected in April, 2005.	14
DOL/OSHA	OSHA Directive CPL 2.100, Application of the Permit-Required Confined Spaces (PRCS) Standards	OSHA is developing a Directive, which is expected in May, 2005	15
Labor/OSHA	Multi-Employer Citation Policy	OSHA had discussions and exchanged correspondence with several organizations (including the petitioners) on developing guidance to further clarify the responsibilities of the general contractor.	16
DOT/FAA	General Operating and Flight Rules	Decided not to pursue	17
DOT/Coast Guard (now DHS)	Marine Safety Manual	The Department is continuing to review this nomination.	18
Treasury/IRS	Low-Income Housing Tax Credit	The commenter suggests that the IRS issue regulations regarding certain issues addressed in the identified Technical Advice Memoranda (TAMs). Issuance of formal guidance on these issues is not necessary because the positions taken in the TAMs generally are based on general tax principles. Agency indicated that it is not likely that this item will be pursued further.	19
Access Board	ADA/ABA Guidelines	The Board published new final guidelines under the ADA and ABA on July 23, 2004, (69 FR 44083). These guidelines are non-enforceable standards until adopted by various agencies. The Department of Justice (DOJ) is the agency responsible for incorporating most of these standards into its regulations, which then have the force and effect of law. While the Access Board only addresses accessibility requirements for new or altered structures, the DOJ regulations will also address the need for retrofitting for existing facilities under the ADA. DOJ published an ANPRM seeking comment on the new guidelines on September 30, 2004 (69 FR 58768).	20
EPA	EPA Index of Applicability Decisions	Response Complete. EPA's action on this issue was completed with the publication of a notice on February 13, 2003.	21

Table 17B: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Status**	**Ref. Number**
EPA	New Source Review	Response Complete. Final rule published on October 27, 2003.	22
EPA	"Once In, Always In" Policy	Initiated Reform. Administrator's signature expected on final rule February 2005.	23
EPA	Improving Air Quality Through Land Use Activities	Response Complete. No action necessary	24
EPA	Improving Air Quality Using Economic Incentive Programs	Response Complete. EPA issued guidance on January 19, 2001, and the States are now using the guidance in developing economic incentive programs.	25
EPA	TRI Reporting Forms and Instructions	Initiated Reform. Being considered in context of Burden Reduction Initiative.	26
EPA	TRI Reporting Questions and Answers	Initiated Reform. Q&A's at OMB for review as of this publication.	27
EPA	Waterborne Diseases	Initiated Reform. Draft Report expected early 2005.	28
EPA	Food Quality Protection Act Policy Papers	Response Complete. No action necessary	29
EPA	Integrated Risk Information System	Continuous improvement. EPA continues to complete review of assessments and add to IRIS database.	30
EPA	Investigating Title VI Administrative Complaints	Response Complete. No action necessary	31
EPA	Economic Benefit of Noncompliance in Civil Penalty Cases	Initiated Reform. FR Notice expected November 2004.	32
EPA	TRI Lead Reporting	Initiated Reform. This reform nomination would modify a final rule issued in January 2001. EPA is currently considering various burden reduction options for the TRI program and expects to issue a proposed rule in the summer of 2005.	33
EPA	Pesticide Registration Notices	Response Complete. No action necessary	34
EPA	Site-Specific Risk Assessments in RCRA	Initiated Reform. Final rule expected June 2005.	35
EPA	Cancer Risk Assessment Guidance	Initiated Reform. Final guidelines expected March 2005.	36
EPA	RCRA Spent Catalyst Policy	Response Complete. No action necessary	37
EPA	Superfund Indirect Costs	Response Complete. No action necessary	38

Table 17B: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Status**	**Ref. Number**
EPA	Ecoregional Nutrient Criteria Documents	Response Complete. No action necessary	39
EPA	Submetering Water Systems	Response Complete. Final policy memorandum signed on December 16, 2003	40
EPA	Drinking Water Affordability	Initiated reform. Proposal expected May 2005. FACA Committee (NDWAC) has submitted recommendations on how to proceed.	41
EPA	Clean Water Act Jurisdiction ("SWANCC Decision")	Response complete. ANPRM published on January 15, 2003.	42
EEOC	Guidance Document: Mandatory Binding Arbitration	The EEOC issued a policy statement in 1997 taking the position that pre-dispute mandatory arbitration agreements covering statutory EEO claims are inconsistent with the law and undermine public enforcement. Employers nominated this guidance for reform because they favor pre-dispute mandatory arbitration as a means to resolve employee disputes and avoid litigation. Although the EEOC policy statement remains in effect, EEOC staff is currently examining the fairness issues raised by the use of mandatory arbitration agreements and drafting guidance on the standards that such agreements must meet in order to be enforceable. This is a long-term drafting project that is still in the initial stages. Therefore, we are unable to provide a timeline for its completion.	43

Table 17B: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Status**	**Ref. Number**
FTC	Guidance Document: FCRA & Workplace Investigations	Several commenters proposed the rescission of staff letters and guidance explaining the operation of the Fair Credit Reporting Act (15 U.S.C. §1681 et seq.) with respect to workplace investigations. Under the FCRA, investigations by third parties of alleged or suspected workplace illegality may constitute a "consumer report" and trigger certain FCRA protections. Section 603(f) of the FCRA defines a "consumer reporting agency" as any person which, for monetary fees . . . regularly engages in whole or in part in the practice of assembling or evaluating consumer credit information or other information on consumers for the purpose of furnishing consumer reports to third parties, and which uses any means or facility of interstate commerce for the purpose of preparing or furnishing consumer reports. (15 U.S.C. §1681a(f)). "Consumer report" is defined in Section 603(d)(1) as a communication of information bearing on a consumer's "credit worthiness, credit standing, credit capacity, character, general reputation, personal characteristics, or mode of living" that is used or expected to be used for the purpose of serving as a factor in establishing the consumer's eligibility for, among other things, employment. (15 U.S.C. §1681a(d)). Under the FCRA, the FTC has jurisdiction over non-bank entities, such as employers. Thus, FTC staff guidance has been that under the requirements of the FCRA, an outside entity hired to assist an employer in investigating an employee may constitute a credit reporting agency because that entity furnishes "consumer reports" to a third party (the employer). Staff letters and guidance on this issue merely state the legal requirements of the FCRA to protect consumers with advanced notice and disclosure under Sections 604, 606, and 615 (15 U.S.C. §§ 1681b, 1681d, and 1681m). Amendment of the FCRA could change these requirements. Such an amendment could exempt investigations of suspected or alleged misconduct by an employee from compliance with the provisions of the FCRA that require advance notice to investigation targets and disclosure of full reports to such targets. (Sections 604(b)(2) and (3), 606(a) and (b), and 615(a).). It may also be appropriate to provide through legislation that compliance with Section 609(a)(1) would not be required except that the consumer reporting agency must disclose to the employee a summary containing the nature and substance of information in the consumer's file at the time of the request.	44

Table 17B: 2002 Guidance Reform Nomination Status			
Agency	**Regulation**	**Status**	**Ref. Number**
OMB	OMB Analytic Guidance	OMB's revised final guidelines were issued as Circular A-4 on September 17, 2003. These guidelines will be fully active on January 1, 2005.	45
OMB	Performance of Commercial Activities	OMB published a draft revision to Circular A-76 in the Federal Register on November 19, 2002. OMB issued the final revision on May 29, 2003.	46
OMB	Cost Accounting Standards for Educational Institutions	Decided not to pursue	47
SBA	Guidance on Credit Unions	On February 14, 2003, the Small Business Administration (SBA) issued a legal opinion that in effect authorized any credit union to participate in the SBA's 7(a) loan program regardless of its common bond of membership, so long as it satisfies the relevant eligibility criteria. Thus, there was no need to for any regulatory changes or guidance documents.	48
U.S. Army Corps	Wetlands Delineation Guidance Documents	The Corps, in conjunction with the Environmental Protection Agency, the Fish and Wildlife Service, and the Natural Resources Conservation Service, is updating and clarifying its 1987 Wetland Delineation Manual to provide more regionally specific guidance resulting in more precise and consistent wetland delineations.	49

APPENDIX E: Bibliography

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APPENDIX F: List of Peer Reviewers and Public Comments

OMB greatly appreciates all of the comments we received in response to the draft Report. In particular, we would like to thank our invited peer reviewers: James Gattuso (Heritage Foundation), Robert Hahn and Robert Litan (AEI Brookings Joint Center for Regulatory Studies), Arik Levinson (Georgetown University), Richard Morgenstern (Resources for the Future), and Robert Verchick (University of Missouri at Kansas City and Loyola University, New Orleans). Below is a listing of all the written comments we have received (including from the peer reviewers), and the numbers or letters we have assigned to their comments. The public and peer review comments are available for review at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

Public Comments

1. Jim Nitzschke, Deere & Company
2. Winifred DePalma, Public Citizen's Congress Watch
3. David Ailor, American Coke and Coal Chemicals Institute
4. Deanna R. Gelak, FMLA Technical Corrections Coalition
5. James Gattuso, Heritage Foundation
6. Sally Remedios, Delta Faucet Company
7. Douglas H. Green, Utility Solid Waste Activities Group
8. Andrew Langer, National Federation of Independent Business (NFIB)
9. Larry Fineran, National Association of Manufacturers (NAM)
10. Robb MacKie, American Bankers Association (ABA)
11. Teresa Pugh, American Public Power Association (APPA)
12. Kyle Isakower, American Petroleum Institute (API)
13. Steve Risotto, The HM-223 Coalition
14. Cynthia E. Miles, Hunton & Williams
15. J. Robert Shull, OMB Watch
16. Alan Roberson, American Water Works Association (AWWA)
17. Rashida Holmes, Synthetic Organic Chemical Manufacturers Association (SOCMA)
18. Alison Keane, Paint
19. Laura Brooks, U.S. Chamber of Commerce
20. Brandon Viars, National Stone, & Gravel Association (NSGA)
21. Evan R. Gaddis, The Gas Appliance Manufacturers Association (GAMA)
22. Alan Roberts, DGAC
23. Greg Dana, Alliance of Automobile Manufacturers (AAM)
24. Molly Brogan, National Small Business Association (NSBA)
25. Susan Moriak, Recreation Vehicle Industry Association (RVIA)
26. Vincent Giordano, General Electric Company (GE)
27. Danielle Waterfield, Specialty Graphic Imaging Association (SGIA)
28. Jeff Hannapel, The Policy Group
29. Lisa Heinzerling, Georgetown University Law Center
30. William A. Russell, Jr., William Russell & Associates, Inc.
31. Jim Solyst, American Chemistry Council (ACC)

32. Fern Abrams, IPC -The Association Connecting Electronics Industries (ACEI)
33. Andy Bopp, Society of Glass and Ceramic Decorators (SGCD)
34. Maggie Clarke, American Iron and Steel Institute (AISI)
35. Chris Pearce, American Furniture Manufacturers Association (AFMA)
36. Susan L. Hall, PETA
37. Colleen Morretta, Mercatus Center at George Mason University
38. Cindy L. Squires, Esq., National Marine Manufacturers Association (NMMA)
39. Office of Advocacy, Small Business Administration (SBA)
40. The Honorable Doug Ose, U.S. House of Representatives
41. The Motor and Equipment Manufacturers Association (MEMA)
42. Associated Wire Rope Fabricators (AWRF)
43. Andrew T. O'Hare, VP, Portland Cement Association (PCA)
44. Cynthia L. Brown, President, American Shipbuilding Association (ASA)
45. John Arnett, Government Affairs Counsel, Copper and Brass Fabricators Council
46. Michael P. Aitken, Director, Government Affairs, Society for Human Resources Management (SHRM)

Peer Reviewers

A. James Gattuso, Heritage Foundation
B. Robert Hahn and Robert Litan, AEI Brookings Joint Center for Regulatory Studies
C. Arik Levinson, Georgetown University
D. Richard Morgenstern, Resources for the Future
E. Robert Verchick, University of Missouri at Kansas City and Loyola University, New Orleans

Ninth Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act

INTRODUCTION

This report represents OMB's ninth annual submission to Congress on agency compliance with the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 etseq.). As section 208 of the UMRA (2 U.S.C. 1538) requires, this report details agency actions to involve State, local, and tribal governments in regulatory decisions that affect them, including expanded efforts to involve them in agency decision-making processes.

As has been done in recent years, this report is being included along with our annual report to Congress on the benefits and costs of Federal regulations. This is done because the two reports together address many of the same issues and both highlight the need for regulating in a responsible manner that accounts for the costs and benefits of rules and takes into consideration the interests of our intergovernmental partners. As OMB stated in previous reports, we intend to continue to publish these two reports together. This report on agency compliance with the Act covers the period of October of 2002 through September of 2003 (rules published before October of 2002 were described in last year's report.) The period covered by this year's report will correspond with the period covered by the cost-benefit report.

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

Title I of the Act focuses on the Legislative Branch, addressing the processes Congress should follow before enactment of any statutory unfunded mandates. Title II addresses the Executive Branch. It begins with a general directive for agencies to assess, unless otherwise prohibited by law, the effects of their rules on the other levels of government and on the private sector (Section 201). Title II also describes specific analyses and consultations that agencies must undertake for rules that may result in expenditures of over $100 million (adjusted annually for inflation) in any year by State, local, and tribal governments in the aggregate, or by the private sector. Specifically, Section 202 requires an agency to prepare a written statement for intergovernmental mandates that describes in detail the required analyses and consultations on the unfunded mandate. Section 205 requires that for all rules subject to Section 202, agencies must identify and consider a reasonable number of regulatory alternatives, and then generally select from among them the least costly, most cost-effective, or least burdensome option that achieves the objectives of the rule. Exceptions require the agency head to explain in

the final rule why such a selection was not made or why such a selection would be inconsistent with law.

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

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

The scope of consultation activities undertaken by Federal departments such as Homeland Security, Agriculture, Commerce, Education, Health and Human Services, Interior, Justice, Labor, Transportation, and the Environmental Protection Agency demonstrate this Administration's commitment to building strong relationships with our intergovernmental partners based upon the constitutional principles of federalism embodied in Title II of the Act. Federal agencies have been actively consulting with States, localities, and tribal governments in order to ensure that regulatory activities were conducted consistent with the requirements of the Act. This year's report shows an increased level of engagement, as several agencies have begun major consultation initiatives.

Examples of Consultative Initiatives

The Department of Commerce=s policy is to consult with State, Local and Tribal governments concerning actions of the Department which might impact its intergovernmental partners. For instance, the National Oceanic and Atmospheric Administration (NOAA) consulted extensively with representatives of the State of Georgia, the South Atlantic Fishery Management Council and other interested parties in the development of regulations governing the Gray=s Reef National Marine Sanctuary (Sanctuary).

Education has undertaken major consultation initiatives with State, local and tribal governments intended to implement the No Child Left Behind Act (NCLBA). The NCLBA, which reauthorized the Elementary and Secondary Education Act and incorporated the major education reforms proposed by President Bush in his No Child Left Behind initiative, focused on accountability and school improvement. To implement NCLBA, Education established a negotiated rulemaking process that included the participation of individuals representing parents, students and educators. In addition, Education held focus group sessions in Tampa, Florida; New Orleans, Louisiana; Washington, DC; and Denver, Colorado to consult with interested State, local and tribal governments and the public to obtain input in the development of its regulations. At these sessions and throughout the negotiated rulemaking process, Education raised questions regarding regulatory policy and asked for suggestions on how it could best implement the changes made by the NCLBA of 2001 to Title I of the Elementary and Secondary Education Act of 1965, as amended, with the least amount of burden to the entities affected by the changes. (May 6, 2002, 67 FR 30452) Education believes that the regulations were easier to implement because consensus was reached on issues in the draft regulations. (July 5, 2002, 67 FR 45038) The result was the development of regulations implementing NCLBA's provisions on academic standards and accountability. Negotiated rulemaking efforts have continued, as other portions of NCLBA are implemented.

In developing Federal Student Aid Programs regulations through the negotiated rulemaking process, ED developed a list of proposed regulatory changes from advice and recommendations submitted by individuals and organizations in response to a May 24, 2001, request for recommendations on improving the Title IV student assistance programs from the U.S. House of Representatives. ED's intent in amending these regulations was to reduce administrative burden for program participants, to provide benefits to students and borrowers, and to protect taxpayers' interests. (August 6, 2002, 67 FR 51036; August 8, 2002, 67 FR 51718) The negotiated regulations were easier to implement because consensus was reached on most issues in advance of publication. These regulations were published in the *Federal Register* on November 1, 2002 (67 FR 67048), and became effective on July 1, 2003.

The Secretary and Deputy Secretary of the Department of Health and Human Services met with tribal leaders in their home communities on 5 occasions. During these trips, they visited 19 tribal communities and met with representatives of 104 American Indian and Alaska Native tribes. In addition to these visits the Secretary and Deputy Secretary have met with the National Congress of American Indians, the National Indian Health Board, the Tribal Self-Governance Advisory Committee, and the American Indian Higher Education Consortium as well as a number of locally based governmental and non-governmental tribal organizations.

These various tribal consultations were in response to tribal leaders comments at the regional tribal consultation sessions requesting HHS to help bridge tribal/state relations for HHS programs administered through states. HHS, the National Congress of American Indians (NCAI) and the American Public Human Services Association

(APHSA) have entered into a Federal /State/Tribal collaborative project to work together on health and human services provided to Indian tribes and Native organizations. HHS is forming a workgroup to focus on key areas of priorities identified by tribes (TANF, Child Welfare, Information Systems, etc.).

The Environmental Protection Agency, since passage of the Unfunded Mandates Reform Act in 1995, and Executive Order 13132 on Federalism in 1999, has increased efforts to include government officials from States, localities, and Tribes in developing regulations, policies, and guidance that affects them. EPA continues to strengthen its partnership with Tribal governments through implementing EO 13175: Consultation and Coordination with Indian Tribal Governments. EPA is completing guidance for EO 13175 that will include procedures for implementing the EO, and information on how to analyze regulatory impacts on Tribes and Tribal lands. It will also provide guidance on selecting proper techniques for sharing information and gathering advice from Tribal officials during the early stages of the policy process.

Finally, the President signed an Executive Memorandum on September 23, 2004, reaffirming the government-to-government relationship with Tribal governments.

Sections 206 and 208 of the Act direct OMB to send copies of required agency analyses to the Congressional Budget Office (CBO), and to submit an annual report to Congress on agency compliance with Title II. Section 207 calls for the establishment of pilot programs for providing greater flexibility to small governments.

The remainder of this report discusses the results of agency actions in response to the Act between October 1, 2002 and September 30, 2003. Not all agencies take many significant actions that affect other levels of government; therefore this report focuses on the agencies that have regular and substantive interactions on regulatory matters that involve States, localities, and tribes, as well as the private sector. This report also lists and briefly discusses the regulations meeting the Title II threshold and the specific requirements of Sections 202 and 205 of the Act. Seven rules have met this threshold – none were intergovernmental mandates. The appendix to this report discusses agency consultation efforts. These include both those efforts required under the Act and the many actions conducted by agencies above and beyond these requirements, consistent with the spirit of the Act.

CHAPTER I: Impacts on State, Local, and Tribal Governments

Over the past eight years, seven rules have imposed costs of more than $100 million per year (adjusted for inflation) on State, local, and tribal governments (and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995).[47]

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

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

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

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

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

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

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

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

private sector at an approximate annualized cost of $206 million. The monetized benefits of the rule range from $140 to $198 million per year. The EPA selected a standard of 10 ppb because it determined that this was the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits, as required by the Safe Drinking Water Act.

- *EPA's Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category* (2002): This rule proposed three options to address storm water discharges from construction sites. Option one proposed technology-based effluent limitation guidelines and standards (ELGs) for storm water discharges from construction sites required to obtain National Pollutant Discharge Elimination System (NPDES) permits. Option two proposed not to establish ELGs for storm water discharges from those sites, but to allow technology-based permit requirements to continue to be established based upon the best professional judgment of the permit authority. Option three would establish inspection and certification requirements that would be incorporated into the storm water permits issued by EPA and States, with other permit requirements based on the best professional judgment of the permit authority. EPA is considering each of the three options, and did not state a preferred option in the proposed rule. Options one and two would impose a mandate on the States, local, or tribal governments, in the aggregate, or private sector that would exceed $100 million per year. Option 3 would not impose a mandate with costs that exceed $100 million per year for the public or private sectors.

CHAPTER II: A Review of Significant Regulatory Mandates

In FY2003, Federal agencies issued 17 rules that were subject to Sections 202 and 205 of the Unfunded Mandates Reform Act because they require expenditures in any year by State, local or tribal governments, in the aggregate, or by the private sector, of at least $100 million in any one year (adjusted annually for inflation).[48] The Department of Agriculture issued one proposed rule, the Department of Health and Human Services issued five proposed rules and three final rules, the Department of Justice issued one proposed rule, the Department of Transportation issued two proposed and two final rules, and the Environmental Protection Agency issued six proposed and two final rules. There were no rules for which agency analyses demonstrated expected expenditures in any year by State, local or tribal governments, in the aggregate, totaling more than $100 million. All of the rules discussed were covered by the Act because of anticipated expenditures by the private sector.

OMB worked with the agencies to ensure that the selection of the regulatory option for final rules fully complied with the requirements of Title II of the Act. For proposed rules, OMB often worked with the agency to ensure that they also solicited comment on alternatives. These were generally alternatives that could, in light of further public comment and additional analysis, be shown to be the least costly, most cost-effective, or least burdensome option at the final rule stage. Agency statements regarding compliance with the Act are included with the descriptions of the rules below.

[48] This listing includes only those rules meeting the Section 202 threshold published during the time period covered by this report (October 1, 2002 through September 30, 2003). Rules subject to Section 202 that were published after September 30, 2003, or that were withdrawn by the agency are not included in this report. Rules with unfunded mandates issued after September 30, 2003 will be addressed in next year's report.

USDA Mandatory Country of Origin Labeling of Beef, Lamb, Pork, Fish, Perishable Agricultural Commodities, and Peanuts (NPRM)

The Farm Security and Rural Investment Act of 2002 (Farm Bill) and the 2002 Supplemental Appropriations Act (Appropriations Act) amended the Agricultural Marketing Act of 1946 (Act) to require retailers to notify their customers of the country of origin of covered commodities beginning September 30, 2004. The law also requires the Department of Agriculture (USDA) to issue regulations to implement a mandatory country of origin labeling (COOL) program not later than September 30, 2004. Covered commodities include muscle cuts of beef (including veal), lamb, and pork; ground beef, ground lamb, and ground pork; farm-raised fish and shellfish; wild fish and shellfish; perishable agricultural commodities (fresh and frozen fruits and vegetables); and peanuts. This proposed rule contains definitions, the requirements for consumer notification and product marking, and the recordkeeping responsibilities of both retailers and suppliers.

The estimated benefits associated with this rule are likely to be negligible. The estimated first-year incremental cost for growers, producers, processors, wholesalers, and retailers ranges from $582 million to $3.9 billion. The estimated cost to the U.S. economy in higher food prices and reduced food production in the tenth year after implementation of the rule ranges from $138 million to $596 million.

HHS Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements (NPRM)

The proposed rule would establish the minimum Current Good Manufacturing Practices necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. The provisions would require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule is one of many actions related to dietary supplements to promote and protect the public health.

The future costs from the rule include the recurring costs, which reach their long-term value in the third year after the proposed rule would become final. These costs would be incurred by the establishments that manufacture, process, pack, transport, distribute, receive, hold, or import dietary ingredients or dietary products. Recurring costs from the regulatory requirements would be incurred in each future year. The total estimated cost exceeds $100 million only in the third year - $105 million. The costs of the rule will be shared among manufacturers, processors, packagers, transporters, receivers, holders, and importers of dietary ingredients or dietary products as well as domestic consumers. The higher costs incurred by domestic suppliers of dietary supplement products as a result of these regulations will be passed on to consumers in the form of higher prices. Since consumer demand for dietary supplements is price elastic, most of the higher costs incurred by suppliers will be passed on to consumers. Consequently, higher dietary supplement prices will reduce real incomes for many consumers. However, the reduction in real incomes is thought to be more than offset by the benefits

from these regulations. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental contamination of dietary supplements.

HHS Safety Reporting Requirements for Human Drug and Biological Products (NPRM)

The proposed rule will harmonize FDA's safety reporting requirements with international initiatives and improve the quality of information contained in post marketing individual case safety reports for human drug and biological products.

Total annualized costs are $155.6 million (assuming a 10-year regulatory period and a 7 percent discount rate). A 10-year regulatory period for annualizing the costs and benefits of this proposed rule was selected as a reasonable time frame to adjust for investments, returns and savings given the potential for unforeseen advances in both medical and information technology.

HHS Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (NPRM)

The proposed rule includes new record keeping requirements throughout the production and distribution chain for food that will provide an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental or deliberate contamination of food. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

The mean future cost of the proposed rule is $229.68 million.

HHS Health Insurance Reform Security Standards (Final Rule)

This final rule adopts standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses, and certain health care providers. The use of the security standards will improve the Medicare and Medicaid programs, and other Federal health programs and private health programs, and the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information. This final rule implements some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Implementation of all the standards will require the expenditure of more than $110 million by the private sector. This rule affects over 2 million entities, so requirements as low as $50 per entity would render this rule economically significant.

This rule requires each of these entities to engage in, for example, at least some risk assessment activity. There is no estimate of the marginal impact of the additional security standards.

DOJ Carrier Arrival and Departure Electronic Manifest Requirements and Imposition of Fines under Section 231 of the Act (NPRM)

This rule proposes to implement section 402 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Pub. L. 107-173), which requires the submission of arrival and departure manifests electronically in advance of an aircraft or vessel's arrival in or departure from the United States. This rule also proposes to require manifest data on certain passengers and voyages previously exempt from this requirement. This rule is necessary to provide the U.S. Immigration and Naturalization Service (Service) with advance notification of information necessary for the identification of passengers, crewmembers and any other occupant transported. This information will assist in the efficient inspection of passengers and crew members, and is necessary for the effective enforcement of the immigration laws.

This rule may result in approximately $124 million in operational costs and one-time programming costs of approximately $42 million on the private sector. Carriers currently submit arrival and departure manifests electronically to APIS. In accordance with section 402 of Public Law 107-173, this proposed rule also requires carriers to transmit additional data elements (e.g., U.S. address, visa information, PNR locator). These additional data elements are not currently included in the APIS data being transmitted and carriers would have to incur some costs adapting their systems to include these elements. However, many of the carriers stated that they have decided not to add the additional data elements to their APIS submissions but instead plan on converting their systems from the US EDIFACT format to the UN EDIFACT format.

DOT Hours of Service Drivers; Driver Rest and Sleep for Safe Operation (Final Rule)

The Federal Motor Carrier Safety Administration (FMCSA) revises its hours-of-service (HOS) regulations to require motor carriers of property to provide drivers with better opportunities to obtain sleep, and thereby reduce the incidence of crashes attributed in whole or in part to drivers operating commercial motor vehicles (CMVs) while drowsy, tired, or fatigued. This action is necessary because the FMCSA estimates that between 196 and 585 fatalities occur each year on the Nation's roads because of drowsy, tired, or fatigued CMV drivers transporting property. The FMCSA estimates that this final rule when adhered to fully will save between 24 and 75 lives each year as a result of giving truck drivers an increased incremental amount of time to obtain rest and sleep.

The options discussed in this final rule would cost between $744 million and $5.5 billion per year, relative to the Status Quo. The FMCSA option would cost an estimated $1.3 billion per year. Relative to the status quo with full compliance, the options will cost between positive $3.4 billion and negative $1.4 billion per year (meaning that they will result in cost savings). The FMCSA option would result in

savings of about $900 million per year. The cost applies only to motor carriers subject to the FMCSA regulations.

DOT Light Truck Average Fuel Economy Standards, Model Years 2005-2007 (NPRM and Final Rule)

The final rule establishes corporate average fuel economy standards for light trucks, pursuant to 49 U.S.C. Chapter 329, manufactured in model years 2005 through 2007. NHTSA is setting a standard of 21.0 miles per gallon (mpg) for model year 2005, 21.6 mpg for model year 2006, and 22.2 mpg for model year 2007. There was no change from the proposed rule standard.

The rule will result in the expenditure of $100 million annually by vehicle manufacturers and/or their suppliers. In promulgating this rule, NHTSA considered whether average fuel economy standards lower and higher than those adopted would be appropriate. NHTSA has concluded that the standards established by this final rule are the maximum feasible standards for the light truck fleet for model years 2005-2007, based on a balancing of the statutory considerations.

DOT Pipeline Integrity Management in High Consequence Areas; Gas Transmission Pipelines (NPRM)

This proposal requires operators to develop integrity management programs for gas transmission pipelines located where a leak or rupture could do the most harm. The rule requires gas transmission pipeline operators to perform ongoing assessments of pipeline integrity, to improve data collection, integration, and analysis, to repair and remediate the pipeline as necessary, and to implement preventive and mitigation actions. RSPA/OPS has also modified the definition of high consequence areas in response to a petition for reconsideration from industry associations. This proposal comprehensively addresses statutory mandates, safety recommendations, and conclusions from accident analyses, all of which indicate that coordinated risk control measures are needed to improve pipeline safety.

This proposed rule does impose unfunded mandates under the Unfunded Mandates Reform Act of 1995, because it may result in the expenditure by the private sector of 100 million or more in any one year. Annual cost of additional baseline assessment that will be required by this proposed rule is between approximately $59 million and $298 million annually. The cost for additional re-assessment is estimated at approximately $32 million per year. A ten-year baseline assessment period, with 50% of covered segments being assessed within five years, will allow the impact on gas supply and cost to be adequately managed by the operators. The estimated economic impact on gas consumers for the ten year baseline period is large, ranging from $3.9 billion to $6.1 billion.

EPA Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category (NPRM) – Addition to Docket

On June 24, 2002, EPA proposed a range of options to address storm water discharges from construction sites. This proposed rulemaking extends the comment period and includes two references inadvertently omitted in June 2002. As one option, EPA is proposing technology-based effluent limitation guidelines and standards for storm water discharges from construction sites required to obtain National Pollutant Discharge Elimination System (NPDES) permits. As another option, EPA is proposing not to establish effluent limitation guidelines and standards for storm water discharges from those sites, but to allow technology-based permit requirements to continue to be established based upon the best professional judgment of the permit authority. A third option would establish inspection and certification requirements that would be incorporated into the storm water permits issued by EPA and States, with other permit requirements based on the best professional judgment of the permit authority. This proposal, if implemented, is expected to significantly reduce the amount of sediment discharged from construction sites. The deposition of sediment from construction site runoff has contributed to the loss of capacity in small streams, lakes, and reservoirs, leading to the necessity for mitigation efforts such as dredging or replacement.

The first and second options would impose a mandate on the States, local, or Tribal governments, in the aggregate, or private sector that would exceed $100 million per year; $130 million for the first option [$13 million State and local governments, $117 million private sector] and $505 million for the second option [$50 million State and local governments, $455 million private sector]. The third option, the no regulation option, would not impose a mandate with costs that exceed $100 million per year for the public or private sectors.

EPA National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs) (Final Rule)

This final rule revises and clarifies the regulatory requirements for concentrated animal feeding operations (CAFOs) under the Clean Water Act to ensure that CAFOs take appropriate actions to manage manure effectively in order to protect the nation's water quality. Improper management of manure from CAFOs is among the many contributors to remaining water quality problems. Improperly managed manure has caused serious acute and chronic water quality problems throughout the United States. The rule establishes a mandatory duty for all CAFOs to (1) apply for a National Pollutant Discharge Elimination System permit and (2) to develop and implement a nutrient management plan. The guidelines establish performance expectations for existing and new sources to ensure appropriate storage of manure, as well as expectations for proper land application practices at the CAFO. The required nutrient management plan would identify the site-specific actions to be taken by the CAFO to ensure proper and effective manure and wastewater management, including compliance with the Effluent Limitation Guidelines. Both sections of the rule also contain new regulatory requirements for dry-litter chicken operations. EPA believes that these regulations will substantially benefit human health and the environment by assuring that an estimated 15,500 CAFOs effectively manage the 300 million tons of manure that they produce annually. The rule

also acknowledges the States' flexibility and range of tools to assist small and medium-size AFOs.

In large part, the private sector, not other governments, will incur the costs. EPA estimates total compliance costs to industry of $326 million per year (pre-tax, 2001 dollars). EPA estimates that the monetized benefits of the final regulations range from $204 million to $355 million annually. The total average annual State administrative cost to implement the permit program is approximately $9 million. This rule contains no regulatory requirements that might significantly or uniquely affect local or Tribal governments.

EPA National Primary Drinking Water Regulations: Long-term 2 Enhanced Surface Water Treatment Rule (NPRM)

This proposed rulemaking requires the use of treatment techniques, along with monitoring, reporting, and public notification requirements, for all public water systems that use surface water sources in order to improve control of microbial pathogens, including specifically the protozoan Cryptosporidium in drinking water, and to address risk-risk trade-offs with the control of disinfection byproducts. Key provisions include the following: source water monitoring for Cryptosporidium, with reduced monitoring requirements for small systems; additional Cryptosporidium treatment for filtered systems based on source water Cryptosporidium concentrations; inactivation of Cryptosporidium by all unfiltered systems; disinfection profiling and benchmarking to ensure continued levels of microbial protection while public water systems take the necessary steps to comply with new disinfection byproduct standards; covering, treating, or implementing a risk management plan for uncovered finished water storage facilities; and criteria for a number of treatment and management options that public water systems may implement to meet additional Cryptosporidium treatment requirements. The proposal builds upon the treatment technique requirements of the Interim Enhanced Surface Water Treatment Rule and the Long Term 1 Enhanced Surface Water Treatment Rule.

Public Water Systems costs (annualized 3%) are estimated at $69 million, State costs $1 million, Tribal costs $0.2 million, and private costs $40.4 million, for a total public and private cost of $110.6 million.

EPA National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines (NPRM)

This action proposes national emission standards for hazardous air pollutants (NESHAP) for stationary reciprocating internal combustion engines (RICE) with manufacturer's nameplate rating above 500 brake horsepower located at major sources of hazardous air pollutants (HAP). Stationary RICE have been identified as a major source category of HAP emissions such as formaldehyde, acrolein, methanol, and acetaldehyde. The proposed rule would implement section 112(d) of the Clean Air Act by requiring all major sources to meet HAP emission standards reflecting the application of the maximum achievable control technology for RICE. Forty percent of stationary RICE will be located

at major sources and thus subject to the proposed rule. The proposed rule would reduce nationwide HAP emissions from major stationary RICE by approximately 5,000 tons/year in the 5th year after the standards are implemented. The emissions reductions achieved by these standards will provide protection to the public and achieve a primary goal of the Clean Air Act.

The RIA prepared for the proposed rule, including the Agency's assessment of costs and benefits, is detailed in the "Regulatory Impact Analysis for the Proposed RICE NESHAP'" in the docket. Based on estimated compliance costs on all sources associated with the proposed rule and the predicted change in prices and production in the affected industries, the estimated social costs of the proposed rule are $254 million (1998$) private sector costs.

EPA National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks (NPRM)

This action proposes national emission standards for hazardous air pollutants (NESHAP) for automobile and light-duty truck surface coating operations located at major sources of hazardous air pollutants (HAP). The proposed NESHAP would implement section 112(d) of the Clean Air Act by requiring these operations to meet HAP emission standards reflecting the application of the maximum achievable control technology. The primary HAP emitted by these operations are toluene, xylene, glycol ethers, methyl ethyl ketone, methyl isobutyl ketone, ethylbenzene, and methanol. The proposed rule would reduce nationwide HAP emissions from these major sources by about 60 percent. This action also proposes to amend the Air Emission Standards for Equipment Leaks for owners and operators of hazardous waste treatment, storage, and disposal facilities to exempt certain activities covered by the proposed NESHAP from these standards.

The RIA prepared for the proposed rule, including EPA's assessment of costs and benefits, is detailed in the ``Regulatory Impact Analysis for the Automobiles and Light-Duty Trucks Coating NESHAP" in the docket. Based on the estimated compliance costs associated with the proposed rule and the predicted changes in prices and production in the affected industry, the estimated annual social costs of the proposed rule is projected to be $161 million (1999 dollars). It is estimated that 5 years after implementation of the rule as proposed, HAP will be reduced from 10,000 tpy to 4,000 tpy. This represents a 60 percent reduction (6,000 tpy) of toluene, xylene, glycol ethers, methyl ethyl ketone, methyl isobutyl ketone, ethylbenzene, and methanol. Based on scientific studies conducted over the past 20 years, EPA has classified ethylene glycol monobutyl ether as a "possible human carcinogen," while ethylbenzene, methyl ethyl ketone, toluene, and xylenes are considered by the Agency as "not classifiable as to human carcinogenicity."

The estimated direct cost to the automobile and light-duty truck manufacturing industry of compliance with the proposed rule is approximately $154 million (1999 dollars) annually. Indirect costs of the proposed rule to industries other than the automobile and light-duty truck manufacturing industry, governments, tribes, and other affected entities are expected to be minor.

EPA National Emission Standards for Hazardous Air Pollutants for Industrial/Commercial/Institutional Boilers and Process Heaters (NPRM)

The proposed rulemaking proposes national emission standards for hazardous air pollutants (NESHAP) for industrial/commercial/institutional boilers and process heaters. The EPA has identified industrial/commercial/institutional boilers and process heaters as major sources of hazardous air pollutants (HAP) emissions. The proposed rule would implement section 112(d) of the Clean Air Act by requiring all major sources to meet HAP emissions standards reflecting the application of the maximum achievable control technology. The proposed rule would reduce HAP emissions by 58,000 tons per year; hydrogen chloride--a substance that is not considered to be a carcinogen--accounts for 42,000 tons per year (72 percent) of total HAP emissions reductions. The proposed rule would protect air quality and promote the public health by reducing emissions of some of the HAP listed in section 112(b)(1) of the Clean Air Act. The HAP emitted by facilities in the boiler and process heater source category include arsenic, cadmium, chromium, hydrogen chloride (HCl), hydrogen fluoride, lead, manganese, mercury, and nickel. Exposure to these substances has been demonstrated to cause adverse health effects such as irritation to the lung, skin, and mucus membranes, effects on the central nervous system, kidney damage, and cancer. In general, these findings have only been shown with concentrations higher than those typically in the ambient air.

Based on estimated compliance costs associated with the proposed rule and the predicted change in prices and production in the affected industries, the estimated social costs of the proposed rule are $780 million (1999 dollars). It is estimated that 5 years after implementation of the proposed rule, HAP will be reduced by 58,500 tons per year due to reductions in arsenic, beryllium, dioxin, hydrochloric acid, and several other HAP from industrial boilers and process heaters.

EPA National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products (NPRM)

This proposed rulemaking proposes national emission standards for hazardous air pollutants (NESHAP) for the plywood and composite wood products source category. The EPA has determined that the plywood and composite wood products source category contains major sources of hazardous air pollutants (HAP), including acetaldehyde, acrolein, formaldehyde, methanol, phenol, and propionaldehyde. These HAP are associated with a variety of adverse health effects including chronic health disorders (e.g., damage to nasal membranes, reproductive disorders, and problems with pregnancies) and acute health disorders (e.g., irritation of eyes, throat, and mucous membranes, dizziness, headache, and nausea). Three of the HAP have been classified as probable or possible human carcinogens. These proposed standards would implement section 112(d) of the Clean Air Act by requiring all major sources subject to the rule to meet HAP emission standards reflecting the application of the maximum achievable control technology. Implementation of the proposed standards would reduce HAP emissions from the plywood and composite wood products source category by approximately 9,700 megagrams per year (Mg/yr) (11,000 tons per year (tons/yr)). In

addition, the proposed standards would reduce emissions of volatile organic compounds by 25,000 Mg/yr (27,000 tons/yr). This action also proposes to add a method to the relevant General Provisions to measure methanol, formaldehyde, and phenol and a method to measure total HAP at plywood and composite wood products facilities.

Based on estimated compliance costs associated with this proposed rule and the predicted change in prices and production in the affected industries, the estimated social costs of this proposed rule are $134.2 million (1999 dollars). The social costs of this proposed rule are the costs imposed upon society as a result of efforts toward compliance, and include the effects upon consumers of products made by the affected facilities. Total industry compliance costs are $142 million.

EPA Control of Emissions From Nonroad Large Spark-Ignition Engines, and Recreational Engines (Marine and Land-Based) (Final Rule)

This action adopts emission standards for several groups of nonroad engines that have not been subject to EPA emission standards. These engines are large spark-ignition engines such as those used in forklifts and airport ground-service equipment; recreational vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines. Nationwide, these engines and vehicles cause or contribute to ozone, carbon-monoxide, and particulate-matter nonattainment, as well as other types of pollution impacting human health and welfare. Manufacturers are expected to be able to maintain or even improve the performance of their products when producing engines and equipment meeting the new standards. Many engines will substantially reduce their fuel consumption, partially or completely offsetting any costs associated with the emission standards. Overall, the gasoline-equivalent fuel savings associated with the anticipated changes in technology resulting from this rule are estimated to be about 800 million gallons per year once the program is fully phased in. Health and environmental benefits from the controls included are estimated to be approximately $8 billion per year once the controls are fully phased in. There are also several provisions to address the unique limitations of small-volume manufacturers.

This final rule imposes costs on private industry that exceed $100 million. There is no impact on State, local or tribal entities.

APPENDIX: Agency Consultation Activities Under the Unfunded Mandates Reform Act of 1995

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

Nine agencies (the Departments of Agriculture, Commerce, Education, Health and Human Services, Interior, Justice, Labor, Transportation, and the Environmental Protection Agency) have involved State, local, and tribal governments not only in their regulatory processes, but also in their program planning and implementation phases. These agencies have worked to enhance the regulatory environment by improving the way in which the Federal government relates to its intergovernmental partners. In general, the Departments not listed here (e.g., Veterans Affairs, Small Business Administration, State, Defense, Energy) do not often impose mandates upon States, localities, or tribes and so have fewer occasions to consult with other levels of domestic government.

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

United States Department of Agriculture

Food and Nutrition Services (FNS)

1. **Child Nutrition Programs**

A. Promoting Summer Feeding: Delegation of Authority to States to Approve Seamless Summer Feeding Waivers

The Seamless Summer Feeding Waiver streamlines program management and operations normally associated in feeding low-income children in the summer and during other times when school is not in session by allowing school districts to operate under procedures that combine aspects of the Summer Food Service Program (SFSP) and the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). School Food Authorities (SFAs) apply to operate the waiver and, if approved, provide summer free meals in low-income areas to children through age 18. State agencies that administer the NSLP and SBP ensure that waiver procedures are followed and reimburse SFAs for meals through the NSLP/SBP.

The waiver began in FY 2001 with 5 school districts in California and Florida. Responding to the high level of interest that the waiver generated among State agencies,

school districts, and advocates, FNS expanded the waiver nationwide in FY 2002. Continued success with the seamless waiver, prompted FNS in FY 2003 to delegate authority to the State agencies to approve waiver requests submitted by their SFAs. This eliminated the requirement that State agencies submit waiver requests to FNS for approval, further streamlining the process. The decision to delegate waiver authority to State agencies resulted from consultations between State education agencies and FNS Headquarters and Regional Offices. In FY 2003, USDA officials, including the Under Secretary for Food and Consumer Services, continued to promote the seamless waiver at numerous conferences held around the country.

Some SFAs, State agencies, and advocates of summer feeding have long-standing concerns that the SFSP is burdensome to operate. As the primary Federal food program for children during the summer months, the SFSP is available to all children in low-income areas, including children attending summer school (provided that the school meal service is open to all children residing in the community), but its cost accounting and monitoring requirements are more demanding than the NSLP and SBP. Based on the positive experiences with the seamless waiver that continued to be reported by State agencies, school districts, and program advocates, FNS sought additional ways to promote the operation of the waiver and to simplify its operation.

B. Promoting summer feeding: Alternate Documentation of Eligibility for Upward Bound Programs in the Summer Food Service Program (SFSP)

This policy allows Upward Bound sites to qualify for participation in the SFSP based on the eligibility criteria of the Upward Bound Program. It exempts Upward Bound sites from having to document, through SFSP income applications, the income eligibility of its participants. SFSP sites that serve only Upward Bound participants are affected by this policy. The request for this policy came from Upward Bound Program administrators in Florida. The request to permit Upward Bound income eligibility to stand for the SFSP income eligibility applications of individual participants in qualifying a site for participation in the SFSP was communicated by Upward Bound program administrators to the FNS Southeast Regional Office in Atlanta, Georgia.

Upward Bound Program administrators pointed out that the eligibility criteria for Upward Bound participants meet or exceed the income eligibility for SFSP participants. Both programs have an income eligibility threshold of 185% of the national poverty guidelines. In addition, the Upward Bound program requires that a minimum of two thirds of its participants must qualify as low income, which exceeds the 50% requirement of the SFSP. In FY 2003, FNS extended the policy issued in 2002 that allowed Upward Bound SFSP sites to use Upward Bound applications to determine eligibility to participate in the SFSP.

C. Promoting Summer Feeding: Eliminating the SFSP budget submission requirement for school sponsors participating in the 14-State Pilot Project.

Under this policy, the 14 States participating in the pilot project to eliminate cost accounting have the authority to waive the budget requirement for eligible sponsors. Normally, SFSP regulations require that sponsors must submit a budget as part of the application process each year. The purpose of this policy is to provide administrative relief to school sponsors in the pilot States, thereby allowing the schools to operate the SFSP in a manner similar to their operation of the NSLP during the school year.

This policy applies to public and private schools in the 14 States that participated in the National School Lunch Program (NSLP) in the preceding school year or that currently participate in a year-round NSLP and provide SFSP meals during vacation breaks. The 14 pilot States, which met statutorily-defined criteria for participation in the pilot project, are: Alaska, Arkansas, Idaho, Indiana, Iowa, Kansas, Kentucky, Nebraska, New Hampshire, North Dakota, Oklahoma, Puerto Rico (counted as a State for this purpose), Texas, and Wyoming. North Dakota was among the States requesting this policy change on behalf of its sponsors.

FNS formed a partnership with three primary groups including the Food Research and Action Center (FRAC), America's Second Harvest, and the American School Food Service Association (ASFSA). During monthly meetings held in 2002 and 2003, FNS and partners discussed ways to promote the SFSP, especially how to encourage program growth in the 14 pilot States. On occasion, State agency representatives participated in the meetings via telephone tie-ins. These meetings provided the State agencies with the opportunity to express concerns or issues with the operation of the pilot project. FNS Regional Offices conducted telephone conferences with the States in their region and hosted meetings annually with these States. In addition, FNS staff provided technical assistance to the 14 States during visits and reviews in the States.

Several State agencies questioned the need for budget submission by the sponsors participating in the pilot project based on their interpretation of the statutory language authorizing the pilot project. In addition, there was considerable interest in reducing paperwork burdens where possible, especially for schools, as an inducement to sponsor the SFSP. As a result of discussions with State agency staff and in view of a positive assessment of operations by sponsors in pilot States, FNS extended this policy for FY 2003.

D. Promoting Summer Feeding: Permitting more flexibility in meal service times.

This policy permits State agencies to grant exceptions to SFSP sponsors to program regulations that stipulate specific time intervals between meals. The purpose of this policy is to remove barriers that some sponsors have experienced in providing meal services to SFSP participants.

Sponsors benefit from this policy. State agencies are responsible for approving requests for exemptions to required time intervals between meals. Sponsors, State agencies, and interested groups such as FRAC and America's Second Harvest, advocated for flexibility in the operation of the program. The request for greater flexibility of meal service times and intervals between meals has been expressed at numerous regional and national meetings. During these occasions, State agencies, sponsors and advocates encouraged flexibility.

Current SFSP regulations at §225.16(c) require that at least three hours elapse between the beginning of one meal service and the beginning of another (four hours must elapse between lunch and supper if no snack is served). The duration of meal service is limited to two hours for lunch and supper and one hour for breakfast and snacks. Several sources expressed concern to FNS that these time intervals may impose barriers to participation for some sites serving meals to children. In FY 2003, FNS extended a policy initially issued in 2002 that provides State agencies with the authority to waive the regulations at §225.16(c) on a case-by-case basis.

E. Promoting Summer Feeding: Waiver for Closed Enrolled Sites

In FY 2003, FNS issued a nationwide waiver of the requirements for establishing the eligibility of closed enrolled sites. The SFSP regulations at 7 CFR 225.2 define a closed enrolled site as a feeding location that is available only to children enrolled in a specific program. The site may participate in the SFSP if at least 50 percent of the enrolled children are eligible for free or reduced price school meals based on income eligibility applications. To promote the SFSP, FNS waived the requirement to take income applications from the enrolled children at closed enrolled sites located in low-income areas as defined by the regulations. Instead, sponsors may use either school data or census data to establish the eligibility of closed enrolled sites in low-income areas.

The regulatory requirement to collect income eligibility applications from families of enrolled children primarily affect the site operators and the SFSP sponsors, which must provide the applications to families and then collect and examine the completed applications to determine whether the family meets the income eligibility standards for free or reduced price school meals. In addition, State and Federal reviewers must examine the completed income applications as part of a review of sponsor operations. This has been an ongoing program issue that has been discussed at State and FNS regional meetings and training sessions.

State agencies, SFSP sponsors, and program advocates have long argued that the requirement to collect income eligibility applications from enrolled children discourages participation in the program. Since the area level data is available to open SFSP sites operating in low-income areas, State agencies, sponsors, and program advocates have suggested that closed enrolled sites that are also located in these low-income areas (as defined by the regulations) should be permitted to use this data to establish eligibility. In November 2002, FNS agreed with this reasoning and issued the policy exempting closed

enrolled sites located in eligible areas from the requirement to base site eligibility for SFSP participation on the individual income eligibility of the enrolled children.

F. Promoting Summer Feeding: Permitting State agencies to Count USDA Reviews

This policy authorizes FNS regional offices to allow State agencies to count USDA reviews of SFSP sponsor toward the number of required State-agency conducted reviews that must be completed each year. State agencies are responsible for resolving review findings, including any appeals by sponsors. State agencies that administer the SFSP are affected by this policy. State agencies and FNS were the principal partners involved in the consultation.

The consultation process on this policy, like many other SFSP policies, occurred through normal channels of communication between FNS and State agencies, including meetings and conferences, telephone conferences, and during exit conferences of management evaluation reviews of State agency operations conducted by FNS. State agencies have requested relief from conducting all required reviews of SFSP sponsors as outlined in the regulations at 7 CFR 225.7(d)(2)(ii). In FY 2003, FNS extended this policy, which was initially issued in FY 2002.

G. Promoting Summer Feeding: Permitting State agencies to Waive First-Week Visits at SFSP Sites

In FY 2003, FNS extended a 2002 policy that permits State agencies to relieve sponsors who are experienced in the program and who operate trouble-free sites from the regulatory requirement at 7 CFR 225.15(d)(2) to conduct a visit at every site in the first week of program operations. A similar policy in effect since FY 1999 had been limited to school sponsors. SFSP sponsors who operate the program at the local level are most affected by this policy. FNS consulted with State agencies, some sponsors, and program advocates.

The consultation process on this policy, like many other SFSP policies, occurred through normal channels of communication between FNS and State agencies, including meetings and conferences, telephone conferences, and during exit conferences of management evaluation reviews of State agency operations conducted by FNS. State agencies, program advocates, and sponsors had suggested that any sponsor, not just a school sponsor, that used experienced staff to operate sites and that had experienced no operational problems in the previous year should be permitted to waive the required first-week visit. State agencies are in the best position of knowing which sponsors fit this description.

FNS agreed in 2002 that State agencies should be permitted to waive the first-week visit requirement for any sponsor that operated well-run sites in the previous year. This policy was extended for FY 2003. In 2003, FNS also rescinded a requirement that State agencies submit information to FNS regional offices on the sponsors and sites exempted from the first-week visit requirement.

H. Promoting Summer Feeding: Exceptions to Approving SFSP Sponsors Prior to Program Operations

SFSP regulations at 7 CFR 225.14(c)(7) require that sponsors may not participate in the program without a written agreement with the State agency that has approved an application for participation. Due to the rush of applications that occur before the June 15th deadline (or earlier deadline that the State agency may impose), not all sponsor applications may be approved before the program operations were scheduled to begin. To ease the administrative burden that occurs for State agencies in processing applications, FNS regional offices may permit requesting State agencies to reimburse sponsors for meals served prior to application approval under certain circumstances. This policy affects State agencies, sponsoring organizations that operate the program at the local level, and children who receive the meals.

The request for relief of the regulations came from several State agencies, communicated through normal channels to FNS regional offices. The consequences of not providing the leniency would be the delay of program operations for some sponsors and potentially, the absence of meal service for eligible children.

In FY 2003, FNS extended this policy that had first been issued in 2002. Approval to reimburse sponsors extends only to situations where the State agency experienced extenuating circumstances in delaying a decision on applications that had been submitted on-time. A sponsor that provides meal service prior to approval of the application must understand that final reimbursement is not guaranteed, should the State agency determine that the application is not approvable.

I. Waiver to allow Alaska to reduce the number of required SFSP sponsor reviews.

FNS approved a waiver of 7 CFR 225.7(d)(2)(ii)(B) of the SFSP regulations, permitting Alaska to review fewer than the required number of annual sponsor reviews the State agency would otherwise have to conduct. The Alaska Department of Education and Early Development requested the waiver. This request from the Alaska State agency came through the FNS Western Regional Office.

A rapid expansion of the SFSP over a large geographic area in Alaska prompted the State agency to request relief from the regulatory requirement. Alaska is one of the States participating in the 14-State Pilot Project and has experienced sizable program growth. The rapid expansion has strained the resources of the State agency. By requesting relief from the regulatory requirement to review the number of sponsors whose aggregate reimbursements account for half of all reimbursements, Alaska requested permission to focus its resources on the newest sponsors to the program. FNS approved the waiver for 2003 operations contingent upon the following: all new sponsors from the current and previous years must be reviewed, at least 1/3 of all sponsors must be reviewed, and there must be no reduction of Alaska's overall review efforts.

J. Waiver to allow Oregon to reduce the number of required SFSP sponsor reviews.

FNS approved a waiver of 7 CFR 225.7(d)(2)(ii)(B) of the SFSP regulations, permitting Oregon to review fewer than the required number of annual sponsor reviews the State agency would otherwise have to conduct. The Oregon Department of Education requested the waiver. This request from the Oregon State agency came through the FNS Western Regional Office.

The State agency asked for relief from the requirement because the make-up of the State's SFSP sponsorship would require the State to review one very large and many small sponsors, resulting in a burdensome review requirement. Instead, the State requested to skip a review of the largest sponsorship in order to be able to review the newest sponsor in the program. FNS approved the waiver for FY 2003 stipulating that all new sponsors in 2003 will be reviewed, a total of 22 reviews will be conducted, and Oregon does not reduce its overall review efforts from the previous years.

K. Promoting Summer Feeding: Waiver of some Program Requirements for Oklahoma City SFSP Sponsor

Due to an emergency situation that occurred in Oklahoma City, certain regulations pertaining to procurement of services of a food service management company (FSMC) were waived for the summer of 2003. The affected parties included the Oklahoma Department of Education, the Oklahoma Food Bank, and the Oklahoma City ISD (school district).

The Oklahoma State agency contacted the FNS regional office to relay the information that the Oklahoma City School Food Authority had withdrawn its application to participate in the SFSP for the summer of 2003. Because the school district was the largest SFSP sponsor in Oklahoma City, the State agency was very concerned that needy children residing in the city would not receive free meal service.

To ensure the continuation of SFSP meal service, FNS waived 7 CFR 225.6(b)(6)(ii) to permit the Oklahoma Food Bank to operate more than 25 sites in the city. FNS also waived FSMC bonding requirements in 7 CFR 225.6(h), and most procurement requirements in 7 CFR 225.15(h). FNS held in place the requirement that a vended sponsor is responsible for the adherence to the agreement executed with the State agency to operate the program regulations. Waiver of these requirements was limited to this situation in Oklahoma City for summer of 2003 only.

L. Implementation of Monitor Staffing Standards in the Child and Adult Care Food Program

As mandated by Public Law 106-224, FNS published regulations that required CACFP sponsoring organizations to meet staffing standards for the program staff that are employed to monitor program operations in day care homes and child care centers.

Regulations published on June 27, 2002, set the deadline for implementation of the staffing standards for July 29, 2003. The affected parties include CACFP sponsoring organizations, the monitors employed by the sponsoring organizations, and the CACFP State agencies.

In the fall of 2002 and early winter of 2003, FNS held several training sessions for State agencies on new CACFP regulations that are designed to strengthen the management of the program. Implementation of the new monitor staffing standards was included in the training session. FNS received feedback from State agencies and sponsors about the staffing standards during the training session. Some of the issues and concerns raised by the State agencies and sponsors included the difficulty that some sponsors would have in meeting the staffing standards and the need for more time for State agencies to develop state-specific factors that would be used to assess the staffing plans submitted by the sponsoring organizations. Based on the many concerns expressed by State and sponsors, FNS provided written guidance in February 2003 that clarified certain aspects of the regulatory requirements and that moved the mandatory implementation to October 1, 2004.

2. Food Distribution Division

A. Policy Memorandum No. FD-020, National School Lunch Program (NSLP) and other Child Nutrition Programs: Single Inventory and Related Commodity Issues—Clarification of Regulatory Changes and Other Guidance (May 23, 2003)

The policy memorandum clarifies that certain school food authorities and other recipient agencies are not required to store and inventory donated foods (i.e., USDA commodities) separately from commercially purchased foods and other foods. Hence, unless the distributing agency imposes such a requirement, these recipient agencies may use a single inventory management system. The memorandum also reduces reporting and recordkeeping requirements for these recipient agencies relating to donated foods, and makes it easier to transfer donated foods between recipient agencies.

Affected parties include State education agencies, and school food authorities, child and adult care institutions, service institutions, and elderly nutrition programs in NSLP, the Child and Adult Care Food Program (CACFP), the Summer Food Service Program (SFSP), and the Nutrition Services Incentive Program (NSIP), as well as charitable institutions receiving donated foods. Recipient agencies in other food distribution programs (i.e., CSFP, FDPIR, and TEFAP) are still required to store and inventory donated foods separately from other foods.

Proposed and final rules were published in 2002 addressing storage and inventory management of donated foods. Comments were received on the proposed rule and addressed in the final rule. Further consultation occurred at meetings over the last few years, including meetings of the American Commodity Distribution Association (ACDA), and the American School Food Service Association (ASFSA). Comments received in response to the rules, at meetings, and less formal input indicated some

confusion as to the applicability of single inventory management to various food distribution programs, and the implications of such a system in other areas of food distribution. This policy memorandum is intended to clarify these issues and provide further guidance. FNS is also developing a proposed rule to further clarify and streamline Federal regulations in 7 CFR Part 250 related to storage and inventory management of donated foods, and related issues.

B. Policy Memorandum No. FD-007, State Processing—Net Off Invoice Hybrid Value Pass-Through Method (March 18, 2003)

The policy memorandum provides a greater degree of flexibility in ensuring that the sale of processed end products to school food authorities includes a discount for the donated foods contained in those end products. Commercial processors often sell their products to school food authorities through distributors, including those products that contain donated foods. A distributor may then sell the end product to a school food authority at a discounted price, to account for the donated food contained in that end product. Rather than submit a refund application to the processor for the value of the donated food, as required in Federal regulations at 7 CFR 250.30(k)(2), this policy memorandum allows the distributor to deduct the discount from the processor's invoice. This alternate means of ensuring "value pass-through" of donated foods is called "net off invoice". Affected parties include State education agencies, school food authorities and other recipient agencies in child nutrition programs, processors, and distributors.

Input was received from program operators at State and local levels, and processors and distributors, over the last few years, at meetings of the American Commodity Distribution Association (ACDA) and the American School Food Service Association (ASFSA), and through less formal contact. The input received indicated that the time and paperwork required by the submittal of refund applications for donated foods by distributors was not cost-effective. This resulted in fewer opportunities for school food authorities to purchase food products from distributors, including those products that were most desirable for the school food service. Hence, this policy memorandum provides a more streamlined alternative—the net off invoice method—for distributors to demonstrate value pass-through of donated foods contained in end products sold to school food authorities.

C. Food Distribution Program on Indian Reservations (FDPIR) Food Package Review

FNS manages an ongoing review process for improving the appeal and nutritional profile of the food package provided under FDPIR. Affected parties are the FDPIR participants. Consultants involved in this effort include Tribal and State FDPIR Program Directors, USDA, Agricultural Marketing Service. USDA, Farm Service Agency, DHHS, Indian Health Service, and DHHS, Center for Disease Control and Prevention. Consultants are members of a work group that meets via conference calls and face-to-face meetings to discuss and recommend improvements to the FDPIR food package

Concerns focused on improvements to the FDPIR food package that will appeal to program participants and will offer nutritional benefits to a population that has high rates of diabetes, obesity, and heart disease. The Food and Nutrition Service is implementing food package changes recommended by the review work group. The changes involve the addition of new products, such as whole-wheat flour, and improvements to products currently offered in the FDPIR food package, such as replacing the current orange juice with a calcium/Vitamin D fortified orange juice.

Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine

A. Plant Biotechnology Regulations

APHIS amended its plant biotechnology regulations (7 CFR part 340) as they pertain to plants designed to produce industrial compounds. APHIS' Biotechnology Regulatory Services program administers these regulations. The regulations affect USDA, other Federal Agencies, State Governments of Agriculture, biotechnology industry associations, and biotechnology companies and other public entities.

The consultation process consisted of informal discussions at meetings and other events with various stakeholders including representatives from industry groups and other non-governmental organizations, and representatives from State Governments. These informal discussions focused on many biotechnology issues including APHIS' biotechnology regulations as they pertain to plants designed to produce industrial compounds and the strengthening of these regulations.

Concerns over the lack of scientific familiarity and experience with the kinds of traits in planned introductions of plants engineered to produce industrial compounds were raised by public and governmental entities. These traits were non-food and non-feed related and utilized new and less familiar processes. APHIS shared these concerns. Prior to amending the biotechnology regulation, APHIS allowed companies and institutions to field test, move, or import plants genetically engineered to produce industrial compounds under its notification process. The notification process is oriented toward low risk introductions.

While the informal consultations with stakeholders were not solely responsible for changes to the Agency's biotechnology regulations, they did contribute to the Agency's decision to change the regulations regarding plants designed to produce industrial compounds. On August 6, 2003, the Agency published an interim rule on the introduction of plants genetically engineered to produce industrial compounds, with an effective date of August 6, 2003. Under the amended regulations, requests from companies and institutions to field test, move, and import these plants designed to produce industrial compounds must now be reviewed under our permits process. The permits process is primarily used for higher risk introductions.

B. Plant Pests

APHIS' Plant Protection and Quarantine (PPQ) program carries out numerous activities to detect and contain, and in some cases, to manage or eradicate plant pests damaging to agricultural and environmental resources of the United States. Specific pest programs include activities to detect, contain, manage, or eradicate, among other plant pests, *Phytophthora ramorum* (a fungus that attacks numerous plant species, but that is commonly known as Sudden Oak Death), emerald ash borer (an exotic pest of ash trees), and exotic fruit flies (e.g., Mexican fruit fly, Mediterranean fruit fly, etc.).

These programs were conducted cooperatively with State agencies, which share the costs with APHIS. In cases where APHIS regulations could affect Native American tribes, those tribes were included in our consultations. Operational plans were prepared jointly and reflected the respective roles of State and Federal partners. We consulted on program strategies, methods, operations, and progress. PPQ cultivated consultative relationships with State agencies through National Plant Board meetings, task forces, and special committees to resolve issues of mutual concern. PPQ contacted and consulted with Tribal governments affected by contemplated PPQ activities and resolved issues of mutual concern.

Concerns arose over the effects of APHIS regulations and policy on States, who were largely responsible for enforcing the regulations under cooperative agreements. Points of concern included availability of resources, practical obstacles to program success, coordinated national approach, and balancing the interests of stakeholders affected by quarantine actions with those who could be adversely affected by spread of the pest of concern. Tribal issues concerned the impact of regulation on Tribal businesses.

> Emerald Ash Borer: Through monthly consultations with the States of Ohio, Indiana, Virginia, Maryland, and Michigan, we were able to devise regulatory strategies that protect against the interstate spread of this pest while being practical to enforce given the affected industries. States are provided funds through cooperative agreements to assist in enforcement of the regulations.
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> *Phytophthora ramorum*: Through consultations with the States of California and Oregon, we were able to devise regulatory strategies that protect against the interstate spread of this pest while being practical to enforce given the affected industries. During the summer of 2003, we consulted with some tribes in Northern California to discuss possible affects of *P. Ramorum* regulations.
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> Mexican fruit fly: Through consultations with States that produce citrus, we were able to devise protocols to facilitate the movement of Mexican fruit fly host crops while protecting against the spread of the pest to unaffected areas.

Animal and Plant Health Inspection Service (APHIS)/Veterinary Services

A. Avian Influenza

Veterinary Services consulted with States to develop a National Low Pathogenic Avian Influenza (LPAI) Program for Subtypes H5 and H7. The goal of the LPAI program is the elimination of LPAI subtypes H5 and H7 in the United States. Additionally, APHIS compensated owners and growers of poultry for losses suffered due to LPAI in Virginia and Texas. APHIS' The program affects USDA, State governments, poultry owners and growers, egg processing plants, egg and poultry markets, and live bird markets. State veterinary officials and the State commissioners of agriculture were consulted individually and as part of the U.S. Animal Health Organization's Transmissible Diseases of Poultry Committee (referred to below as the Committee), which includes USDA, State, industry, and academic representatives.

Meetings of the Committee were conducted at intervals as determined by the Committee. Additionally, APHIS conducted a monthly telephone conference with members of the National Association of State Departments of Agriculture. The overarching concern of State/Federal/industry representatives was the detection, elimination, and prevention of LPAI in the United States. To this end, the Committee developed and presented to APHIS a model plan that included recommendations regarding live bird markets, commercial surveillance, and vaccine use. Additionally, in 2003, there were detections of LPAI in several States. State representatives in the affected States raised the issues of the limits and scope of indemnity payments for poultry and materials destroyed because of LPAI, trade ramifications of the outbreaks, and the State and industry liability.

APHIS is currently in consultation with the Committee regarding its recommended model program. In 2003, APHIS worked closely with State officials in Connecticut and Rhode Island and surrounding States to control and eliminate the LPAI outbreak.

B. Brucellosis in Yellowstone National Park Bison

How best to prevent brucellosis-infected bison in Yellowstone National Park from transmitting the disease to domestic livestock in States containing or in proximity to the park is an on-going issue. Affected parties include producers of domestic livestock, State governments, and Federal agencies. Each of these entities is represented on the Greater Yellowstone Interagency Brucellosis Committee. Governmental representatives to the committee include the States of Wyoming, Montana, and Idaho, as well as APHIS, the Forest Service, the National Parks Service, and the Department of the Interior.

Consultation was carried out through regular meetings of the committee, which had previously developed the Yellowstone Bison Management Plan. Public and intergovernmental partners worked with the Federal Government to determine what research should be done as part of the plan. The committee made recommendations for research and ranked the recommended research in priority order. APHIS is providing funds for the research in the order recommended by the Committee.

C. U.S. Tuberculosis Eradication Program

The U.S. program to eradicate bovine tuberculosis in domestic livestock administered by Veterinary Services includes regulations on the importation and Interstate movement of cattle and other susceptible animals. Affected parties include livestock owners, dairy owners, States, and the USDA. Venues for these consultations included semi-annual meetings with the U.S. Animal Health Association's Government Relations Group, including representatives of State Departments of Agriculture. Semi-annual meetings were also held with the Animal Agricultural Coalition, which also includes State representatives. Veterinary Services held monthly conference calls with the National Association of State Departments of Agriculture. Additionally, State officials provided Veterinary Services with comments and recommendations during public comment periods as part of rulemaking.

State representatives provided information to Veterinary Services that allowed USDA to accurately classify each State with regard to tuberculosis risk, which in turn determines what conditions must be met before cattle, bison, and captive cervids may be moved interstate. Additionally, State representatives made recommendations to Veterinary Serices regarding eradication program requirements. In 2003, based on consultation with States and on comments received during a rulemaking process, APHIS initiated rulemaking to modify certain provisions of the domestic tuberculosis regulations. Also, in response to comments jointly submitted by State veterinarians, APHIS is modifying an interim rule that revised testing requirements for cattle imported into the United States. The modification will strengthen requirements regarding certification of herd testing.

Animal and Plant Health Inspection Service (APHIS)/Wildlife Services

Tribal Government Cooperative Agreements for Wildlife Damage Mitigation

Wildlife Services provided opportunities for tribal governments to participate in developing programs through establishing cooperative technical assistance and direct control projects and educational programs designed to alleviate wildlife damage. Wildlife Services conducts these programs though cooperative agreements negotiated by the tribes and Wildlife Services management. Native American farmers and ranchers are affected by these agreements.

Each Wildlife Services state director or designee notified tribes of opportunities to participate in cooperative wildlife damage management programs. These contacts included formal and informal meetings at the tribal level, state and national levels or through contact with other wildlife professionals representing various tribes. Common issues raised at these cooperative meetings in FY 2003 included concerns by tribal members over livestock losses to avian and mammalian predators, impacts of endangered species on tribal wildlife management programs, available federal funds to cooperate in wildlife damage management projects, wildlife disease surveillance and monitoring, and

educational and career opportunities in wildlife damage management and other APHIS professional career fields.

In FY 2003, Wildlife Services field program managers remained active in working with Native American Tribes. In Oklahoma, Wildlife Services attended workshops, formal and informal meetings, job fairs, and media events to present the Wildlife Services mission. Also in FY 2003, Wildlife Services met with other States, such as New Mexico, Nevada, Arizona, and Montana, and with tribal leaders to discuss and develop cooperative working arrangements to protect livestock from predation, foreign animal and wildlife disease transmission, and human health and safety concerns with rabies.

Forest Service

Forest Land Enhancement Program (FLEP)

A interim regulation at subpart C in part 230 of Title 36 Code of the Federal Regulations have been promulgated to establish procedures for administration of the new Forest Land Enhancement Program (FLEP), which was authorized in the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill). The intended effect of this interim rule is to encourage the long-term sustainability of nonindustrial private forest lands in the United States by assisting landowners, through State foresters, in more actively managing their forest lands and related resources through the use of State, Federal, and private sector resource management expertise, financial assistance, and educational programs.

The Forest Land Enhancement Program promotes sustainable forest management on nonindustrial private forest land and complements other sustainable forestry programs in the States. The Forest Land Enhancement Program establishes or supplements existing nonindustrial private forest land programs to provide technical, educational, and financial assistance to landowners.

The Forest Land Enhancement Program is administered by the Chief of the Forest Service through the responsible officials, in partnership with State forestry agencies. Therefore, State foresters in collaboration with their State Forest Stewardship Coordination Committees were included in a team set up to develop the interim rule. The State foresters will be further consulted in the development of the final rule. The team held a series of meetings, teleconferences, and corresponded through email during the development of the interim rule. The Forest Service worked with State forestry agencies to address the following issues:

(1) How would the Forest Land Enhancement Program funds be distributed to the States, and
(2) What would be the participating State's role in implementing the program in accordance with the interim rule and authorizing legislation?

As a result of consultation, the Forest Service and the State foresters agreed on the procedures that would be included in the interim rule to implement the Forest Land Enhancement Program, which include voluntary participation by States, the criteria that States must meet in order to participate in the program, and the distribution of Forest Land Enhancement Program funds from the agency to the States.

Department of Commerce

The National Oceanic and Atmospheric Administration

Gray=s Reef National Marine Sanctuary (Sanctuary).

The National Ocean Service of the National Oceanic and Atmospheric Administration (NOAA) has proposed a draft revised management plan and revised regulations for the Gray=s Reef National Marine Sanctuary. As proposed, the revised regulations would prohibit anchoring and restrict all fishing except that conducted by rod and reel and handline gear. The Sanctuary, designated in 1981, consists of approximately seventeen square miles of ocean waters and submerged lands off the coast of Georgia. It includes and protects one of the largest nearshore rocky reefs off the southeastern United States and is in a transition zone between temperate and tropical waters. It is located near an area of Georgia coastline that has experienced a dramatic increase in population, and, as a result, visitation to the Sanctuary has increased significantly. The goal of the proposed new management plan and proposed regulations is to continue to accommodate the increased use of the sanctuary while also protecting the reef and the species of fish that live there. Among other things, the regulations would amend the existing regulations to make clear that the protected area shall include submerged lands within the boundary of the Sanctuary, consistent with the National Marine Sanctuaries Act, and revise the permit regulations for certain activities within the Sanctuary.

Since the Sanctuary was first designated, its use has greatly increased. Thus, there are tensions between the need to preserve the valuable resources while also allowing for sport diving, sport fishing and other activities. In order to ensure that all interested parties could participate in the development of the Sanctuary=s final management scheme, a Sanctuary Advisory Council (SAC) was established to provide advice on the management and protection of the Sanctuary. The members of the SAC represent a wide range of entities, including educational groups, Georgia state agencies, conservation groups, sport fishing groups, sport diving groups, and federal agencies including the National Marine Fisheries Service and the Coast Guard. The SAC, through its members, serves as a liaison to the community regarding Sanctuary issues and represents community interests, concerns and management needs to the Sanctuary. Specifically, they are tasked with providing advice on:

- Protecting natural and cultural resources, and identifying and evaluating emergent or critical issues involving Sanctuary use or resources;
- Identifying and realizing the Sanctuary=s research objectives;

- Identifying and realizing educational opportunities to increase the public knowledge and stewardship of the Sanctuary environment; and
- Assisting to develop an informed constituency to increase awareness and understanding of the purpose and value of the sanctuary and of the National Marine Sanctuary Program.

The SAC conducts itself in an open, transparent and publicly accessible process. This allows for comprehensive and effective participation of all stakeholders. All SAC meetings are advertised and open to the public, and each member links the Sanctuary to extensive networks of constituencies. The Council has thus served as an entry point for community participation in Sanctuary management. As a result of issues and concerns raised by intergovernmental partners and other interested parties, the National Ocean Service sought to protect reef habitat and reef species from potentially harmful activities, while still allowing certain activities to continue, such as recreational fishing and recreational scuba diving.

As a result of the collaborative process among federal officials, the State of Georgia, and other interested stakeholders, as well as comments from members of the public, the Department of Commerce plans to publish a final rule codifying revised regulations and a revised management plan for the Sanctuary. As a result of input from members of the SAC and public comments, several key issues were clarified. For example, since most recreational fishing targets species that are not associated directly with the reef, the National Ocean Service has proposed allowing only rod and reel and handline fishing, while prohibiting all other sorts of gear. This decision was the direct result of consultation with the State of Georgia, the South Atlantic Fishery Management Council, and NMFS, and would result in an allowable gear regulation that would be more easily implemented by the Sanctuary and more clearly understood by the public.

With respect to the anchoring prohibition, consultation with the State of Georgia and the South Atlantic Fishery Management Council indicated that most recreational activities in this area do not require anchoring. Thus, as a direct result of such consultation, the Ocean Service was armed with knowledge that enabled it to draft regulations which would protect the reef from anchor damage without impinging on most recreational activities.

Subsequent to the publication of the rule, consultation between the Federal government and other interested parties will continue for the foreseeable future. In order to address the continuing challenge of appropriately regulating the Gray=s Reef, the National Ocean Service has entered into a Memorandum of Agreement with the South Atlantic Fishery Management Council, the State of Georgia, and NMFS which will foster continued collaboration in the form of the exchange of ideas and information while allowing maximum public input.

The Department of Education (ED)

The Department of Education consulted with State, local, and tribal governments concerning Federal Student Aid Programs and Title I - Improving the Academic Achievement of the Disadvantaged. The following descriptions include changes to regulations, improved service delivery, and other policy improvements that were the direct result of the Department of Education's outreach to its intergovernmental partners.

1. Federal Student Aid Programs

A. Federal Perkins Loan Program

Under this program, institutions of higher education provide their students with loans to pay the costs of attendance. The loans are made from a fund maintained by the institution that includes both federally provided funds and institutional funds. Once the borrower enters repayment, the institution is required to take steps to collect on the loan. Many of the institutions participating in this Program are State institutions. Many of these institutions asked for more discretion in determining how to maintain documents relating to the loans and on when to stop collecting on low balance loans. The Department met with representatives of State institutions of higher education and conducted a formal negotiated rulemaking process that included representatives of these institutions.

The State institutions of higher education asked the Department to increase the level at which an institution could write off a loan from the current level of $5 to $25 or more. The Department agreed to raise the limit to $25. These same institutions also asked the Department to give them more discretion for deciding when to file suit against a borrower and how often to review cases for purposes of litigation. The draft and final regulations were modified to give the schools more discretion in this area. The institutions also asked for certain reductions in requirements relating to promissory notes and other records used in the Perkins Loan Program. The Department largely agreed to make these changes.

B. Higher Education Act

Under the Higher Education Act of 1965, as amended (HEA), a student loan borrower who has defaulted on a student loan, may regain eligibility for more student aid by making 12 consecutive reasonable and affordable monthly payments. This is referred to as "rehabilitation." In the past, the Department's regulations have allowed borrowers who are subject to a judgment for the defaulted loan to have the opportunity for "rehabilitation." A number of institutions of higher education that make loans under the Federal Perkins Loan Program argued that offering these borrowers rehabilitation was not in the best interests of the program because of the significant costs of litigating these cases in the first place and because these borrowers remain likely not to pay their loans even after rehabilitation.

Representatives of institutions of higher education that make loans under the Federal Perkins Loan Program, including State institutions, participated in the Department's negotiated rulemaking process. State Attorneys General offices that

represent State institutions of higher education provided comments on the proposals through the representatives of the institutions. The Department conducted meetings and negotiated rulemaking sessions with representatives of student loan participants, including institutions of higher education, students, loan holders, loan servicers and guaranty agencies. Eventually, the negotiated rulemaking process resulted in the agreement to the terms of proposed regulations which were published by the Secretary in two notices of proposed rulemaking (NPRMs). The terms of the NPRMs were generally kept and published in final regulations after the review of public comments on the NPRMs.

A number of institutions of higher education that make loans under the Federal Perkins Loan Program argued that offering borrowers who are subject to a judgment for the defaulted loan the opportunity for rehabilitation was not in the best interests of the program because of the significant costs of litigating these cases in the first place and because these borrowers remain likely not to pay their loans even after rehabilitation. Also, representatives of some State institutions of higher education and State guaranty agencies wanted to maintain some discretion to offer borrowers against whom they have judgments many of the benefits of rehabilitation even if these borrowers would not be entitled to rehabilitation.

The regulations were modified to provide that borrowers who are subject to a judgment for defaulted loans are no longer entitled to rehabilitation, however, the regulations were amended to provide specifically that institutions and guaranty agencies have the authority to offer borrowers against whom they have judgments many of the benefits of rehabilitation.

C. Federal Family Education Loan Program

Guaranty agencies in the Federal Family Education Loan Program, which are either State agencies or non-profit agencies, are required to take appropriate action to try to recover student loans that are due if the borrower files for bankruptcy. To get a loan discharged in bankruptcy, the borrower must file an adversary action against the holder of the loan. However, many courts have held that a State guaranty agency may assert its right to sovereign immunity to avoid such adversary actions. The Department's regulations needed to be revised to avoid restrictions on the State agency's authority to assert sovereign immunity.

State guaranty agencies were the party most affected by the regulations. The Department addressed the issue through a negotiated rulemaking process that included representatives from organizations representing guaranty agencies. The Department had meetings with interested members of the student loan industry, including guaranty agencies, lenders, and loan servicers as well as representatives of students and borrowers and different types of institutions of higher education. The State guaranty agencies wanted to ensure that their authority to assert sovereign immunity to avoid adversary actions by debtors in bankruptcy was protected by the regulations. These agencies asked

the Department to modify the regulations to ensure that actions by lenders would not preclude the assertion of sovereign immunity.

The Department modified the regulations to authorize State guaranty agencies that hold loans affected by bankruptcy filings to instruct lenders not to file a proof of claim in the bankruptcy. This will protect the State guaranty agency's ability to assert sovereign immunity.

D. Higher Education Act

Under the Higher Education Act of 1965, as amended (HEA), institutions that participate in the Federal student financial aid programs are required to return unearned funds on behalf of students that withdraw within 30 days after the institution knows the student left. Many of the institutions participating in the HEA Program are State institutions. Many of these institutions asked for more lenient timeframes for returning funds due to the complexities and delays present in the State government payment systems.

The Department met with representatives of State institutions of higher education and conducted a formal negotiated rulemaking process that included representatives of these institutions. The State institutions of higher education asked the Department to increase the timeframes for returning unearned student funds from the current 30 day period, particularly for funds that were returned by mailing checks rather than using an electronic funds transfer. Some State representatives suggested that, as an alternative standard, the Department consider using the date when the payment request was initiated by the institution, rather than the date when the funds were actually returned.

The Department kept the 30 day requirement for returning unearned student funds, but added a new provision that allows a timely issued check to clear within 45 days after the institution knew the student left. An appeal process was also added that permits an institution to demonstrate that a failure to make the required timely payments was due to exceptional circumstances.

E. Title I - Improving the Academic Achievement of the Disadvantaged

In developing final regulations implementing various provisions of Title I of the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001, the Department requested and received comments from the public, including State and local educational agencies. Based on the comments received, a number of changes to the regulations were made. These regulations were published in the *Federal Register* on December 2, 2002 (67 FR 71710) and became effective on January 2, 2003.

On December 2, 2002 (67 FR 71710), the Department issued final regulations implementing various provisions of Title I of the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001. Most significantly, these regulations address the accountability provisions in Title I dealing with determining

adequate yearly progress and identifying schools and districts for improvement. The final regulations also implement other significant provisions in Title I, such as public school choice, supplemental educational services, qualifications of teachers and paraprofessionals, schoolwide programs, services to private school children, and allocating funds to districts and schools.

This regulation affects State educational agencies, local educational agencies, and public elementary and secondary schools. ED published a notice of proposed rulemaking in the *Federal Register* on August 6, 2002 (67 FR 50986) and invited all interested parties to submit written comments during a 30-day comment period. Over 100 comments were received from State and local educational agencies and other interested parties that it took into consideration in developing the final regulations. Because this was a major regulation implementing significant provisions of Title I, as amended by the No Child Left Behind Act of 2001, ED received many comments. The most significant comments concerned adequate yearly progress (AYP), and the need for greater flexibility. Many States asked ED to provide flexibility for them to continue to use their existing accountability systems in lieu of the accountability scheme set forth in the statute. ED also received significant comments concerning the teacher and paraprofessional quality provisions.

Based on public comments, ED made a number of changes in the final regulations. With regard to AYP, it was unable to take many of the commenters' suggestions because they were not consistent with the very specific, rigorous requirements in the statute. However, in response to comments on graduation rate, ED clarified that it must be calculated in a way so as to take into consideration students who drop out of school. ED also clarified, in response to comments, that students in subgroups that are too small to be included in determining AYP at the school level must be included in determining AYP at the district and state levels. ED responded to comments that the proposed regulations on schoolwide programs were confusing by reorganizing the provisions and aligning other provisions more closely to the statutory language. Further, ED added provisions to ensure that supplemental educational services were available for students with disabilities and limited English proficient students. It also added language to circumscribe alternate routes to certification, in response to comments that all teachers be required to complete an approved educator preparation program.

Department of Health and Human Services

1. HHS policies and programs on Indian Tribal governments

The Secretary traveled to Alaska on August 4-8, 2003. He visited the Alaska Area Office, IHS, Alaska Native Medical Center, South Central Foundation, Cook Inlet Housing Authority, Cook Inlet Regional Corporation, Arctic Slope Native Association, North Slope Borough, the Village of Point Hope, the Village of Shishmaref, Norton Sound Health Corporation, Kawerak Native Association, and Bristol Bay Native Association. His trip included a formal consultation session with the tribal leaders from

Region X. This session was conducted in Anchorage, Alaska and was attended by representatives from 45 tribes from Alaska, Oregon, Washington and Idaho.

During FY 2003 the Deputy Secretary traveled to Indian country on 4 occasions:

On November 7, 2002 the Deputy Secretary presented the keynote address at the Tribal Self-Governance Meeting in San Diego, California. Upon the conclusion of his remarks he spent the remainder of the day visiting American Indian facilities in San Diego County. He visited the Youth Regional Treatment Center on the La Posta Indian Reservation, the Southern Indian Health Council Health Facility where he conducted a round table discussion convened by the Southern California Tribal Chairmen's Association, the San Diego American Indian Health Center and the Indian Human Resources Center.

On February 28 – March 2, 2003, the Deputy Secretary traveled to Arizona and visited the Salt River Pima Maricopa Indian Community, Ak-Chin Indian Community, Tohono O'odham Nation and Pascua Yaqui Tribe. In addition he toured the Phoenix Indian Medical Center, the National Institutes of Health Diabetes Research Center and held a tribal leaders round table meeting at the Phoenix Area Office. Tribal leaders representing 5 different tribes participated in the roundtable.

On June 23 – 26, 2003, the Deputy Secretary traveled to Oklahoma and visited the Cherokee Nation of Oklahoma, the Sac and Fox Nation, the Absentee Shawnee Tribe of Oklahoma, the Chickasaw Nation, the Choctaw Nation of Oklahoma, and the Citizen Potawatomi Nation. In addition the Oklahoma Area Indian Health Board and the Potawatomi Nation hosted a tribal leaders roundtable meeting at which tribal leaders from 9 tribes were represented.

On July 14-16, 2003 the Deputy Secretary traveled to Albuquerque NM and participated in the Albuquerque Area Health Summit and the Region VI Consultation session. In the course of these events the Deputy Secretary met with representatives of 21 tribes.

A. Improved Tribal Access to HHS

Resources - Between FY 2001 and 2003 HHS resources that were provided to tribes or expended for the benefit of tribes increased from $3.9 billion in 2001 to $4.4 billion in 2003. These gains came in both appropriated funding as well as increased tribal access to non earmarked funds and increases in discretionary set asides. This reflects an 11% increase in access to HHS funding for tribes over a 2-year period.

B. Medicare Reform Act

Sec.506 – Medicare-like rates, Sec. 630 – Billing for all Part B Services, Sec.1011 – Federal reimbursement of emergency health services furnished to undocumented aliens,

the Temporary Drug Discount Card (temporary provisions), and the Permanent Medicare Part D Drug Benefit (beginning January 2006), are all responsive to tribal legislative priorities identified for Centers for Medicare and Medicaid Services (CMS). HHS is in the process of preparing tribal specific briefing and information materials for distribution to the tribes.

C. CMS Tribal Technical Advisory Group (TTAG)

In response to tribal leader comments at the regional tribal consultation session supporting a CMS-TTAG, HHS established the TTAG requested by tribal leaders. The first formal meeting was held on February 10, 2004 at the Hubert Humphrey Building in Washington, DC.

D. Tribal Consultation Policy

In response to tribal leader comments at the regional tribal consultation sessions to improve tribal consultation and intergovernmental relations, the Secretary is revising the existing HHS tribal consultation policy and is involving tribal leaders in this process. A workgroup is being formed to assist HHS in completing the revisions HS Tribal/State Relations Collaboration Project

2. Health Insurance Portability and Accountability Act (HIPAA) Regulations

During 2002 and 2003, HHS developed and began implementing regulations to related to the health care records provisions of the Health Insurance Portability and Accountability Act. On October 23, 2002 and July 17, 2003 senior representatives from the HHS Office for Civil Rights, Centers for Medicare and Medicaid Services, Office of Intergovernmental Affairs, and other HHS offices participated in two HIPAA implementation roundtables with the National Governors Association, other state government organizations and Governor's health policy advisors. HHS and state representatives discussed specific issues related to the HIPAA medical records privacy rule, HIPAA security and administrative simplification rules, and the HIPAA transactions and codes rules.

As a result of these and other interactions with state leaders, HHS was able to resolve issues related to appropriate records disclosures, receipt of non-electronic health records, enforcement responsibilities, and other state concerns in advance of implementation deadlines.

3. Election Assistance for Individuals with Disabilities (EAID)

The President signed into law the Help America Vote Act (HAVA) on October 29, 2002. HAVA contains several provisions that enable state and local units of government responsible for elections, and individuals associated with operating the election process, to establish, expand and improve access to and participation by

individuals with disabilities in the voting process. This provision of the law is called the Election Assistance for Individuals with Disabilities (EAID).

Congress appropriated $13 million for the EAID grant program. Within HHS, the Administration on Developmental Disabilities (ADD) has responsibility for the administration of EAID and the associated grant program. Staff from HHS's Office of Intergovernmental Affairs (IGA) worked closely with ADD to develop the process for applying for grant funds. On March 18, 2003, IGA and ADD met with representatives from the National Association of Counties, National Conference of State Legislatures, and the National Association of Secretaries of State to discuss several key implementation issues. This consultation helped successful implementation of the program by the July 2003 deadline.

4. Urban Partnership Initiative

On November 25, 2002, the Secretary announced the selection of 10 major metropolitan areas that will participate in the Urban Partnership Initiative. He made the announcement at a meeting of the U.S. Conference of Mayors. Urban areas with populations of at least 300,000 were eligible to apply to participate. This initiative is designed to help communities that continue to have relatively high concentrations of welfare recipients.

The selected locations received intense technical assistance on strategies for working through their welfare caseloads. HHS's Office of Intergovernmental Affairs and Administration for Children and Families consulted with the U.S. Conference of Mayors, the National League of Cities, and the National Association of Counties concerning local caseloads and employment information that helped improve implementation of the initiative.

5. Rural Consultation

Through participation in the National Rural Development Partnership (NRDP), HHS provided several opportunities for rural elected officials and community members to comment on the differential impact of HHS policies and programs in rural America. During the NRDP Policy Conference in April 2003, representatives from the Centers for Medicare and Medicaid Services (CMS) met with NRDP to discuss the impact of lower rural provider reimbursement rates on healthcare workforce retention. Rural community representatives emphasized the economic impact of HHS funding in rural communities. Subsequent to these consultations, Congress passed and the President enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). The Act addressed several of the rural provider reimbursement issues that NRDP representatives had raised.

During the NRDP Policy Conference, the Department's Health Resources and Services Administration (HRSA) discussed with NRDP ways to improve the

effectiveness of the network of state offices of rural health. In follow up to those discussions, HRSA has facilitated a closer working relationship between the state offices of rural health and the state rural development councils.

The HHS Administration on Aging (AoA) officials also discussed meeting the needs of the isolated rural elderly with limited community resources. AoA has designated a staffperson with rural aging program experience to identify opportunities to better support rural communities.

6. Trade Act-Consultation with States

The Trade Adjustment Assistance Reform Act of 2002 appropriated $20 million for seed grants to States to create qualified high risk health insurance pools and $80 million for operation grants to States with existing qualified high risk pool to fund losses incurred in the operation of the pools. State high risk health insurance pools are, in most cases, operated under the jurisdiction of the State Department of Insurance. Accordingly, it will be the State Departments of Insurance that will be applying for the grants. Up to 29 States may be eligible to apply for seed grants to create a qualified high risk pool (or modify an existing risk pool to make it a qualified pool) and 22 States currently have qualified high risk pools that may be eligible for an operation grant.

Individual telephone consultations have occurred with officials from State Departments of Insurance, with officials from the National Association of State Comprehensive Health Insurance Plans (NASCHIP), with high risk pool administrators, State legislative officials, staff from State congressional delegations and with several non-profit agencies interested in health insurance issues. Formal venues were as follows: Presentation on Trade Act high risk pool funding at HIPAA conference in Tampa, Fla. in August 2002 and in Washington D.C. in August 2003. Presentation at NASCHIP conferences in October 2003 and October 2003. Presentations at HHS/HRSA conferences in February 2003 and February 2004.

Most of the concerns raised fall into two categories. First is the concern over the timing of the grants. The second concern is the requirements for eligibility for the grants. CMS staff learned extensively about the operation of State high risk pools and was able to announce the grant application procedures for the seed grant program on November 26, 2002. The procedures for the operation grant program were initially published in the Federal Register on May 2, 2003 and finalized on March 26, 2004 in the Federal Register. As of April 1, 2004, three states (Maryland, South Dakota and New Hampshire) have been awarded grants of $1 million to create a high risk pool. Five more applications for start-up grants are pending. For the operation grants, $ 29.8 million has been awarded to 16 states to offset losses incurred by their existing high risk pools in their FY 2002.

7. Independence Plus

Independence Plus is a Medicaid initiative, introduced by the Secretary on May 9, 2002, to promote individual or family choices regarding the selection of long-term care supports and services provided in the home. Notice of the two Independence Plus template applications for Section 1915 (c) waivers and 1115 demonstrations appeared in the Federal Register on May 13, 2002, pursuant to the Emergency Rule of the Paperwork Reductions Act. Public comment on the template applications was accepted until July 1, 2002.

The Independence Plus Initiative affected States, advocacy organizations, providers, elders and persons with disabilities of all ages. Between October 2002 and September 2003, input to the Independence Plus template applications and/or the Independence Plus Draft Technical Guide was received from all these parties in response to the Federal Register notice, surveys, technical assistance meetings and conferences.

CMS answered ongoing questions about the Independence Plus template applications after July 1, 2002 via two self-direction web sites – Selfdirectionwaiver@cms.hhs.gov (for 1915 (c) waivers) and Selfdirectiondemo@cms.hhs.gov (for 1115 demonstrations). CMS received input to the Draft Independence Plus Technical Guide from stakeholders between October 31, 2002 and November 18, 2002. CMS provides continuous technical assistance to states interested in pursuing Independence Plus applications and receives continuous feedback at meetings and conferences.

The various stakeholders desired more clarity and greater guidance with respect to the Independence Plus program requirements. CMS is developing a new waiver application and instructional guidance materials in response to public and intergovernmental comments.

8. Program for All-Inclusive Care for the Elderly (PACE)

The Final Rule: *Programs of All-inclusive Care for the Elderly (PACE); Program Revisions* revised the November 24, 1999 interim final rule with comment period that established requirements for Program of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The revisions in this rule implemented section 903 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) by establishing a process through which PACE organizations may request waiver of certain Medicare and Medicaid regulatory requirements. The rule was published on October 1, 2002, with an effective date of October 31, 2002.

Consultations were held with PACE organizations (who serve elderly consumers age 55 and over) and States that offer the optional PACE benefit. The rule was developed in response to comments on the November 24, 1999 Interim Final Rule establishing requirements for PACE in accordance with section 4801 of Public Law 105-33 (BBA 1997) and section 903 of Public Law 106–554 (BIPA 2000).

The original rule raised concerns about providing flexibility in the program model, and especially with respect to the contracting of staff members. CMS-1201-IFC was published to permit PACE organizations to request waivers of most requirements in the interim final rule in order to provide for greater flexibility in adapting the PACE service delivery model to the needs of the particular organization. Additionally, the October 1, 2002 rule removed the requirement that PACE organizations directly employ the interdisciplinary team, the program director, and medical director. Instead the PACE organization may contract with these staff members.

9. Section 1115 Demonstrations: Health Insurance Flexibility and Accountability (HIFA) Initiative

In August 2001 the President announced a new section 1115 approach called the Health Insurance Flexibility and Accountability, or HIFA, initiative, which makes it easier for states to expand coverage to the uninsured. The HIFA initiative enables states to use Medicaid and unspent State Children's Health Insurance Program (SCHIP) funds in concert with private insurance options to expand coverage to low-income uninsured individuals. The goal of the HIFA initiative is to create a Federal framework that encourages state innovation to improve health insurance options.

Although there has been public interest in the HIFA initiative, waiver requests must be submitted by a state's Medicaid/SCHIP agency. Thus, CMS works primarily with state agencies on the HIFA initiative, although CMS requires states to consult with the public (including Tribes) in the development of HIFA proposals. We have designed a user friendly, electronic HIFA template that is available on the CMS website and have worked with several states in the pre-application phase as they developed their proposals.

CMS has been involved in pre-application discussions with several states about HIFA proposals, and there is currently one formal HIFA application under review. Consultation occurs through conference calls, concept papers, correspondence, and throughout the review of formal HIFA proposals. In the midst of fiscal crises, some states have raised concerns about CMS' policy that HIFA demonstrations must include some expansion to previously uninsured individuals. Concerns have also been raised by other partners about reducing benefits to persons previously eligible under the State's Medicaid plan through a HIFA demonstration.

There are currently nine approved HIFA initiatives. Through consultation and technical assistance provided throughout the approval process, states have been able to administer their Medicaid/SCHIP programs in more flexible ways to better meet the needs of their citizens, at no additional cost to the Federal government. Through consultation and technical assistance, CMS has worked to expedite the review process and reach closure in a timely way about HIFA concepts and proposals.

Department of the Interior

Minerals Management Service

The International Activities and Marine Minerals Division has been working with nine States along the East and Gulf Coasts to identify sand resources in Federal waters that could be used for beach renourishment and wetlands protection projects. In addition, MMS has conducted environmental studies to examine the biological and physical oceanographic implications of using sand from Outer Continental Shelf sites. During 2003, millions of cubic yards of sand were conveyed for shore protection projects.

The Alaska Region conducts an extensive outreach program associated with both pre-lease and post-lease activities of the Secretary's 5-year Oil and Gas Leasing Program. Examples of the outreach program include:

- Government-to-government consultations with potentially affected federally recognized Indian Tribes;
- Meetings with commercial fishing groups, environmental organizations, and local governments to obtain views on leasing, exploration, or development proposals; and
- Public meetings held recently across the North Slope of Alaska and South Central Alaska to obtain input on Beaufort Sea and Cook Inlet sales.

Office of Surface Mining

There are 24 coal mining States that regulate surface coal mining and reclamation operations under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). During the specified time period, OSM met regularly with individuals from State and local governments on issues that affected them. OSM also met with organizations representing elected State officials on a regular basis.

1. Abandoned Mine Land Issues

OSM consults extensively with the National Association of Abandoned Mine Land Programs. The Association is an organization of 26 State agencies and 3 Indian tribes that implement federally funded programs to reclaim abandoned or inadequately restored land and water resources adversely affected by past coal mining. The Association, organized in 1982, provides a forum to address current issues, discuss common problems, and share new technologies regarding the reclamation of abandoned mine lands. It fosters positive and productive relationships between the States and Indian tribes and the Federal Government. OSM participated in the Association's national conference as well as other issue-specific meetings during the year.

Through the Appalachian Clean Streams Program, OSM works with States and watershed organizations to reclaim streams impacted by acid mine drainage from abandoned coal mines. This can involve directly helping them with grant applications as well as funding summer interns that work for watershed organizations, assisting in a wide

variety of stream-related activities such as fund raising and complying with environmental regulations.

2. Coal Mining on Indian Lands

OSM is involved in an active partnership with representatives of tribal governments that have coal mining operations on tribal lands. Specifically, the Navajo Nation, the Hopi Tribe and the Crow Tribe are involved in the review of all permitting actions and representatives of these Tribes participate in the monthly inspections of mining operations and citizen complaint investigations.

OSM participated in the revision of the OSM-BIA-BLM Memorandum of Understanding (MOU) for the Management of Coal Mining on Indian Lands. The MOU is the result of unprecedented cooperation among 15 BIA, BLM and OSM offices as well as six Tribal governments (the Navajo Nation, the Crow, Hopi, Northern Cheyenne, Ute Mountain Ute and Southern Ute Tribes) who were given a meaningful opportunity to participate and comment. Numerous meetings and discussions were held over the past few years to clarify inter-bureau roles, procedures and responsibilities. The bureaus were very successful in resolving long-standing field operational issues. The revisions to the MOU were completed in 2003 and will provide needed guidance to the field personnel of the three bureaus and will ensure consistent management of coal mining activities on Indian lands.

Minerals Revenue Management Program

Our Minerals Revenue Management program (MRM) collects, verifies, and distributes mineral revenues from Federal and Indian lands. This program has been going through an extensive re-engineering initiative for the past 4 years, encompassing its core business processes and automated support systems. MRM has consulted with its customers on every aspect of the re-engineering effort.

State and Tribal Royalty Audit Committee - One means of consultation is the State and Tribal Royalty Audit Committee, comprised of State and Tribal audit managers who have cooperative audit agreements with MMS under the Federal Oil and Gas Royalty Management Act. The Committee meets at least quarterly, and subgroups of the committee may meet more often. This Committee has achieved results in a number of areas.

- State and Tribal auditors from Colorado, North Dakota, and Oklahoma helped design various tools used in the new compliance system and will help train system users.
- New Mexico is working with MMS on electronic data acquisition from company databases that should reduce information collection time and burden.
- Representatives from Colorado, Utah, Wyoming, and the Northern and Southern Ute Tribes helped design the compliance process for onshore oil and gas.
- Representatives from Colorado, Utah, New Mexico, Wyoming, and the Navajo and Crow tribes helped design the new compliance and asset management process

for solid minerals. MMS also consulted with industry on improvements to the compliance activities.

Work with State and tribal auditors - MMS worked with State and tribal auditors:

- Improved the language and content of orders sent to companies for royalty underpayment;
- Resolved valuation issues for royalty purposes involving Federal leases in their State or Indian leases on their Indian reservations
- Developed case-specific valuation guidance for companies who request solid minerals valuation determinations; and
- Resolved complicated royalty disputes through negotiation.

Royalty Policy Committee - Another avenue of consultation is the Royalty Policy Committee (RPC). RPC provides policy advice representing the collective viewpoint of the States, Indians, mineral industry and other parties. This advice concerns performance of discretionary functions in the Department's management of Federal and Indian mineral leases and revenues. RPC reviews and comments on royalty management and other mineral-related policies and conveys the views of mineral lessees, operators, revenue payers, recipients, governmental agencies and the interested public. Some recent results from the RPC work include:

- State representatives worked together with MMS, Industry, and Interior Department Solicitor's Office to draft rules on accounting and auditing relief and prepayment of royalties for marginal properties.
- The RPC Coal subcommittee worked with MRM on issues about coal waste piles, advance royalties, and alternative valuation methods.
- Every 6 months MMS has meetings at the Rocky Boys Indian reservation in Montana to discuss mineral royalty issues.

Bureau of Land Management

BLM's planning process established goals and objectives for resource management and defines parameters for using BLM lands. During the planning process BLM considers socioeconomic impacts to State, local, and tribal governments and resource management programs. Consultation and coordination early in our planning process encouraged identification of issues and concerns allowing managers to make appropriate adjustments to proposed actions. Consultation with officials of federally recognized tribes provided them opportunities to comment on land use plans. It identified cultural or historical resources on and off trust lands that could be affected by BLM activities. At a minimum, tribal governments had the same level of involvement as State and county governments.

BLM can't delegate our authority to make decisions affecting the public lands we manage. However, BLM strives to cooperate and communicate with State, local, and tribal governments to implement sound decisions that support a community's economic and infrastructure development. BLM involved State and local governments by closely

coordinating with State and local land use boards. In addition, all BLM land use plans or plan amendments and revisions underwent a 60-day Governor's consistency review before final approval.

U.S. Fish and Wildlife Service Refuge Management Program

The Fish and Wildlife Service's refuge management policies form a solid foundation to guide the most important aspects of modern refuge management. They represent the key steps to implement the National Wildlife Refuge System Improvement Act of 1997 and to help ensure that national wildlife refuges are administered consistently as a national network of lands, as called for in the Act.

Stakeholders were involved during policy development. After passage of the Act, an important first step was to provide State fish and wildlife agencies a meaningful role in policy development. The International Association of Fish and Wildlife Agencies facilitated State involvement. During North American Wildlife and Natural Resources Conferences, State directors were given a special opportunity for input on draft documents. As each policy was developed, partners, especially the States and the public, were encouraged to provide input. Particular stakeholder concerns were addressed in final policies. This outreach effort is a new way of doing business for Interior that has resulted in an influx of expertise and ideas and ultimately is helping develop better policies and stronger partner relationships.

Migratory Bird Hunting Regulations –

In FY2003, after consultation with Indian tribes, the Service published special migratory bird hunting regulations for the 2002–03 hunting season for Indian tribes. Fish and Wildlife Service publishes special Indian tribe regulations in response to tribes' requests for recognition of their reserved hunting rights and of some tribes' authority to regulate hunting by reservation members. The guidelines used accommodated the reserved hunting rights and management authority of Indian tribes while ensuring that migratory birds receive necessary protection. Coordination with the tribes in 2003 was highly effective. This program continues to grow as the Service and participating tribes cooperatively work to conserve this important international resource.

Department of Labor

1. Employee Retirement Income Security Act of 1974 (ERISA)

On April 9, 2003, the Department published the regulations *Plans Established or Maintained Under or Pursuant to Collective Bargaining Agreements Under Section 3(40)(A) of ERISA* (at 29 CFR 2510.3-40(a)) and *Procedures for Administrative Hearings Regarding Plans Established or Maintained Under or Pursuant to Collective Bargaining Agreements Under Section 3(40)(A) of ERISA* (at 29 CFR 2570 Subpart H). The regulations set forth specific criteria that, if met and if certain other factors set forth in the regulation are not present, constitute a finding by the Secretary of Labor (the Secretary)

that a plan is established or maintained under or pursuant to one or more collective bargaining agreements for purposes of section 3(40) of ERISA.

Employee welfare benefit plans, such as health care plans, that meet the requirements of the regulation are excluded from the definition of "multiple employer welfare arrangements" under section 3(40) of ERISA and consequently are not subject to state regulation of multiple employer welfare arrangements as provided for by the Act. The procedural regulations set forth a procedure for obtaining a determination by the Secretary as to whether a particular employee welfare benefit plan is established or maintained under or pursuant to one or more agreements that are collective bargaining agreements for purposes of section 3(40) of ERISA. The procedure is available only in situations where the jurisdiction or law of a state has been asserted against an entity that contends it meets the exception for plans established or maintained under or pursuant to one or more collective bargaining agreements.

This regulation is intended to assist labor organizations, plan sponsors, participants in multiemployer welfare benefit plans, MEWAs and state insurance departments in determining whether a plan is a "multiple employer welfare arrangement" within the meaning of section 3(40) of ERISA. The Department developed the regulations through negotiated rulemaking. The negotiated rulemaking committee was composed of representatives from labor unions, multiemployer plans, employer/management associations, Railway Labor Act plans, third party administrators, independent agents and brokers of health care products, insurance carriers, and the Federal government. State insurance regulators were represented through the participation of the National Association of Insurance Commissioners (NAIC).

The proposed regulations followed the recommendations of the ERISA section 3(40) Negotiated Rulemaking Advisory Committee (the Committee). The Committee was convened under the Negotiated Rulemaking Act (the NRA) and the Federal Advisory Committee Act (the FACA), to assist the Department in developing proposed regulations to implement section 3(40)(A)(i) of ERISA. In preparing the final regulations, the Department used the proposed regulations developed by the Committee and held a public meeting of the Committee on March 1, 2002, to obtain the Committee's input on public comments to the proposed rules.

The major concerns raised were by state insurance regulators and representatives of organized labor. State insurance regulators were concerned that the regulation not impede or delay state enforcement actions against sham MEWA operators. On the other hand, representatives of organized labor were concerned that the regulations not unduly impede permissible labor organizing and outreach nor interfere with the operation of legitimate collectively bargained plans.

In response to concerns raised by state regulators, the regulations specifically provide that they are not meant to impede or delay state enforcement action. In response to the concerns of representatives of organized labor, the Department made available a forum in which entities against whom state law or jurisdiction is asserted can seek to

obtain a finding in a federal forum as to whether such an entity is a plan established or maintained under or pursuant to a collective bargaining agreement for the purposes of section 3(40) of ERISA.

2. OSHA-Approved State Plans

State and local governments and their employees are specifically excluded from Federal coverage under the Occupational Safety and Health Act; thus, there is no OSHA intergovernmental mandate with regard to State and local governments. However, States that elect to accept responsibility (and up to 50 percent Federal funding of the cost of their program) for occupational safety and health enforcement in their State must first obtain OSHA approval of their "State plan," and as a condition of that approval, extend their protection to State and local workers. (States may also obtain approval of Public Employee Only State Plans.) Thus, in 24 States and two Territories, OSHA standards apply to State and local governments, as part of a voluntary program, not as a Federal mandate. (In July 2003, OSHA approved the conversion of the approved Virgin Islands State Plan, which covered private sector-safety as well as Territorial employees, to a Public Employee Only State Plan.) Nonetheless, OSHA does seek and consider State and local government views through its own and the State plans' standards promulgation processes.

OSHA actively seeks input on proposed standards and regulations from States participating in the program through its regular coordination with its State plan partners. OSHA meets regularly with the State plans States by attending meetings of their organization, the Occupational Safety and Health State Plan Association (OSHSPA). At these meetings, specifics of new and proposed standards and regulations are discussed.

Several State plan representatives serve as appointed members of the National Advisory Committee on Occupational Safety and Health (NACOSH), the Maritime Advisory Committee for Occupational Safety and Health (MACOSH), and the Advisory Committee on Construction Safety and Health (ACCSH) where they can assure consideration is given to the roles and the views of the State plans in broad national policy deliberations, including standards development.

State plan representatives have been invited to provide input to OSHA regulatory teams, and to participate in stakeholder meetings where new standards and regulations are discussed. In addition, State plan representatives have regularly participated as members of various OSHA policy development task groups (e.g., on Hispanic worker outreach, construction targeting, strategic planning, compliance assistance, management system redesign, etc.) In FY 2004, OSHA will continue its commitment to consult with the State plans on regulatory and policy issues by their continued participation in OSHA's Executive Board, the Information Technology Executive Steering Committee and the Homeland Security Executive Steering Committee. State representatives also attend all OSHA Senior Management planning conferences and Deputy Assistant Secretary Team Meetings.

The States have also participated in local Small Business Regulatory Enforcement Fairness Act hearings held throughout the nation. This participation is significant because small businesses and small municipalities often have the same concerns about regulatory burdens. In FY 2004, OSHA will continue to work with the State plans to provide outreach to small businesses nationwide and expand compliance assistance opportunities available to employers in their States.

OSHA's relationship with the approved State plans is based on the principle of partnership. The basic policies and procedures for monitoring State plans were developed as a Federal-State initiative over several years. The primary focus of program evaluation is the States' progress toward achieving their own OSHA-approved, results-oriented goals, in a manner consistent with the approach taken by OSHA under the Government Performance and Results Act (GPRA). This allows the States real flexibility to tailor their programs to State-specific circumstances, including the safety and health of State and local government workers, while contributing to the nationwide goals of reducing the incidence of occupational injuries, illnesses and fatalities. OSHA also monitors whether the States meet statutory mandates. The States' efforts are reported annually in both State and Federal evaluation reports. OSHA also continues to assist the States with various technology and data issues as part of this initiative.

Department of Justice

Community Oriented Policing Services (COPS)

Information sharing between Federal, and state, local, and tribal law enforcement agencies for counter-terrorism purposes was an initiative in FY2003. State, local and tribal law enforcement agencies were all affected by the new demands being placed on them with regard to homeland security and information sharing with Federal law enforcement agencies.

COPS has a history of working closely with state and local government. Since its inception in 1994 through the Violent Crime Control Act, COPS has consulted regularly with professional law enforcement organizations, such as the International Association of Chiefs of Police, National Sheriffs Association, the Police Executive Research Forum, the Police Foundation, and NOBLE on current issues in law enforcement. COPS also maintains regular contact with intergovernmental organizations such as the U.S. Conference of Mayors, the National League of Cities, and the National Association of Counties, which provides the perspective of local government on law enforcement issues. Throughout the last nine years, COPS has conducted research and evaluations with local police departments to identify barriers and challenges to their implementation of community policing. COPS consultation with state and local government is reflected in the training provided through the Regional Community Policing Institutes, best practices publications and other problem-specific guides, and targeted initiatives. In March 2003, the COPS Office, FBI, and Bureau of Justice Assistance came together to discuss collaborative ways to enhance the provision of counterterrorism training and technical assistance to state, local, and tribal law enforcement.

The primary concern raised at this working session was the issue of how homeland security information is being shared with non-Federal law enforcement agencies. Following is a summary of what has been accomplished as a result of the March 2003 COPS/FBI/BJA session:

- A law enforcement executive counterterrorism conference training module was piloted at the COPS annual conference and the National Sheriffs Association conference.
- Joint advertising of the three agencies' resources through counterterrorismtraing.gov, presentations, and agency web sites.
- The 31 COPS RCPI police training centers, serving all 50 states, have been certified to teach the FBI/BJA State and Local Anti-Terrorism Training (SLATT) curriculum.
- 12 RCPIs are working in partnership with their local FBI field office to deliver SLATT. In these classes FBI and RCPI trainers are working side-by-side to co-teach state, local, and tribal law enforcement counterterrorism and officer safety strategies.
- In less than a year, COPS and the FBI have co-trained over 5,000 law enforcement officers across the country and the number grows every day.

Additionally, the COPS Office funded the Police Executive Research Forum (PERF) to conduct a project entitled *Community Policing in a Security Conscious World*. This included a series of five executive sessions for law enforcement leaders to explore, debate, and exchange information on providing community policing services in a security conscious world. The five sessions were: Federal/Local partnerships, Working with Diverse Communities, Bio-Terrorism, Intelligence, and Homeland Security. Several white papers will be produced and disseminated from this series.

The COPS Office and staff have also produced several publications on counterterrorism topics such as Local Law Enforcement Lessons in Terrorism Prevention and Preparedness and Connecting the Dots for a Proactive Approach. The COPS Office plans to expand its partnership with the FBI and BJA by producing an Intelligence Guide for managers overseeing their departments' intelligence function, and a counterterrorism roll call training course for line officers. The COPS Office is also preparing a guide of best practices for the reduction of fear of terrorism.

Environment & Natural Resources Division (ENRD)

The Environment and Natural Resources Division of the Department of Justice ("Environment Division" or "Division") does not adopt rules imposing mandates on states or local governments that implicate the reporting requirements of the Unfunded Mandates Reform Act of 1995. The Environment Division does, however, work closely with state and local governments in its cases enforcing environmental laws and in other cases. Since 1994 the Environment Division has included a counsel who serves as a liaison with state and local governments.

1. Civil Environmental Enforcement Initiative

Environmental laws are a model of cooperative federalism. Federal laws on controlling air and water pollution and managing waste generally set national standards and encourage states to implement them through state environmental laws. See Clean Air Act, 42 U.S.C. 7401, et seq.; Clean Water Act, 33 U.S.C. 1251, et seq.; Resource Conservation and Recovery Act, 42 U.S.C. 6901, et seq. These laws preserve federal enforcement authority.

In the past, the Environment Division and state attorney general offices did not regularly collaborate in civil enforcement cases. While they occasionally brought cases jointly, they more often proceeded with their own actions without collaborating. There was no effective mechanism for early or regular communication. At times, the result was competing cases in federal and state courts – so-called "overfiling" or "underfiling" – with occasional conflicts.

In 2001, the Environment Division and the National Association of Attorneys General (NAAG) began an initiative to promote collaboration in civil environmental enforcement. The initiative has helped fuel record numbers of joint state/federal enforcement cases that have resulted in significant environmental protections. While the Environment Division and NAAG have been the main partners in the initiative, the Division has also partnered with national associations for governors, state legislators and state environmental regulators.

The Environment Division/NAAG civil enforcement initiative has identified and responded to a series of challenges since 2001. The responses include a series of first-ever events to bring state and federal officials together. The Division and NAAG first considered how to promote working relationships among state and federal counterparts. Some state and federal managers had not met their counterparts. Also, in some instances there were past feelings of mistrust from earlier races to the courthouse with competing cases. They responded by holding annual meetings of state and federal counterparts. Since 2001, NAAG and the Division have held annual meetings of state chiefs and Division managers. At the meetings, they get to know each other and discuss regional and national enforcement issues as well as particular cases. Developing these working relationships has helped foster an atmosphere of trust that promotes confidential discussion of cases.

In early 2003, NAAG and the Division released the "Guidelines for Joint State/Federal Civil Environmental Enforcement Litigation" ("Guidelines") at NAAG's annual meeting of State Attorneys General. Oklahoma Attorney General Drew Edmondson, NAAG's then-President, and Tom Sansonetti, Assistant Attorney General for the Environment Division, hailed the benefit of cooperative enforcement in leading to more comprehensive case resolutions. The release was just two weeks after U.S. Attorney General John Ashcroft had announced a Department priority for promoting

federal and state cooperation in cracking down on polluters in environmental enforcement cases in order to level the corporate playing field.

The Guidelines provide practical tips and discussions of legal issues. The Guidelines are on the Division and NAAG's respective webpages. See **www.usdoj.gov/enrd/ltopics.htm**; **www.naag.org/issues/issue-environment.php**; see also Partners in Pursuit of Polluters: State/Federal Civil Environmental Enforcement, Natural Resources & Environment, American Bar Association, vol. 18, no. 4 (spring 2004), at p. 24 (describing development of the Guidelines).

The Division and NAAG encountered a special challenge in the area of wetlands enforcement. A Supreme Court decision in 2001 ("SWANCC") appeared to limit the scope of federal protections for many "isolated wetlands" under the Clean Water Act. The decision resulted not only in a potential gap in federal protections, but also increased attention to potential gaps in state law protections. A significant amount of "isolated wetlands" appeared to be at risk of falling outside federal and state protections. Many federal and state enforcers felt that they could no longer be certain that the Clean Water Act would protect some of these wetlands. Collaboration was more important than ever.

The Division responded by holding in late 2002 a summit for state and federal officials on wetlands protection laws, called "Wetlands Protection & Enforcement: A State/Federal Conference." NAAG was a co-convener. The conference brought together over 150 state and federal officials who focused not only on collaboration in carrying out and enforcing wetlands laws, but also on providing governors and state legislatures with tools for filling gaps. Other co-conveners were: EPA, US Army Corps of Engineers, National Governors Association (Center for Best Practices), National Conference of State Legislatures, and Association of State Wetland Managers. Several elected state legislators participated in the summit.

The initiative is promoting increased collaboration among between federal and state civil enforcement litigators, with an emphasis on bringing cases together. The Division has had record numbers of joint civil enforcement cases with States. The United States and nearly every State have joined as co-plaintiffs. In fiscal years 2001 to 2003, states (and local governments and tribes) were awarded, through settlement or judgment, more than $144 million as the result of joint actions with the Division. States participate in most of the Division's prominent cases and their participation ensures more comprehensive resolutions. In 2002, for example, joint cases yielded $3.3 billion in environmental injunctive relief, compared to a total of $3.6 billion for all federal cases.

- The Department of Justice joined with 11 states and 3 counties in obtaining a Clean Air Act consent decree with a major grain company. The decree requires the company to implement sweeping environmental improvements at 52 plants in 16 states to reduce air pollution by 63,000 tons per year. The estimated cost of the work is $340 million over 10 years. The settlement also

includes a civil penalty of $4.6 million and supplemental environmental projects of $6.3 million.

- The Department of Justice and the State of Washington obtained a civil and criminal settlement from a pipeline company after a rupture killed two young people. The State approached the Environment Division about conducting a joint case to take advantage of relative strengths in state and federal laws. The proposed consent decree requires $62 million in improvements to 2100 miles of pipelines in seven states. Civil penalties and criminal fines total $36 million.

- The Department of Justice and the State of Wisconsin obtained a Superfund consent decree requiring $66 million of work to remediate a portion of Fox River. The defendants also must pay $3 million to the governments as partial payment of natural resource damages and government costs.

- The Department of Justice, the States of Delaware and Louisiana, and a local air pollution control agency in Washington State obtained a Clean Air Act consent decree with companies operating nine petroleum refineries. The decree will reduce air emissions by over 60,000 tons per year. The companies also will collectively pay a $9.5 million civil penalty and spend about $5.5 million on environmental projects in communities affected by the refineries' pollution.

- The Department of Justice and the States of Alabama, Arkansas, Nebraska, Utah, South Carolina and Texas obtained a consent decree with a steel manufacturer under three environmental statutes: Clean Air Act; Clean Water Act; and Resource Conservation and Recovery Act ("RCRA"). The decree requires reduction of nitrogen oxide emissions, remediation of areas of contamination and improvements in waste management. The company will pay a civil penalty of $9 million, and spend $4 million on supplemental environmental projects.

2. Criminal Environmental Enforcement

Almost all major federal environmental statutes provide for delegation of programs to the states and recognize state enforcement authorities including criminal enforcement. Therefore, it has been essential to work closely with state and local agencies. Today, in nearly every case, information and other assistance is sought and obtained from state and local law enforcement and regulatory agencies. Environment Division attorneys frequently serve as faculty for state and local training programs.

Task forces have been formed in many districts to address environmental crimes and related enforcement concerns. The Division's attorneys act as members of the task forces as they work jointly with Assistant United States Attorneys on cases in the district.

They also provide information, general assistance, and support to all such task forces as called upon.

- The Tin Products case is an example of a recent prosecution that involved particularly close coordination with state officials. The facility's illegal discharges of toxic wastewater caused a fishkill and the shut down of a wastewater treatment plant. The facility's vice president was sentenced to 18 months in prison and 100 hours of community service. The environmental supervisor was sentenced to 5 months in prison, 5 months home detention and a $7,500 fine. The wastewater operator was sentenced to 6 months home detention, 5 years probation and 100 hours community service.

3. Indian Resource Cases

The Environment Division, through its Indian Resources Section, represents the United States in its capacity as trustee for American Indian tribes. To this end, the Section litigates cases in order to establish and protect the following: treaty hunting and fishing rights; tribal water rights; tribal lands and natural resources; and tribal jurisdiction and authority. The Section also defends actions by the Secretary of the Interior and Congress intended to further tribal sovereignty and Indian rights. This litigation is of vital importance to Indian tribes and Indian people.

Although the Indian Resources Section represents the interests of the United States and particularly the interests of the Interior Department, these interests are often aligned with the interests of Indian tribes. The Section therefore works both informally and formally with tribes in pursuing litigation and negotiating settlements. In the past several years the Section has had remarkable success in working with tribes, states, and private parties to settle disputes. For example, in FY2003 the Section negotiated the resolution of a land into trust challenge by the State of Nevada regarding a decision on behalf of the Fallon-Paiute Shoshone Tribe. The agreement was the first such negotiated resolution of a land into trust challenge among a tribe, State and federal government. In summer of 2003, the Section met with the Conference of Western Attorneys General to promote the Department's role as mediator in such disputes.

Department of Transportation

Federal Railroad Administration

Interim Final Rule on Use of Locomotive Horns at Highway-Rail Grade Crossings

The rule requires that locomotive horns be sounded at all public highway-rail grade crossings and also provides for exceptions in which there is not a significant risk of loss of life or personal injury, use of the horn is impractical or use supplementary safety measures fully compensate for the absence of the warning provided by the horn.

Individuals and businesses living and working near highway-rail grade crossings are affected, as are State and local governments. State and local officials and organizations representing such officials were consulted.

Consultation with State and local officials were expressed in written comments and testimony at twelve public hearings. FRA staff provided briefings to many State and local officials and organizations during the rulemaking comment period to encourage full public participation in the process. FRA had earlier been involved in extensive public outreach. FRA also established a public docket prior to the initiation of the rulemaking to solicit comments from the public and State and local officials. State and local officials expressed concern about what were considered somewhat inflexible requirements for creation of quiet zones and the time frame permitted for creation, as well as the cost associated with creation. FRA provided increased flexibility to State and local governments in creating quiet zones and in the time frames for creation. This greater flexibility reduced the potential costs of creating quiet zones.

Federal Motor Carrier Safety Administration

Hours-of-Service for Commercial Motor Vehicle Drivers

The FMCSA's hours-of-service regulations [49 CFR Part 395] regulate the maximum driving hours and minimum off-duty time of commercial motor vehicle (CMV) drivers. The affected parties are several million CMV drivers and several hundred thousand motor carriers that employ them. The States are required to adopt and enforce hours-of-service regulations consistent with the Federal standards in order to remain eligible for Motor Carrier Safety Assistance Program (MCSAP) grants. Many States participated directly in FMCSA's recently completed revision of the hours-of-service regulations, and all of them were represented indirectly through the Commercial Vehicle Safety Alliance (CVSA), which commented extensively on the agency's proposals.

Because the hours-of-service rules do not preempt any State law or regulation, FMCSA simply solicited written comments from the public. The agency treated the States like any other important public stakeholder in the process. When invitations to special roundtable discussions of the proposed rules were issued to groups critically affected, CVSA was invited and participated.
The States and CVSA argued that the proposed rules were excessively complex, would require a great deal of re-training of enforcement officers, and were virtually unenforceable at roadside. Motor carriers and CMV drivers argued that the rules were disruptive of trucking operations, excessively complex, far more expensive than the agency recognized, and ultimately self-defeating because the rules would require more drivers and trucks on the road in peak traffic periods, thus producing more – not fewer – accidents. In response to these concerns, the proposed hours-of-service rules were fundamentally revised. The final regulation is simpler and cheaper, easier to enforce, and more compatible with current motor carrier operations.

Federal Highway Administration

Statewide Transportation Planning; Metropolitan Transportation Planning

The Statewide Transportation Planning; Metropolitan Transportation Planning (23 CFR Part 450) final rule was issued on January 23, 2003 (68 FR 3176). This regulation implements 23 U.S.C. 135, which requires each State to carry out a continuing, comprehensive, and intermodal statewide transportation planning process, including the development of a statewide transportation plan and transportation improvement program, that facilitates the efficient, economic movement of people and goods in all areas of the State. The primary focus of this action is on consultation between State Departments of Transportation (DOT) and non-metropolitan local elected officials.

The Federal Highway Administration (FHWA), in consultation with the Federal Transit Administration (FTA) amended the planning regulation (23 CFR 450) to implement the provision of section 1025 of the Transportation Equity Act for the 21st Century (TEA-21), specifically as it relates to consultation with non-metropolitan local officials in the statewide and metropolitan planning process. In the process of developing the final rule, the FHWA consulted with local governments, Metropolitan Planning Organizations (MPO), Councils of Governments (COG) and regional governments, State DOTs, the National Association of Counties (NACO), the National Association of Development Organizations (NADO), and the American Association of State Highway and Transportation Officials (AASHTO).

On May 25, 2000, the FHWA and the FTA issued a notice of proposed rulemaking (NPRM) that proposed revisions to the existing planning regulation issued in 1993. During the comment period of this NPRM, the agencies held seven public meetings to present information on the NPRM; however, a final rule was not issued. Then the House report that accompanied the U.S. DOT Appropriations Act for fiscal year (FY) 2002, and the conference report for the Department of Defense FY 2002 Appropriations Act, which contained several transportation issues, directed the U.S. DOT to promulgate a final rule not later than February 1, 2002, to ensure transportation officials from rural areas are consulted in long range transportation projects and programming. As a result, the agencies issued a supplemental notice of proposed rulemaking in June 2002 proposing to amend the regulation as it relates to consultation with non-metropolitan officials.

In response to the SNPRM, the agencies received comments from a joint coalition made up of representatives from NACO, NADO, and AASHTO. These organizations representing both State and local officials presented the FHWA with proposed regulatory language developed jointly among these stakeholders. The agencies relied heavily on this suggested language to formulate the final rule because it came from the organizations whose members are most affected by the final rule.

A long unresolved issue regarding the role of rural local officials in the statewide transportation planning process was finally resolved. The consultation raised the issue regarding the role of rural and non-metropolitan local officials, a concern that had been left unclear for several years. The final rule reflects a compromise jointly agreed to, and submitted to the docket, by the National Association of Counties, the National Association of Development Organizations, and the American Association of State Highway and Transportation Officials whose members are most directly affected by the new rule. The new rule now requires that States create and document a process, separate from the public involvement process, to consult with non-metropolitan local officials and provide for their participation in statewide transportation planning and programming.

Environmental Protection Agency

Consultation Mechanisms, General Outreach Activities and Communication Aids

The Environmental Protection Agency used several mechanisms to help State, local, and Tribal officials learn about its regulatory plans and to let them know how they can engage in the rule-development process. These and other activities contributed to more efficient and effective regulation by reducing unnecessary regulatory burden, freeing up resources, and strengthening partnerships with States and other organizations that share environmental responsibilities. For example, EPA distributes reprints of the semi-annual Regulatory Agenda to more than 300 State, local, and Tribal government organizations and leaders. EPA also participates in a Federal government-wide State and local Governments Web site. In addition, it support hotlines in both EPA Headquarters and the Regions where callers can get information on several topics, including regulatory and compliance information (further discussion of these communication aids below).

EPA chartered a cross-media FACA advisory body, the Local Government Advisory Committee. Its Small Community Advisory Subcommittee routinely advises EPA on issues and concerns, and provides recommendations on regulations, policies, and guidance affecting the development and delivery of environmental services. The Tribal Operations Committee similarly addresses Tribal interests. EPA program offices regularly work with groups of State, local, and Tribal officials to address specific environmental and programmatic issues. Examples include media-specific FACA committees, regulatory negotiation advisory committees and policy groups.

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

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) used outreach mechanisms related to its mission to secure State and Tribal insights and advice on issues related to the implementation of OPPTS' role in protecting public health and the environment from potential risk from toxic chemicals. These institutionalized processes are therefore to some extent independent of specific rulemaking activities. Some of the most important outreach mechanisms are identified below.

Office of Pollution Prevention and Toxics (OPPT)

OPPT created the *Forum on State Tribal Toxics Action (FOSTTA)* in the early 1990s as a vehicle to encourage State and Tribal involvement in OPPT decision making. In recent years, OPPT established a Tribal program to better communicate our programs and activities with Native American Indian Tribes, to build more effective partnerships with Tribes to safeguard and protect the environment from toxic hazards, and to promote pollution prevention in Indian country. Some major activities of the Tribal program include grants funding, internal training on Tribal issues, follow-up activities from EPA Tribal Operations Committee meetings, interagency coordination efforts, and stakeholder outreach. OPPT is committed to working in partnership with Tribal governments.

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

The Office of Pesticide Programs (OPP)

OPP uses the *State Federal FIFRA Issues Research and Evaluation Group (SFIREG),* established in 1974 by cooperative agreement between EPA and the American Association of Pesticide Control Officials, the association that represents State level pesticide regulatory officials. SFIREG identifies, analyzes and provides State comment on pesticide regulatory issues and provides a mechanism for ongoing exchange of information about EPA and State pesticide programs. With a full committee and two subcommittees, there are eight regularly scheduled meetings each year that offer State officials the opportunity to meet to discuss issues including regulations in progress. One example of results from consulting with SFIREG was the formation of joint EPA-State workgroup to address a number of issues and projects.

OPPTS also support the *Tribal Pesticide Program Council (TPPC),* a Tribal technical resource, and program and policy dialogue and development group that focuses on pesticide issues and concerns. It is composed of authorized representatives from federally recognized Tribes and Indian nations and inter-Tribal organizations.

National Center for Environmental Innovation (NCEI), in the Office of Policy, Economics, and Innovation (OPEI)

EPA routinely consults with States to promote regulatory efficiency and improved environmental results. Much of this consultation occurs through the *Environmental*

Council of the States (ECOS), in particular through the ECOS Cross-media Committee, and it is often influenced by the issues and concerns that States bring from their interactions with local governments. In FY 2003, members of ECOS's Cross Media Committee were invited to participate in meetings of EPA's Innovation Action Council, a policy-making group that is charged with overseeing EPA's regulatory and voluntary innovation activities. Likewise, EPA participated in the Cross Media Committee's meetings. These interactions led EPA and ECOS to prepare a joint innovation work plan to focus on several regulatory priorities, including development of Total Maximum Daily Loads for impaired waters.

Another effective mechanism for addressing State regulatory concerns is the *Joint EPA/State Agreement to Pursue Regulatory Innovation.* In FY 2003, approximately 30 projects addressing a broad array of regulatory issues were in various stages of development or implementation. These projects are designed to test ideas that can be implemented to improve results on a larger scale. To further support State regulatory innovation, NCEI awarded grants to States under a State Innovation Grant pilot program. Six States received a total of $742,000 under the first competition to explore innovative approaches to environmental permitting. In response to the strong State interest, NCEI committed to expand the program and consulted with States on the design of a second competition. NCEI also worked with States to develop flexible air permits based on their potential for reducing regulatory burden for permitted facilities and permitting agencies.

Likewise, NCEI provided information and assistance to States interested in the Environmental Results Program (ERP), an alternative regulatory approach that replaces environmental permits with a package of self-certification procedures, performance measures, and compliance assistance. In FY 2003, eight States pursued ERP programs to improve environmental performance for select small business sectors that have not received significant regulatory attention historically. NCEI also provided support for State small business assistance programs.

Several NCEI programs engaged States in creating a more performance-based environmental regulatory system. States were involved in the development of incentives for Performance Track, a voluntary program that rewards and recognizes members for top environmental performance. In addition, NCEI worked with States to provide recognition for Performance Track members through State environmental leadership programs. In FY 2003, NCEI also consulted with States to address regulatory issues that can hinder smart growth at the local level and improved environmental performance by specific industry sectors. Through the Sector Strategies Program, NCEI and other stakeholders focused on tailored approaches for 12 sectors that make up 23 percent of manufacturing revenue and employ 19 percent of workers in the United States.

EPA materials intended to help small governments more easily understand Agency regulations

Profile of Local Government Operations: The Profile details all the environmental requirements with which a local government must comply and organizes the information

based on operations, i.e., motor vehicle servicing, property management, etc. This makes it easier for the representative of a local government responsible for an operation to find out about all the environmental requirements that might impact his or her operation and where to find more detailed compliance information.

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

Small Government Agency Plan: The Agency's interim Small Government Agency Plan supplements the intergovernmental consultations. The Plan outlines the analysis rule writers must complete to determine whether the regulatory requirements of a rule might uniquely affect small governments. Under the plan, we encourage attention to such factors as whether small governments will experience higher per-capita costs because of economies of scale. The Plan also considers whether they would need to hire professional staff or consultants for implementation or be required to purchase and operate expensive or sophisticated equipment. We publish the findings under the Small Government Agency Plan in the *Federal Register* with proposed and final rules. When there are unique or significant impacts on small governments, we take action to inform and assist them.

Newsletter/Internet Site for Small Governments: Under a cooperative agreement funded by EPA, the International City/County Management Association (ICMA) publishes a newsletter designed for small governments covering regulatory and other environmental programs of interest to them. ICMA's *Environmental SCAN* is also published electronically on the Internet. Access is free to anyone interested in local government issues. The ICMA site links electronically to EPA's Federal Register site so readers interested in a regulation covered in the newsletter can immediately gain access to the actual text. As part of the project, ICMA has also conducted several workshops for small government officials on regulatory and other environmental management topics.

Guide to Federal Environmental Requirements for Small Governments: EPA publishes and distributes the small communities guide --a reference handbook to help local officials become familiar with Federal environmental requirements that may apply to their jurisdictions. The guide explains Federal regulations in a simple, straightforward manner. Mandated programs described in the guide include those for which small communities have major responsibilities, such as landfills, public power plants, and sewage and water systems.

Regional Guides to Federal Environmental Requirements for Small Governments: EPA Region VIII publishes and distributes a small community reference handbook to help local officials in Colorado, Montana, North and South Dakota, Utah and Wyoming become familiar with Federal environmental requirements that may apply to their jurisdictions. The guide includes up-to-date contact lists for State environmental programs.

Office of Solid Waste and Emergency Response

40 CFR Part 35, Subpart O, "Cooperative Agreements and Superfund State Contracts for Superfund Response Actions" (Subpart O) is EPA's rule for awarding and administering Superfund Cooperative Agreements (CAs) and Superfund State Contracts (SSCs). EPA established a workgroup to update and revise the Subpart O regulation by incorporating Superfund administrative reforms and streamlining the rule to identify more flexible procedures for the award and administration of CAs and SSCs to States, political subdivisions, and Indian Tribes. Workgroup members reviewed and evaluated issues raised regarding the revision and recommend changes to Senior Management. This is an assistance rule that awards Federal funds to carry out parts of the Superfund Program and is therefore not subject to UMRA

Subpart O affects all EPA regional offices, States, political subdivisions of States, and Indian Tribes. The Workgroup is comprised of representatives from the ten EPA Regions, representatives from the States of Illinois and Kansas, the Minnesota Chippewa Tribe, the Region 7 and Region 8 Inspector General Offices, and EPA Headquarters offices including the Office of General Counsel, the Office of Grants and Debarment, and the State, Tribe and Site Identification Branch within the Office of Superfund Remediation and Technology Innovation (OSRTI).

EPA will publish Subpart O in the Federal Register for at least 60 days in an effort to solicit comments from the affected community. State members from KS and IL have fully participated on the workgroup from the beginning of this effort, have presented their viewpoints, which were largely accepted and incorporated in the rule revision. A member of the Minnesota Chippewa has also fully participated on the workgroup from the beginning of this effort. Most workgroup meetings were held by conference call, minimizing travel funding costs. OSRTI briefed the Association of State and Territorial Solid Waste Management Officials, and presented a mini-course on the new Subpart O rule at the 2002 National Sites Assessment Symposium. Further outreach is planned to inform political subdivisions of the rule.

States argued that their procurement systems are now fully functional for Superfund purposes and recommended that the Part 31 rule be used as much as possible. This approach will match the requirements of the Subpart O rule more closely with grants requirements for EPA's other categorical grants programs. Further, States were interested in institutionalizing the current EPA pilot for consolidated cooperative agreements. The workgroup suggested that EPA transfer Superfund property directly to third parties with State assurance and noted that States want more flexible reporting. Tribes suggested that

EPA eliminate the cost share for Core Program Cooperative Agreements, and that the Agency institutionalize the class deviation allowing Tribes to receive a Support Agency Cooperative Agreement without the need to establish jurisdiction. The workgroup also suggested that EPA add Time-critical removals to the rule.

States and Tribes should be pleased. Key enhancements made during the workgroup process are being incorporated into the revised rule and include:

1. **States may now use their procurement systems;**
2. **Use Part 31 as much as possible;**
3. **Clarification of credit provisions;**
4. **Authorization to consolidate cooperative agreements;**
5. **Clarification of final payment provisions;**
6. **Remedial Action support now from Pipeline Advice of Allowance - no cost share required;**
7. **Property transfer directly to third parties with State assurance;**
8. **Flexible reporting annually, semi-annually, or quarterly;**
9. **Elimination of Core cost share for Tribes; and**
10. **Elimination of Support Agency jurisdiction for Tribes**

Based on one workgroup recommendation, the Agency decided to continue limiting the funding for time-critical removals to EPA-lead cleanups. Of course, States, Tribes and political subdivisions may respond to these emergency actions with their resources, but Federal funding is not available for States or political subdivisions or Tribes at this time.

Office of Air and Radiation

Over the last year, the Office of Air and Radiation (OAR) had only one rule that had any appreciable interaction with States, Tribes, and/or other governments. That rule is the "Clean Air Implementation Rule" (RIN 2060-AJ99, SAN 4625) for the 8-hour ozone NAAQS. This rule did not trigger UMRA since it did not impose any mandates on any governments. Nonetheless, EPA did do a lot of consultation during its development since it is essentially a guidance document showing States the procedures they need to follow in order to develop adequate plans to attain the 8-hour ozone standard. Below is included the pertinent section from the preamble of the May 2003 proposal:

EPA initiated a process to obtain stakeholder feedback on options the Agency developed for implementation of the 8-hour ozone NAAQS. Three public meetings were held in addition to a number of conference calls and meetings with State, local and Tribal governments, environmental groups and industry representatives. The purpose of the meetings and conference calls was to obtain stakeholder feedback regarding the options that we had developed as well as to listen to any new or different ideas that stakeholders were interested in presenting.

EPA received comments in response to the meetings and conference calls. The comments from the public meetings addressed a number of issues related to the implementation approach. In addition to comments received at the public meetings, a number of written comments were received on how to implement the 8-hour ozone NAAQS. EPA considered these comments in the implementation approach proposed [in this proposed rule].