Making Sense of Regulation:

2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities

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Office of Management and Budget

Office of Information and Regulatory Affairs

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Preface

Regulatory policy is critical to the welfare of the country. On the positive side, regulations have an essential role to play in protecting the environment, assuring a safe workplace, providing protection to consumers and in other ways addressing the needs of the American people. Yet regulations can also be costly. When designed poorly, regulations can create distortions in the economy by punishing small and large businesses and thwarting innovation and productivity improvements. Unfunded mandates on state and local governments can create serious fiscal problems for Mayors, Governors and other local officials. Common sense can sometimes distinguish a good rule from a bad one but in many complex situations a formal regulatory analysis is necessary to guide regulatory decision making.

The Bush Administration is committed to developing a smarter regulatory system based on sound science and economics. A smarter system adopts cost-effective rules when market and state and local efforts fail, revises existing rules to make them less costly and/or more effective, and rescinds outmoded rules whose benefits do not justify their costs. In pursuing this agenda, the Administration is actively seeking suggestions from the scientific community, stakeholders, and the general public.

This document fulfills two statutory requirements for reporting to Congress on Federal regulatory activity. The first of these reports is Office of Management and Budget's fourth report to Congress on the costs and benefits of Federal regulations as required by Section 628(a) of the FY2000 Treasury and General Government Appropriations Act. Starting next year, Section 624 of the Consolidated Appropriations Act of 2001 requires us to update this report and deliver it to Congress with the budget on an annual basis. This requirement gives us an opportunity to develop a longer run and permanent strategy to produce more comprehensive and higher quality reports. With this in mind, this year's cost-benefit report is designed to be a first step in achieving this long term goal.

The second reporting requirement on unfunded mandates is contained in Title II of the Unfunded Mandates Reform Act (the "Act"), which was signed into law on March 22, 1995 (P.L. 104-4). The Act was designed to ensure that Congress and Executive Branch agencies consider the impact of legislation and regulations on States, local governments, and tribal governments, and the private sector. With respect to States and localities, the Act was an important step in recognizing State and local governments as partners in our intergovernmental system, rather than mere entities to be regulated or extensions of the federal government through which to advance Washington's priorities. This report details the activities of the Federal government that impacted State, local, and Tribal governments between June 2000 and May 2001.

This is the first time that these two reports have been issued as one document. The reason for doing so is that both reports are attempts to provide annual information on federal regulatory activity. We hope to better integrate these reports in the future and would be interested in views on how this integration can be made a more worthwhile exercise. Together these reports represent an effort by the Administration to ensure that regulatory policy is transparent, based on sound analytical principles, and reflects the input of those who are most affected by regulatory policy. While these reports are only a first step, the Administration is committed to developing a smarter regulatory system.

Table of Contents

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

EXECUTIVE SUMMARY

Regulatory policy is critical to our nation's welfare. The Bush Administration is committed to developing a smarter regulatory system based on sound science and economics. A smarter system is more transparent, accountable, and cost-effective. It adopts cost-effective rules where market and State and local efforts fail and streamlines existing rules to make them less costly and more effective. This report takes an important step toward creating a regulatory system that "makes sense."

This document fulfills two statutory requirements for reporting Federal regulatory activity to Congress. The first of these reporting requirements is contained in appropriations statutes and directs the Office of Management and Budget to submit a Report to Congress on the Costs and Benefits of Federal Regulations. The second is contained in Title II of the Unfunded Mandates Reform Act and directs OMB to report on agency efforts to consult with intergovernmental partners. Together these two reports, Part I and Part II, represent an effort by the Administration to ensure that regulatory policy is transparent, based on sound analytical principles, and reflects the input of those most affected by regulatory policy.

Part I presents OMB's estimates of the annual costs and benefits of Federal regulation and paperwork in the aggregate, by agency and agency program, and for major rules. It also discusses OMB's analysis of the impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth. Part I uses agency regulatory impact analyses to present new quantitative estimates and qualitative descriptions of the benefits and costs of the 31 major rules issued by Federal agencies and reviewed by OMB during the 12- month period beginning April 1, 1999. It also discusses cost and benefit information for the 10 major rules independent agencies issued during this period.

The report indicates that the cost of social regulation -- health, safety, and environmental regulation -- ranged from approximately $150 billion to $230 billion per year. Estimates on benefits -- which are more difficult to measure -- ranged from $250 billion per year to more than $1 trillion. The cost of economic regulation -- transportation, energy, telecommunications, and international trade regulation -- is approximately $230 billion per year. The annual cost of paperwork or process regulation is approximately $195 billion -- $160 billion of which is for tax compliance. These estimates indicate that the total cost of regulation is nearly equal to the $584 billion Congress appropriated for all discretionary programs in FY 2000.

The first action taken by the Administration was to gain control over the regulatory pipeline by assuring that the President's appointees had time to review the large number of rules issued during the last days of the previous administration. In reviewing rules issued during the last days of the previous administration, The Bush Administration was following a precedent set by previous administrations.

The Administration next turned to designing several proposals to improve both rulemaking outcomes and the rulemaking process. Some of these proposals already have been implemented, while others are proposals still under review. Included in the proposals mentioned in Part I are a proposal to rejuvenate the "return letter," the mechanism OMB uses to deny approval to a proposed or final rule, and a new proposal to use a "prompt letter" to suggest that a new rule be adopted or that an existing rule be rescinded or revised. Also included are proposals that would increase early involvement of OMB in agency rulemaking decisions, promote peer review and sound risk assessment, analyze the impacts of rules on the nation's energy supply, and make improvements to the OMB guidelines on cost-benefit analysis.

A regulatory system that makes sense entails a targeted examination of existing rules and an assessment of whether changes to these rules are necessary. In the draft report on costs and benefits published May 2, 2001, we asked for public comments on specific regulations that if rescinded or changed would increase public welfare by either reducing costs or increasing benefits. From 33 commentators, we received 71 suggestions involving 17 agencies. Part I lists these proposals and includes OIRA's initial review of these comments.

A regulatory system that makes sense also gets stakeholders involved in regulatory decisions. Among the most critical stakeholders in the regulatory process are our intergovernmental partners. For 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 and the lack of consultation they receive on regulations that affect them. Part II of this report details Federal agency consultations with State, local and Tribal governments. Several examples that might serve as a model for successful consultation include:

- In response to concerns voiced during consultations with States, the Administration for Children and Families modified its Head Start regulations to accommodate State variation in the regulation and oversight of transportation services.

- The Fish and Wildlife Service has included Alaska natives in the development of policies related to the conservation and management of polar bears. As a result, Alaska and Russia natives will manage the polar bear harvest through enforceable quotas, seasons, and other control mechanisms.

- The Employment and Training Administration (ETA) continuously consulted with representatives of State and local stakeholders to create the definition of administrative costs

under the Workforce Investment Act (WIA). ETA worked directly with the League of Cities, the US Conference of Mayors, and the National Association of Counties to identify sites that were willing to study how modifications of administrative costs would affect WIA. ETA used this feedback to revise the administrative cost provisions before publishing the Final Rule.

- The Environmental Protection Agency (EPA) consulted with States, local governments and Tribes in drafting its proposed rule on ground water standards. In response to the concerns voiced by these stakeholders, EPA selected a risk based targeting approach to identify water systems needing improvement.

While Part II contains numerous success stories, the Administration understands that even more timely and meaningful consultation is needed to get our intergovernmental partners sufficiently involved in regulatory decision-making. The Administration is committed to ensuring that this level of consultation is achieved.

Our goal is that future regulatory reports will reflect the changes that are being undertaken now. If this is the case, the regulations described in future reports will be the products of a regulatory system that makes sense.

PART 1: Report to Congress
On The Costs and Benefits of Federal Regulations

This is the Office of Management and Budget's fourth report to Congress on the costs and benefits of Federal regulations.[1] This report is required by Section 628(a) of the FY2000 Treasury and General Government Appropriations Act (the Act). The Act requires OMB to submit "an accounting statement and associated report" containing:

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

The Act at Section 628 (b), (c), and (d) also specifies how we are to produce the report. We must:

> "(b) ... provide public notice and an opportunity to comment on the statement and report,
>
> "(c) ... issue guidelines to agencies to standardize (1) measures of costs and benefits and (2) the format of accounting statements, and
>
> "(d) ... provide for independent and external review of the guidelines and each accounting statement and associated report under this section."

In early October 1999, we drafted "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements" (Guidelines). We circulated them for "independent and external review" by nine experts in the field of benefit cost analysis. Based on these comments we finalized the Guidelines and issued them as a Memorandum for the Heads of Departments and Agencies (M-00-08) on March 22, 2000.[2] On August 7, 2000, we asked the Departments and Agencies to use

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[1] This report uses the terms "rule" and "regulation" interchangeably.

[2] See <http://www.whitehouse.gov/omb/memoranda/m00-08.pdf>

the Guidelines to provide the "accounting statements" on the benefits and costs of regulations that we would use to prepare the report to Congress on the costs and benefits of Federal regulations. Using this information as well as other information from the agencies and published literature on the costs, benefits, and impacts of Federal regulation, we prepared a draft report, which we published in the *Federal Register* on May 2, 2001 for public comment.[3] On July 2, 2001, we extended the original 60 day public comment period to August 15th at the request of several members of the public and congressional staff.

This final report is based on the draft report and the comments we received on it. In addition, it reflects suggestions from the four external and independent reviewers we asked to comment on the report.[4] It is OMB's fourth report to Congress on the costs and benefits of Federal regulation that has been required by a series of appropriations' riders asking for substantially the same regulatory information. Starting next year, Section 624 of the Consolidated Appropriations Act of 2001 requires us to update this report and deliver it to Congress with the Budget on an annual basis. This requirement gives us an opportunity to develop a strategy to produce more comprehensive and higher quality reports.

Since only a limited amount of additional information on aggregate effects has become available since the third report was issued on June 2, 2000, we are not revising our estimates of aggregate, agency, and program cost and benefits. Several commentators and a peer reviewer suggested that this not be a high priority relative to cost benefit information on recent individual regulations. In response, we present cost benefit information on the major regulations issued between April 1, 1999, and March 31, 2000. This information was not included in the 2000 report.

In the draft report for comment, we specifically asked for suggestions where the public interest would be served by updating, revising, or rescinding Federal regulations. In response to requests from commentators, we also present a list of regulations that we have selected for priority review, a list culled from the recommendations for regulatory reform that we received from the public.

As required by statute, Chapter I presents our estimates of total annual costs and benefits of Federal regulation and paperwork in the aggregate, by agency and agency program, and for major rules. It also discusses our analysis of the impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth. Chapter I uses agency regulatory impact analyses to present new quantitative estimates and qualitative descriptions of the benefits and costs of the 31 major rules issued by Federal agencies for which we concluded review during the 12- month period between April 1, 1999 and March 31, 2000. It also discusses cost and benefit information for the ten major rules issued during this period by the independent agencies. This "regulatory year" is the

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[3] See <http://www.whitehouse.gov/omb/fedreg/cb_report_notice.pdf>

[4] The names and affiliations of the peer reviewers are listed in the Appendix.

same period we used for the first three reports.

Because of the change in Administrations between the third report and this one, Chapter II presents a discussion of the how the transition affected the rulemaking process. It discusses the results of the review and "second look" process established by what has become known as the "Card Memorandum."

Chapter III presents our proposals for improving the regulatory development and review process. We developed many of our proposals after reviewing the public comments requesting advice on how to improve rulemaking outcomes and process. In particular, we present a set of new directions to follow over the next few years that reflect a more proactive, transparent, and analytical emphasis. For example, we discuss the return of the "return letter" and the birth of the "prompt letter" as a more open and analytical approach to coordinating and managing our regulatory state.

In Chapter IV, we discuss the answers the public gave us to the six questions we asked in the May 2nd draft report as well as the 18 other general suggestions received from the public to improve the report. Finally, Chapter IV prioritizes the suggestions we received on how to improve and reform 71 specific regulations.

The Appendix presents the 71 suggestions we received for reforming specific regulations, lists of the independent and external reviewers and the public commentators, and a bibliography.

Chapter I: Estimating the Total Annual Costs, Benefits, and Impacts of Federal Regulations and Paperwork

I. Overview

As required by statute, Chapter I presents our estimates of total annual costs and benefits of Federal regulation and paperwork in the aggregate, by agency and agency program, and for major rules. It also discusses our analysis of the impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth. Chapter I uses agency regulatory impact analyses to present new quantitative estimates and qualitative descriptions of the benefits and costs of the 31 major rules issued by Federal agencies for which we concluded review during the 12- month period between April 1, 1999 and March 31, 2000. It also discusses cost and benefit information for the ten major rules issued during this period by the independent agencies. This "regulatory year" is the same period we used for the first three reports.

Except for the estimates of the new major regulations, this chapter is based on Chapter II of last year's Report, *Report to Congress On the Costs and Benefits of Federal Regulations*

(OMB, 2000).[5] In the draft report published in the *Federal Register* on May 2, 2001, we asked the public six questions designed to solicit specific suggestions and information that would help us improve the estimates of costs and benefits of regulations contained in past reports. In Chapter IV, we discuss in detail the comments we received. Because the comments did not provide us with new information on costs and benefits that we could use directly to improve the estimates at this time, we are not modifying them. Most of the suggested ways to improve our estimates were of a methodological and conceptual variety.

Last year's estimates represented our third estimation attempt. Each successive report added new information, both on new and existing regulations, as it became available during the intervening period. The new information significantly affected our estimates. This was not true this year for the period April 1, 1999 to March 31, 2000. The addition of the costs and benefits of the regulations issued during this period did not significantly affect the totals. Because of uncertainty, we characterize the estimates with wide ranges. Even with these ranges, wide gaps remain in both the cost and benefit estimates due to our inability to quantify and monetize many types of costs and benefits. Many commentators (past and present) including the peer reviewers, expressed doubts about the accuracy of the estimates and suggested ways to improve the estimates, but few offered alternative estimates.[6]

Given the concerns with our estimates and new statutory requirements to do this report on an annual basis, we are stepping back and taking a more careful look at both the methodologies and assumptions behind the hundred or so individual studies upon which our estimates are based and our approach to aggregating them.

On March 22, 2000, we issued "Guidelines to Standardize Measures of Costs and Benefits and the Formats of Accounting Statements" (OMB Memorandum M-00-08), which dealt with many of the challenges that analysts face in estimating the costs and benefits of individual regulations. Most analyses of the impacts of regulations are not simple or clear cut. Many equally plausible assumptions exist and when strung together can provide widely divergent results. Guidelines call for sensitivity analysis when more than one reasonable assumption or estimating technique exists. Moreover to be credible and to assure high quality, the Guidelines require transparency. All assumptions and results should be described and explained. This is difficult enough for one regulation and herculean for all.

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[5] The report may be found on OMB's home page at:
http://www.whitehouse.gov/omb/inforeg/2000fedreg-report.pdf
The charts are in a separate file at:
http://www.whitehouse.gov/omb/inforeg/2000fedreg-charts.pdf

[6] See Chapter I of last year's report, which presents a discussion of the peer reviewers' and public's comments on last years draft report as well as Chapter IV of this year's report.

II. The Costs and Benefits of Regulation and Paperwork

Since there are so many different types of Federal regulation, it is useful to break rules down into categories. Three main categories of regulations are widely used: social, economic, and process. The discussions in earlier reports provide examples for each of these categories.

A. Social Regulation

Table 1 presents estimates of the total annual costs and benefits of Federal health, safety and environment rules issued between 1987 and 2000. Table 2 presents the total costs and benefits of Federal health, safety, and environmental rules as of the first quarter of 2000.[7] The estimates are the same as those in last year's report. Unlike the previous reports, this one does not include information about new regulations issued during the last year. There are several reasons for this. First, during the past year, there were only six new regulations for which agencies provided quantified information on both benefits and costs. Their effect on the cumulative aggregate estimates would be small. Second, for three of these six rules, the agency provided information for only a limited period after the rule takes effect. In one case, the agency estimated benefits for only one year and that year occurs more than 20 years after the rule will take effect. For at least three of them, it is also likely that their inclusion would constitute double-counting with estimates from prior years.

B. Economic Regulation

In our 1997, 1998, and 2000 reports, we presented an estimate that the efficiency costs of economic regulation amounted to $71 billion. This is based on an estimate by Hopkins (1992) of $81 billion, which we adjusted downward by $10 billion to account for the deregulation and increased competition that has occurred in the financial and telecommunications sectors since Hopkins' 1992 estimates. In a recent comprehensive report on regulatory reform in the United States by a panel of experts from around world, the OECD estimated that additional reforms in the transportation, energy, and telecommunications sectors would lead to an increase in GDP of 1 percent (OECD, 1999). One percent of the revised first quarter 2001 GDP of $10.1 trillion is about $100 billion.

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[7] Table 2 differs from Table 1 by adding the estimates of the costs and benefits of rules issued before 1988 to the Table estimates. As several commenters and peer reviewers pointed out, these latter estimates are quite problematic and even the large ranges that we present may not capture the correct numbers. The benefits are dominated by a very large Environmental Protection Agency estimate of $1.25 trillion which is largely attributed to the projected health benefits of cleaner air. OMB remains concerned about the plausibility of these estimates. These concerns are also described in detail in earlier reports.

Table 1:
Estimates of Total Annual Monetized Costs and Monetized Benefits of Social Regulations Issued Between 1987 and First Quarter of 2000
(Billions of 1996 dollars)

	Environ-mental	Transpor-tation	Labor	Other	Total
Costs	71	6	7	7	92
Benefits	75 to 145	50	28 to 30	45 to 49	198 to 274

Source: The 1987 to 1994 estimates of costs are from OMB (1996) p. A-5. The 1987 to 1994 estimates of benefits are calculated by taking the benefit/cost ratios for the final rules issued between 1990 and 1995 from Hahn (1996) Table 10-4 and applying them to our costs estimates to derive benefit estimates. (See caveats above and the discussion in OMB (1997) for the rationale for this approach). The benefit/cost ratios are 1.4 for environmental, 9.7 for transportation, 3.8 for labor and 7.9 for other social regulations. The estimates for 1995 through the first quarter of 2000 are derived as described in tables 6 through 17(OMB 2000). Note that totals may not add because of rounding.
Note: The dollar figures in this table do not reflect benefits that were quantified but not monetized. They also do not reflect benefits and costs(including indirect costs) that were not quantified.

Table 2:
Estimates of Total Annual Monetized Costs and Monetized Benefits of Social Regulations
(Billions of 1996 dollars as of 2000, Q1)

	Environ-mental	Transpor-tation	Labor	Other	Total
Costs	$96 to 170	$15 to 18	$18 to 19	$17 to 22	$146 to 229
Benefits	$97 to 1,610[b]	$84 to 110	$28 to 30	$45 to 49	$254 to 1,799
Net Benefits[a]	$-73 to 1,514	$66 to 95	$9 to 12	$23 to 32	$25 to 1,653

Source: Tables 1,2 and 3 from (OMB 2000).
[a] Lower estimate calculated by subtracting high cost from low benefit. Higher estimate calculated by subtracting low cost from high benefit.
[b] This benefits estimate is dominated by an EPA estimate that the benefits of air pollution reduction are $1.25 trillion. OMB remains concerned about the plausibility of these estimates. These concerns are also described in more detail in earlier reports.
Note: The dollar figures in this table do not reflect benefits that were quantified but not monetized. They also do not reflect benefits and costs (including indirect costs) that were not quantified.

This estimate does not include the costs of international trade protection, which Hopkins included in his estimate of the cost of economic regulation. According to a recent study, the static gains from removing trade barriers existing in 1990 would be about 1.3 percent of GDP (Council of Economic Advisers 1998) or $130 billion for the first quarter of 2001, assuming trade barriers have not changed.[8] These estimates taken together suggest that Hopkins' estimate may be too low.

Economic regulation also results in income transfers from one group to another. In our previous three reports, we used an approach used by Hahn and Hird, and Hopkins, to estimate transfers as a multiple of the efficiency losses. Based on the OECD estimate of efficiency losses, Hopkins' multiple of two (1992) gives rise to an estimate of transfer costs for economic regulation (not counting trade protection) of $200 billion. Since transfers are not net costs to society (one person's loss in another's gain), transfers should not be added to our other costs estimates. Nevertheless, transfers may affect economic incentives and produce indirect costs to society.

C. Process Regulation

The main costs of process regulation consist of the paperwork costs imposed on the public. Section 638(a)(1)(A) of the Act calls on OMB to examine the costs and benefits of paperwork. OMB has worked in the past with IRS on this issue. Currently, IRS is developing the first phase of a new model that will estimate the amount of burden incurred by wage and investment taxpayers as a result of complying with the tax system. IRS has undertaken this study to improve our understanding of taxpayer burdens, to enable us to measure both current and future levels of burden, and to help us isolate the burden of particular tax provisions, regulations, or procedures. To help provide input into our reporting of monetized burdens, the IRS paperwork burden study included the development of a White Paper, "Revealed and Stated Preference Estimation of the Value of Time Spent for Tax Compliance" (Cameron 2000).

In our *Information Collection Budgets*, published annually, we calculate paperwork burden imposed on the public, using information that agencies give us with their information collection requests. Below in Table 3, we present estimates of paperwork burden in terms of the hours the public devotes annually to gathering and providing information for the Federal government. At a future point in time, we hope to be able to provide information on the dollar cost of paperwork burden imposed by Federal agencies. At present, we do not know how to estimate the value of the total annual benefits to society of the information the government collects from the public.

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[8] The CEA report also went on to state that studies of this type only capture static costs, fail to capture value of foregone varieties of products, quality improvements, and productivity enhancements that would take place in the absence of trade barriers, and thus understate the benefits from trade (CEA 1998, p. 238).

Table 3
Information Collection Budget for FY 2000
(millions of hours)

Department/Agency	Expected Total Hour Burden
Agriculture	75.19
Commerce	38.57
nonperiodic	7.99
periodic	30.58
Defense	93.62
Education	41.98
Energy	2.92
Health and Human Services	173.71
Housing and Urban Development	12.46
Interior	5.64
Justice	36.82
Labor	181.59
State	29.19
Transportation	117.65
Treasury	6,156.80
Veterans Affairs	5.98
EPA	128.75
FAR	23.30
FCC	29.01
FDIC	8.27
FEMA	5.14
FERC	3.70
FTC	73.76
NASA	7.19
NSF	4.75
NRC	9.52
SEC	71.78
SBA	2.18
SSA	22.27
Government Total	7,361.72

Table 3 shows our estimates of the expected paperwork burden hours for FY 2000 by agency. The total burden of 7,362 million hours is made up of 6,157 million hours for the Treasury Department (84 percent) and 1,205 million hours for the rest of the Federal government (16 percent). Using the estimate of average value of time from our previous three reports ($26.50 per hour for individuals and entities that provide information to the government), we derive a cost estimate of public paperwork of $195 billion. Note, however, that (1) this is a rough average and should not be applied to individual agencies or agency collections, and (2) this estimate should not be added to our estimates of the costs of regulation because it would result in some double counting. Our estimates of regulatory costs already include some paperwork costs. Many paperwork costs arise from regulations, often for enforcement and disclosure purposes.[9]

III. The Other Impacts of Federal Regulation

Sec. 638 (a)(2) of the Act calls on OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth.

A. Impact on State, Local, and Tribal Government

Over the past five years, five rules have imposed costs of more than $100 million on State, local, and Tribal governments (and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995).[10] All five of these rules were issued by the Environmental Protection Agency. These rules are described in greater detail below.

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[9] One way to eliminate overlap is to focus on tax compliance costs by using the burden estimate for the Treasury Department. This produces an estimate of $160 billion.

[10] 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 on 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 air quality standards are health-based and EPA is not to consider costs.

1. *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 aggregate capacities to combust greater than 35 megagrams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The standards require sources to achieve emission levels reflecting the maximum degree of reduction in emissions of air pollutants that the Administrator determined is achievable, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements.

   EPA estimated the national total annualized cost for the emissions standards and guidelines to be $320 million per year (in constant 1990 dollars) over existing regulations. EPA estimated the cost of the emissions standards for new sources to be $43 million per year. EPA estimated the cost of the emissions guidelines for existing sources to be $277 million per year. The annual emissions reductions achieved through this regulatory actions include, for example, 21,000 Mg. of SO2; 2,800 Mg. of particulate matter (PM); 19,200 Mg of NOX; 54 Mg. of mercury; and 41 Kg. of dioxin/furans.

2. *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 to implement 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 remainder are publicly owned. The total nationwide annualized costs for collection and control of air emissions from new and existing MSW landfills are estimated to be $94 million per year annualized over 5 years, and $110 million per year annualized over 15 years.

3. *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 affected by this rule. 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. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

4. *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 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 mean reductions of from 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.

5. *National Pollutant Discharge Elimination System – Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule would expand the existing National Pollutant Discharge Elimination System program for storm water to cover smaller municipal separate storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain of these 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."

While these five EPA rules were the only ones over the past five 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, 15%, 10%, and 6% of rules listed in the April 2000 Unified Regulatory Agenda cited some impact on State, local or Tribal governments, respectively. In general, OMB works with the agencies to ensure that the selection of the regulatory option for all final rules complies fully with the Unfunded Mandates Reform Act. For proposed rules, OMB works with the agencies to ensure that they also solicited comment on alternatives that would reduce costs to all regulated parties, including State, local and Tribal governments.

Agencies have also significantly increased their consultation with State, local, and Tribal governments on all regulatory actions that impact them. For example, EPA and the Department of Health and Human Services have engaged in particularly extensive consultation efforts over a wide variety of programs, on both formal unfunded mandates as defined by the Unfunded Mandates Reform Act and other rules with intergovernmental impacts. Agencies have also made real progress in improving their internal systems to manage consultations better. This has helped them analyze specific rules in ways that reduce costs and increase flexibility for all levels of government and for the private sector, while implementing important national priorities.

This Administration will bring more uniformity to the consultation process to help both agencies and our intergovernmental partners know when, how and with whom to communicate. States and localities should have a clear point of contact in each agency, and agencies must understand that "consultation" means more than making a telephone call the day before a rulemaking action is published in the Federal Register. Finally, this Administration will enforce the Unfunded Mandates Reform Act to ensure that agencies are complying with both the letter and the spirit of the law. If an agency is unsure whether a rule contains a significant mandate, it should err on the side of caution and prepare an impact statement prior to issuing the regulation.

Clearly more still needs to be done to ensure that this consultation takes place in all instances where it is needed and early in the federal decisionmaking process. Toward that end, the President established an Interagency Working Group on Federalism. Devolving authority and responsibility to State and local governments, and to the people, is a central tenet of the President's management of the Executive Branch and this working group is striving to turn this principle into policy.

B. Impact on Small Business

The Administration explicitly recognizes the need to be sensitive to the impact of regulations and paperwork on small business with 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 streamlined 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.

This observation is supported by empirical information from a study sponsored by the Office of Advocacy of the Small Business Administration (Crain and Hopkins 2001). 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 (2001) estimates that the total cost of 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.[11]

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[11] The average per employee regulatory costs were $6,975 for firms with under 20 employees compared to $4,463 for firms with over 500 employees. These findings are based on their overall estimate of the cost of Federal regulation for 2000 of $843 billion. (See Crain and Hopkins, "The Impact of Regulatory Costs for Small

These results do not indicate, however, the extent to which reducing regulatory requirements on small firms would affect net benefits. That depends upon the differences between relative benefits per dollar of costs by firm size, not on differences in costs per employee. If benefits per dollar of costs are smaller for small firms than large firms, then decreasing requirements for small firms while increasing them for large firms should increase net benefits. The reverse may be true in some cases.

C. Impact on Wages

The impact of Federal regulations on wages depends upon how "wages" is 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

By a broad measure of welfare, social regulation, regulation directed at improving health, safety, and the environment, is intended to create benefits for workers and consumers that outweigh the costs. 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 text book 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]

Viewed in terms of overall welfare, the regulatory benefits of improved health, safety, and environmental improvements for workers can outweigh their costs assuming the regulation produces net benefits. 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.[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 benefitting from safer products and a cleaner environment may also come out ahead if regulation produces significant net

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Firms" SBA, Office of Advocacy, 2001).

[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).

benefits for society.

2. Economic Regulation

For economic regulation, designed to set prices or conditions of entry for specific sectors, these effects may at times be reversed to some degree. Economic regulation can result in increases in income narrowly defined for workers in the regulated industries, 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. Examples include the airline and trucking industries in the 1970's and trade protection, today. These wage gains come at a cost in inefficiency from reduced competition, however, which consumers must bear. Moreover, real wages, which depend upon productivity, will not grow as fast without the stimulation of outside competition.[14]

These statements are generalizations for 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.

D. Economic Growth

The conventional measurement of GDP does not take into account the market value of improvements in health, safety, and the environment. It does incorporate the direct compliance costs of social regulation. Accordingly, conventional measurement of GDP can suggest that regulation reduces economic growth.[15] In fact, sensible regulation and economic growth are not inconsistent once all benefits are taken into account. By the same token, inefficient regulation reduces true economic growth.

The OECD (1999) estimates that the economic deregulation that occurred in the US over the last 20 years permanently increased GDP by 2 percent. The OECD also estimates that further deregulation of the transportation, energy, and telecommunication sectors would increase US GDP by another 1 percent. Jaffe, Peterson, Portney, and Stavins (1995) summarize their findings after surveying the evidence of the effects of environmental regulation on economic growth as follows: "Empirical analysis of the productivity effects have found modest adverse impacts of environmental

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[14] Winston (1998) estimates that real operating costs declined between 25 and 75 percent in the sectors that were deregulated over the last 20 years -- transportation, energy, and telecommunications.

[15] Social regulation reduces measured growth by diverting resources from the production of goods and services that are counted in GDP to the production or enhancement of "goods and services" such as longevity, health, and environmental quality that generally are not counted in GDP.

regulation." Based on the studies that tried to explain the decline in productivity that occurred in the US during the 1970's, they placed the range attributable to environmental regulation from 8 percent to 16 percent (p. 151).

As indicated above, conventionally measured GDP growth does not take into account the market value of the improvements in health, safety, and the environment that social regulation has brought us. If even our lower range estimate of the benefits of social regulation ($266 billion) were added to GDP, then the more comprehensive measure of GDP, one that includes the value of nonmarket goods and services provided by regulation, would be about 3 percent greater.[16] Focusing on the effect of social regulation on economic growth is misleading if it does not take into account the full benefits of regulation.

More important than knowing the impact of regulation in general on growth is the impact of specific regulations and alternative regulatory designs on economic growth. As Jaffe *et al* put it: "Any discussion of the productivity impacts of environmental protection efforts should recognize that not all environmental regulations are created equal in terms of their costs or their benefits." (p 152).

In this regard, market-based or economic-incentive regulations will tend to be more cost-effective than those requiring specific technologies or engineering solutions. Under market-based regulation, profit-maximizing firms have strong incentives to find the cheapest way to produce the social benefits called for by regulation. How you regulate can go a long way toward reducing any negative impacts on economic growth and increasing the overall long run benefits to society.

IV. Estimates of Benefits and Costs of This Year's "Major" Rules

In this section, we examine the benefits and costs of each "major rule," as required by section 628(a)(1)(C). We have included in our review those final regulations on which OMB concluded review during the 12-month period April 1, 1999, through March 31, 2000. This "regulatory year" is the same calendar period we have used for our three previous reports.

The statutory language categorizing the rules we consider for this report differs from the definition of "economically significant" in Executive Order 12866 (section 3(f)(1)). 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

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[16] Including the value of increasing life expectancy in the GDP accounts to come up with a more comprehensive measure of the full output of the economy is not as far fetched as it sounds. It was first proposed and estimated in 1973 by D. Usher in "An Imputation to the Measure of Economic Growth for Changes in Life Expectancy" *NBER Conference on Research in Income and Wealth.*

these varying definitions, we interpreted section 638(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)

- rules designated as meeting the threshold under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1531 - 1538)

We also include 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 General Accounting Office (GAO) under the Congressional Review Act.

During the regulatory year selected, OMB reviewed 31 final rules that met the criteria noted above. Of these final rules, HHS submitted eight; EPA six; USDA six; DOT three; DOI three; and DOC, HUD, FEMA, and the Emergency Oil and Gas Guarantee Loan Board and the Emergency Steel Guarantee Loan Board, one each. These 31 rules represent about 16 percent of the 190 final rules reviewed by OMB between April 1, 1999, and March 31, 2000, and less than one percent of the 4,679 final rule documents published in the *Federal Register* during this period. Nevertheless, because of their scale and scope, we believe that they represent the vast majority of the costs and benefits of new Federal regulations issued during this period.

A. Overview

We found that the benefit cost analyses accompanying the 31 final rules listed in Table 4 vary substantially in type, form, and format of the estimates the agencies generated and presented. For example, agencies developed estimates of benefits, costs, and transfers that were sometimes monetized, sometimes quantified but not monetized, sometimes qualitative, and, most often, some combination of the three.

TABLE 4: SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00
(As of date of completion of OMB review)

AGENCY	RULE	BENEFITS	COSTS	OTHER INFORMATION
USDA	Irradiation of Meat Food Products	Not Estimated	$35 - 105 million/yr. (1995 dollars) assuming 25 percent of ground beef irradiated	"Society also may realize benefits from these final regulations if the use of irradiation results in a reduction of illnesses beyond what is achieved by current technologies. Several types of harmful microbial pathogens can be present in meat food products, including E. coli O157:H7, Salmonella, Clostridium perfringens, and the protozoan parasite Toxoplasma gondii. Irradiation at the dose levels allowed by this action can reduce the levels of these pathogens substantially. Economic benefits associated with these reductions would be decreases in the diseases associated with these pathogens. The reductions in the disease rates would translate into a reduction in the number of visits to physicians and hospitals." [64FR72163]
DOC	Endangered and Threatened Species; Threatened Status for Two Chinook Salmon ESUs	Not Estimated	Not Estimated	

TABLE 4: SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00
(As of date of completion of OMB review)

AGENCY	RULE	BENEFITS	COSTS	OTHER INFORMATION
HUD	Lead-Based Paint Hazards	$715.6 million (1996 dollars) for first five years of activity	$564.2 million (1996 dollars) for first five years of activity	Costs and benefits include the present value of future costs and benefits associated with the first five years of hazard reduction activities. Monetized benefits based on prevention of elevated blood lead levels (EBLs) in children. "Such benefits include avoiding the costs of special education and medical treatment for EBL children, as well as increasing lifetime earnings associated with higher IQs for children with lower blood lead levels." [64FR50187] "The monetized benefit of increased lifetime earnings due to lower blood lead levels accounts for 99 percent of all monetized health benefits of the rule." [64FR50187] "HUD believes that an intergenerational discount rate is applicable to the final rule because the costs will be borne by adult taxpayers, and lifetime earnings will be realized by the children and grandchildren of these adult taxpayers." [64FR50186] Application of a 3% discount rate implies a benefit estimate of $2.65 billion for the first five years of activity.
DOI	Migratory Bird Hunting (Early Season Frameworks)	$50-192 million/yr.	Not Estimated	"Estimates of individual's willingness to pay indicate the size of this benefit. Willingness to pay for generally improved duck hunting in California was $32. Willingness to pay for taking twice as many birds in Montana was $123. Expanding these estimates nationwide, the welfare benefit of the duck hunting frameworks in on the order of $50 to $192 million" (RIA, p. 1).
DOI	Migratory Bird Hunting (Late Season Frameworks)	$50-192 million/yr.	Not Estimated	"Estimates of individual's willingness to pay indicate the size of this benefit. Willingness to pay for generally improved duck hunting in California was $32. Willingness to pay for taking twice as many birds in Montana was $123. Expanding these estimates nationwide, the welfare benefit of the duck hunting frameworks in on the order of $50 to $192 million" (RIA, p. 1).

TABLE 4: SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00
(As of date of completion of OMB review)

AGENCY	RULE	BENEFITS	COSTS	OTHER INFORMATION
DOT	Light Truck CAFÉ Model-Year 2002	Not Estimated	Not Estimated	
EPA	Storm Water Discharges (Phase II)	$671.5 million/yr.- 1.628 billion/yr. (1998 dollars)	$847.6 - 981.3 million/yr. (1998 dollars)	Estimates of individual willingness to pay for water quality improvements in fresh water and marine water indicate the size of the monetized benefit. "There are additional benefits to storm water control that cannot be quantified or monetized. Thus, the current estimate of monetized benefits may understate the true value of storm water controls because it omits many ways in which society is likely to benefit from reduced storm water pollution, such as improved aesthetic quality of waters, benefits to wildlife and to threatened and endangered species, cultural values, and biodiversity benefits." [64FR68794]
EPA	Tier 2 / New Motor Vehicle Emissions Standards	$13.7 - 25.2 billion/yr. (1997 dollars) in 2030.	$5.3 billion/yr. (1997 dollars) in 2030.	Agency estimates are based on analysis of 2030. Estimates represent "a single year 'snapshot' of the yearly benefits and costs expected to be realized once the standards have been fully implemented and non-compliant vehicles have all been retired. Near-term costs will be higher than long-run costs as vehicle manufacturers and oil companies invest in new capital equipment and develop and implement new technologies. In addition, near-term benefits will be lower than long-run benefits because it will take a number of years for Tier 2-compliant vehicles to fully displace older, more polluting vehicles." [65FR6783] "A full appreciation of the overall economic consequences of the Tier 2/gasoline sulfur standards requires consideration of all benefits and costs expected to result from the new standards, not just those benefits and costs which could be expressed here in dollar terms." [65FR6785]

TABLE 4: SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00
(As of date of completion of OMB review)

AGENCY	RULE	BENEFITS	COSTS	OTHER INFORMATION
EPA	Regional Haze Rule	$0.8 - 19.3 billion/yr. (1990 dollars) in 2015	$0.8 - 4.4 billion/yr. (1990 dollars) in 2015	Agency estimates are based on analysis of effects in 2015. Monetized benefits reflect improvements in health and visibility. "This benefit analysis does not quantify all potential benefits or disbenefits. The magnitude of the unquantified benefits associated with omitted categories, such as damage to ecosystems or damage to industrial equipment and national monuments, is not known." [RIA, p.9-1] EPA notes that "the RIA is not a precise reflection of the actual costs, economic impacts, and benefits associated with the progress goals and emission management strategies developed as a result of the final regional haze rule. This is due to the fact that under the regional haze rule, the States bear the primary responsibility for establishing reasonable progress goals as well as emission management strategies for meeting these goals. Until such time as the States make those decisions, EPA can only speculate as to which goals may be established and what types of control requirements or emission limits might result from the associated emission management strategies." [64FR35760]

TABLE 4: SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00
(As of date of completion of OMB review)

AGENCY	RULE	BENEFITS	COSTS	OTHER INFORMATION
EPA	Handheld Engines	$80 million /yr. in fuel savings (1998 dollars) plus 310,000 tons/yr. combined annualized emission reductions in tons of nitrogen oxides and hydrocarbons	$180 - $240 million/year (1998 dollars)	Agency expects additional reductions in CO levels beyond Phase I levels, due to improved technology. These potential benefits have not been estimated. [65FR24296]
EPA	Section 126 Petitions for Purposes of Reducing Interstate Ozone Transport	$0.9 - 1.4 billion/yr. (1997 dollars)	$1.15 billion/yr. (1997 dollars)	

TABLE 4: SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00
(As of date of completion of OMB review)

AGENCY	RULE	BENEFITS	COSTS	OTHER INFORMATION
EPA	Persistent Bio-accumulative Toxic Chemicals	Not estimated	$147 million in the first year; $82 million/yr. thereafter	"Because the state of knowledge about the economics of information is not highly developed, EPA has not attempted to quantify the benefits of adding chemicals to EPCRA section 313 or changing reporting thresholds. Furthermore, because of the inherent uncertainty in the subsequent chain of events, EPA has also not attempted to predict the changes in behavior that result from the information, or the resultant net benefits (i.e., the difference between benefits and costs). EPA does not believe that there are adequate methodologies to make reasonable monetary estimates of either the benefits of the activities required by the rule, or the follow-on activities. The economic analysis of the rule, however, does provide illustrative examples of how the rule will improve the availability of information on PBT chemicals (Ref. 67)." [64FR58743]

TABLE 4: **SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00**

(As of date of completion of OMB review)

TRANSFER RULES

Dept. of Agriculture (USDA)

Dairy Market Loss assistance Program
Crop Loss Disaster Assistance Program (1998)
Crop Loss Disaster Assistance Program (1999)
Food Stamp Provisions
New England Milk Marketing Orders

Dept. of Health and Human Services (HHS)

Physician Fee Schedule for CY2000
Vaccine Injury Compensation Program: Addition of Rotavirus Vaccines
Medicare Program: Prospective Payment System for Hospital Outpatient Services
Medicare Program: Changes to Hospital Inpatient Prospective Payment Systems
Medicare Program: Medicare Disproportionate Share Hospital Adjustment Calculation

Dept. of the Interior (DOI)

Bureau of Indian Affairs: Indian Reservation Roads Funds for FY2000

Dept. of Transportation (DOT)

Credit Assistance for Surface Transportation Projects
Operation of Motor Vehicles by Intoxicated Drivers

TABLE 4: **SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 4/1/99 - 3/31/00**
(As of date of completion of OMB review)

TRANSFER RULES

Emergency Oil and Gas Guaranteed Loan Board

Emergency Oil and Gas Guaranteed Loan Program

Emergency Steel Guarantee Loan Board

Emergency Steel Guarantee Loan Program

Federal Emergency Management Agency (FEMA)

Hurricane Floyd Property Acquisition and Relocation Grants

Social Security Administration

Old-Age, Survivors, and Disability Insurance and Supplemental Security Income for Aged, Blind, and Disabled
Revised Medical Criteria for Determination of Disability, Endocrine System and Related Criteria
Effective Date of Application for Supplemental Security Income (SSI) Benefits

B. Social Regulation

Of the 31 economically significant rules reviewed by OMB, 12 are regulations requiring substantial additional private expenditures and/or providing new social benefits,[17] as described in Table 4.[18] EPA issued six of these rules; DOI two; and USDA, DOC, HUD, and DOT one each. Agency estimates and discussion are presented in a variety of ways, ranging from a purely qualitative discussion, for example, the benefits of USDA's irradiation rule, to a more complete benefit-cost analysis, for example, EPA's storm water discharges rule.

1. Benefits Analysis.

Agencies monetized at least some benefit estimates for seven of the 12 rules including: (1) HUD's estimate of $715.6 million over the first five years from reduced lead exposure; (2) DOI's estimate of $50 to $192 million per year in benefits from its migratory bird hunting regulations; and (3) EPA's $.8 to $19.3 billion per year in human health and visibility improvements from its regional haze rule. In one case, the agency provided some of the benefit estimates in monetized and quantified form, but did not monetize other, important quantified components of benefits. EPA's analysis of its handheld engines rule monetized the projected fuel savings, but not the estimated hydrocarbon and nitrogen oxide emission reductions.

In three cases, agencies did not report any quantified (or monetized) benefit estimates. In one case, the agency provided a qualitative description of benefits. USDA's irradiation rule discusses the benefits associated with the reductions in diseases associated with reduced pathogen exposure.

2. Cost Analysis.

For eight of the 12 rules, agencies provided monetized cost estimates. These include such items as USDA's estimate of $35 to $105 million per year as the cost of its irradiation rule and EPA's estimate of $5.3 billion in the year 2030 as the cost of its Tier 2 rule. For the remaining four rules, the agencies did not estimate costs. These rules included DOI's two migratory bird hunting rules, DOC's endangered species rule and NHTSA's light truck fuel economy rule.

3. Net Monetized Benefits.

Six of the 12 rules provided at least some monetized estimates of both benefits and costs. Of those, three have positive net monetized benefits, that is, estimated monetized benefits that

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[17] The other 19 are "transfer" rules.

[18] Note that all dollar figures Table 4 are in 1996 dollars unless otherwise noted.

unambiguously exceed the estimated monetized costs of the rules. For example, HUD's lead-based paint rule will generate an estimated net benefit of about $150 million (present value) over its first five years. EPA's tier 2 rule will result in an estimated net benefit of between $8.5 and $19.9 billion in 2030. One, EPA's handheld engines rule, has negative net monetized benefits because EPA only monetized final savings and did not attempt a quantitative benefits analysis for other benefit categories. Since EPA did not develop benefit estimates for the expected emission reductions of this rule, we can not determine whether the benefits exceed the costs.

Two EPA rules yielded estimates that included the possibility of both positive or negative net benefits. For example, EPA's storm water rule was estimated to generate between $671.5 million and $1.63 billion in benefits and between $848 and $981 million in costs. The monetized benefit and cost estimates for EPA's Section 126 rule are essentially equal.

4. Rules Without Quantified Effects.

Two of the rules in Table 4 are classified as economically significant even though the agency did not provide any quantified estimates their effects.

DOC - Threatened Status for Two Chinook Salmon ESUs: Based upon publicly available information, OMB determined that rules covering these species were major. Citing the Conference Report on the 1982 amendments to the Endangered Species Act, however, the agency did not perform a benefit-cost analysis of the final rules. This report specifically provides that economic impacts cannot be considered in assessing the status of a species.

DOT - Light Truck CAFE: For each model year, DOT must establish a corporate average fuel economy (CAFE) standard for light trucks, including sport-utility vehicles and minivans. (DOT also sets a separate standard for passenger cars, but is not required to revisit the standard each year.) For the past five years, however, appropriations language has prohibited NHTSA from spending any funds to change the standards. In effect, it has frozen the light truck standard at its existing level of 20.7 miles per gallon (mpg) and has prohibited NHTSA from analyzing effects at either 20.7 mpg or alternative levels. Although DOT did not estimate the benefits and costs of the standards, the agency's experience in previous years indicates that they may be substantial. Over 5 million new light trucks are subject to these standards each year, and the standard, at 20.7 mpg, is binding on several manufacturers. In view of these likely, substantial effects, we designated the rule as economically significant even though analysis of the effects was prohibited by law.

C. Transfer Regulations

Of the 31 rules listed in Table 4, 19 implement Federal budgetary programs. The budget outlays associated with these rules are "transfers" to program beneficiaries. Of the 19, three are USDA rules implementing Federal appropriations language regarding disaster aid for farmers; one deals with

the food stamp program; five are HHS rules implementing Medicare and Medicaid policy; three deal with social security eligibility; two are DOT rules regarding grants to states to pay for highway projects and reduce intoxicated driving; one is a BIA rule regarding funding for road-building on Indian reservations; two are loan guarantees (oil and gas, and steel); and one is a FEMA rule providing assistance to the victims of Hurricane Floyd.

D. Major Rules for Independent Agencies

The Congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) require the General Accounting Office (GAO) to submit reports on major rules to the Committees of jurisdiction in both Houses of Congress, including rules issued by agencies not subject to Executive Order 12866 (the "independent" agencies). We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of April 1, 1999 to March 31, 2000. GAO reported that four independent agencies issued ten major rules during this period. GAO reported that the agencies said they were not required to do benefit-cost analysis for the ten rules. We list the agencies and the type of information provided by them (as summarized by GAO) in Table 5.

In comparison to the agencies subject to E.O. 12866, the independent agencies provided relatively little quantitative information on the costs and benefits of the major rules. As Table 5 indicates, seven of the ten rules included some discussion of benefits and costs. None of the ten regulations had any monetized cost information; one regulation monetized benefits.

The one rule that estimated benefits was "Regional Transmission Organizations (RTO)" by the Federal Energy Regulatory Commission. The rule cited an estimate that EPA produced in connection with the environmental assessment that RTO formation would result in annual benefits of $2.4 billion.

Table 5
Benefit and Cost Information on Independent Agency Rules

Agency	Total Rules	Rules with Some Information on Costs or Benefits	Monetized Information on Costs	Monetized Information on Benefits
Federal Communications Commission (FCC)	5	2	0	0
Securities and Exchange Commission (SEC)	3	3	0	0
Nuclear Regulatory Commission (NRC)*	1	1	0	0
Federal Energy Regulatory Commission (FERC)	1	1	0	1
Total	10	7	0	1

* The NRC states that this rule is statutorily required and not appropriate for the usual cost-benefit analysis. (See comment 22).

Chapter II: Impact of the Change in Administrations on the Rulemaking Process

During the transition between the Clinton and Bush Administrations, Federal agencies continued to develop regulations and publish them in the *Federal Register*. Many final rules published during this period were not yet effective at the start of the Bush Administration, since final regulations typically go into effect one or two months after publication. Other rules that agencies had not yet published were still under development at the agencies, were under review at the Office of Management and Budget, or were pending at the *Federal Register* for publication. While the vast majority of regulations issued at the end of the Clinton Administration were not significant or controversial, several of them were, such as the Forest Service's "Roadless" rule and EPA's rule on arsenic in drinking water.

One of the first actions taken by the incoming Bush Administration was asserting control over the regulatory process. This underscored the importance of regulatory policy and reflected a long-standing, bipartisan consensus supporting the President's authority to oversee Executive Branch rulemaking. Following the practice of the Reagan and Clinton Administrations, the Bush Administration sought to ensure that its new political appointees in the agencies had the opportunity to review regulations that had either not been issued or had not yet become effective. In doing so, Bush Administration policy officials could decide whether or not to modify these regulations and/or issue them.

To implement this policy, the Chief of Staff to President Bush, Andrew H. Card, Jr., issued a memorandum to the heads of agencies on January 20, 2001 – the day of President Bush's inauguration – that outlined the President's "plan for managing the Federal regulatory process at the outset of his Administration." The memo, entitled "Regulatory Review Plan" and subsequently referred to as the "Card Memorandum," directed agency heads to take various steps to "ensure that the President's appointees have the opportunity to review any new or pending regulations."[19] Specifically, the memorandum prohibited agencies from submitting proposed and final regulations to the *Federal Register* after noon on January 20th unless they had been reviewed by agency heads appointed by President Bush or exempted by the OMB Director due to an "emergency or other urgent situations relating to health and safety." Regulations subject to statutory or judicial deadlines were also exempted.

The Card Memorandum also addressed regulations that had been approved by agencies during the Clinton Administration. For regulations agencies had already sent to the *Register* but were not yet published, the memo directed agencies to withdraw them from the *Federal Register* unless they were approved by a Bush-appointed official. For those regulations that had been published in the *Federal*

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[19] See <http://www.whitehouse.gov/omb/inforeg/regreview_plan.pdf> for a copy.

Register but were not yet in effect, the memorandum instructed agencies to extend their effective dates by 60 days unless a Bush-appointed official determined that an extension was not necessary.

Following the Card Memorandum, on January 26, 2001, OMB Director Mitchell E. Daniels, Jr., issued OMB Memorandum M-01-09, "Effective Regulatory Review." The OMB memorandum was intended to ensure effective implementation of the Card Memorandum and reaffirm the procedures for formally submitting regulations to OMB's Office of Information and Regulatory Affairs (OIRA) for review under Executive Order 12866, Regulatory Planning & Review (58 Fed. Reg. 51735, 51742 (1993)). The OMB memorandum asked agencies, subject to the exemptions described in the Card Memorandum, to withdraw from OIRA review any regulations submitted on or before January 20, 2001.

With the guidance provided by the Card Memorandum and OMB Memorandum M-01-09, agencies proceeded to withdraw regulations pending at the *Federal Register* and at OMB. Agencies were thus able to ensure that Bush appointees could review and approve these rules. Agencies then worked with OIRA to process them under the existing regulatory review and clearance procedures established in Executive Order 12866.

Agencies acted quickly in response the Card Memorandum and OMB Memorandum M-01-09. According to an informal poll of the agencies conducted by OIRA, as of early February, agencies withdrew a total of 124 regulations that were in the publication "queue" at the *Federal Register*. OMB's records indicate that agencies withdrew 130 regulations from OIRA review between January 20, 2001, and May 18, 2001. Pursuant to the Card Memorandum and OMB guidance, the President's appointees reviewed the withdrawn regulations and then decided whether or not to approve non-significant rules for publication in the *Federal Register* or resubmit the significant rules to OIRA for formal Executive Order 12866 review.

Under Executive Order 12866, OIRA formally reviews a relatively small percentage of all regulations issued by the agencies. These rules are designated by the OIRA Administrator as "significant." The Order defines a "significant" regulatory action as one that may have "an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities," or one that could interfere with another agency's regulatory activities, materially impact the Federal budget, or raise novel legal or policy issues.

OIRA did not formally review non-significant regulations, either prior to January 20th or after agencies withdrew them from the *Federal Register*. Most of the 124 regulations withdrawn from the *Federal Register* were not significant. Consequently, they were not subject to OIRA review under Executive Order 12866, although the OMB memorandum did request that agencies provide OIRA with list describing these rules prior to their re-submission to the *Federal Register* for publication.

According to OMB's records, between January 20, 2001, and May 18, 2001, OIRA cleared a total of 86 regulations. Of these, four were regulations that agencies had withdrawn from the *Federal Register* and subsequently resubmitted to OIRA for review; 59 were "new" regulations that agencies submitted to OIRA for the first time after January 20, 2001 (OIRA had previously reviewed some of these regulations, but at different stages in the rulemaking process); 14 were regulations that agencies withdrew from OIRA and subsequently resubmitted to OIRA for review; and nine were regulations that agencies submitted to OIRA prior to January 20, 2001. [For the same time periods in 1998, 1999, and 2000, OIRA cleared 151, 181, and 173 regulations, respectively.]

As noted above, most of the regulations developed and issued at the end of Clinton Administration were not controversial. The Card Memorandum, however, did affect a number of prominent Clinton Administration regulations. Below is a brief discussion of some of the rules that appointees of the Bush Administration did review. In most cases, the rules were allowed to go into effect after a delay to permit a policy review.

- **Department of Agriculture: Mandatory Price Reporting Final Rule.** This rule required increased reporting on pricing, contracting for purchase, and supply and demand conditions for livestock (beef, pork and lamb) and established an electronic reporting program that requires certain livestock packers and importers to report to USDA one to three times daily. The effective date of this rule, which was published on December 1, 2000, was extended from January 30, 2001, to April 2, 2001. It then went into effect.

- **Department of Agriculture: National Organic Program Final Rule.** This regulation created (1) national standards governing the labeling of agricultural products to be marketed as "organic;" (2) an accreditation program in which state officials and private entities would act as certifying agents, certifying farms and handling operations as organic; and (3) a certification program for farms and handling operations that want to label their products as organic. The effective date of this rule, which was published on December 21, 2000, was extended from February 20, 2001, to April 21, 2001. It then went into effect.

- **Department of Agriculture/Forest Service: "Roadless" Final Rule.** This rule prohibited road construction in approximately 58.5 million acres of roadless areas of national forests and prohibited timber harvesting in most roadless areas. The rule restricted access to significant quantities of natural gas, oil, coal and other minerals, and would have impacted over 4,000 jobs, resulting in economic costs of about $200 million per year. The rule was published on January 12, 2001, and its effective date was extended to May 12, 2001. On May 10th, before the regulation went into effect, a Federal judge enjoined the Forest Service from implementing it. On July 10th, the Forest Service published a proposal to revise the rule.

- **Department of Health and Human Services: Head Start Standards for Safe Transportation Final Rule.** The Head Start Improvement Act directed the Secretary to issue regulations establishing requirements for the safety features and safe operation of vehicles used to transport children participating in Head Start programs. This rule required child-restraint systems and reverse beepers in all vehicles purchased using Head Start grant funds. This rule was published on January 18, 2001, and went into effect on February 27, 2001.

- **Department of Health and Human Services: Final Rule on Registration and Listing of Human Cellular and Tissue-Based Products.** This rule improved the safe use of human cell and tissue products, such as skin, heart valves, and corneas. It required manufacturers of human cell and tissue products to register with FDA and to submit a list of their products. This rule was published on January 19, 2001, and went into effect on April 4, 2001.

- **Department of Interior/National Park Service: Final Rule on Snowmobile Use**. This rule required a phase-out by the winter of 2003 - 2004 of snowmobile use in Yellowstone National Park, John D. Rockefeller, Jr. Memorial Parkway, and (with some exceptions) Grand Teton National Park. It also provided for interim actions to be implemented to reduce the impacts of snowmobile use during the winter use season of 2002-2003. DOI sent this rule to the *Federal Register* only hours after the comment period on the proposal had ended, during which the agency had received over 5,000 comments. It was published on January 22, 2001, and its effective date was extended to April 22, 2001. It then went into effect. Under a settlement agreement, DOI has agreed to issue a new final regulation on this matter by November 15, 2002.

- **Department of Labor: Service Contract Act Final Rule**. This rule implemented exemptions from the Service Contract Act for commercial services where the Government had trouble obtaining a sufficient number of bids. Services were only exempted if they also met additional criteria designed to ensure protection of prevailing labor standards. This rule was published on January 18, 2001, and went into effect on March 19, 2001.

- **EPA: Final Rule on Diesel Fuel Sulfur Control.** This rule established stringent emission standards for new heavy-duty trucks and buses beginning with the 2007 model year. The rule also required refiners to reduce the maximum sulfur content of diesel fuel produced for use in on-road vehicles from 500 parts per million (ppm) to 15 ppm, beginning in 2006. This rule was published on January 18, 2001, and went into effect on March 19, 2001.

- **EPA: Final Rule on Identification of Dangerous Levels of Lead.** This rule established uniform, national standards for paint, dust and soil in pre-1978 housing and child-care facilities. EPA estimated that carrying out this cleanup of U.S. housing stock to meet the hazard levels in the rule will yield net present value benefits ranging from $48.5 to $192.2 billion over 50 years and will impose net present value costs of $68.9 billion. This rule was published on January 5,

2001, and went into effect on March 6, 2001.

- **EPA: Arsenic in Drinking Water Final Rule.** This rule would lower the arsenic standard for drinking water from 50 micrograms per liter to 10 (one microgram per liter equals 1 part per billion). EPA estimated that the rule would impose costs of over $200 million per year, primarily on small drinking water systems. The rule was published on January 22, 2001 and its effective date was extended, first to May 22, 2001, and later to February 22, 2002, in order to allow for expert reviews of the science and economics underlying the rule. The expert reviews have now been completed and the Bush Administration will issue a final rule based on the results by February 22, 2002. Administrator Whitman has indicated, based on a review of the expert reviews, that the Administration intends to reduce the arsenic standard from 50 to 10 parts per billion, in effect reinstating the level of protection reflected in the January rule.

By the end of May 2001, the regulatory clearance procedures of Executive Order 12866 had become routinized, and almost all of the regulations initially subject to the Card Memorandum and the January 26th OMB memo had been reviewed by the Bush Administration.

After this period of transition, OMB sought to focus agencies' attention on the importance of regulatory impact analyses. On June 19, 2001, OMB Director Daniels issued OMB Memorandum M-01-23, "Improving Regulatory Impact Analyses." In this memorandum, OMB emphasized the need for high quality analysis:

The Bush Administration is committed to improving the quality of the Regulatory Impact Analyses (RIAs) that departments and agencies prepare under Executive Order 12866. Improved analysis will lead to more effective and efficient regulation by providing the public and policy officials with better information on the effects of these important rules.

The Director specifically stressed the need for agencies, in preparing their RIAs, to use the "OMB Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements" (M-00-08), which OMB issued on March 22, 2000. OIRA will continue to support agency efforts to improve and enhance regulatory analysis.

Chapter III: Directions for Regulatory Improvement

Through the public comment process on this report, a variety of suggestions were made to improve the regulatory and information collection processes. By "improved" rulemaking we mean adoption of rules whose costs are justified by their benefits, modifying existing rules to make them more effective and/or less costly, and rescinding outmoded rules whose benefits do not justify costs. Improved information collection means less burden to the public without compromising the practical utility of information or blocking agency efforts to acquire necessary information. A basic challenge is how to infuse analytical contributions into the decision-making processes at points of time in the agency's deliberations where they can make a difference in rules and information collections.

This chapter discusses several recent administrative actions we have taken to improve both regulations and the regulatory process. We also discuss other actions that we are contemplating based on suggestions we received from the public. In some cases the material below is drawn directly from a suggestion from one or more comments while in other cases our analysis of a comment's suggestion led us in the direction of a slightly or significantly modified suggestion. Some of the public comments are cited below but they all are available in full text in OIRA's public docket room.

A. Return of the "Return Letter"

In order for agencies to take seriously the requirement for quality regulatory analysis, there must be some formal negative response for submitting rules to OMB that are not supported by quality analysis. In OMB's budgetary work, the response is denial of a specific budget request. On the rulemaking side of OMB's work, a "return" -- at least in its strictest form -- is a decision by us not to give approval to a proposed or final rule submitted to us for review.

The official "return letter" to agencies represents a professional judgement by OMB that a rulemaking package needs further justification from the agency or modification to the draft rule itself. A well-crafted return letter states specifically yet concisely the reasons that a proposed or final rule has been denied clearance. The possible grounds for a "return letter" were recently discussed by the OIRA Administrator in a September 2001 memorandum to the President's Management Council, an interagency committee comprised of the deputies of each federal agency and department.[20] In addition to the quality of the agency's analysis being inadequate, the memorandum lists three other grounds for a "return letter". They are:

- if the regulatory standards adopted are not justified by the analyses,
- if the rule is not consistent with the regulatory principles stated in the Executive Order 12866,

[20] (See <http://www.whitehouse.gov/omb/inforeg/oira_review-process.html>)

Regulatory Planning and Review, or with the President's policies and priorities, and

- if the rule is not compatible with other Executive Orders or statutes.

Over OIRA's 20-year history, the return letter has been deployed with varying degrees of frequency (See Table 6). There were several dozen returns per year through most of the 1980s but very few returns in the 1990s. Part of the explanation may be that OIRA operated under a different Executive Order starting in 1993, which both changed the criteria under which OIRA reviewed rules and reduced the number of rules reviewed by OIRA by roughly 80 percent (i.e., non-significant rules are no longer reviewed by OIRA). Even apart from these differences, simple statistics about the number of returns need to be interpreted carefully. For example, numerous returns could mean that OIRA's expectations were not transparent or consistent or it could be indicative of different policy priorities. Very few returns could be an indication that the agency-OIRA relationship was tilted too heavily in favor of the agencies or that agencies were meeting OIRA's expectations. Even as we and the agencies work together in a smart regulatory system, there may still be some returns that arise from natural yet continuous institutional tensions.

We recently adopted a practice of posting all "return letters" on the OMB web site as well as making them available in OIRA's public docket room.[21] This practice is not completely new, as such materials were made public in the pre-OIRA years (e.g., the analyses of specific rules prepared by the Council on Wage and Price Stability in the Carter Administration) and at various points in the 1980s.

One peer reviewer expressed concerns that the practice of returning rules exceeds OIRA's legal authority and, even if lawful, should be done with care. OMB's Office of General Counsel has reviewed these concerns and concluded that OIRA does possess ample legal authority to return proposed and final rules to agencies for further consideration. We share the view of the reviewer that OIRA should not return a rule to an agency for reasons that would compel an agency to act in ways that are inconsistent or incompatible with the statute under which the agency is operating. This point is made specifically in E.O. 12866. We also agree with the same reviewer's comment that OIRA, when judging whether an agency's analysis justifies its decision, should be careful not to intrude too far into the agency's sphere of expertise and outside of our area of expertise. When judging whether an agency's analysis is of adequate quality, we further recognize that it will not always be feasible for any agency to fully quantify and monetize benefits and costs. E.O. 12866 clearly authorizes us to consider both unquantified and quantified effects of regulatory action. When quantification is clearly feasible at modest analytical cost, we may be inclined to insist on quantification unless the issues at stake are unimportant to the ultimate decision at hand and of little public interest.

[21] See http://www.whitehouse.gov/omb/inforeg/return_letter.html

Table 6
EXECUTIVE ORDER REVIEWS
1981 – 2000

Year	Total Reviews	Returns	%
All	34,411	396	1.2%
2000	579	0	0.0%
1999	583	0	0.0%
1998	486	0	0.0%
1997	507	4	0.8%
1996	503	0	0.0%
1995	619	3	0.5%
1994	861	0	0.0%
1993	2,167	9	0.4%
1992	2,286	9	0.4%
1991	2,525	28	1.1%
1990	2,138	21	1.0%
1989	2,220	29	1.3%
1988	2,362	29	1.2%
1987	2,315	10	0.4%
1986	2,011	29	1.4%
1985	2,213	34	1.5%
1984	2,113	58	2.7%
1983	2,484	32	1.3%
1982	2,641	56	2.1%
1981	2,798	45	1.6%

Making return letters widely available exposes our rationales to public scrutiny and allows outside parties to criticize or praise particular OIRA positions. Public return letters can cause some consternation at agencies but they also have the virtue of clearly presenting OIRA's concerns, so agency personnel can address more precisely those concerns. The peer reviewers were generally supportive of the practice of making return letters available to the public.

In the process of reviewing this report, however, several agencies -- though they did not question the value of formal return letters -- questioned the wisdom of publishing these letters. These agencies argued that "return" letters should be treated as "predecisional" communications between different arms of the Administration. Under the theory of a unitary executive, these predecisional communications can be considered internal deliberations and are best concealed from public view in order to promote candid and complete communications among public servants, without fear of public disclosure.

Although we see value in a unitary executive and acknowledge that making return letters public has some drawbacks, we believe that the arguments in favor of public return letters outweigh the stated drawbacks. First, if OIRA's return letters were never released, the reasons for OIRA's decisions about rules would be unknown to the public, which inevitably creates suspicions about motives. Secrecy about returns fuels public concerns, voiced vigorously at various points in OIRA's history, that OIRA does not engage in principled, analytic reviews but instead simply acts at the behest of certain interest groups. The public nature of return letters allows OIRA to explain the technical and policy rationales for its decisions about regulatory review. The transparency about decision rationale will shift criticism away from decision process to the merits of the issue under consideration. We believe that such a shift in locus of public debate about regulation advances the cause of good government. Second, a theory of the unitary executive should seek to accommodate the interests of Congress, the branch of government that has historically expressed the strongest interest in a more open approach to OIRA decision making. The insistence that the OIRA Administrator be confirmed by the Senate and that public disclosure requirements be added to Executive Order 12866 reflect in part a demand by Congress for OIRA to conduct its activities in a more open manner. Both the OMB Director and the OMB OIRA Administrator pledged a stronger commitment to openness on regulatory matters because they recognized the interests of Congress and the public in a transparent regulatory process. Finally, and most practically, even the best efforts by OMB and agencies to maintain the privacy of written communications about regulatory matters runs the risk of leaks to the public. Rather than allow some members of the public to have privileged access to internal communications about returns through leaks, we believe it is wiser to recognize the public interest in return letters and make them generally available.

The return letter may constitute outright rejection of the substance of a regulatory proposal but more commonly the letter directs agency reconsideration in light of analytical concerns. In June 2001, the OMB Director informed agencies in writing that OIRA will return economically significant rules to agencies that are not supported by analyses that follow OMB's analytic guidelines. The presence of analytic guidelines brings a degree of professionalism to the OIRA-agency relationship that would not

exist if there were no ground rules for what constitutes quality analysis. OMB's current analytic guidelines, issued March 22, 2000, are drawn from a 1996 "best practices" document prepared by an interagency committee of analysts. These guidelines need to be updated periodically as the field advances. We intend to consider the suggestion made by one reviewer that future revisions of OMB's analytic guidelines be subjected to both public comment and peer review.

B. Practice Early OIRA Participation in Agency Deliberations

OIRA's original regulatory review process was designed as an end-of-the-pipeline check against poorly conceived regulations. Although such a check is needed, there are significant limits on the effectiveness of this kind of review system.

Agency staff may spend several years building the technical foundations of a regulatory package, possibly in loose collaboration with authorizing committees in the Congress. Once staff have laid the technical and legal groundwork for a rule, they typically work with their policy-level leadership to manage the delicate relationships with stakeholders that are necessary to establish durable regulations. By the time the agency formally submits a rulemaking package to OIRA for review, agency staff and policy leaders may be personally invested in the proposal and be reluctant to reopen issues or upset the stakeholder equilibrium that was achieved in the agency's process.

In light of the strong institutional momentum behind an agency proposal that is being submitted formally for OIRA review, there is value in promoting a role for OIRA's analytic perspective earlier in the process, before the agency's commitments become too entrenched. Such early involvement can be valuable if OMB's perspective helps agencies frame the problem in constructive ways, suggests creative regulatory alternatives, or offers insight into how particular types of costs and benefits may be quantified or weighed.

Since there are only about 25 regulatory analysts at OIRA, compared to thousands of rulemakings per year at the agencies, OIRA cannot possibly engage in early involvement on each possible agency rulemaking. The challenge is how to target agency rules for early OIRA involvement. The agency's semi-annual regulatory agendas provide some indications of where an agency is headed but it is not always clear which rules will be most significant or might benefit most from early OIRA involvement.

A common yet informal practice is for agencies to share preliminary drafts of rules and/or analyses with OIRA desk officers prior to final decision making at the agency. This practice is useful for agencies since they have the opportunity to educate OIRA desk officers in a more patient way, before the formal 90-day review clock at OMB begins to tick. The practice is also useful for OIRA analysts because they have an opportunity to flag serious problems early enough to facilitate correction before the agency's position is irreversible.

Interested outside parties have gradually learned about this informal process of agency-OIRA discussion and thus attempts are made to provide information to agency and OIRA analysts. In order to protect the integrity of OIRA and the administrative record, an informal practice has developed that communications between OIRA and outside parties are treated as "covered by E.O. 12866" as soon as a rulemaking has proceeded to a point where OIRA desk officers have received from agencies copies of preliminary draft regulatory text or analysis. This informal practice goes beyond the letter but we believe complies with the spirit of the public disclosure provisions in E.O. 12866. The OIRA Administrator recently instructed OIRA staff to honor the letter and spirit of the public disclosure provisions in EO 12866.

Some of the comments on this report suggested that a smarter regulatory system will not be accomplished until an analytic tradition is built into the culture of agencies. Some have suggested that a "mini-OIRA" be established within each agency to bring an analytic perspective into the agency's deliberations at an early stage. Although this idea certainly has merit and several agencies are now moving in this direction, it can be expected that analytic units within agencies will wax and wane in their influence depending upon a variety of factors. It is no accident that every President since Richard Nixon, Republican and Democrat, has insisted on some form of centralized, Presidential oversight of agencies by professional analysts.

C. Suggest Regulatory Priorities: The "Prompt Letter"

For many years OIRA's process of regulatory review has been largely reactive, as OIRA evaluates specific regulatory initiatives devised by agencies. When OIRA has, in previous years, sought to influence regulatory priorities through informal communication, concerns were raised that OIRA was behaving in an improper manner since public scrutiny of informal OIRA communication was very difficult. Although some pre-decisional communications between OIRA and agencies should clearly by protected from disclosure under a unitary theory of the executive, the practice of OIRA suggesting priorities to agencies is a particularly strong candidate for public disclosure since the Congress, through authorization, appropriations, and oversight, has a clear interest in the priority-setting process.

OIRA has recently devised the public "prompt letter" to permit us to suggest regulatory priorities to one or more agencies in a transparent manner. A "prompt letter" may suggest that a new rule be adopted or an existing rule be rescinded or revised. Unlike a "return letter," which is authorized under presidential Executive order,[22] the "prompt letter" simply represents a suggestion that an agency make an addition to their upcoming semi-annual regulatory agenda or somehow elevate the matter to a priority. Like the "return letter," the "prompt letter" provides a specific yet concise technical or policy rationale while leaving the more indepth investigation in the hands of the administrative agency. The peer reviewers were generally supportive of the new practice of issuing public prompt letters.

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[22] See Sect.6(b)(3) of E.O. 12866.

OIRA's first two prompt letters, one to FDA on consumer labeling of trans-fatty acids in foods and the other on promotion of automated external defibrillators in the workplace, were selected because OIRA believes that they represent fruitful opportunities for cost-effective regulatory action.[23] It is too early to determine whether these prompt letters will stimulate constructive agency actions.

It is important that "prompt letters", which are suggestions, be distinguished from Presidential directives that instruct an agency to elevate in priority a particular issue or rulemaking. Prompt letters are a modest exercise of OMB authority that permits public deliberation and decision making by the expert agency. A Presidential directive is of course binding under a unitary theory of the executive.

Several agencies expressed concerns that public prompt and return letters may have an unintended yet adverse effect on the government's litigating position, once a rulemaking decision is made and challenged. We share these concerns and believe that such letters should be reviewed by OMB's lawyers to prevent or minimize unacceptable legal risks. Any form of public communication about a regulatory matter poses legal risks and thus it is important for OIRA to consider carefully when a public communication is necessary and appropriate. In some cases it may also be appropriate for counsel in agencies to review draft letters to avoid unnecessary legal risks. Although such legal considerations are important, we believe they should not be allowed to paralyze the ability of OIRA and agencies to communicate in a publicly transparent manner.

The first draft of this report requested suggestions from the public about reforms of specific regulatory programs, including modifications to existing rules or rescission of outmoded rules. A specific format for such requests was provided and OIRA received 71 specific suggestions. OIRA reviewed these suggestions (summarized in Appendix A) and will be sharing some of these suggestions with agencies through prompt letters.

Prompt letters need to be deployed wisely because the resources that agencies expend in responding to them are resources that might otherwise be expended on priorities that the agency otherwise identifies. The public nature of prompt letters (and agency responses) allows the public to evaluate both OIRA's case for the prompt as well as the appropriateness of the agency's response.

D. Promote Formal, Independent External Peer Review

In addition to the public review that accompanies a rulemaking process, OIRA believes that economically significant rules should be supported by analyses that were subjected to formal, independent external peer review. Peer review is a process involving qualified experts who often have no affiliation with stakeholders. Rather than require such review in a one-size-fits-all manner, we have

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[23] Prompt letters may be found at: <http://www.whitehouse.gov/omb/pubpress/2001-35.html>.

adopted a policy where we will give an extra measure of deference to agency analyses that have been subjected to appropriate peer review processes. Such procedures (a) select reviewers based primarily on necessary technical expertise, (b) seek from reviewers information on any prior policy/technical positions on the matter under review, and (c) seek from reviewers information on private and institutional sources of revenue. Peer reviews that follow these practices are, we believe, more objective and credible. The analyses that should be reviewed include the regulatory impact analyses plus key supporting technical documents (e.g., risk assessments).

Scientists are inclined to associate the phrase "peer review" with the practices used by journal editors to review submitted papers for quality, relevance, and publication priority. Peer reviews commissioned by agencies can be similar but may also have differences. Some agencies select and assemble scientific advisory groups and peer review panels on specific issues. The charges given to these groups are very important and are often considered carefully by agencies and OIRA. The recent arsenic decision by the EPA employed three peer review activities: a report on health risk by a committee of the National Academy of Sciences, a report on cost by the National Drinking Water Advisory Council, and a report on benefits by a committee of the EPA Science Advisory Board. OIRA accorded an extra measure of deference to EPA's recent decision on arsenic because of the extent of scientific peer review of the key technical inputs to the decision.

As important as peer review is, it must be recognized that the quality of peer review processes varies enormously. Even a well-designed peer review process may not produce a complete or valid report in a specific case. It must also be recognized that the policy opinions of reviewers, important as they are, may prove to be incompatible with a legislative mandate or contrary to the President's policies or priorities. For these reasons, a case can be made that peer reviewers should focus on specific technical issues within their province of expertise that are relevant to an agency's deliberation.

Some reviewers raised a concern that it may not be appropriate to compel all agencies to adopt specific peer review practices. The OIRA policy does not compel agency use of peer review and instead offers an extra measure of deference to agencies that employ specified practices of peer review. The question of whether peer review should be mandated by legislation or executive order is beyond the scope of this report.

E. Develop, Use, and Disseminate Sound Risk Assessment Information

In the recent memorandum to the President's Management Council cited above, OIRA encouraged agencies to adopt or adapt the principles of sound risk assessment adopted by Congress in the Safe Drinking Water Act Amendments of 1996. Congress directed agencies when taking actions based on science to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and (ii) data collected by accepted methods or best available methods (if reliability of the method and nature of the decision

justifies use of the data)."[24] Moreover, Congress also directed agencies under the Safe Drinking Water Act of 1996 "in a document made available to the public in support of a regulation [to] specify, to the extent practicable - (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer- reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data.[25] In OIRA's recent information quality guidelines, we also urged agencies to embrace these principles in agency-specific guidelines governing the dissemination of quality information to the public.[26]

One reviewer expressed concern that OIRA might require all agencies to adopt these specific principles, which the reviewer regards as highly specific and prescriptive. OIRA recognizes that these principles were devised in the context of drinking water and thus may need to be adapted or modified for appropriate use in other contexts. We are not aware of any health, safety or environmental statute whose provisions regarding risk assessment are incompatible with the generic principles provided in the Safe Drinking Water Act. It is certainly true that the risk-management standards in various statutes vary enormously but we view the recommended principles of risk assessment as sufficiently general to inform agencies operating under a wide variety of risk management standards. For example, the risk assessment principles we have recommended are compatible with the risk-management standards in the Food Quality and Protection Act that are aimed at protection of children from chemical exposures.

F. Analyze Impact on Energy, Supply, Production, and Consumption

OIRA is also reviewing agency "Statements of Energy Effects". Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," requires agencies to prepare and submit to OIRA a "Statement of Energy Effects" whenever they submit a significant energy action for OIRA review under E. O. 12866.[27]

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[24] 42 U.S.C. 300g-1(b)(3)(A)

[25] 42 U.S.C. 300g-1(b)(3)(B)

[26] See <ttp://www.whitehouse.gov/omb/fedreg/final_information_quality_guidelines.html>.

[27] See E. O. 13211 of May 18, 2001 (66 *Federal Register* 28355 (May 22, 2001)).

G. Make this Report More Useful

Commentators made a variety of suggestions about how this report can be made more productive in the future. We highlight suggestions that we believe are appropriate and intend to implement in the years ahead.

Deemphasize Reporting of the Aggregate Costs and Benefits of Federal Regulation.

Although we have complied with the statutory obligation to report what is known about the aggregate costs and benefits of federal regulation, we share the concerns of several commentators that this information is of limited utility and validity. The information is of limited utility because decisions about regulation should be based on the costs and benefits of specific rules rather than the aggregate effects of all rules. Information on the aggregate costs and benefits of regulation is most useful for determining the overall impact of government intervention on the macro economy.[28] The validity of the information is also limited because the few available studies are outdated, selective in what has been included, and based on data and estimates of questionable quality. Both the "top-down" and "bottom-up" methods of collecting information on the costs of regulation have flaws. Commentators were split on whether OIRA should invest resources analyzing rules prior to 1990. Our view is that at this point such analyses should be accorded fewer of OIRA's limited resources than analyses of proposed or more recent regulations.

Provide Depth about New Rules Adopted in the Preceding Year.

Some commentators, including several peers, urged OIRA to offer objective assessments of the quality of the analyses that supported rules in the previous year. They suggested that it would be useful to indicate how different assumptions, methods or data sources might have caused the agency to report significantly different estimates of costs and benefits. Yet if we are doing our job of promoting quality regulatory analysis, then the final analyses released by agencies to support rules should stand on their own without significant OIRA commentary. The exception may occur where a regulation is issued under statutory or judicial deadline without adequate analysis.

There is merit in developing cost and benefit estimates for specific categories of regulations or for specific industry sectors. However, OIRA does not have adequate resources to engage in original analyses of these sorts and the information supplied by agencies does not readily facilitate such

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[28] Information on the aggregate costs of regulation is of analogous value to information on the aggregate costs of government spending, which is used primarily by economists for comparisons over time and across countries to determine its impact on economic growth. Note that the aggregate benefits of government spending are not calculated.

breakdowns. We believe it may be more appropriate for the regulatory think tanks in universities and elsewhere to perform this function.

Better information on the impacts of regulation on state, local and tribal governments would be useful but will require that agencies develop such estimates in the first place. The impacts on small businesses also can be summarized to the extent that agencies prepare such information. In a recent memorandum to the Presdent's Management Council, OIRA indicated that it will be scrutinizing with special care rulemaking proposals with impacts on state, local, and Tribal governments and small businesses.

OIRA believes that the best course for improving the quality of such information is to periodically refine our analytic guidance and enforce these analytic guidelines in the review process. It is not realistic to expect that we will have the data and resources to redo these analyses each year in the annual report.

There were disparate views about how OIRA should present or revise EPA's aggregate estimates of the costs and benefits of the Clean Air Act. Since a Committee of the National Research Council/National Academy of Sciences is charged with reviewing EPA's benefit estimates for air quality gains, OIRA does not believe it is appropriate for us to invest analytic resources on this topic at this time.[29] We intend to offer suggestions to the NRC/NAS Committee and formally revisit this issue when the NRC/NAS report is available for pubic scrutiny.

H. Focus Future OIRA Guideline Revision on Critical Analytic Issues

Several groups raised a variety of cogent concerns about specific analytic practices contained in OMB's guidelines.[30] OMB concludes that our next round of guideline revision should focus on these critical questions, rather than revisit each and every aspect of the current

[29] The full name is the Committee on Estimating the Health-Risk Reduction Benefits of Proposed Air Pollution Regulations of the National Research Council/National Academy of Sciences.

[30] See comments (1, 3, 5, 12, 20, 23, and 27). Comments are identified in the appendix.

guidelines. The following analytic practices seem especially ripe for review in the foreseeable future:

- the practice of determining which discount rates to apply to future costs and benefits;
- the methods employed to account for latency periods between exposure to toxic agents and the expression of chronic diseases;
- the methods employed to assign a dollar value to prevention of premature death, particularly the relative advantages and disadvantages of the value-of-statistical life (VSL) approach and the quality-adjusted-life-year (QALY) approach;[31]
- the need for use of methods of risk assessment that supply central estimates of risk as well as upper and lower bounds on the true yet unknown risks; and
- the need for methods of risk assessment to account for the vulnerabilities of specific subpopulations such as the children, the elderly, and the infirm.
- methods for valuing improvements in the health of children.

In order to facilitate comparison of analyses across programs and time, the OIRA Guidelines should also be revised to require a reference-case analysis based on common assumptions, methods, and reporting. Such an approach was recently recommended by an Expert Panel commissioned by the US Department of Health and Human Services and a similar approach could be adopted government-wide.[32]

OIRA agrees that agency analyses should be transparent about data, methods, and assumptions so that analytic results are substantially reproducible. OIRA's recent information quality guidelines include a provision that significant technical information disseminated by agencies be capable of being substantially reproduced.[33]

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[31] The quality-adjusted-life-year or QALY approach weights life-years extended based on criteria established by medical experts, patients, and community residents to allow comparisons of different health outcomes. See MR Gold, JE Siegel, LB Russell, and MC Weinstein, (eds.) *Cost-Effectiveness in Health and Medicine*. New York, NY, Oxford University Press, 1996.

[32] See Gold *et. al.* above.

[33] See <http://www.whitehouse.gov/omb/fedreg/final_information_quality_guidelines.html>

Within the next two years, OIRA plans to initiate an interagency process aimed at refining our guidelines and clarifying the relationship between OIRA and agency guidelines. Although Congress has already stipulated such a process for information quality guidelines, OIRA believes that a similar process would be productive for analytic guidelines, assuming a manageable number of critical analytic issues are addressed. In next year's draft annual report, we intend to elicit public suggestions of specific analytic issues that are worthy of in-depth work by an expert interagency panel of analysts.

Chapter IV: Discussion of Public Comments

On May 2, 2001, as required by Section 628 (b) of the FY2000 Treasury and General Government Appropriations Act (the Act), we published in the *Federal Register* a draft report to Congress on the Costs and Benefits of Federal Regulations that asked for specific suggestions on how to improve the final report. We also asked the public to nominate specific regulations that we should propose for reform. This chapter along with the Appendix provides a summary of those comments including our reaction to them. The commentators are also listed in the Appendix and their comments are available in OIRA's Record Management Center.[34]

In addition as required by Section 628 (d) of the Act, we asked independent and external peers to review the draft final report. The peer reviewers are:

- Scott Farrow; Ph.D.
  Director, Center for the Study and Improvement of Government Regulation
  Carnegie Mellon University

- Lisa Heinzerling
  Professor of Law
  Georgetown University Law Center

- Randall Lutter, Ph.D.
  Resident Scholar
  AEI-Brookings Joint Center for Regulatory Studies

- Cass R. Sunstein
  Karl N. Llewellyn Distinguished Service Professor of Jurisprudence
  Law School and Political Science
  University of Chicago

Their comments are also available to the public in OIRA's Records Management Center. In general the peer reviewers applauded the approach taken by this year's report but suggested various ways that OIRA could improve its regulatory review duties. The suggestions, however, ranged from more direct oversight and independent analysis to less. They all welcomed our move toward more transparent analysis and operations. We discuss their suggestions below.

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[34] To view the comments an appointment must be made in advance. Call OIRA's record Management Center at 202 395 6880.

A. The Six Questions

We posed six questions about ways that our aggregate estimates of the benefits and costs of regulation might be improved, since our previous reports acknowledged important analytic weaknesses in the aggregate figures.

1. *Should We Assess Older Regulations?*

One option would be to stop analysis of rules adopted before 1990 on the grounds that conditions have presumably changed and some of the methods used to estimate the costs and benefits of pre-1990 rules are questionable. Commentators were split on whether assessment of pre-1990 rules would be a useful allocation of OIRA resources.

Several commentators noted that since the statute does not distinguish pre-1990 from post-1990 rules, OIRA should make a good faith effort to quantify the costs and benefits of older rules as well as newer rules (11, 13, 33).[35] Others noted that including pre-1990 rules is necessary to provide an accurate aggregate baseline (14, 15) and to identify rules that are outmoded (15). If older rules are assessed, one commentator recommended that entire statutes instead of individual rules be assessed in order to avoid double (or inconsistent) counting of costs and benefits (1). Another commentator suggested that older rules be assessed by industrial sector, possibly using surveys of regulated entities to acquire current information (14). A different commentator sees such surveys as an undesirable information burden on the private sector (11). If older rules are assessed, one commentator recommended such assessments be performed by an outside contractor due to the immensity of task (31).

Other commentators recommended against assessment of pre-1990 regulations. Given OIRA's limited resources, they recommended that priority should be given to proper assessment of new rules until that job is done well (4, 5, 25, 31). Even those favoring analysis of older rules acknowledged the following problems: the absence of regulatory analyses prior to 1981 (33) and the likelihood that there have been dynamic responses in the marketplace to older rules (11). One commentator opposed assessment of older regulations if it means continued reliance on the same limited studies that OIRA has used in the past (3).

Two commentators suggested that OIRA undertake the more limited task of assessing, for several old rules, whether the actual benefits and costs of older rules have been similar to what was projected in regulatory analyses conducted prior to enactment of the rules (1, 31). One of those commentators noted that it might be better for neutral third parties, rather than agencies or OIRA, to perform such validation studies (31).

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[35] The numbers identify the commentators, which are listed in the Appendix.

We believe that our first priority efforts are most appropriately directed at improving the analysis of new rules. We are aware of no new data or methods that would permit better assessment of either older rules or the aggregate effects of all rules. Thus, the statutory requirement is satisfied in this report by reference to and discussion of the assessment of older rules contained in our previous annual reports, with recognition of the limitations of those estimates (3).

2. *Should We Focus On Specific Statutes Or Categories of Regulations?*

One commentator urged OIRA to satisfy the legal demands first (breakdowns by agency and agency program) before tackling additional categories (33). From a business perspective, one commentator saw cumulative impacts by industry sector as more useful than any other categorization (14). Several commentators saw value in reporting costs and benefits in various types of categories (5, 11, 14, 15, 31): by statute, by amount of paperwork, by category related to environmental health and safety, by workplace, by source of drinking water and by independent agencies.

Two commentators recommended against a focus on aggregation by category because the underlying information on individual rules is too uncertain to justify aggregation (31) and OIRA's expertise is better suited to assessment of specific rules rather than the aggregation of multiple rules (4). If more categories of rules are assessed, one commentator (31) recommended that priority be given to entire categories of rules/impacts that were not assessed in previous OIRA reports (e.g., civil rights rules, indirect effects, independent agencies and agricultural marketing orders).

As our first priority, we will focus on rough estimates of the costs and benefits of rules by agency and, where possible, by agency program.

3. *Should We Seek A Better Way to Estimate the Aggregate Cost of Federal Regulation?*

OIRA has historically used a "bottom-up" approach to aggregating costs and benefits, executed by simply adding the impacts of each and every rule. One commentator questioned the feasibility of this entire enterprise (31) while another questioned the utility of aggregate estimates (12). Yet other commentators suggested a variety of alternatives or supplements to the current approach.

Some commentators saw value in expanded use of surveys of regulated entities to quantify the cumulative costs of regulations (14, 33). Others question the validity of these surveys (31) and are concerned about the information collection burdens they impose on the private sector (11).

One commentator suggested OIRA use its information-collection data to prepare annual estimates of regulatory paperwork (11). Other possibilities include summation of data reported by firms to the IRS or by firms in specific industries to specific agencies (11). For environmental costs, surveying the revenues of pollution control/prevention suppliers is another possible method of overall cost estimation (11).

No commentators suggested any new ideas for estimating the aggregate benefits of rules and the rule-by-rule approach is the only method known to us, except for specialized benefit studies of particular agency programs (e.g., OSHA's safety program and NHTSA's motor vehicle safety standards).

We concur with one commentator (4) that development of better ways to aggregate the costs of regulation should not be the primary focus of our efforts. Methods development is appropriate for research-oriented agencies, universities and private organizations that are insulated from the day-to-day pressures of reviewing agency rules and information collection requests. As better methods are developed, peer-reviewed and published, we will use them. Until then, we will sum the impacts of specific rules in order to fulfill our statutory obligation.

4. *How Should We Estimate Effects On State, Local and Tribal Government, Small Businesses, Wages, and Economic Growth?*

Although such information would be valuable, one commentator acknowledged that "economists have not done much relevant work in this area" (4). We receive some information from agencies pursuant to the Unfunded Mandates Reform Act but one commentator urges us to be cautious about the validity and reliability of this information (31). With regard to impacts on small business, one commentator suggested that we should permit or encourage the Small Business Administration's Office of Advocacy to include estimates of impacts on small business in OIRA's regulatory accounting reports (31). Another possibility is for OIRA to ask the relevant interest groups for information that they have on these impacts (33).

We are encouraged by two recent developments: a new study of small business impacts by Crain and Hopkins for the Small Business Administration and a new regulatory model commissioned by the National Federation of Independent Business to estimate distributional impacts on firms (11, 26). We intend to review these contributions to determine how they might be used to augment our treatment of these important categories of impacts.

5. *How Can We Improve the Estimates of Costs and Benefits of Major Regulations?*

Our current approach relies primarily on agency estimates of the costs and benefits of rules. There are analytic weaknesses in these estimates and thus the question becomes how such estimates can be made more valid and precise.

Commentators noted the following problems with existing estimates submitted by agencies: they are not based on consistent assumptions or methods (7, 11), they may employ a controversial rate of discount to future benefits and costs (3, 12), they employ monetization techniques that have serious technical and ethical limitations (3, 12), and they do not always adhere to the analytic "best practices" and guidelines published by OIRA (11, 14).

A common theme of commentators is that OIRA should review agency analyses more rigorously and insist that they be performed in accordance with our guidelines before they are approved and the associated rule cleared (5, 11, 14, 15, 31, 33). Three commentators suggested that we should publish our own estimates of the impacts of new rules (4, 5, 11, 17). Another commentator recommended that OIRA require agencies to publish alternative independent estimates of the costs and benefits of an agency's proposed rule, or that we do so in our annual report (5).

We concur that the heart of our approach to improving regulatory analysis should be the careful scrutiny of analyses underlying new rules, including suggestions for improvement of agency analyses and return of agency submissions that do not comply with our analytic guidelines. If we must conclude review of new rules with substandard analyses (e.g., due to judicial or statutory deadlines), we will, when appropriate and constructive, publish a technical critique of such analyses. We do not have plans at this point to publish a "report card" on each regulatory analysis (11, 31).

6. *How Should We Treat EPA's Aggregate Estimates of the Benefits of the Clean Air Act?*

The estimated benefits of the Clean Air Act account for a substantial portion of the overall benefits of Federal regulation that we reported in the past. Questions have been raised about whether the benefits of the Clean Air Act, as estimated by EPA, are accurate (31). In previous versions of this report, we have expressed analytic concerns about EPA estimates, concerns that were shared by some public commentators. Yet the EPA estimates have also been subjected to a significant amount of external peer review (1). There were a wide range of comments submitted on this issue, ranging from a recommendation that we refrain from criticizing EPA benefit estimates (1) and instead use them (16) to a recommendation that we perform independent assessments in this area or adjust EPA estimates as appropriate (4, 7, 11, 15).

Since publication of the draft report, we have become aware of the workings of a new Committee of the National Research Council/National Academy of Sciences that is reviewing the data, assumptions, and methods used by EPA to estimate the benefits of air quality improvements.[36] In light of the work of this Committee, we have decided to share the relevant public comments on this report with the NRC/NAS Committee. Moreover, we have decided to continue reliance on our past practice in annual reports until the work of the NRC/NAS has been completed and we have had an opportunity to study it and discuss it with analysts from EPA and elsewhere.

[36] The full name is the Committee on Estimating the Health-Risk Reduction Benefits of Proposed Air Pollution Regulations of the National Research Council/National Academy of Sciences.

A. General Reform Recommendations

In addition to answering our specific questions, we also received many other suggestions on how the regulatory process could be improved.

1. *Congress should pass a law requiring that all regulatory agencies comply with OIRA guidelines when analyzing the impact of economically significant regulations (2, 4).*

If such analyses were conducted in accordance with OIRA guidance and related agency guidance, these analyses could be made more comparable and useful. We agree that this is a promising idea, subject to the qualification that we are able periodically to revise the guidelines to reflect advances in the state of the art. In addition, the resource implications for agencies need to be considered.

2. *Congress should codify some version of the recent Presidential Executive Orders on regulatory review (4).*

Although Congress has provided statutory authority for OIRA's work on paperwork reduction and elimination, no comparable authority exists with regard to OIRA's regulatory review function. This function has been ordered through Presidential executive order and other means by the last five Presidents, Democrat and Republican. In the last Congress, the Regulatory Improvement Act (S.981, 105th Cong., 2nd Session,1999) co-sponsored by Senators Fred Thompson and Carl Levin was a modest yet generally constructive step in the right direction. An important feature of this bill is a requirement that agencies determine whether the benefits of a new rule justify costs, taking into account both quantifiable and unquantifiable factors. Although this determination will have more impact under some statutory schemes than others, the information on costs and benefits will be useful for Congress and the public. Congress could build on the initial Thompson-Levin effort to provide OIRA's regulatory-review role a sound statutory authorization, without altering the organic statutes of agencies or creating unnecessary barriers to expeditious agency action. An argument against codification is based on a possible loss of flexibility: Why do by statute what can and is being done successfully by Executive Order?

In sum, we agree that this is a promising idea, which deserves careful consideration. We will carefully analyze regulatory reform bills introduced in the Congress to see if they will improve the process without unduly burdening it or creating more "ossification" of the administrative process.

3. *OIRA should issue a scorecard on the extent to which regulatory analyses comply with their analytic guidelines (4, 31).*

Several peer reviewers joined the public in suggesting that agency RIAs were of varying quality, used inconsistent estimates of valuations, and did not always follow the OMB Guidelines. In addition to working with the agencies as described above to improve RIAs, we intend to issue in certain circumstances "scorecards". When OIRA concludes review of rules that have been supported by inadequate regulatory analyses (e.g., due to court or statutory deadlines) and when appropriate and constructive, we will publish a critique of the agency's analysis.

4. *OIRA should calculate (and report) net benefits of all significant regulations (4).*

To the extent possible, OIRA seeks to present net benefits. Net benefits, as well as other types of considerations, are important information in regulatory deliberatons.

5. *Congress should require each Federal regulatory agency to produce an annual report on the costs and benefits of its regulatory activities, which can be used in the OIRA annual report (4).*

We agree that this is a promising idea that we intend to explore and note that there is legislative history to support this approach. In addition, the resource implications for agencies need to be considered.

6. *OIRA should rely more heavily on its own expertise to inform judgements about the benefits and costs of regulation (4, 19, 27).*

We agree with the recommendation, which was also made by several peers, that we should do this during the regulatory review process. If we must conclude review of new rules with substandard analyses (e.g., due to judicial or statutory deadlines), we will, when appropriate and constructive, publish a technical critique of such analyses.

7. *OIRA should require that agencies have OIRA approval on published protocols for each regulatory impact analysis before regulatory development begins. The process should include an opportunity for public comment on draft RIA protocols prepared by agencies (31).*

Although this is a promising idea, OIRA does not currently have adequate staff resources to execute such early involvement for each economically significant rule. We may consider this approach for billion-dollar plus rules.

8. *OIRA should simplify and streamline the approval of surveys and information collections in cases where agencies are seeking approval to gather information that will enhance the costs and benefits of regulatory programs (15).*

We agree with the sentiment expressed but are not aware that agencies have had significant difficulties in gaining approval for information collections that would be useful in the development of regulatory impact analyses. We will pay particular attention to simplifying and streamlining our procedures.

9. *OIRA should review a sample of past regulatory actions claimed as not major rules to assess the validity of agency determinations (15).*

This is an interesting study proposal that might better be performed by an independent third party.

10. *OIRA should establish a multi-year schedule for systematic review of all regulatory programs by major topic and agency (15).*

Although broad-based reviews of existing rules are conceptually appealing, we question whether such efforts are cost-effective and feasible given the current resources available to OIRA and the agencies. We believe a more targeted approach to the evaluation of existing rules is appropriate.

11. *OIRA should require agencies to provide the public access to all tables, spreadsheets, algorithms and data used to calculate the estimates of benefits and costs of proposed and final regulations or existing regulations under review (15).*

We agree with this recommendation for published proposed and final regulations subject to the qualifications contained in OMB's 1999 rule on data access and OMB's 2001 guidelines on information quality.

12. *OIRA should require that, for all economically significant regulations, agencies hold public hearings at which agency staff who are responsible for cost and benefit estimates are available for questioning by members of the public (15).*

In general we agree that public hearings can be useful for certain economically significant regulations. We note that the agencies have different procedures for informal rulemakings that are designed for their own administrative circumstances and statutory requirements.

13. *OIRA's Report to Congress should encourage investment in the development of data, models, methodology, and human capital that will enhance agencies' long-term ability to provide accurate estimates of the benefits and costs of their regulations (1).*

We agree that this is a promising idea worthy of further consideration. A possible first step in this direction would be for Congress, through the National Science Foundation, to fund centers of excellence in regulatory analysis at 5 to 10 universities and/or think tanks around the country. The core funding for these Centers would support data and methods development, education and training, and commentary to agencies on the technical quality of draft regulatory analyses. Possible tradeoffs with other NSF programs need to be considered.

14. *The SBREFA Panel Review Process, now applied only to EPA and OSHA, should be extended to other Federal regulatory agencies (26).*

OIRA believes that the SBREFA process has brought a useful and practical influence into the way EPA and OSHA define problems and shape regulatory options. However, since the panel process is very resource intensive, we believe that Congress should consider extending it to other regulatory agencies only where appropriate and practical.

15. *OIRA should recognize and act on an emerging category of economic and valuation research which is providing evidence that children are improperly valued – and often grossly undervalued – in present efforts to measure costs and benefits of federal regulations (23).*

The proper valuation of the effects on children of regulatory actions is a topic that we will consider in the next revision of our guidelines on regulatory analysis.

16. *OIRA should review agency "Comment-Response Documents" to better ensure that EPA (and other federal regulatory agencies) fully and suitably consider public comments (5).*

We agree that we should be, and indeed generally are, familiar with the public comments that agencies receive on their proposed rules.

17. *OIRA should expand its Guidelines so that they explicitly address and illustrate how benefits should be compared to costs. This is a key element that is missing from the Guidelines, and it is a very important issue. The focus should be on how incremental benefits should be compared to incremental costs, so that regulations can be selected that may maximize net social benefits (5).*

We agree with this point and plan to make a corresponding revision to the next version of our Guidelines.

18. *Congress, through its authorization and appropriations committees, should undertake an assessment of whether agencies and OIRA have adequate tools, data, and expertise to undertake the regulatory analyses required under existing statutes and executive orders.*

It may be particularly useful to commission the National Research Council/National Academy of Sciences to undertake an overall assessment of the analytic capabilities needed to produce and review high quality regulatory analyses, including a call for recommendations on concrete steps to strengthen these capabilities. An important yet related component of this evaluation would include the above mentioned assessment of the adequacy of university-based training programs in regulatory analysis and methodological research at the National Science Foundation and other federal agencies. Examples of research needs include methods for assessing the aggregate costs and benefits of rulemaking and *ex post* assessments of the validity of *ex ante* predictions of regulatory benefits and costs.

A. Recommendations Regarding Specific Rules

In the draft report published May 2, 2001, we asked for suggestions from the public on specific regulations that could be rescinded or changed that would increase net benefits to the public by either reducing costs and/or increasing benefits. We asked commenters to identify regulations that are obsolete or outmoded, and could be rescinded or updated. If possible we asked commenters to be as specific as possible in their suggested reforms including whether the reform could be accomplished by agencies through rulemaking or would require statutory changes. In addition to supplying whatever documentation and supporting materials (including citations to published studies) commenters considered appropriate, we asked them to use the following suggested format to summarize the recommendations.

Format for Suggested Regulatory Reform Improvements

Name of Regulation:	
Agency Regulating:	(Include any subagency)
Citation:	(Code of Federal Regulations)
Authority:	(Statute)
Description of Problem:	(Harmful impact and on whom)
Proposed Solution:	(Both the fix and the procedure to fix it)
Estimate of Economic Impacts	(Quantified benefits and costs if possible)

It is important to note that these rankings are preliminary, based on the public comments and OIRA's initial review. At this point, these rankings do not reflect agency agendas, resources, or Congressional directives. Further discussion and deliberation undoubtedly will be needed before these suggestions are implemented.

We received 71 suggestions from 33 commentators involving 17 agencies that contained the requested information. OIRA has completed an initial review of these comments and has placed the suggestions into one of three categories: (1) high priority, we are inclined to agree and look into the suggestion, (2) medium priority, we need more information, and (3) low priority, we are not convinced at this point of the merits of the suggestion. In those cases where OIRA agrees with the suggestion, a "prompt letter" may be crafted and sent to the responsible agency for deliberation and response. Where additional information is required from an agency to make a determination, OIRA may request -- through a prompt letter -- that the responsible agency seek the necessary information and report back to us for a final determination.

Table 7 lists the priority 1 suggestions. We have preliminarily listed 23 suggestions, about one third of the 71, as priority 1. Eight are EPA regulations, five DOL, two HHS, Ag, and Interior, and one each from DOE, DOT, Ed, and EEOC. Appendix A contains the 71 suggestions we received from the public. We describe them in the format presented above based on information found in the public comments. We also include our preliminary priority categorizations.

Table 7 High Priority Regulatory Review Issues	
Agency	**Regulation**
Department of Agriculture/Forest Service	Forest Service Planning Rules
Department of Agriculture/Forest Service	Roadless Area Conservation Regulations
Department of Education	Regulations Related to Financial Aid
Department of Energy	Central Air Conditioner and Heat Pump Energy Conservation Standards
Department of Health and Human Services	Standards for Privacy of Individually Identifiable Health Information
Department of Health and Human Services/Food and Drug Administration	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content and Health Claims
Department of Interior/National Park Service	Amendments to National Park Service's Snowmobile Regulations
Department of Interior/Bureau of Land Management	Regulations Governing Hardrock Mining Operations
Department of Labor/Office of Federal Contract Compliance Programs	OFCCP's "60-2" Regulation - The Equal Opportunity Survey
Department of Labor/Employment and Training Administration	Procedures for Certification of Employment Based Immigration and Guest Worker Applications
Department of Labor/Employment and Standards Administration	Proposal Governing "Helpers" on Davis-Bacon Act Projects
Department of Labor/Wage and Hour Division	Overtime Compensation Regulation
Department of Labor/Wage and Hour Division	Record Keeping and Notification Requirements
Department of Transportation/Federal Motor Carrier Safety Administration	Hours of Service of Drivers; Driver Rest and Sleep for Safe Operation
Equal Employment Opportunity Commission	Uniform Guidelines for Employee Selection Procedures
Environmental Protection Agency	Mixture and Derived From Rule
Environmental Protection Agency	Proposed Changes to the Total Maximum Daily Load Program

Environmental Protection Agency	Drinking Water Regulations: Cost-Benefit Analysis
Environmental Protection Agency	Economic Incentive Program Guidance
Environmental Protection Agency	New Source Review
Environmental Protection Agency	Concentrated Animal Feeding Operations (CAFOs) Effluent Guidelines
Environmental Protection Agency	Arsenic in Drinking Water
Environmental Protection Agency	Notice of Substantial Risk - TSCA

Appendix A

Seventy one Suggestions From the Public for Reform

Name of Regulation: Nationwide Permits for Discharge of Dredge or Fill Material

Agency Regulating: Department of Defense/US Army Corps of Engineers

Citation: FR, Vol 63, No 198, Oct 14, 1998

Authority: CWA Sec 404

Description of Problem: This rule restricts the the use of Nationwide (general) permits for discharges of dredge or fill material into waters of the US, and requires more projects to obtain individual permits, which entails significant cost and delay.

Proposed Solution: Commenter would like the NWP program expanded to authorize more activities with a minimum of paperwork and delay.

Estimate of Economic Impacts: The Corps estimated the direct compliance costs of the rule which restricted the use of NWPs at $46 million per year, but acknowledged that potentially significant indirect costs (eg, permitting delays, greater land requirements for some projects) were not included in these estimates.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Title IV Regulations

Agency Regulating: Department of Education

Citation: 20 U.S.C. 1094c

Authority: Higher Education Act

Description of Problem: Title IV regulations are redundant and place inappropriate administrative burdens on institutions of higher education.

Proposed Solution: The Department should focus its regulatory efforts based upon performance or outcomes rather than process.

Estimate of Economic Impacts: None provided.

Commenter: Notre Dame University (32)

Priority: 1

Name of Regulation: Clothes Washer Energy Conservation Standards

Agency Regulating: Department of Energy

Citation: None provided.

Authority: None provided.

Description of Problem: The proposed standards would reduce consumer choice by eliminating the most popular washing machine models and force consumers to purchase washing machines that DOE estimates will be 57% more expensive and contain fewer features than current models. Many consumers will be worse off as a result of the rule

Proposed Solution: The commenter suggests that DOE would help consumers more by providing them with information to make an informed decision than by issuing this restrictive regulation.

Estimate of Economic Impacts: None provided

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Central Air Conditioner and Heat Pump Energy Conservation Standards

Agency Regulating: Department of Energy

Citation: None provided.

Authority: None provided.

Description of Problem: DOE's analysis does not adequately consider key differences among consumers. Many will be worse off as a result of the rule. Projected energy savings may be overstated.

Proposed Solution: None provided.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Standards for Privacy of Individually Identifiable Health Information

Agency Regulating: Department of Health and Human Services

Citation: None provided.

Authority: Health Insurance Portability and Accountability Act of 1996

Description of Problem: The rule imposes a costly, "one-size-fits-all" approach to medical privacy protections, while failing to offer tangible benefits. The cost of compliance could reduce access to health care by increasing the cost of treatment.

Proposed Solution: Clearly delineating ownership rights in the information and protecting those rights (including the use and disposal of that information.) Individuals would seek and plans/providers would offer, privacy protections that more closely parallel the desires and budgets of those concerned.

Estimate of Economic Impacts: Initial start-up costs of compliance will be $4 billion (versus HHS' estimate of $3.5 billion) and ongoing compliance with the rule will be $1.8 billion annually (versus HHS' estimate of $1.6 billion).

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims

Agency Regulating: Department of Health & Human Services/The Food and Drug Administration

Citation: 21CFR101

Authority: None provided.

Description of Problem: FDA's proposed rule would treat trans fats as a subset of saturated fats, even though their own analysis concludes that they are not. In trying to take advantage of consumers' awareness of the harmful effects of saturated fats, FDA is misleading the public by lumping together different categories of harmful fats.

Proposed Solution: FDA should approve a health claim about the relationship between trans fats and heart disease and expand the available claims regarding trans fat content, as well as the sellers that are permitted to sell them. FDA also should also revise the disqualifying criteria for health claims about fatty acid content and provide information about trans fats in a format that clearly differentiates between trans and saturated fats.

Estimate of Economic Impacts: No estimate of economic impacts was provided, but Mercatus believes that FDA overstated benefits by relying on a study of shelf labels rather than nutrition labels and understated the benefits by neglecting possible health risks that could arise if consumers found it more difficult to locate products low in saturated fat and cholesterol.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Hardrock Mining (Section 3809) (proposal)

Agency Regulating: Department of the Interior/Bureau of Land Management

Citation: 43 CFR Part 3800

Authority: Federal Land Policy and Management Act

Description of Problem: The costs of this rule outweigh the benefits, and requirements to perform Environmental Assessments are unnecessary and costly.

Proposed Solution: Require financial assurances, even in excess of expected reclamation requirements.

Estimate of Economic Impacts: About $150 million in compliance costs and the value of foregone production.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Snowmobile Use in Rocky Mountain National Park (proposal)

Agency Regulating: Department of the Interior/National Park Service

Citation: 36 CFR Part 7

Authority: National Park Service Organic Act

Description of Problem: By prohibiting snowmobiling, this rule does not allow for different types of users to enjoy the park, but instead claims one set of users is superior to another set.

Proposed Solution: NPS might consider requesting authority from Congress to charge differential fees based on the type of use.

Estimate of Economic Impacts: Total impact on businesses could range from an annual decrease of $265,800 to $728,200 in business revenues.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: OFCCP "60-2" regulation

Agency Regulating: Department of Labor/ Office of Federal Contract Compliance Programs

Citation: 41CFR 60-2

Authority: Executive Order 11246

Description of Problem: The 2000 revision of the requirements for federal contractors to maintain affirmative action plans required that such plans be developed for each physical establishment. Doing so neglects the way that most companies do business and manage personnel. OFCCP is very slow in negotiating agreements for doing plans differently.

Proposed Solution: Allow companies to report as they always have, by functional groupings. Develop guidelines for functional Affirmative Action Plans.

Estimate of Economic Impacts: IBM says impact is $1 million on it's company.

Commenter: IBM(6) EEAC(10)

Priority: 2

Name of Regulation: OFCCP's "60-2" regulation. T he Equal Opportunity Survey

Agency Regulating: Department of Labor/Office of Federal Contract Compliance Programs.

Citation: 41CFR 60-2

Authority: Executive Order 11246

Description of Problem: OFCCP's Equal Opportunity Survey which 50,000 contractors must complete annually, is excessively burdensome and does not help OFCCP accomplish its stated goal of more efficiently targeting contractors for compliance audits.

Proposed Solution: Eliminate or significantly modify the EO Survey.

Estimate of Economic Impacts: Over 1 million hours annually.

Commenter: EEAC(10)

Priority: 1

Name of Regulation: OFCCP Scheduling Letter

Agency Regulating: Department of Labor/Office of Federal Contract Compliance Programs.

Citation: 41CFR 60-2

Authority: Executive Order 11246

Description of Problem: OFCCP asks federal contractors to provide summary compensation data at the outset of a compliance review. This data is both burdensome to provide and raises concerns about confidentiality of information sensitive to firms.

Proposed Solution: OFCCP should wait until the onsite phase of a compliance review prior to requesting compensation data.

Estimate of Economic Impacts: None provided.

Commenter: EEAC(10)

Priority: 2

Name of Regulation: Annual Report For Federal Contractors

Agency Regulating: Department of Labor/ Veterans Employment and Training Services

Citation: 41 CFR 61-250

Authority: Executive Order 11246

Description of Problem: These recently published final rules increase the requirements for Federal Contractors to report on the veteran populations in their workforce. Contractors will now have to face increased burden and also know that new statutory requirements mean that these rules will have to be changed again soon, further increasing burdens.

Proposed Solution: Allow old reporting requirements to remain in effect until new statutory requirements are put in place through rulemaking.

Estimate of Economic Impacts: None provided.

Commenter: EEAC (10)

Priority: 3

Name of Regulation: Occupational Injury and Illness Record Keeping and Reporting

Agency Regulating: Department of Labor/Occupational Safety and Health Administration (OSHA)

Citation: 29 CFR 1904

Authority: Occupational Safety and Health Act

Description of Problem: The regulatory changes issued by OSHA on January 19, 2001 left significant areas of needless complexity and excessive administrative burden on employers. Of particular concern is the scope of the recordkeeping requirements with employers required to make no distinction between serious and minor cases.

Proposed Solution: Revise the employment threshold for compliance from 10 to 40 employees. Clarify the definition of recordable injuries to include only serious conditions resulting in death, compensable disability, hospitalization, or absence from work for multiple days.

Estimate of Economic Impacts: None provided.

Commenter: EPF(15)

Priority: 3

Name of Regulation: OSHA Consultation Program

Agency Regulating: Department of Labor/Occupational Safety and Health Administration (OSHA)

Citation: 29 CFR 1908

Authority: OSHA Compliance Assistance Authorization Act

Description of Problem: OSHA's rule makes the consultation program less attractive to employers by raising the litigation risk of participating.

Proposed Solution: Eliminate the requirements for employee participation in the opening and closing conferences, the posting of a hazards list, and making the consultant's report available for enforcement purposes.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Procedures for Certification of Employment Based Immigration and Guest Worker Applications.

Agency Regulating: Department of Labor/Employment and Training Administration

Citation: 20 CFR 655-656

Description of Problem: Current regulations affecting most employment based immigration cause needless expenditure of administrative effort and delays. The regulations discourage employers from seeking immigrant employees who would otherwise be able to make contributions to American productivity and competitiveness.

Proposed Solution: Replace the certification process with the simpler attestation procedure now used for the H-1B program.

Estimate of Economic Impacts: None provided.

Commenter: EPF(15)

Priority: 1

Name of Regulation: Davis-Bacon Act "Helpers" Regulation

Agency Regulating: Department of Labor/Employment Standards Administration

Citation: 29 CFR Parts 1 and 5

Authority: Davis-Bacon Act

Description of Problem: The Department of Labor should attempt to conform its regulations to private sector practices rather than impose its view of optimal practices. Specifically, a definition of helpers that allows the number of helpers to mirror the number in the private sector should be given a strong preference over the definition chosen by DOL which constrains private practices and innovation.

Proposed Solution: Modify the definition of "helper"

Estimate of Economic Impacts: DOL estimate in promulgating the definition was $108.6 million.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Defining and delimiting the terms "Any employee employed in a bona fide executive, administrative, or professional capacity or in the capacity of outside salesman"

Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R § 541 (2001)

Authority: Fair Labor Standards Act

Description of Problem: Individuals who should be exempt from FLSA's minimum wage and overtime requirements are not exempt, given current definitions of executive, professional, and administrative employees. Similarly, individuals who should not be exempt from these requirements are currently exempt, given existing definitions.

Proposed Solutions: (1) Exempt all employees who are paid on a salary basis and earn over a certain amount; (2) Adopt a separate exemption for "knowledge workers"; (3) Modernize duties tests under existing exemptions to reflect current workplace realities; (4) Make computer professionals exemption more flexible.

Economic Impacts: None provided.

Commenter: LPA (20)

Priority: 2

Name of Regulation: Overtime Compensation

Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R. § 778.201-211

Authority: Fair Labor Standards Act

Description of Problem: Disincentive for employers to offer bonuses as it complicates calculations for employee's regular rate for the time period in which bonus applies.

Proposed Solution: Permit employers to offer incentive bonuses to hourly employees without having to recalculate regular rate.

Economic Impacts: None provided.

Commenter: LPA (20)

Priority: 1

Statutory Change: Accrual of compensatory time and provision of more flexible schedules.
Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R. § 778

Authority: Fair Labor Standards Act

Description of Problem: Private sector employees are currently prohibited from accruing compensatory time, leading to inflexible work schedules.

Proposed Solutions: Pass legislation similar to section 207(o) of FLSA and adopting regulations similar to 29 C.F.R. § 553. Pass legislation similar to the Working Families Flexibility Act H.R. 1982 or section 2 of the Workplace Flexibility Act, S. 624. Allow employees to adopt biweekly work programs, through change in Section 207(a)(1) of FLSA.

Economic Impacts: None provided.

Commenter: LPA (20)

Priority: 3

Name of Regulation: Definition of "Serious Health Condition"

Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R. 825.114(2)

Authority: Family Medical Leave Act

Description of Problem: Definition of "serious health condition" is too broad resulting in inconsistent interpretations and employee abuse of the policy.

Proposed Solutions: Clarify in 29 C.F.R. 825.114(2) that "serious health condition" does not include "a short-term illness, injury, impairment, or condition for which treatment and recovery are very brief."

Economic Impacts: None provided.

Commenter: LPA (20)

Priority: 2

Name of Regulation: Limits on how employers may take intermittent leave

Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R. 825.203(d)

Authority: Family Medical Leave Act

Description of Problem: Existing regulation creates administrative burden by tracking intermittent leave in fractions of an hour.

Proposed Solutions: Clarify that intermittent leave can be taken only in half-day increments in C.F.R. 825.203(d).

Economic Impacts: None provided.

Commenter: LPA (20)

Priority: 2

Name of Regulation: Information needed for Employer to Designate Leave

Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R. 825.208

Authority: Family Medical Leave Act

Description of Problem: Employers currently may be liable for employees' violations of the FMLA.

Proposed Solutions: Shift burden of designating leave to employee (amend 29 C.F.R. 825.208) by: (1) allowing employers to require employees to file written application for FMLA in cases of foreseeable leave; (2) Allowing employers to require employees to provide oral notification to employer on the date leave commences.

Economic Impacts: None provided.

Commenter: LPA (20)

Priority: 2

Name of Regulation: Reform of Wage Determination Process

Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R. 4 et seq.

Authority: Service Contract Act

Description of Problem: Wage determinations made by Wage and Hour division do not reflect the true market-based wages of service contractor's employees.

Proposed Solutions: (1) Reform definition of "in the locality" (29 C.F.R. 4 et seq.) so wage determinations directly reflect wages in the nearby area instead of excessively broad areas; (2) Reform regulations setting wage calculation process; (3) Reform directory of occupations to reflect current jobs; (4) in the absence of regular wage determinations, amend Service Contract Act to provide for regular wage increases based on cost-of-living adjustment provided to federal employees.

Economic Impacts: None provided.

Commenter: LPA (20)

Priority: 2

Name of Regulation: Record keeping and notification regulations

Agency Regulating: Department of Labor/Wage and Hour Division

Citation: 29 C.F.R. 825

Authority: Family and Medical Leave Act

Description of Problem: Current regulations regarding record keeping and notification are burdensome and ambiguous. Confusion about practices and procedures has led to conflict and litigation. However, NPWF stressed the importance of employer notification of employees' rights under FMLA.

Proposed Solutions: Conduct further surveys and studies to determine full dimensions of the problem and how it can be remedied. Recommends agency form a collaborative task force that includes employers and employees to assist the government in analyzing the problem.

Economic Impacts: None provided.

Commenter: EPF(15) NPWF (28)

Priority: 1

Name of Regulation: Hours of Service of Drivers; Driver Rest and Sleep for Safe Operations

Agency Regulating: Department of Transportation/Federal Motor Carrier Safety Administration

Citation: 49 CFR Parts 350, 390, 394, 395, and 398

Authority: Interstate Commerce Commission Termination Act of 1995

Description of Problem: DOT did not present data supporting its conclusions that (1) driver fatigue contributes to highway fatalities or (2) its proposal would address either driver fatigue or highway accidents. Other factors, such as road congestion and road quality, may contribute to accidents involving motor vehicles, and these and other factors might even be exacerbated by DOT's proposal.

Proposed Solution: DOT should re-estimate the proposal's costs and benefits, taking into account the costs of new trucks and hiring new drivers and revising the key assumptions on which the fatality-reduction benefits are based.

Estimate of Economic Impacts: The Mercatus Center estimates that, after adjusting for the flaws in DOT's analysis, the proposal would impose annual net costs ranging from over $1 billion (if paperwork-reduction benefits are included) to $5 billion (if paperwork-reduction benefits are excluded).

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Advanced Air Bags

Agency Regulating: Department of Transportation: National Highway Traffic Safety Administration

Citation: 49 CFR Part 571; Standard No. 208, Occupant Crash Protection

Authority: Transportation Equity Act for the 21st Century (TEA 21)

Description of Problem: NHTSA adopted a one-size-fits-all standard that reduces consumer choice and "precludes manufacturers from meeting diverse [consumer] demands with a variety of safety measures and levels." Advanced air bags continue the differential safety impact on consumers, skewing safety benefits to occupants who do not wear seat belts.

Proposed Solution: NHTSA should allow consumers to make decisions based on information about individual tradeoffs. Permitting manual on-off switches would let consumers decide when an air bag was necessary, as opposed to relying on the automatic deployment of an advanced air bag.

Estimate of Economic: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Mixture and Derived-From Rule

Agency Regulating: Environmental Protection Agency

Citation: 40 CFR 261.3

Authority: RCRA

Description of Problem: Requires that low-risk waste streams, particularly those resulting from treatment of hazardous wastes, be managed according to RCRA subtitle C requirements.

Proposed Solution: Exempt waste streams resulting from the treatment of hazardous wastes from RCRA subtitle C, unless those waste streams themselves exhibit a characteristic of hazardous wastes.

Estimate of Economic Impacts: None provided.

Commenter: American Chemistry Council (14)

Priority: 1

Name of Regulation: Definition of "solid waste"

Agency Regulating: Environmental Protection Agency

Citation: 40 CFR 261.2

Authority: RCRA

Description of Problem: Definition includes all materials that exit the original generating process. This subjects hazardous materials that are destined for recycling or reuse to management as wastes under RCRA subtitle C and may discourage recycling of those materials.

Proposed Solution: Grant an exemption from RCRA for materials destined for recycling or reuse.

Estimate of Economic Impacts: None provided.

Commenter: American Chemistry Council (14)

Priority: 2

Name of Regulation: Toxic Release Inventory, Persistent, Bioaccumulative, Toxics (PBT) Rule

Agency Regulating: Environmental Protection Agency

Citation: RIN 2070-AD09

Authority: EPCRA Section 313

Description of Problem: This rule continues a trend of expanding information reported to TRI without adequately considering the usefulness of the information or the magnitude of the risks that it addresses.

Proposed Solution: Commenter does not propose specific solutions, other than that EPA should "take stock" of the program and "take seriously its responsibility of informing but not alarming communities."

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Total Maximum Daily Loads

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: CWA, Sec 303(d)

Description of Problem: Commenter believes EPA's recent revisions to the TMDL program are overly prescriptive and could result in billions of dollars of costs to States that might be better spent.

Proposed Solution: Commenter believes decisions on water quality and how best to restore it are best left to the States and local governments.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Drinking Water Regulations -- Cost-Benefit Analysis

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Safe Drinking Water Act

Description of Problem: The SDWA explicitly allows balancing of costs and benefits in setting drinking water standards. Commenter believes EPA consistently overestimates benefits and underestimates costs in order to set overly stringent standards.

Proposed Solution: EPA should improve its cost-benefit estimates. Three areas in particular which should be addressed are overly conservative risk estimates, inappropriate discount rates, and inadequate consideration of latency. EPA should also use a VSLY rather than a VSL approach to valuing fatal risk reduction.

Estimate of Economic Impacts: None provided.

Commenter: City of Austin (27)

Priority: 1

Name of Regulation: High Production Volume (HPV) Chemical-Testing Program Voluntary Children's Chemical Evaluation Program Endocrine Disruptor Screening Program (EDSP)

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: TSCA

Description of Problem: Collectively, these programs represent the largest chemical – and animal – testing exercise in history. The programs are costly but offer little hope of protecting the public or environment – EPA has made no commitment to reduce emissions or prevent human exposure to toxic chemicals on the basis of these testing programs. PETA notes that these programs represent the increasing EPA trend of undertaking costly chemical testing programs under the banner of "voluntary" initiatives in lieu of the normal rulemaking process in an attempt to circumvent administrative requirements and the associated external review.

Proposed Solution: None provided.

Estimate of Economic Impacts: None provided.

Commenter: People for the Ethical Treatment of Animals (PETA) (29)

Priority: 2

Name of Regulation: Importation Rules for Special Classes of Merchandise

Agency Regulating: Environmental Protection Agency and US Customs Service

Citation: 19 CFR § 12.110

Authority: 5 U.S.C. 301, 7 U.S.C. 136, 19 U.S.C. 66

Description of Problem: Barriers to importing samples of unregistered residential use pesticides for R&D purposes inhibits free flow of technology into the US and puts US industry at a disadvantage. Importers are required to submit a form (Form 3540-1) and obtain approval from a regional office prior to importation. This approved form must then be submitted to US customs further delaying import. In addition, importers must set up pesticide producing establishments in every global region from which they are interested in importing samples (for the purpose of obtaining a "foreign establishment number") and report annual productions at these foreign sites. These requirements add to reporting burden without providing health and safety benefits.

Proposed Solution: (1) Create an R&D exemption process for the importation of non-registered residential use pesticides in the US. (2) Allow import of registered residential pesticides without prior EPA approval via Form 3540-1.

Estimate of Economic Impacts: Commenter estimates that it would save over $100,000 per year as a result of the proposed relief. Additional monetary savings would result from reduction of paperwork for EPA and Customs. Non-monetized benefits would include: improved flow of technology into the US; gains for US industries competing for market share against foreign competition; benefits for consumers from swifter availability of the latest global technologies.

Commenter: Procter & Gamble Company, Janice L. Dhonau (24)

Priority: 2

Name of Regulation: Export Notification Requirements, TSCA Section 12(b)

Agency Regulating: Environmental Protection Agency

Citation: 40 CFR 707

Authority: TSCA

Description of Problem: TSCA Section 12(b) requires that persons notify EPA if they intend to export to a foreign country chemical substances or mixtures that are subject to various TSCA regulations. EPA must then notify the government of the country of destination of the availability of test data submitted on the substance and of any rule, order, or action under TSCA. EPA interprets 12(b) as applying to all persons exporting any product that contains the test substance – even products containing the substances as an impurity or minor mixture component. This interpretation does not reflect the statute and requires unnecessary effort. In addition, these export notices must be made to EPA in an extremely short time frame although it is unclear what benefits are gained from the extremely stringent deadlines. Utility of the requirements is also called into question because EPA in some cases does not forward their required notifications to recipient governments within the specified time and, because industrial chemical export notifications that provide no risk perspective have limited value, some receiving embassies discount the notices that are sent. In general, reporting burdens have increased as additional substances are subject to testing requirements and will significantly increase in the future as a result of regulatory actions (test rules) EPA is currently undertaking.

Proposed Solution: EPA could reduce burden via several options. These include: limiting reporting to "identified" substances; creating a de minimis exemption for TSCA 12(b) reporting based on the percentage of a substance in a product; establishing less restrictive reporting deadlines, eliminating unnecessary notification; establishing an R&D exemption, and clarifying which chemicals are covered by the notification period.

Estimate of Economic Impacts: Based on its prior survey results, ACC estimates that costs could be reduced by several million dollars per year with negligible effect on benefits. ACC also notes that, based on EPA ICR estimates, a de minimis exemption alone would result in industry cost savings of $325,000 to $411,000 annually. P&G projects savings in excess of $100,000 per year.

Commenter: *American Chemistry Council (ACC) (14)
Proctor & Gamble (P&G) (24)

Priority: 2

* Note: both commenters provided similar comments.

Name of Regulation: Export Notification Requirements, TSCA Section 12(b)

Agency Regulating: Environmental Protection Agency

Citation: 40 CFR 707

Authority: TSCA

Description of Problem: Export notification requirements impose significant burden with no discernable benefits. For example, businesses must implement compliance tracking systems and the government must expend significant resources to process and record notifications whose only purpose is to enable EPA to send a notice to a receiving country – a purpose for which EPA has not identified benefits. In addition, the export notification regulations contain virtually no exemptions, making compliance unnecessarily difficult. Finally, implementation of the regulations has been confusing because no complete published list of chemicals subject to export notification exists.

Proposed Solution: EPA could improve the regulations via several options. These include: limiting reporting only to exports of "bulk" chemicals; promulgating export notification exemptions; including a standard sunset provision in export notification requirements; allowing addition time for companies to submit export notifications; eliminating notices from companies to EPA.

Estimate of Economic Impacts: Commenter indicated that EPA's current ICR estimate of the total costs of the regulation over three years – $1.2 million for respondents and over $210,000 for the federal government – is low.

Commenter: American Petroleum Institute (API) (21)

Priority: 2

* Note: American Chemistry Council (ACC) and Proctor & Gamble (P&G) also commented (see above).

Name of Regulation: Notification of Substantial Risk, TSCA Section 8(e)

Agency Regulating: Environmental Protection Agency

Citation: 15 U.S.C. 2607

Authority: TSCA

Description of Problem: TSCA 8(e) requires any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment to immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information. EPA has been implementing and enforcing TSCA 8(e) through a 1978 Statement of Interpretation and Enforcement Policy. EPA's guidance on what information should be reported is haphazard and not easily accessible. EPA's guidance is still unresolved on several key points such as the timeframe for reporting and what information is considered known to EPA. The failure to clarify what is known to the Administrator has led to duplicate reporting and unnecessary burden. In the absence of a clear and updated policy, reporting is not focused on true substantial risk information.

Proposed Solution: EPA should publish, in one place a current and complete policy or regulation on TSCA section 8(e) reporting and should limit reporting to information that truly meets the statutory standard of substantial risk. EPA should also update the policy to require submission of only that information of which is not otherwise adequately informed through reporting requirements of other programs. Finally, EPA should finalize its proposed revisions to the reporting timeframe that would constitute "immediately informed."

Estimate of Economic Impacts: None provided.

Commenter: American Petroleum Institute (API) (21)

Priority: 1

Name of Regulation: Economic Incentive Program Guidance

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Clean Air Act

Description of Problem: EPA issued guidance on States' use of economic incentive programs to achieve air quality standards. In this guidance, EPA identifies principles that require States to show that using an incentive program will achieve faster attainment or greater reductions than would command-and-control (rather than the same speed and reduction at a lower cost). The comment also objects to EPA's principle that States should step in to prevent a trading program from yielding an "uneven" distribution of emissions or non-emissions effects.

Proposed Solution: Change the guidance to identify any program that yields an equal or faster attainment and equal or greater emissions reductions at a lower cost as an acceptable program. Eliminate or modify the equity principle.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: "New Source Review 90-Day Review Background Paper"

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Clean Air Act

Description of Problem: NSR is a deterrent to investment in new oil refinery and power generation capacity. Existing sources are at risk of triggering NSR even when making relatively minor modifications and even when those modifications will improve environmental performance. The cumbersome NSR process and EPA's aggressive application of NSR provide perverse incentives and encourage litigation.

Proposed Solution: For new sources, EPA should continue its efforts to reduce permitting times and to clarify BACT and LAER requirements. For existing sources EPA should use the settlement process to alter its NSR policy in ways that will improve the environment – allow the two industries to modernize and upgrade – while providing flexibility and regulatory certainty.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Concentrated Animal Feeding Operations (CAFOs) Effluent Guidelines

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: CWA

Description of Problem: While CAFOs are a significant problem in some watersheds, benefits of national rule proposed by EPA do not justify costs.

Proposed Solution: EPA should promote community based approaches that rely on market incentives and allow targeting to areas where there is actually a problem.

Estimate of Economic Impacts: According to commenter, EPA's own analysis shows net social costs of $660 to $800 million. Commenter believes these figures understate true social costs.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: National Ambient Air Quality Standard for Particulate Matter

Agency Regulating: Environmental Protection Agency

Citation: 61 FR 65638

Authority: Clean Air Act

Description of Problem: EPA's proposal does not offer a solid case for adopting a stringent new standard for small particles (PM 2.5). EPA's RIA is flawed. Benefits are overstated due to an overestimate of monetary valuation of life and an overestimate of premature deaths avoided. EPA's cost estimate assumes partial compliance in some counties and no costs in others, significantly understating national costs. The commenter notes that EPA should consider broader public health implications of imposing standards that offer limited and uncertain health benefits (risk-risk trade-off).

Proposed Solution: EPA should not finalize the more stringent PM 2.5 standard. (Solution implied but not explicitly stated.)

Estimate of Economic Impacts: Commenters estimate that the full costs of compliance would be about $55 billion annually compared to EPA's partial compliance estimate of $6.3 billion per year.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Heavy-Duty Engine and Diesel Rule

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Clean Air Act

Description of Problem: Commenter argues that EPA has not justified the need, feasibility, or cost-effectiveness of the proposed rule (since made final). Commenter further argues that EPA has not performed a benefit-cost analysis of the rule, and the cost-effectiveness analysis is flawed.

Proposed Solution: None provided.

Estimate of Economic Impacts: Commenter argues that incremental cost-effectiveness of reducing sulfur in highway diesel fuel from 25 ppm to 15 ppm is more than $80,000 per ton.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Request for Comments on Petition: Control of Emissions from New and In-Use Highway Vehicles and Engines

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Clean Air Act

Description of Problem: Commenters argue that EPA should deny a petition requesting that EPA regulate certain greenhouse gas emissions.

Proposed Solution: Deny petition

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: EPA's and DOJ's Worst Case Scenario Proposal

Agency Regulating: Environmental Protection Agency & Department of Justice

Citation: None provided.

Authority: Clean Air Act section 112(r)(7), as amended

Description of Problem: Commenter argues that information provided under the rule is likely to unduly alarm the public and is of little value. The rule also permits private citizens to post information on other internet sites.

Proposed Solution: The rule should not permit private dissemination of this information.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: National Ambient Air Quality Standard for Ozone

Agency Regulating: Environmental Protection Agency

Citation: 61 FR 65716

Authority: Clean Air Act

Description of Problem: EPA's proposed standard was based on weak and uncertain science and ignored health and welfare effects associated with ozone's protective properties (against UV-B penetration). EPA estimated that the partial costs of achieving the standard would exceed the benefits.

Proposed Solution: Non-regulatory approaches, including public health advisories and other targeted approaches.

Estimate of Economic Impacts: Commenters estimate that the full costs of compliance would exceed $80 billion per year.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Supplemental Notice for the Finding of Significant Contribution and Rulemaking for certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone; Proposed Rule

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Clean Air Act

Description of Problem: Use of market incentives in this proposal fails to maximize social welfare for two reasons. First, the goal is not set to maximize social welfare because achieving the ozone standard that underlies the proposal will not improve public health and welfare. Second, the emission limitations and trading allowances are not denominated in units that reflect the risk of concern (health risks from human exposure to high ozone concentrations in non-attainment areas during peak ozone periods).

Proposed Solution: Market incentives that encourage temporary measures to reduce ozone concentrations on peak days in key areas.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Request for Comments on Environmental Enforcement and Compliance Assistance Activities

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: None provided.

Description of Problem: Enforcement efforts do not always focus on the violations that pose the greatest real risks to health and the environment.

Proposed Solution: Target enforcement in such a way as to maximize the efficient use of enforcement resources. Set compliance expectations that are linked to reductions in health and environmental risks and then leave enforcement actions to States.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: EPA's Tier 2 Standards for Vehicle Emissions and Gasoline Sulfur Content

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Clean Air Act

Description of Problem: The commenter argues that EPA's Tier 2 rules have not met the statutory burden to demonstrate that they are necessary, cost-effective, and feasible. The commenter further argues that the standards will not be cost-effective for Western states. In a separate but related comment, the same commenter took issue with EPA's air quality modeling and argued that this rule may increase ozone emissions in some areas.

Proposed Solution: EPA should not proceed with the standards. (Note: The comments were filed during the comment period on the proposed rule.)

Estimate of Economic Impacts: None provided

Commenter: Mercatus Center (11)

Priority: 3

[NOTE: This page summarizes two Mercatus comments. (Mercatus also provided a separate comment (p. 20 of Appx III) that summarized public comments on an FR Notice of Supplemental Information and Request for Comment related to this rulemaking

Name of Regulation: Filter Backwash Recycling Rule

Agency Regulating: Environmental Protection Agency

Citation: 40 CFR Parts 9, 141, and 142

Authority: 42 USC 300g – 1(b)(14) – Safe Drinking Water Act Section 1412(b)(14)

Description of Problem: The Filter Backwash Recycling Rule is duplicative. Public water systems are subject to regulations that govern the microbiological quality of their finished water. These regulations include the Surface Water Treatment Rule, the Interim Enhanced Surface Water Treatment Rule, the Long-Term 1 Enhanced Surface Water Treatment Rule, and the Total Coliform Rule. An additional regulation, the Long-Term 2 Enhanced Surface Water Treatment Rule is currently under development. As long as these rules are met, the microbiological quality of the water is high and the Filter Backwash Recycling Rule is not necessary.

Proposed Solution: Vacate, in its entirety, the Filter Backwash Recycling Rule.

Estimate of Economic Impacts: Annual estimated cost savings of $5.8 to $7.2 million dollars.

Commenter: City of Austin (27)

Priority: 3

Name of Regulation: Arsenic in Drinking Water

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: Safe Drinking Water Act

Description of Problem: Mercatus states that based on EPA's own analysis, benefits do not justify costs at standards of either 5 or 10 ppb. Based on "more robust" analyses, these levels are even less attractive.

Proposed Solution: Mercatus believes that the EPA should set a standard such that benefits justify costs. Presumably commenter means a level higher than 10, though no specific level is suggested. AMWA supports the use of discretionary authority under SWDA to set levels that are less stringent than the "feasible" level if the benefits do not justify the costs and recommends that EPA conduct a thorough "incremental" analysis of the costs and benefits.

Estimate of Economic Impacts: Mercatus asserts that a standard of 5 ppb has net costs of1.4 billion. EPA's most recent analysis shows net costs at 10 ppb of $10 to $60 million, but these numbers are likely to change substantially as a result of several recent reports. AMWA asserts that the *incremental* costs of an arsenic standard less than 10 ppb would be over $250 million, while the *incremental* benefits of such a standard would be less than $50 million.

Commenter: Mercatus Center (11) Association of Metropolitan Water Agencies (AMWA) (18)

Priority: 1

Name of Regulation: Ground Water Rule

Agency Regulating: Environmental Protection Agency

Citation: None provided.

Authority: SDWA

Description of Problem: Proposed rule has some risk-based targeting of requirements (to protect drinking water wells from microbial contamination) but will still impose costs on small systems that are likely not justified by benefits.

Proposed Solution: Allow more risk based targeting of requirements (eg, monitoring), especially for small systems. Place greater emphasis on protecting source water and proper well siting and design.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Roadless Area Conservation (draft Environmental Impact Statement)

Agency Regulating: United States Department of Agriculture: Forest Service

Citation: 36 CFR Part 294

Authority: National Forest Management Act

Description of Problem: The proposed rule will cause unnecessary economic and environmental costs on forests by increasing the cost of forest health activities and allowing the deterioration of some ecosytems.

Proposed Solution: Absent a major reform of FS' budgetary process, FS should consider an alternative that would ban permanent roads but allow temporary, low-impact roads in certain areas.

Estimate of Economic Impacts: Could result in the loss of over 4,500 jobs and about $200 million in economic impact.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Forest Service Planning Rules

Agency Regulating: United States Department of Agriculture: Forest Service

Citation: 36 CFR Parts 217 and 219

Authority: National Forest Management Act

Description of Problem: These planning procedures polarize the public and are a drain on FS resources.

Proposed Solution: FS should consider alternatives to planning, such as an increased reliance on markets and incentive-based mechanisms.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Forest Service's Roadless Area EIS Notice

Agency Regulating: United States Department of Agriculture: Forest Service

Citation: 36 CFR Part 294

Authority: National Forest Management Act

Description of Problem: This blanket policy is likely to create ecological havoc and may not address potential problems related to incentives that reward managers for overbuilding roads and losing money on timber sales.

Proposed Solution: FS should consider the potential economic and environmental costs of this rule and alternatives that would focus on changing the incentives that influence forest managers.

Estimate of Economic Impacts: This notice was a prelude to the roadless rule, which (if enacted) may have resulted in the loss of over 4,500 jobs and about $200 million in economic impact.

Commenter: Mercatus Center (11)

Priority: 1

Name of Regulation: Second Consultative Package on the New Basel Capital Accord

Agency Regulating: Basel Committee on Banking Supervision, United States Banking Supervision Agencies: OCC, FDIC and Board of Governors of the Federal Reserve

Citation: None provided.

Authority: None provided.

Description of Problem: By relying on capital charges to mitigate unexpected operational losses, the rule undermines supervisory review and market discipline.

Proposed Solution: A combination of well-designed systems, controls and insurance that satisfies minimum requirements is a reasonable and less expensive substitute to regulatory capital for mitigating operational risk.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Request for Comments on Proposed Rules Relating to a New Regulatory Framework for Multilateral Transaction Execution Facilities, Intermediaries and Clearing Organizations; Exemption for Bilateral Transactions

Agency Regulating: Commodity Futures Trading Commission

Citation: None provided.

Authority: None provided.

Description of Problem: The proposed approach may increase legal uncertainty by broadening the category of products over which the CFTC could in the future exercise control, even though such products may not be futures contracts, and should not be regulated as such.

Proposed Solution: The CFTC should develop procedures for implementing these proposals that are transparent, fair and efficient.

Estimate of Economic Impacts: None provided..

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Fast-track Designation and Rule Approval Procedures

Agency Regulating: Commodity Futures Trading Commission

Citation: None provided.

Authority: None provided.

Description of Problem: Commenter supported the proposed course of action.

Proposed Solution: Commenter suggested that the CFTC also consider a multi-tier pricing structure, with lower application fees for contracts.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Uniform Guidelines for Employee Selection Procedures (UGESP)

Agency Regulating: Equal Employment Opportunity Commission (EEOC)

Citation: 29 CFR 1607 and 41 CFR 60-3

Authority: Executive Order 11246 and Civil Rights Act.

Description of Problem: Various agencies require employers to collect and report data on the race, gender, and ethnicity of job applicants.. There is no standard definition for applicant and various federal agencies have interpreted the term very broadly requiring firms to solicit this data from anyone who expresses interest in employment.

Proposed Solution: Clarify UGESP to clearly define "job applicant" and ensure that the definition does not impose undue burden on employers to solicit race and gender information.

Estimate of Economic Impacts: None provided.

Commenter: EEAC(10)

Priority: 1

Name of Regulation: EEO1 form

Agency Regulating: Equal Employment Opportunity Commission.

Citation: 29 CFR 1607.2

Authority: Title VII Civil Rights Act Section 709(c)

Description of Problem: The EEO1 report will soon be modified to include 14 job categories and to comply with OMB guidance on race and ethnicity. This will increase the burden on employers by increasing the number of categories for which they are responsible for reporting.

Proposed Solution: None proposed by commenter. Appears to prefer leaving EEO1 form in current state.

Estimate of Economic Impacts: None provided.

Commenter: EEAC (10)

Priority: 3

Name of Regulation: Minimum Security Devices, and Procedures and Bank Secrecy Act Compliance

Agency Regulating: Federal Deposit Insurance Corporation

Citation: 12 CFR Part 326

Authority: None provided.

Description of Problem: The rule would treat all citizens as potential suspects. The FDIC has not demonstrated a compelling social need for this information that would justify its potential imposition on customers' individual liberties and property rights.

Proposed Solution: This proposal should be withdrawn.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Regulation of Short-Term and Long-Term Gas Transportation

Agency Regulating: Federal Energy Regulatory Commission

Citation: None provided.

Authority: None provided.

Description of Problem: FERC has issued a proposed rule mandating auction markets for short-term gas transportation and regulates long-term transportation contracts for natural gas.

Proposed Solution: FERC should not mandate any particular market for trading of short-term gas transportation, at least until it is proven that an efficient exchange mechanism has not evolved. Use a model akin to Texas intrastate pipeline regulation to deal with pockets of market power in long-term gas transport rather than the current regulatory approach.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Revision to Regulation B

Agency Regulating: Federal Reserve Board

Citation: None provided.

Authority: None provided.

Description of Problem: The proposed modifications offer little substantive benefit; while at the same time imposing additional costs on banks and credit consumers.

Proposed Solution: The commenter suggests that the Board abstain from further changes to Regulation B.

Estimate of Economic Impacts: Mercatus estimates that the ongoing costs of the proposed changes would range from $500,000 to $2,100,000 annually. Moreover, using OMB's standard discount rate of 7% produces a present value of these cost estimates that ranges from $7.1 million to $30 million.

Commenter: Mercatus Center (11)

Priority: 3

Name of Regulation: Privacy of Consumer Financial Information

Agencies Regulating: Federal Reserve Board, the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision

Citation: 12 CFR Parts 40, 216, 332, and 573

Authority: Gramm-Leach-Bliley Act of 1999

Description of Problem: The agencies' interpretation of "nonpublic personal information," which has significant effects on the scope of the rule, is more strict than Congress intended. This may have long-run negative consequences.

Proposed Solution: The agencies should more clearly delineate ownership rights in the information and then protect those rights. They should allow financial institutions and their customers to develop tailored approaches to privacy instead of prescribing rules.

Estimate of Economic Impacts: The Mercatus Center estimates the compliance costs to be at least $220 million annually, translating into long-run costs of over $3.2 billion.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Nasdaq Integrated Order Delivery and Execution System

Agency Regulating: Securities and Exchange Commission

Citation: None provided.

Authority: None provided.

Description of Problem: Although the proposed changes to Nasdaq's integrated order delivery and execution system would generate net benefits to investors, several operational components are likely to reduce market transparency. These include the proposed time delay for large orders and the Firm Quote Compliance Facility's closure of market makers' quotes while continuing to display the price.

Proposed Solution: Provide immediate automatic execution of all orders regardless of size and move a market maker's quoted price away from the current side of the quote that is at risk.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Concept Release on Regulation of Market Information, Fees and Revenues

Agency Regulating: Securities and Exchange Commission

Citation: None provided.

Authority: None provided.

Description of Problem: By proposing to establish cost-based guidelines that networks must use to set their fees for stock quotations and transaction prices, SEC is attempting to adopt an approach that has failed in the past.

Proposed Solution: The SEC should focus on promoting competition in the provision of information instead of regulating a government-created information cartel.

Estimate of Economic Impacts: No specific estimates were provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Commission Request for Comment on Issues Relating to Market Fragmentation

Agency Regulating: Securities and Exchange Commission

Citation: None provided.

Authority: None provided.

Description of Problem: There is little evidence that the fragmentation that the SEC fears is significant and its proposed solution would create cumbersome disclosure systems.

Proposed Solution: No regulation is necessary. Instead, the SEC should promote competition in market data provision and market-based trading linkages.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Disclosure of Mutual Fund After-Tax Returns

Agency Regulating: Securities and Exchange Commission

Citation: 17 CFR Parts 230, 239, 270, & 274

Authority: Securities and Exchange Act of 1934/Investment Company Act of 1940

Description of Problem: The SEC's proposal to require mutual funds to report standardized after-tax returns along with the standardized pre-tax returns they already report is inferior to the current market response and is unlikely to generate net benefits to investors.

Proposed Solution: The SEC should withdraw this proposal.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Disclosure of Order Routing and Execution Practices

Agency Regulating: Securities and Exchange Commission

Citation: None provided.

Authority: None provided.

Description of Problem: There is no evidence that the market segmentation described by the SEC to justify the proposed regulation reduces the ability of stock prices to incorporate relevant information. No market failure has been documented.

Proposed Solution: SEC should withdraw this proposal.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Proposed Rule Changes of Self-Regulatory Organizations

Agency Regulating: Securities and Exchange Commission

Citation: 17 CFR Parts 240 & 249

Authority: Securities Exchange Act of 1934

Description of Problem: It is unlikely that significant innovations will result from this proposed rule change since fundamental structural changes are directly excluded from expedited consideration under the new rule.

Proposed Solution: No specific solutions are proposed.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Registration of Broker-Dealers Pursuant to Section 15(b)(11) of the Securities Exchange Act of 1934

Agency Regulating: Securities and Exchange Commission

Citation: None provided.

Authority: Securities Exchange Act of 1934/Commodity Futures Modernization Act of 2000

Description of Problem: SEC has proposed a registration format that would result in time-consuming duplication of registration procedures for futures commission merchants and introducing brokers already duly registered with the Commodity Futures Exchange Commission.

Proposed Solution: No specific solution is advocated.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 2

Name of Regulation: Delivery of Mail to a Commercial Mail Receiving Agency

Agency Regulating: United States Postal Service

Citation: None provided.

Authority: None provided.

Description of Problem: The Postal Service has not shown that the proposed labeling requirement is necessary or desirable. The inflexibility of the address designation requirement imposes real costs on the home-based businesses and customers generally.

Proposed Solution: The Postal Service should withdraw the address designation requirement and carefully consider the benefits and costs of any labeling requirements before proceeding.

Estimate of Economic Impacts: None provided.

Commenter: Mercatus Center (11)

Priority: 3

Appendix B

Key to Comments
Report to Congress On the Costs
and Benefits of Federal Regulations

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Appendix C

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PART 2 AGENCY COMPLIANCE WITH TITLE II OF THE UNFUNDED MANDATES REFORM ACT OF 1995

CHAPTER I – BACKGROUND

Over the past two decades, State, local, and tribal governments increasingly have expressed deep-felt concerns about the difficulty of complying with Federal mandates without additional Federal resources. In response, Congress passed the Unfunded Mandates Reform Act (the "Act"), which was signed into law on March 22, 1995 (P.L. 104-4). OMB sent guidance to the agencies on implementing Title II of the Act on March 31, 1995. OMB then issued further guidance on Section 204 of the Act on September 21, 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 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 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). 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 Act was designed to ensure that Congress and Executive Branch agencies consider the impact of legislation and regulations on States, local governments, and tribal governments, and the private sector. With respect to States and localities, the Act was an important step in recognizing State and local governments as partners in our intergovernmental system, rather than mere entities to be regulated or extensions of the federal government through which to advance Washington's priorities.

Unfortunately, the implementation of the Act has not progressed as initially envisioned. State, local, and tribal governments continue to believe that the Federal government is taking actions that affect them without the necessary consultation. States and localities report that many agencies think simply *informing* State and local governments of a rulemaking action is the equivalent of consultation. They have also indicated that consultation processes lack uniformity, that consultation does not occur early enough in the rulemaking process, and when consultation does occur, agencies often contact their State or local counterparts instead of the elected officials (or chief appointed officials) entrusted by the public with running the government.

While this report details a large number of instances in which agencies did consult with States, clearly more still needs to be done to ensure that this consultation takes place in all instances where it is needed and early in the federal decisionmaking process. Toward that end, the President established an Interagency Working Group on Federalism. Devolving authority and responsibility to State and local governments, and to the people, is a central tenet of the President's management of the Executive Branch and this working group is striving to turn this principle into policy.

This working group will issue a new Executive Order on Federalism which will spell out explicit requirements for agencies to consult with State and local governments. This Administration will do more to involve State and local governments early in the rulemaking process. Consultation means little if it occurs after the opportunity to improve a rule has passed. Agencies should consult with State and local governments, including their elected officials and Washington representatives, before they commit to any particular rulemaking alternative.

In addition, this Administration will bring more uniformity to the consultation process to help both agencies and our intergovernmental partners know when, how and with whom to communicate. States and localities should have a clear point of contact in each agency, and agencies must understand that "consultation" means more than making a telephone call the day before a rulemaking action is published in the Federal Register. Finally, this Administration will enforce the Unfunded Mandates Reform Act to ensure that agencies are complying with both the letter and the spirit of the law. If an agency is unsure whether a rule contains a significant mandate, it should err on the side of caution and prepare a mandates impact statement prior to issuing the regulation.

The remainder of this report discusses the results of agency actions in response to the Act. The report covers agency actions taken between June 2000 and May 2001. Since not all agencies take actions that affect other levels of government, this report focuses on the agencies that have regular and substantive interactions on regulatory matters that involve States, localities, and tribes. Chapter 2 discusses agency consultation efforts. These include both those efforts required under the Act and other consultations conducted by agencies. Chapter 3 lists and briefly discusses the regulations that agencies have indicated meet Title II's $100 million threshold and the specific requirements of Sections 202 and 205 of the Act. According to the agencies, eighteen rules have met this threshold in the past year and only two regulations that required the preparation of an agency analytical statement because of

aggregate expenditures by State, local, and tribal governments of more than $100 million.

CHAPTER II-- AGENCY CONSULTATION ACTIVITIES

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. Executive Order 13132 also requires consultation with State and local governments on regulations that either impose substantial direct compliance costs or preempt state law. This chapter summarizes consultation activities by agencies whose actions significantly affect State, local, and tribal governments in this way.

Eleven agencies (Agriculture, Commerce, Education, Health and Human Services, Housing and Urban Development, Interior, Justice, Labor, Transportation, Veteran's Affairs and EPA)[37] have involved State, local, and tribal governments in their regulatory processes. It is clear from the descriptions below that there are a large number of interactions between the Federal government and its counterparts at the State, local and tribal levels. However, as noted in Chapter 1, many of our intergovernmental partners feel that they are not being consulted sufficiently on those issues that matter the most to them.

There are a number of possible reasons for this sentiment despite the consultations described below. Perhaps the agencies are incorrectly assessing which of its regulatory activities most concern State, local, and tribal governments. Another possibility is that agencies are consulting with their counterparts at the State level rather than elected officials or their representatives. Many of the consultations described below are with professional staff at State or local agencies. Finally, perhaps the consultations described below are not sufficient in either their depth or their timing to give State, local and tribal governments the voice they desire in federal decisionmaking processes.

The Office of Management and Budget is particularly interested in what State, local, and tribal governments perceive as failures in the consultation process. We invite public comment on the two questions listed below:

1. In the examples of federal consultation described in this chapter, was the consultation sufficient? Was it conducted at a time in the decisionmaking process when it was meaningful? Were the views of States, local governments and tribes sufficiently solicited by the agencies?

2. Are there instances other than those described below where consultation should have taken place between an agency and a State, local, or tribal government where it did not?

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[37] In general, the Departments not listed here (for example: State, Defense) do not often impose mandates upon States, localities or tribes and so have fewer occasions to consult with other levels of domestic government.

Responses to these two questions will be very valuable as the Administration develops policies to further the rights of State, local and tribal governments under the Unfunded Mandates Reform Act and the forthcoming Executive Order on Federalism.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

Since the implementation, in early 1993, of the Federal Pesticide Recordkeeping Program, which requires all certified private applicators to keep records of their use of federally restricted use pesticides for a period of 2 years, the emphasis of the program has been to work cooperatively with state designated agencies. The program recognizes state authority to enforce state regulations that are comparable to the Federal regulations. There are 22 state programs currently recognized by AMS. AMS provides funding to some of these states through cooperative agreements to support their regulatory programs.

For those states that are under the Federal program, AMS enforces the program through the use of cooperative agreements with the state designated agencies. State agency officials work closely with AMS personnel to assure the program is administered effectively and efficiently. The close working relations between the state agencies and AMS personnel has allowed for flexible administration of the program through suggested changes by state counterparts. On July 19 and 20, 2000, the annual State/USDA meeting was held in Boise, Idaho on the administration of the Federal Pesticide Recordkeeping Program. The annual meeting provided an opportunity for state agency staff to discuss issues and concerns about the administration of the Federal program. As a result of this meeting, state agency staff endorsed a new enforcement policy for the Federal program.

After holding the State Cooperators Meeting in July of 2000, the State agency representatives encouraged the Agricultural Marketing Service (AMS) to strengthen the enforcement policy on certified private applicator's restricted use pesticide records. The State representatives felt that in order for a certified applicator to be in full compliance with the Federal regulations the restricted use pesticide record should have all the required data elements recorded as defined in the regulation. Pesticide records that had missing data elements should be considered out of compliance. In response, AMS modified its requirements so that certified private applicators who have incomplete records are now considered to be non-compliant with the regulation. However, applicators are still given one year to come into compliance and put their records in order before a compliance action is taken.

There are other examples of flexibility in program administration. In the case of a natural disaster such as floods, the State agency's manpower may need to be redistributed. AMS allows the agency to renegotiate the cooperative agreement to best suit the needs of the State agency and the regulated community. States have provided suggestions on how to reduce the amount of travel time of State inspectors to conduct the record inspections, allowing only certain sections of the state to be

covered each year. This works particularly well in the larger Western states. Finally, AMS allows the inspection work to be scheduled in accordance to the seasonal nature of the agricultural products being grown in the State. States have the flexibility to conduct work according to their workload and to schedule inspections to allow for the least amount of impact on the regulated community.

Animal and Plant Health Inspection Service

Scrapie Control Program

Scrapie control activities continue to be a blend of Federal and state programs working in cooperation. In drafting the proposals, APHIS had many discussions with officials of animal health agencies in affected states. As APHIS prepares to publish a final rule for these proposals, it has continued active consultation with state animal health agencies and the elected officials of affected State and local governments. After consultation with State animal health agencies, APHIS made several changes in its final rule regarding the domestic scrapie program. These changes made Federal requirements more consistent with the requirements of existing State scrapie control programs, thus minimizing the need for States to make changes to their programs in order to be considered a "Consistent State" under the new Federal regulations. For example, we combined the categories of suspect animal and affected animal into one category, which removes the need for States to change their regulations to separately address affected animals. We also changed the definition of brand to include official brand registry brands on eartags in those States whose brand law or regulation recognizes brands placed on eartags as official brands. We also made a change allowing consistent States that have had no cases of scrapie in commercial flocks to exempt such flocks from certain identification requirements of the rule. The final rule was published on August 21, 2001.

Veterinary Services Safeguarding Review

APHIS' Veterinary Services is currently undertaking a safeguarding review, which is being conducted by the National Association of State Departments of Agriculture (NASDA). APHIS selected NASDA to conduct the review because each state plays an integral part in protecting U.S. animal health on a national level by implementing standardized animal health regulations, conducting surveillance, assisting with foreign animal disease investigations, and responding to potential disease introductions. NASDA's review panel and committee chairs are comprised of individuals representing industry, academia and the states whose expertise and knowledge is deep. The review will look at what is working well, what needs to be addressed, and what enhancements or new initiatives would improve the overall safeguarding system.

Swine Moving Interstate in Production Systems

APHIS is about to finalize this proposed rule to reduce the paperwork burden for moving swine from one premises to another within the same production system. Previously, when such movement

crossed state lines, individual health certificates were required for each animal, and state permits were usually issued for each movement. Under this rule, this paperwork will be replaced by enduring agreements (the Swine Health Production Plan) between APHIS, State governments, and swine producers. This approach was developed in close consultation with both industry and State animal health agencies, working through livestock associations and the State Animal Health Officials association. When the final rule is published it will address the comments by State officials.

Food and Nutrition Services

Summer Food Service Program (SFSP)

In FY 2001, FNS and State agency staff attended meetings with potential and currently participating sponsors in targeted locations throughout the country. The purpose of these meetings was to discuss providing SFSP services in non-served areas and areas with low participation. From these meetings, SFSP services were expanded and additional children were served. For example, two new sponsors entered the program; an existing sponsor added five sites; and a school sponsor joined the program in a community which had not had a SFSP sponsor in over ten years.

Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

The Agency and the National Association of WIC Directors (NAWD) continue the Federal/State partnership established to achieve consistency in the nutrition risk criteria used among State agencies to determine eligibility for applicants in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). FNS has also continued its dialogue and communication on various management information systems (MIS)-development issues of mutual interest. Specifically, FNS and NAWD have partnered on revisions to the WIC MIS Functional Requirements Document (FReD) or guide, and in developing a survey of states to obtain information on MIS functionality and costs.

In addition, the Agency is working with NAWD to update and improve the minimum and supplemental data elements collected for the WIC Participant Characteristics (PC) Report. The Agency also meets twice a year with the NAWD EBT/ESD Users Group, comprised of State representatives working on electronic benefit transfer/service delivery system plans/projects, to collaborate on seeking and developing appropriate technological solutions to their service delivery systems.

The Agency also sponsors the National Advisory Council on Maternal, Infant and Fetal Nutrition. Its purpose is to make an ongoing study of WIC and related programs to determine how they may be improved. Categories of membership for the 24-member Council are specified by law, and include officials from State agencies. Finally, in order to improve the quality of nutrition services provided to WIC participants, the Agency, in conjunction with representatives of the National

Association of WIC Directors, developed a document entitled *WIC Nutrition Services Standards*. This document describes standards of practice for State and local WIC agencies.

A revision to the WIC Policy Memorandum 98-9, Nutrition Risk Criteria, was issued in March 2001. This revision was developed through deliberation by and consultation with the Risk Identification Selection Collaborative, a Federal/State partnership established to achieve consistency in the nutrition risk criteria used to determine WIC Program eligibility

Commodity Supplemental Food Program

FNS solicited input from State and local Commodity Supplemental Food Program (CSFP) operators in developing a proposed rule to rewrite CSFP regulations in "plain language," to reduce time and paperwork burden for State and local agencies and increase their flexibility in program operations, and to strengthen program accountability. Additional comments from State and local agencies will be addressed when the rule is finalized.

FNS solicited input from CSFP and WIC State agencies in developing guidance to encourage collaboration between CSFP and WIC State and local agencies to help ensure more effective program management. The guidance addresses collaboration in the development and implementation of State Plans, program referrals, sharing of program information, and preventing dual participation.

National Rural Development Partnership

The National Rural Development Partnership (NRDP) and State Rural Development Councils (SRDCs) were established in 1990 as part of the Presidential Initiative on Rural America to facilitate greater coordination of rural development policies and programs. SRDCs are independent organizations that bring together federal, State, local, and tribal governments with the private and non-profit sectors to identify coordinated responses to rural communities' needs. The NRDP addresses a broad range of issues (e.g., transportation, health care, veteran's affairs, economic development, and housing) that impact State, local, and tribal governments. The ultimate goal of the NRDP is to assist people in rural communities in improving their quality of life.

Since the NRDP's inception, the U.S. Department of Agriculture has played a major role in organizing and sustaining its operation, including providing administrative and logistic support to the National Partnership Office. The NRDP is important to the Department's Title II compliance because it is organized to provide the comprehensive outreach mechanisms needed to maintain continuing communication with State, local, and tribal governments. Mechanisms employed by NRDP help build networks at all levels, bring people and organizations together to solve local problems and meet local needs, remove existing barriers, create opportunities in rural areas, and build the strength of the overall Partnership.

Forty State Rural Development Councils are the primary components of the NRDP. In addition, a national infrastructure supports the State Councils by providing national networking and knowledge-sharing opportunities, peer consultation, and technical assistance. NRDP also has in place a 50-State expansion strategy area and intends to add more Councils when funds become available.

SRDCs offer a direct channel for information on conditions and needs in rural communities. USDA and other Federal Departments have used this capacity to improve the delivery of services to rural areas. Here are two examples:

Vermont Council on Rural Development (VCRD)

VCRD, as part of a grassroots effort to keep in touch with local issues, conducts a community visit program. A team of State and federal resource providers visits a rural town for a day and listens to invited citizens discuss issues important to their communities. In December 1999, in Bradford, more than 80 local citizens participated in focus groups. At a public meeting in January 2000, Bradford's residents discussed and prioritized the issues raised at the December focus groups. Over 50 town residents attended the meeting and more than 50 people signed up to work on issue-based committees. VCRD and its federal, state, legislative, economic development, transportation, and arts partners published a final report in March 2000 that included the list of priorities and suggestions. Community leaders used the report to develop the town's annual work plan. As a result of their participation in this process, town officials now have a better working relationship with key state and federal partners, which will help them advocate more effectively to gain greater state and federal support for local programs.

Idaho Rural Partnership (IRP)

IRP formed a regional partnership with conservation, development, and extension organizations to conduct land use protection workshops. The purpose of the workshops was to address the issue that farmland, grazing land, and private timberland is being taken out of working production at an alarming rate in some parts of Idaho and the Intermountain West. IRP designed a workshop template and developed materials for a series of five workshops. The Council also helped obtain seed funding, gathered the partners, hosted the planning committee meetings, marketed the workshops, and supplied a workshop trainer. As a result of these workshops, rural residents have gained a better understanding of land use challenges in their communities and what tools exist to help guide development.

The National Rural Development Council is another component of the NRDP. The NRDC consists of senior program managers representing federal departments, agencies and national organizations. It provides guidance for NRDP and works on behalf of SRDCs at the national level. This national network also raises awareness of the impact of federal programs and their rules and regulations on rural areas, and it shares program information and encourages coordination within and among departments. The NRDP has established an impediments committee and process, which

SRDCs can access to ameliorate federal barriers that significantly hinder successful application of federal programs in rural areas. The committee has reached out to tribal organizations to raise awareness of tribal issues and increase tribal participation at both the national and state levels as well.

Though the NRDP does not have an SRDC in every state, it does have a state and/or federal contact in every state who can facilitate local communication should the need arise. The NRDP also has a website (http://www.rurdev.usda.gov/nrdp) that carries updated information about the Partnership and efforts to connect states with rural development policies and resources.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

NOAA consults with State, local, and tribal governments in the National Marine Sanctuary designation process. Sanctuary Advisory Councils (SAC) are established to provide constituents greater input into the Sanctuary designation process. The SAC members represent a variety of local user groups, the general public, and State, local, tribal, and Federal governmental entities. The SAC provides a public forum for its constituents, working to enhance communications and provide a conduit for bringing the concerns of user groups and stakeholders to the attention of the site liaison and NOAA.

In the Florida Keys National Marine Sanctuary (FKNMS), the SAC, working in cooperation with the State of Florida, the Gulf of Mexico Fishery Management council, and the National Marine Fisheries Service, recommended that the existing Sanctuary boundary be expanded by approximately 96 square nautical miles, to establish a 151 square nautical mile "no take" ecological reserve to protect the critical coral reef ecosystem of the Tortugas. The plan prohibits anchoring in the expanded zone, prohibits mooring there by vessels over 100 feet in length, and controls access to the "no take" zone through the use of permits.

In developing this plan, the Sanctuary convened a 25 member Working Group comprised of commercial and recreational fishermen, divers, conservationists, scientists, and other concerned citizens, as well as a variety of governmental entities. The Working Group included representatives from the Florida Marine Patrol, the Florida Department of Environmental Protection and the Florida Marine Fisheries Commission. The Working Group gathered information through a site characterization document as well as through the firsthand experiences of interested parties, in order to develop a range of alternatives and recommend a preferred alternative to the State of Florida and SAC.

County and State representatives were involved throughout the site selection process and development of regulatory recommendations. County and State representatives were also present at all meetings and deliberations of the Working Group and SAC at which the proposal was considered, and regularly communicated with NOAA.

Subsequent to the May 2000, issuance of a Draft Supplemental Environmental Impact Statement/Draft Supplemental Management Plan (DSEIS/SMP), the Sanctuary solicited public comments on the proposal and held a series of public hearings in conjunction with the National Park Service/Dry Tortugas National Park, Florida Fish and Wildlife Conservation Commission, and the Gulf of Mexico Fishery Management Council throughout South Florida, as well as in Washington, D.C. Affected counties and the State of Florida submitted comments to NOAA on the DSEIS/SMP and the proposed rule. The final rule, published in the Federal Register on January 17, 2001, provides for the enforcement of Sanctuary regulations primarily through an enforcement agreement between NOAA/National Marine Sanctuary Program and the State of Florida Fish and Wildlife Conservation Commission.

Among other things, the rule provides for the enforcement of Sanctuary regulations primarily through an enforcement agreement between NOAA's National Marine Sanctuary Program and the State of Florida Fish and Wildlife Conservation Commission. NOAA is currently taking steps to expand its enforcement partnership with the State, and to increase the level of financial assistance provided to the state. NOAA has already approved financial assistance which will allow the state to hire ten additional enforcement officers to enforce both State and Federal law in the FKNMS. In addition, the ecological reserve is already providing important opportunities for marine research by scientists from institutions in Florida and elsewhere.

The State of Florida drafted parallel regulations applicable within state waters in the Sanctuary, intended to go into effect at the same time as the Federal regulations. In April, the Governor of Florida and his cabinet (collectively, "The Board of Trustees") unanimously approved those state regulations, and made the corresponding Federal regulations applicable to all state waters in the Sanctuary. The state regulations and the state approval of the federal regulations became effective on July 1, 2001. The Federal/State partnership determined that mutual enforcement goals would be best achieved by reserving to the State of Florida ultimate authority over activities within state waters.

NOAA recognizes that much of the success in its recent efforts in the FKNMS is a result of its close collaboration with state and local agencies, and NOAA is taking a similar approach in other places, such as California, where changes to national marine sanctuary management plans are being considered.

DEPARTMENT OF EDUCATION

During the period covered by this report, a number of principal offices conducted extensive meetings and other exchanges with affected persons and groups, including representatives of State, local, and tribal governments, to design new laws and regulations, develop research priorities, plan program implementation, and provide technical assistance.

The Department provides to local governments and school districts information about regulations that may significantly or uniquely affect them through regular attendance by the Department's staff at meetings across the nation, visits to grantees, program guidance for grantees, and other forms of outreach. In particular, the Office of Intergovernmental and Interagency Affairs (OIIA) works with small governments through regular meetings with organizations such as the National School Boards Association, the United States Conference of Mayors, the League of Cities, the National Association of Counties, and the National Association of Towns and Townships. Along with discussion of policy and budgetary issues, The Department raises regulatory issues and typically invites general comments on its regulatory agenda at these meetings.

The Department's consultation process under the Executive order uses NPRMs, the Departmental Review and the Office of Constituent Affairs' listserv to alert interested State and local elected officials of upcoming regulations that may have federalism implications, including the establishment of any committees to conduct negotiated rulemaking. ED Review, OIIA's biweekly electronic newsletter, provides up-to-date information on its activities and events, written specifically for the intergovernmental and corporate community. The listserv notifies the National School Boards Association and others of opportunities for consultation.

Below are two specific examples of how consultation has helped the Department of Education make policy.

In developing Student Financial Aid Regulations through the negotiated rulemaking process, the Department of Education (ED) held listening sessions in Washington, DC, Atlanta, Chicago, and San Francisco to consult with interested State, local, and tribal governments and the public to obtain input in the development of ED regulations. The Student Financial Assistance Customer Service Task Force conducted additional listening sessions.

At these sessions and throughout the negotiated rulemaking process, ED raised questions regarding regulatory policy and asked for suggestions on how ED could best implement the changes made by the Higher Education Amendments of 1998 to the Higher Education Act of 1965, as amended, with the least amount of burden to the entities affected by the changes. These consultations led to improvements in the final regulations issued on November 1, 2000. In response to comments from State agencies on the Teacher Loan Forgiveness Program, the Department modified the regulations to clarify the amount of the borrower's loans that may be forgiven, the effects of breaks in service on the borrower's qualification for the forgiveness program and the treatment of loans held by guaranty agencies on which the borrower satisfies the criteria for forgiveness.In response to comments from State agencies (among others) on the regulations governing loan discharges based on death and permanent disability, the Department changed the regulations modifying the evidence required for a loan discharge based on death to permit loan holders to get the necessary documentation directly from the government offices rather than require the borrower's family to submit the documentation. The Department also delayed the effective date of the changes in the process for a discharge based on a

total and permanent disability to provide all program participants more time to modify processes and systems.

In developing the Department's amendments to regulations governing the Early Intervention Program for Infants and Toddlers With Disabilities under Part C of the Individuals with Disabilities Education Act the Department asked for comment specifically on whether the proposed regulations would impose substantial direct compliance costs on State and local governments without reimbursement of the costs by the Federal government. The Department also asked whether the proposed regulations would result in any unintended preemption of state law. The Department encouraged State and local elected officials to review the proposed regulations and to comment specifically on these federalism issues. All of the comments received that can be interpreted as responsive to this request concerned the proposed provisions on finance and insurance (proposed §§303.519 through 303.521). In the final regulation, the Department will respond to the state commenters and address their concerns.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Departmental Consultation

The primary function of the Office of Intergovernmental Affairs (IGA) is to assist the HHS Secretary in the development and implementation of the Department's policies by ensuring that the Department diligently considers and incorporates the perspectives of State, local, and tribal governments. The chief tool used to accomplish this objective is the intergovernmental consultation process, in which the leadership of every agency and staff office of the Department plays a role. IGA further uses the consultation process in its role as an intermediary between individual State, local, and tribal governments and the Department. IGA is also responsible for ensuring that the rural perspective is included in Departmental policy, program and regulations, and the Office oversees the HHS role in an interdepartmental effort on the coordination of community transportation resources and services.

Grant Simplification

The Office of Intergovernmental Affairs assisted the Office of Management and Budget (OMB), the Office of the HHS Assistant Secretary for Management and Budget, and federal grant-making agencies in coordinating consultations with State, local, and tribal government representatives on simplification of federal grant programs. This effort was conducted pursuant to the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107) to: (1) improve the effectiveness and performance of federal financial assistance programs; (2) simplify application and reporting requirements; (3) improve the delivery of services to the public; and (3) facilitate greater coordination among all entities responsible for delivering such services.

Over the course of three days, OMB, HHS and other federal agency representatives met with State, local, and tribal government representatives in separate consultation meetings. In response to the comments received at these and other consultations, the federal grant-making agencies prepared an interim/draft plan of action published for public comment in the Federal Register on January 17, 2001.

Implementation of the Olmstead Supreme Court Decision

IGA convened a meeting with intergovernmental partners, hosted by the National Governors' Association (NGA), involving NCSL, ASTHO, NACo, USCM , American Public Human Services Association (APHSA), and state-Washington, DC representatives to discuss the implementation of the Olmstead Supreme Court decision. This decision, which applies to all state programs, provides a legal framework for the joint efforts of federal, State and local entities to enable individuals with disabilities to live in the most integrated setting appropriate to their needs.

Committed to ensuring that persons with disabilities have the tools they need to fully access and participate in their communities, President Bush announced the New Freedom Initiative on February 1, 2001. A key component of this initiative is swift implementation of the Olmstead decision. Aware of the concerns states had expressed about the challenges in implementing Olmstead, in February 2001, Secretary Thompson announced new grants for states to involve consumers and other partners in developing new programs for people with disabilities. The initial $50,000 awards – available to all states that requested one – represent the beginning of the $70 million Real Choice Systems Change Grant Program, which will help states more easily offer services to people with disabilities in the most integrated setting.

On June 18, 2001 President Bush signed Executive Order No. 13217 on Community-based Alternatives for Individuals with Disabilities, which among other things directs federal agencies to assist states with swiftly implementing the Olmstead decision. Pursuant to the Executive Order, on July 27, 2001, HHS issued a Federal Register notice seeking comments on the Department's policies, programs, statutes and regulations to determine whether any should be revised or modified to improve the availability of community-based services for qualified individuals with disabilities.

Administration for Children and Families (ACF)

Two examples of how ACF has used the consultation process in the development of regulations are illustrative of ACF's consultation policy. First, in developing the final Head Start regulations, which implemented the statutory provision for establishing requirements for the safety features and the safe operation of vehicles used by Head Start agencies to transport children participating in the Head Start program, ACF requested input from a wide range of organizations. The Head Start Bureau surveyed the States to determine the applicability of state pupil transportation regulations to the Head Start program and to learn about each state's pupil transportation system.

In consulting with States in developing these rules, we learned that there is extreme variation among the States in regulation of Head Start transportation services and oversight. To accommodate this variation, we substantially revised the proposed rule to provide that within five years of the date of publication, Head Start agencies must use for activities defined as "transportation services", either a school bus or an "Allowable Alternative Vehicle."

The additional category of vehicle was added to address two significant issues raised during the comment period. The first issue related to the fact that some States prohibit Head Start and other community based programs from using school buses. The second issues related to concerns raised by Community Transportation Agencies about heir ability to continue serving Head Start programs if all Head Start agencies providing transportation services were required to use only school buses. In the final rule we attempted to reconcile the opposing issues related to vehicle structural safety and state and local flexibility. The development of the allowable alternative vehicle in the final rule evolved through information exchange, inclusion of multiple perspectives, and willingness to compromise in order to improve the safety of children.

Second, in developing the final Child Support regulation, which implemented the statutory requirement to establish a new performance-based incentive system, the Office of Child Support Enforcement benefitted from years of conversations and meetings with intergovernmental partners. State and local IV-D agencies were consulted over the past seven years in developing two five-year national strategic plans for the child support program and a set of performance measures. A subset of those performance measures and related performance standards were contained in the Department's recommendations to Congress on this issue and subsequently became the basis for the incentives and penalty process contained in the final rule.

As a result of this extensive pre-rulemaking consultation, the proposed rule was well-received and few changes were made in the final rule. However, one area that elicited a strong response was a provision for States to establish administrative complaint procedures. We learned that a number of States had similar procedures in place already and were concerned that the proposed rule would be overly burdensome and divert resources away from existing program priorities. In response, we indicated in the final rule that States have flexibility to set their own procedures. The longstanding collaboration between State and Federal partners has strengthened the program in general, and garnered widespread support for the new incentive system contained in these final rules.

Food and Drug Administration (FDA)

Currently, FDA participates in over 170 Partnership Agreements with a state or group of states within a particular region to address various regulatory issues. These partnerships strengthen Federal-State relationships, and provide valuable information exchanges between FDA and states in solving public health problems. The following are examples of these agreements:

1. The State of California co-located their laboratory facility and staff with the FDA Pacific Regional Lab and formed the first federal/state food and drug partnership laboratory in the nation. Sharing space, equipment, expertise and vital analytical data enhances communication, increases the efficient use of resources, delivers seamless service, and increases public health protection. It breaks down organizational barriers, allows for cross-organizational work assignments, and increased overall sample testing and response capabilities to respond to a variety of consumer protection situations. FDA won a hammer ward for this agreement.

2. The State of North Dakota and FDA established a partnership to conduct compliance testing of new assemblies or re-assemblies of x-ray equipment. This partnership helps reduce redundancies and enhances communication to increase public health protection.

3. The University of Tennessee along with the State of Tennessee Department of Agriculture and FDA established a partnership to expand joint efforts to assist new and small food manufacturers in meeting appropriate State and Federal guidelines for producing and labeling foods. This agreement increases communication between the governments and industry and also educates small businesses to ensure success.

Center for Medicare and Medicaid Services (CMS)

CMS utilizes several methods to consult with State and local governments.

National Association of State Medicaid Directors/Executive Committee (NASMD/EC) -- The major entity used in Medicaid program consultations is the NAMSD/EC. This group is comprised of 11 Medicaid Directors who represent the Medicaid directors in each state, territory, and D.C.

Medicaid Technical Advisory Groups (TAGS) -- In order to provide additional state input on issues emerging out of the NASMD/EC meetings, NASMD and CMSO have established ten TAGs. The TAGs provide ready state expertise to CMS in key Medicaid program areas, such as managed care, long-term care, eligibility, and maternal and child health. They comprised of state Medicaid program staff determined to be experts in a particular area of the Medicaid program. Their expertise is used by CMSO in the development of a variety of policy issuances, including manual issuances, "Dear Medicaid director letters," regulations, etc. Most of the TAGs held at least one in-person meeting during 2000, and a plan is under development for each TAG to convene an in-person meeting in FY 2001. CMS is also in the process of establishing a Tribal TAG.

Consultations with NGA and State Legislators -- CMSO consults with NGA through special briefings for governors' representatives. Some of these meetings are held at the request of NGA, but all of them permit the opportunity to exchange information and provide insight which CMS, the states, and the NGA may use to pursue future policy changes. CMSO participates in and coordinates other CMS staff participation in major meetings that are sponsored by the NCSL, which represents state legislators

and their staff. CMSO works closely with NCSL to ensure that CMS staff participate in workshops to address and obtain state feedback on new and continuing Medicaid, Medicare and other CMS policy concerns that are raised during NCSL's annual meeting. CMS also consults with NCSL on key policies during their Assembly on Federal Issues meeting which is held each spring and fall.

Association of Health Facility Survey Agencies (AHFSA) -- The survey and certification process is intended to ensure quality of care through our nation's health care facilities. CMS contracts with state agencies to oversee and enforce Federal requirements concerning the delivery of quality care for both Medicaid and Medicare beneficiaries. The survey and certification program is funded through both Federal and State government allocations. CMSO consults with the AHFSA to discuss and develop relevant policy. Final policy is communicated through various means including letters to state survey and certification officials, the issuance of operating manual instructions, and other policy issuances.

As a result of these consultations, there have been a number of tangible results in changes in policies.

- CMS has an initiative underway to reward and encourage state innovation to expand health care coverage through speeding up the review process and resolving a backlog of pending requests from states for Medicaid and SCHIP state plan amendments and waivers. As a result of this imitative and for the period of January 20-September 17, 2001, CMS approved 1,049 new and pending Medicaid and SCHIP state plan amendments and waivers. Collectively, these changes have made more than 800,000 additional people eligible for health care coverage across the country. These changes also increased benefits for over 2.5 million people already covered through Medicaid and SCHIP. Additionally, the expedited review process has allowed states to significantly improve their programs. Our latest data indicates that 13 states have simplified eligibility, and 34 states are implementing innovative delivery systems under Medicaid and SCHIP.

- As an additional step to strengthen and improve these programs, CMS has instituted a Health Insurance Flexibility and Accountability initiative (HIFA) to make it faster and easier for states to expand access to health care coverage for low-income individuals through Medicaid and SCHIP demonstrations. This approach will permit states to expand insurance coverage through innovative approaches, including health insurance options available in the private sector. A new electronic application will make it quicker and easier for states to propose and implement new approaches to health care coverage.

- The SCHIP regulation, initially issued on 1/11/01 and reissued 6/22/01, was amended to allow states flexibility to design the most appropriate program to meet local needs. Changes were made to make it easier for states to use a common application form and enrollment process for SCHIP and Medicaid programs-- an approach effective at expanding outreach to eligible families. The amended rule gives states the option of requiring social security numbers for

SCHIP applicants as they must do for Medicaid applicants. The January regulation would have prohibited states from using that information for SCHIP, making it more difficult to use common application forms and enrollment policies for the two programs.

- A new proposed managed care regulation was reissued on August 16, 2001, which will provide states significantly more flexibility to decide how best to provide patient protections and use managed care in their Medicaid plans. For instance, the regulation will allow states, many of which have already implemented protections through state laws and regulations, to keep in place important aspects of their existing programs.

Substance Abuse and Mental Health Services Administration (SAMHSA)

The Center for Mental Health Services (CMHS) and the Center for Substance Abuse Treatment (CSAT) have both been working with the states on the development of performance measures related to the Substance Abuse Prevention and Treatment and the Community Mental Health Services Block Grant programs. By the end of 2001, SAMHSA expects to complete work on a core set of measures that can be used in both programs to evaluate and improve the system of care in each state.

CMHS is also developing regulations concerning their Block Grant program and guidelines for the application of Block Grant funds. In both cases, the Center has been working in tandem with the states to develop regulations and application guidelines that will not create additional funding mandates while maintaining appropriate Federal and State roles in the provision of community based mental health services.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

The following provides examples of HUD's consultation process.

Working with Public Housing Agencies, Public Housing Residents and Other Interested Parties in Implementing a new Public Housing Operating Fund Formula

On July 10, 2000, after a series of meetings with representatives of national housing organizations, public housing agencies, and public housing resident organizations, HUD published a proposed rule to implement the new formula funding system for public housing operations, required by the Quality Housing and Work Responsibility Act of 1998 (Pub.L. 105-276, approved October 21, 1998). The proposed rule published on July 10, 2000 reflects the product of the committee's successful negotiations, and also reflects the consensus decisions reached over nearly a year's worth of deliberations. The proposed rule represents a partnership among HUD, the public housing agencies, public housing residents, and advocates of public housing to achieve a fair and efficient Operating Fund formula.

On March 29, 2001, HUD published an interim rule making effective the policies and procedures described in the July 10, 2000 proposed rule and taking into consideration the 19 public comments on the proposed rule. The interim rule, which became effective on May 29, 2001, will govern the determination of funding distributions to PHAs under the Operating Fund until a final rule, reflecting the results of the Congressionally mandated cost study is developed and published. The interim rule is a direct result of HUD's earlier successful negotiations with PHAs, residents, and advocates of public housing. Work on the cost study continues and, as noted in HUD's earlier report, it is being developed with the active participation of the members of the negotiated rulemaking committee and other interested members of the public. Following and based upon the findings and recommendations of the completed cost study, HUD will develop the final rule implementing the Operating Fund Formula, using the procedures of the Negotiated Rulemaking Act of 1990, subject to compliance with applicable legal requirements prerequisite to the establishment of a negotiated rulemaking committee for such purposes.

Consultation with Indian Tribes and Alaska Native Villages on Revisions to HUD Regulations Governing the Application Process of the Indian Community Development Block Grant Program

On January 17, 2001, HUD issued a final rule that amended its regulations governing Community Development Block Grants for Indian Tribes and Alaska Native Villages (the "ICDBG" program). The regulatory amendments permit the incorporation of the ICDBG grant application and selection procedures into HUD's SuperNOFA process. The SuperNOFA approach, in which the great majority of HUD's competitive funds are announced in one document, is designed to simplify the application process, bring consistency and uniformity to the application and selection process, and accelerate the availability of funding.

HUD's Office of Native American Programs (ONAP) consulted with Indian tribes in the development of the November 6, 2000 proposed rule. Through a letter dated July 12, 2000, ONAP provided Indian tribes and Alaska Native Villages with the opportunity to comment on the substance of the proposed regulatory changes during the development of the proposed rule. In addition to this pre-rule development consultation process, HUD notified its tribal partners that HUD will work with them to address issues of concern before implementing a national ICDBG review panel. HUD also scheduled a series of meetings with Indian tribes to solicit additional input on the implementation of, and possible future changes to, these regulatory amendments to the ICDBG program.

DEPARTMENT OF THE INTERIOR

Under DOI’s decentralized management structure, the Department delegates rulemaking to individual bureaus. During 2000, DOI bureaus consulted with a variety of State, local, and tribal governments as they developed regulations. For example, BLM State Directors and field managers met regularly with State and local representatives on issues that affect State and local governments,

such as resource management plans or considering land sales or exchanges. BLM also consulted extensively with State governments in developing its surface management rules.

Fish and Wildlife Services (FWS)

Since 1947, the Fish and Wildlife Service has developed the annual migratory bird hunting regulations utilizing the flyaway waterfowl management system. The flyway councils with active state representation play a vital role in developing these regulations. FWS includes states as members of this council in recognition of the impacts this program has on the states and the estimated 5 million hunters. By involving the flyway councils in this process, the resource receives adequate protection, hunters have ample opportunity for utilization of the resource, and states are afforded maximum flexibility to provide hunting opportunities within their boundaries. The Service established the frameworks, or outside limits, for these regulations, and the states selected the season dates, bag limits, and other regulatory options.

In 2000, FWS worked with 27 State and Federal agencies, Indian tribes, and conservation organizations on a rule to establish a nonessential experimental population of black-footed ferrets, an endangered species, in north-central South Dakota. The parties involved in this project identified the Cheyenne River Sioux Reservation as a priority reintroduction site due to its extensive population of black-tailed prairie dogs (the primary food source for black-footed ferrets). The tribe welcomed the reintroduction because it will further their prairie management goals. Coordination with the Tribe throughout the project was highly effective. The Service worked in partnership with stakeholders from the planning stage. The Service had no need to change plans as the result of consultations with project partners. By learning about stakeholder concerns and mutual objectives at the beginning, the Service built strong partnerships and relationships based on trust and respect to accomplish both stakeholder and Federal objectives. Other tribes watched this project closely in considering potential recovery actions on other tribal lands.

FWS has involved Alaska natives regarding the conservation and management of polar bears. Russia and the United States signed a bilateral agreement in October 2000 to govern the conservation and management of the shared polar bear stock in the Bering/Chukchi Seas. Alaska natives were deeply involved in this process. Following ratification of the agreement by the Senate, Alaska native involvement will result in management of polar bear harvest by Alaska and Russia natives through enforceable quotas, seasons, and other control mechanisms. Currently, no such controls exist.

FWS recently published in the Federal Register several proposed policy documents and regulations pertaining to administration of the National Wildlife Refuge System (NWRS). The comments received from State partners helped shape and improve the final regulations that will govern the administration of the NWRS. FWS also includes representatives from appropriate State and tribal conservation agencies on NWRS planning teams and invites States, Tribes, and other appropriate agencies to join the refuge planning effort at the beginning of the process.

In response to the draft policy regarding the biological integrity, diversity, and environmental health of refuges, some States expressed concern that the policy would interfere with or eliminate hunting and fishing on refuges or possibly find all public uses of refuges incompatible with ecological integrity. To address this concern, FWS added a section to the final policy that recognizes the legitimacy and appropriateness of the priority public uses of the NWRS, which include hunting and fishing.

State agencies are an integral part of the successful conservation of American fish and wildlife resources. The Service administers several Federal assistance programs to the states. After the Service awards funds to a state, the state has full responsibility to implement funded actions in accordance with applicable guidelines. Examples of some Service grant programs to states include conservation grants, which provide financial assistance to States and Territories to implement conservation projects for listed and nonlisted species, and grants to acquire land associated with approved habitat conservation plans. The Service includes state representatives in organizations such as the Sport Fishing and Boating Partnership Council, which advises the Interior Department Secretary on recreational fishing and boating issues, and the North American Wetlands Conservation Council, which reviews and recommends project proposals to the Migratory Bird Conservation Commission.

The Minerals Management Services (MMS)

The Minerals Management Service (MMS) sponsors a State and Tribal Royalty Audit Committee, which is comprised of State and tribal audit managers and MMS audit managers. They meet quarterly and discuss audit-related issues for MMS regulations. An example of the rules that the committee discusses is the valuation regulations, which give instructions on how to value oil and gas for royalty purposes. MMS considers the committee's input when interpreting and revising the regulations. This Audit Committee has been instrumental in achieving tangible results in a number of different areas:

Audit Committee members from Colorado, North Dakota and Oklahoma have helped design various profiles and other tools within the new royalty compliance system. Also, they participated in testing and outreach sessions and will help present training on the new system.

New Mexico is taking the lead with MMS on "Electronic Data Acquisition" from company databases that should reduce information collection time and burden in the new compliance system.

The onshore oil and gas royalty compliance model included representatives from Colorado, Utah, Wyoming and the Northern and Southern Ute Tribes. The model participants helped develop and design the top-down, end-to-end compliance process, including the creation of business rules, measurements, trending applications and procedures.

The solid minerals royalty compliance model included representatives from Colorado, Utah, New Mexico, Wyoming, and the Navajo and Crow tribes. The model participants helped develop and

design the top-down approach for MMS's new compliance and asset management process including the creation of business rules, data flows, and property surveillance. MMS, State, and tribal representatives met with our customers in industry to improve the efficiency of compliance activities.

MMS staff and Audit Committee members work together to finalize orders sent to companies for royalty underpayment. They also worked together to improve the language and content of these orders. The improvements resulted in better communications with companies and significantly reduced the need for field reports in the appeals process.

Audit Committee members work with MMS on valuation issues for royalty purposes involving Federal leases in their State or Indian leases on their Indian reservation.

Company requests for solid minerals valuation determinations involving Federal onshore or Indian land are shared with State and Tribal auditors. The auditors work with MMS staff to develop case-specific valuation guidance.

Audit Committee members helped develop the topics that were in the training on solid mineral product valuation for royalty purposes.

Based on input from Tribes, specific data elements were added to form MMS 4416- Indian Crude Oil Valuation Report for the new oil valuation rule, effective June 1, 2000 (65 FR 14022 – 3/15/00).

In settlement discussions with companies for royalty underpayment disputes, State and Tribal auditors are active members of the settlement team and work to resolve the disputes through negotiation. Their contribution to the team brings a more local perspective to mineral lease management issues.

DEPARTMENT OF JUSTICE

The Department has engaged in a wide variety of contacts and consultations with State, local, and tribal governments. These actions are described in the sections about the individual DOJ components below.

Office of Community Oriented Policing (COPS)

COPS has committed itself to a vigorous and meaningful partnership with State, local, and tribal governments in the implementation of the Public Safety Partnership and Community Policing Act of 1994. In fact, COPS has developed relationships with over 12,000 of the nation's 18,000 law enforcement agencies. The COPS program continues to strive for and maintain a strong customer

focus in the management and implementation of its grant programs in ways that maximize the benefit for and minimize the burdens on State and local governments.

From the beginning, the COPS grantmaking process was shaped by input from State and local officials. The COPS Mission Statement emphasizes a commitment to dedicate ourselves through partnerships with communities -- State and local -- public and private organizations throughout the country. COPS initial grant programs were developed to respond to requests from mayors, chiefs and others to permit them to begin the process of hiring and training new police officers during the time period in which grant paperwork was prepared and reviewed. The one-page COPS FAST application for smaller towns was designed to respond to frustrations with the complexity of the "standard forms." As a result, hundreds of communities that never before had the benefit of a Federal grant have been COPS customers.

Beginning in 2000, the COPS Office has further streamlined the grant process by introducing user-friendly computer "scannable" progress reports for COPS grantees. Initial feedback has confirmed that grantees are finding it easier and more efficient to respond to required progress reports in this manner. In FY 01, the COPS Office has begun implementation of a comprehensive E-Government plan to allow COPS to continue to address the needs of law enforcement by making its key services accessible to customers through an easy-to-use Internet web site:

- providing access to automated grant applications;
- automating the grantee reporting process;
- publicizing training information;
- providing a feedback forum for grantees
- offering a library of resources on community policing best practices and law enforcement issues.

Almost all of COPS' more than 12,000 grantees are units or agencies of State, local, or tribal governments. Each one is assigned a designated "grant advisor" who is available to answer questions, solve problems, and track the process of the grant. Grant advisors work in regional teams in order to provide comprehensive and uninterrupted assistance when an individual grant advisor is out of the office. Also, while rigorously monitoring compliance with grant terms, COPS staff at the same time offer advice and assistance on such matters as implementing community policing, retention, redeployment of officers, and problem solving. The system of coordinated oversight is based on regular phone contacts, report filing, and site visits by COPS staff - all of which enable grant advisors to identify jurisdictions that could benefit from training and technical assistance and make those resources available to the grantees.

COPS in Schools grants are focused on partnerships between law enforcement agencies and schools. This partnership must define strategies to utilize problem solving and community policing techniques to prevent school violence and implement educational programs. In an effort to address the grantee concern that these partnerships must be solid to succeed, all applicants must submit a

memorandum of understanding (MOU) for consideration under the COPS in Schools Grant Program. This is an agreement between the parties involved that defines the roles and responsibilities of the individuals and partners involved. Both the law enforcement executive and the school official who has general educational oversight and decision-making authority must sign the MOU.

In response to the most serious needs of law enforcement in Indian communities, COPS created a broadened, comprehensive, and flexible hiring program. Options available under this program include salary and benefits for new police personnel to law enforcement training and equipment for new and existing officers. This program focuses on tribal communities, many of which have limited resources and are affected by high rates of crime and violence, and is meant to enhance law enforcement infrastructures and community policing efforts in these communities.

The COPS Office is also committed to providing training for COPS grantees to assist in understanding COPS grant requirements. The COPS Office participates in COPS grantee regional financial management training conferences sponsored by the Office of the Comptroller. Here, COPS staff provide training regarding the specific compliance requirements of the COPS hiring and MORE grant programs. The COPS Office is further enhancing its specialized training for COPS grantees during 2000 as it implements a series of COPS MORE redeployment grant program training conferences across the country. In addition, as of March 2000 the COPS Office is offering specific training to teams of COPS in Schools grantees for School Resource Officers and school administrators. More than 8,000 grantees have been provided the opportunity to receive technical assistance through a range of conferences at the local level. At all training conferences, the COPS Office seeks feedback and suggestions from the grantee participants regarding ways to improve grant compliance materials, advisory and monitoring functions of the COPS Office, and current law enforcement and funding needs.

Federal Bureau of Investigation (FBI)

As of, November 30, 2000, the second anniversary of the implementation of the National Instant Criminal Background Check System (NICS), the NICS had performed 17,573,038 background checks to determine whether the receipt of a firearm by prospective transferee would violate federal or state law. Currently, the FBI conducts these checks for Federal Firearms Licensees (FFLs) in 37 states for long gun and/or handgun purchases, while 26 states conduct the checks in their role as Point of Contacts (POCs) for long gun and/or handgun purchases.

The FBI continues to work with its State and local partners regarding the operation of the NICS program by providing NICS implementation updates to the CJIS Advisory Policy Board (an advisory committee consisting of representatives of the law enforcement and criminal justice communities that provides advice to the Director of the FBI on the philosophy, concept, and operational principles of various criminal justice information systems managed by the FBI's Criminal Justice Information Services Division) and by working with state POCs to ensure the efficient and effective operation of the NICS.

In addition, over the past two years, the FBI has engaged in a concerted outreach effort to educate and assist tribal, State and local courts, court clerk's offices, and criminal justice agencies regarding the need to provide disposition information to the FBI in response to a NICS inquiry. The FBI has also developed brochures concerning the multiple public safety benefits of submitting protection orders and other records which would subject an individual to federal firearm prohibitions to the FBI so that the information is available to the NICS. The FBI meets regularly with groups such as the National Center for State Courts, the National Criminal Justice Association and the International Association of Chiefs of Police to discuss NICS related issues. Further, the NICS Program Office has established a state liaison unit. Personnel from this unit attend state clerks of court conferences in every state at least once every two years and provide educational seminars on the NICS. FBI personnel also participate in regional conferences on Brady Act issues sponsored by the DOJ Violence Against Women Office and DOJ Bureau of Justice Statistics. These conferences are specifically designed for State and tribal court and law enforcement personnel to encourage and assist them in participating in the FBI's Interstate Identification Index, National Crime Information Center, and NICS Index (all repositories of data accessed by the NICS.) There has been a marked increase in cooperation, as a direct result of the concerted outreach effort to educate and assist tribal, state and local courts, court clerk's offices, and criminal justice agencies regarding the need to provide disposition information to the FBI in response to a NICS inquiry.

Office of Justice Programs

OJP and its offices have frequently contacted and listened to various governmental bodies. Their suggestions and comments have been employed to streamline OJP's operating procedures and to lessen the burden on local governments. Some specific examples of successes are listed below.

Violence Against Women Office

The Violence Against Women Office (VAWO) works with State, local, and tribal governments on regulatory issues that relate to the grant programs administered by this office: the STOP Violence Against Women formula grants program, the STOP Violence Against Indian Women discretionary grants program, the Grants to Encourage Arrest Policies, and the Rural Domestic Violence and Child Victimization Enforcement Grant Program. In developing various regulations, VAWO considered the comments of interested parties, including State governments, and made certain suggested modifications. In another instance, VAWO sought input from State Administrators of the STOP formula grants when designing the required reporting form.

VAWO has convened conferences for the STOP Grant State Administrators, and for other grantees, including governments, to provide information about program and regulatory requirements and to obtain input from the grantees. VAWO has also organized several financial workshops for tribal grantees to clarify administrative and financial requirements. The Violence Against Women Office has established a state STOP administrator working group to provide input regarding mandatory reporting

requirements under STOP and assist in the design and development of a revised data collection and reporting form to be used by STOP grantees and subgrantees.

VAWO's position on VAWA 2000 specific to its support of a 5% minimum allocation to state and local courts was informed by feedback received from the field. Finally, Numerous STOP administrating agencies have expressed concerns about the timing of the release of the STOP Program solicitation each fiscal year. OJP/VAWO plans to release the FY 2002 STOP Violence Against Women Formula Grant Solicitation on September 25, 2001, considerably earlier than solicitation release dates in recent years.

Bureau of Justice Assistance

The Bureau of Justice Assistance (BJA) is statutorily authorized to maintain close communications and receive input from State, local, and tribal governments. BJA cooperates with and provides technical assistance to States, units of local government, and other public and private organizations or international agencies involved in criminal justice activities. Each program within BJA has its own directives, all of which involve significant interaction with State, local, and tribal governments. In issuing new rules, BJA informs constituent groups at outreach meetings and through interested organizations.

The State and Local Assistance Division (SLAD) works directly with the State agencies administering the Byrne Formula Grant Program throughout the year. On-site monitoring visits, workshops and the provision of hands-on technical assistance has resulted in the updating and revising of the Program Guidance and Application Kit to provide more detailed instructions for meeting program requirements. Further, the program has implemented the following measures: a move from paper to on-line submission of required reports, a reformatting of a primary reporting document to make it more user-friendly and easier to fill out, the change from an annual to a multi-year submission of the Statewide Drug and Violent Crime Control Strategy to reduce the states' paperwork burden, and the beginning of annual training in Washington, D.C. for new State agency heads has helped State, local, and tribal governments in meeting Byrne requirements.

Office of Juvenile Justice and Delinquency Protection

The Office of Juvenile Justice and Delinquency Prevention assists States and units of local government in the development of more effective education, training, prevention, diversion, treatment and rehabilitation programs in the area of juvenile delinquency and juvenile justice systems. OJJDP does this through assistance in the planning, establishing, operating, coordinating and evaluating of projects. States submit plans to receive assistance under this program and such plans must involve coordinated planning and review at the State and local level. Members of State advisory groups include a cross-section of the State juvenile justice community and provide for the "active consultation with and participation of units of general government" in the development of the plan.

OJJDP involves public participation in its many programs, including the Special Emphasis Discretionary Grants, Gang Programs, State Challenge Grant Programs, Mentoring Programs, Missing and Exploited Children Programs, Preventive Incentive Grants Programs, and programs funded and administered under the Victims of Child Abuse Act. In addition, OJJDP is involved in three major local collaborative efforts. The first "Serious, Violent and Chronic Juvenile Offender Treatment Program," requires the implementation of treatment components that combine accountability and sanctions with increasingly intensive community-based intervention and rehabilitation services consistent with the degree of offense.

The second effort, The Comprehensive Strategy for Serious, Violent, and Chronic Juvenile Offenders Training and Technical Assistance State Initiative, provides eight selected states with two years of intensive strategic planning assistance in forty-six local sites. This strategic planning technical assistance assists in the development of a continuum of delinquency prevention and graduated sanctions for juvenile offenders that is based on research, data, and outcomes. With State and community input, a new implementation module was developed with a heavy emphasis on evaluation.

The third effort, "SafeFutures Partnerships to Reduce Youth Violent and Delinquency," supports six communities (4 urban, 1 rural, and 1 tribal government) in their efforts to implement a comprehensive and coordinated delinquency prevention and intervention program.

Environment and Natural Resource Division

The Division works closely with State and local enforcement agencies in enforcing environmental law. The Division has emphasized cooperative enforcement through joint enforcement actions, through training and support of local prosecutors, and in the development of enforcement policy. Specifically, the Division frequently works with state attorneys general and environmental agencies, local prosecutors, the National Association of Attorneys General and the Environmental Council of the States. In addition, the Division coordinates its litigation on behalf of the Secretary of Interior for the benefit of Indian tribes with the affected tribes.

DEPARTMENT OF LABOR

The following are some examples from DOL agencies of how they involve State, local, or tribal governments in rulemaking or in the post-rulemaking education and outreach process.

Employment Training Administration (ETA)

Throughout the development of the Interim Final Rule and the Final Rule implementing the Workforce Investment Act (WIA), ETA participated in numerous consultations with State and local officials, including organizations representing elected officials. These consultations began with the development of the Interim Final Rule and continued throughout the rulemaking process. The groups

consulted included the National Governors Association, the U.S. Conference of Mayors, the National Association of State Legislators, the Interstate Conference of Employment Security Agencies, the National Association of Counties, the National League of Cities, and the U.S. Conference of Black Mayors.

WIA required ETA to consult with the Governors in developing the definition of administrative costs. To meet this requirement, and to obtain a broader range of views, ETA continuously consulted with representatives of State and local stakeholders. In addition to this input, ETA worked directly with the League of Cities, the US Conference of Mayors, and the National Association of Counties to identify sites that were willing to study how modifications of administrative costs would affect WIA program administration. ETA then used this feedback to revise the administrative cost provisions before publishing the Final Rule.

ETA received numerous letters from States and local areas expressing concern about the lack of a local hold-harmless provision during the first two years a State implemented WIA. A hold-harmless provision would limit the amount formula funding can be reduced, avoiding funding shifts that could have caused service disruptions during the early stages of WIA. As a result of this State and local concern, ETA incorporated a hold-harmless policy into the final rule.

ETA received numerous comments about the requirement cited in parts 661.200(b) and 661.315(a) of the WIA regulations that two or more members of the State and local Boards represent the membership categories set forth in the statute. States expressed concern that a large board membership would require significant administrative resources. ETA considered these comments when revising the regulations and gave the authority to State and local officials to allow for "multiple entity" representation on boards if such individuals who represent multiple entities have "optimum policy-making authority within the entity."

After the publication of the April 15, 1999 Interim Final Rule, ETA continued to provide information to the public and stakeholders through a variety of mechanisms. For example, ETA published a series of consultation papers defining and measuring performance and customer satisfaction, and conducted a second round of town hall meetings. In addition, ETA also hosted public forums where practitioners shared insights and suggestions for successful implementation of WIA. ETA considered the experiences of early implementing states, and studied the suggestions received from partners and stakeholders when writing the Final Rule, which was published in August 2000.

The Division of Native American Programs generally works in partnership with tribal governments to craft rules that reflect their concerns. Specifically, as far as rulemaking is concerned, the INA Welfare to Work (WtW) rule (20 CFR part 646) and the INA-related WIA rule (20 CFR part 668) were crafted in this "spirit of partnership", in which a work group composed of members of the Native American Employment and Training Council, other knowledgeable Native American program staff, and DOL employees crafted the rules together. As a result, WIA regulations include a

separate Subpart on "Services to Communities" in part 668 and a lower minimum grant size threshold for grantee designation for those tribes planning to participate in the demonstration under Public Law 102-477 [found at 20 CFR 668.200(a)(3)].

Occupational Safety and Health Administration

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. Thus, in 23 States and two Territories, OSHA standards apply to State and local governments, as part of a voluntary program, not as a Federal mandate. OSHA seeks and considers 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 its State Plan partners by attending meetings of their organization, the Occupational Safety and Health State Plan Association. At these meetings, specifics of new and proposed standards and regulations are discussed.

State representatives are invited to provide input to OSHA regulatory teams, and to participate in stakeholder meetings where new standards and regulations are discussed. The States have participated in many of the 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. States also have co-hosted and/or participated in stakeholder meetings on various issues. In addition, states regularly participate as members of various OSHA policy development-task groups (e.g., on arborists, nondiscrimination, poultry industry, etc.)

Policy changes that have resulted from OSHA consultations with State, local, or tribal governments are as follows:

- A Federal OSHA Steering Committee and the Occupational Safety and Health State Plan Association Board of Directors conducted a series of joint meetings to assess and to restructure the relationship between Federal OSHA and State plans.

- These groups agreed on a new framework under which States would develop Strategic and Annual Performance Plans. The framework is comparable to Federal OSHA performance plans.

- Based on this framework, which included State representatives, developed operating procedures for States to follow when preparing five-year Strategic and Annual Performance Plans.

- The procedures for the submission and review of State Strategic and Annual Performance Plans resulting from these consultations have been included as Chapter 5 of the revised State Plan Policies and Procedures Manual.

- In conjunction with State strategic planning, OSHA in consultation with its State partners developed revised procedures for monitoring and evaluating State plan performance.

- A task group, which included State representatives, revised monitoring procedures to evaluate a State's achievement of its strategic goals and accomplishment of statutory and regulatory mandates. The procedures were discussed extensively with representatives from all State plans at meetings of the Occupational Safety and Health State Plan Association.

OSHA continues to work with the State Plans to restructure the Federal/State relationship and implement a new concept of partnership and program evaluation based on the states' achievement of their own results-oriented goals, within the context of the requirements of the Occupational Safety and Health Act and the Government Performance and Results Act (GPRA). This allows the states greater flexibility to tailor their programs to state-specific circumstances, including the safety and health of State and local government workers. Each of the states has developed its own Five-Year Strategic Plan and Annual Performance Plans for FY 2000 and FY 2001. A new system for Federal oversight of the states has been jointly developed, and State and Federal staff have been jointly trained in its implementation. The states' efforts in achieving their own goals will be reported in both State and Federal evaluation reports.

Mine Safety and Health Administration (MSHA)

MSHA has ongoing working relationships with State mining agencies, the mining industry, and labor representatives. Some local governments operate mines that are covered by the Mine Safety and Health Act of 1977. These mines typically produce material for road construction and maintenance. MSHA actively seeks input to its proposed standards and regulations from these interests and involves them in other outreach efforts.

MSHA's technical support staff provides individual mine operators with information on dust control technologies for equipment at surface mines, advice about engineering and administrative control feasibility matters relating to excessive noise levels, and a variety of other mine-specific compliance problems. MSHA also provides information on new Part 46 training regulations for many State-run surface mines and engages in outreach activities for State grantees.

MSHA takes deliberate action to prevent conflict with State regulations. For example, MSHA

provided technical assistance to West Virginia on a State regulation, promulgated in June 2000, governing work on stockpiles. MSHA offered similar assistance and support to Kentucky and Pennsylvania, which are moving forward with similar legislation.

DEPARTMENT OF TRANSPORTATION

DOT has reemphasized the importance of the need for early and effective involvement of State, local, and tribal governments since enactment of the Unfunded Mandates Reform Act through various meetings with, and the circulation of summary information to, regulatory officials throughout the Department. Activities of the individual components of the Department are described below.

Federal Highway Administration (FHWA)

Utilities

On November 22, 2000 (65 FR 70307), the FHWA published a final rule amending its regulation concerning the reimbursement provisions for the relocation and adjustment of existing utility facilities, and for the accommodation of new utility facilities and private lines on the right-of-way of Federal-aid and direct Federal highway projects. These changes were in response to the informal requests from several State DOTs that the FHWA relax and/or clarify the Federal utilities regulation.

Value Pricing Pilot and Motor Fuel Tax Evasion Programs

The Office of Transportation Policy Studies involves states and localities in developing and implementing projects under the Value Pricing Pilot Program and Motor Fuel Tax Evasion Program. The collaborative efforts with the states have resulted in projects that are specifically tailored to meet the requirements of the states and localities as they try to achieve mutually determined objectives. While these activities have not resulted in specific rulemaking actions, working with the states in these areas reflects their continuing contribution toward shaping and implementing national policies and programs that provide a benefit to them.

Federal Motor Carrier Safety Administration

New Cargo Securement Standards

On December 18, 2000, the FMCSA proposed to revise its regulations concerning the protection against shifting and falling cargo for commercial motor vehicles engaged in interstate commerce. The FMCSA's proposed new cargo securement standards would be based on the North American Cargo Securement Standard Model Regulations, reflecting: the results of multi-year comprehensive research program to evaluate current U.S. and Canadian cargo securement regulations, the motor carrier industry's best practices, and recommendations presented during a series of public

meetings involving U.S. and Canadian industry experts, Federal, State and Provincial enforcement officials, and other interested parties. Generally, the proposed regulations would require motor carriers to change the way they use cargo securement devices to prevent certain articles from shifting on or within, or falling from, CMVs and how calculations are done. The proposed changes might also require motor carriers to increase the number of tiedown devices used to secure certain types of cargoes.

In examining the costs to the states to train inspectors, the FMCSA worked with its State and Provincial partners to develop training materials that could be used to minimize the costs for the enforcement community and the motor carrier industry. For those states participating in the MCSAP program, training costs were considered to be an eligible expense. Thus, pursuant to this regulatory action, the states could possibly receive Federal funds to help defray the costs of training their roadside inspectors.

Research and Special Programs Administration

Hazardous Materials Emergency Preparedness (HMEP) Grants Program

This final rule, published February 14, 2000, revised the registration and fee assessment program for persons who transport or offer for transportation certain categories and quantities of hazardous materials. The revisions ensure additional funds to enhance support for the national Hazardous Materials Emergency Preparedness (HMEP) Grants Program. HMEP grants provide financial and technical assistance to State, local, and tribal governments for hazardous materials emergency response planning and training. State and local government representatives detailed the need for additional assistance in comments to the docket and at two public meetings. The final rule increases funds available for HMEP grants from $6.8 million to $14.3 million.

Listening Sessions on Customer Service and Regulatory Review

DHM hosted a series of listening sessions to solicit comment on the kind and quality of services agency customers believe are necessary and their level of satisfaction with the services the agency provides to promote understanding and compliance with the Hazardous Materials Regulations. These services include training assistance to State and local government personnel responsible for enforcement of the hazardous materials transportation safety requirements and for emergency response to hazardous materials transportation incidents. In 2000, DHM hosted two such listening sessions at Secaucus, New Jersey, and Cleveland, Ohio. It is using comments received to improve its services.

THE ENVIRONMENTAL PROTECTION AGENCY

Since passage of the Unfunded Mandates Reform Act in 1995, and Executive Order 13132 on Federalism in 1999, EPA has taken steps to include government officials from states, localities, and Tribes in the development of regulations, policies, and guidance that affects them. Among other steps, the Department has:

< finalized Agency guidance for EO 13132; Federalism; which includes procedures for the EO's implementation, technical guidance on how to analyze impacts on states and communities, and guidance on selecting appropriate techniques for sharing information and gathering advice from state and local officials during the formative stages of the policy process,

< expanded Department training of Agency staff regarding intergovernmental consultations to include Regional offices; and

< continued to offer technical assistance to agency program staff from the Office of Congressional and Intergovernmental Relations.

EPA is also seeking to strengthen its partnership with tribal governments through implementation of EO 13175: Consultation with Tribal Governments. Since the Executive Order became effective, EPA has been closely examining rules under development for any potential effect on Tribes and seeking consultation with them under appropriate circumstances. The Agency has formed a workgroup, with the participation of tribal representatives, to develop a consultation guidance for Agency personnel.

Consultation Mechanisms, General Outreach Activities and Communication Aids

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

In addition, EPA has chartered a cross-media FACA advisory body, the Local Governments Advisory Committee. Its Small Communities Advisory Subcommittee routinely advises the Agency on issues and concerns, and makes 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 dialogue groups.

The Agency continues to work with states under the National Environmental Performance Partnership System (NEPPS), principally through the Environmental Council of the States (ECOS). The objective is to ensure that the states are informed and involved in Agency activities, particularly those affecting State-implemented programs. Most of this work is accomplished through committees that have both State and EPA members, but also through forums that are open to other stakeholders. EPA and the ECOS have an active joint work group to address continuing implementation issues and work to identify and remove remaining barriers to effective implementation of NEPPS. ECOS has also initiated a number of other projects with EPA consultation 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 Pollution Prevention and Toxics (OPPT) has a number of ongoing outreach mechanisms related to its mission activities that allow OPPT to routinely secure State and tribal insights and advice. These processes have been institutionalized in many ways and are therefore to some extent independent of specific rulemaking. Some of the most important are identified below:

Established in early 1990's the Forum on State Tribal Toxics Action (FOSTTA) was created as a vehicle through which the Office of Pollution Prevention and Toxics (OPPT) gets State and tribal involvement in OPPT decision making.

During the October 23-24, 2000 meeting, the Chemical Management Project discussed the proposed Integrated Toxics Management Strategy, the Endocrine Disruptor Environmental Monitoring Proposal; Persistent, Bioaccumulative and Toxic Initiative; genetically modified organisms; the Voluntary Children's Chemical Evaluation Program, the Buy Clean Initiative, and the Education Initiative. Significant outcomes that resulted from these discussions include: (a) the initiation of a joint approach, working with States and Tribes and using innovative approaches, to develop a toxics management strategy that better takes into account the relative strengths of the Federal sector and our regulatory partners to deal with toxics issues in the future; and (b) as a result of input from the P2 Project of the FOSTTA, which has advocated for a change in the Agency's Once-in, always in policy, OAQPS has agreed to make changes to the MACT standards policy that would remove the barriers to implementing P2 and industrial ecology principles.

Earlier this year, the FOSTTA Tribal Affairs Project met in Washington DC. This meeting had fifteen tribal representatives from across the country. As a result, significant input was received for the OPPTS Tribal Strategy from these tribal representatives. As a result of this input, OPPT has agreed to investigate opportunities to affect curricula being used in Tribal schools and colleges to better educate Tribes and Tribal members on critical OPPT programs such as pollution prevention and lead hazard reduction. OPPTS has been spearheading an effort to develop, in conjunction with Tribes and Tribal organizations, other EPA program offices, and other federal agencies, Tribal capacity to assess

environmental health threats from toxic chemicals and pesticides, including persistent, bioaccumulative toxics (PBTs), in foods and other materials used in subsistence practices and lifestyles.

OPPT also utilizes the State Federal FIFRA Issues Research and Evaluation Group (SFIREG) which was 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 is a total of eight regularly scheduled meetings each year offering State officials the opportunity to meet with EPA. Regulations in progress are routinely brought to these meetings for discussion.

Some specific examples of results of consulting with SFIREG include the formation of joint EPA-State workgroups to deal with a number of issues/projects, such as: (1) developing guidance documents for use by EPA Regions and State agencies to define Quality Management and Quality Assurance procedures for state pesticide programs (completed in 2000); (2) improving or clarifying a number of pesticide labeling issues, including products used in public health mosquito control programs, restricted reentry intervals for agricultural workers, label precautions to protect bees and other pollinators, and new requirements for the safe handling and use of phosphine gas fumigants (these are on-going now). EPA has also used SFIREG to provide State input on labeling policy in general through comments on revisions to the Label Review Manual used by EPA staff.

EPA has also developed a variety of materials intended to help small governments more easily understand agency regulations.

Profile of Local Government Operations: The Profile details all of the environmental requirements with which a local government must comply. Information in the Profile is organized on the basis of 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 of the environmental requirements that might impact his or her operation and where to get 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 a wealth of information from EPA and eight participating non-governmental 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 assistance, and provides them with a grant writing tutorial.

Small Government Agency Plan: The Agency's interim Small Government Agency Plan supplements the intergovernmental consultations described above. The Plan outlines the analysis rule writers complete to determine whether the regulatory requirements of a rule might uniquely affect small governments. Under the plan, EPA encourages attention to such factors as whether small governments will experience higher per-capita costs due to economies of scale, whether they would need to hire professional staff or consultants for implementation, or if they would be required to purchase and operate expensive or sophisticated equipment. The findings under the Small Government Agency Plan are published in the Federal Register with proposed and final rules. When there are unique or significant impacts on small governments, a range of actions are taken 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 program activities 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 is linked electronically to EPA's Federal Register site so that readers interested in a regulation covered in the newsletter can immediately gain access to the actual text. As part of the project, ICMA has also conducted several workshops for small government officials on regulatory and other environmental management topics.

Guide to Federal Environmental Requirements for Small Governments: EPA also publishes and distributes the small communities guide -- a reference handbook to help local officials become familiar with federal environmental requirements that may apply to their jurisdictions. In the guide, federal regulations are explained 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, sewerage 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. In the guide, federal regulations are explained in a simple, straightforward manner. In addition, up-to-date contact lists for State environmental programs are included.

Consultation Highlights

Since March of 2000, the Agency has published a number of rules subject to the requirements of the Unfunded Mandates Reform Act. What follows is a summary of the Agency's UMRA compliance activities for these rules and others for which EPA was not required by UMRA to consult with the regulated community but conducted outreach for these actions as a matter of Agency policy.

Office of Water

Arsenic; National Primary Drinking Water Regulation (Final Rule)

The final Arsenic regulation contains a Federal mandate that may result in expenditures of $100 million or more for State, tribal, and local governments, in the aggregate, or the private sector in any one year. A detailed description of this analysis is presented in EPA's Economic Analysis of the arsenic rule which is included in the Office of Water docket for this rule. The final Arsenic Rule was published in the *Federal Register* on January 22, 2001.

In developing the proposed rule, EPA consulted with small governments, State and local officials, and private entities. EPA held five public meetings for stakeholders in Washington, DC; San Antonio, TX; and Monterey, CA prior to proposal and a meeting in Reno, NV during the public comment period for the proposal. Participants in EPA's stakeholder meetings included representatives from the National Rural Water Association, Association of Metropolitan Water Agencies, American Water Works Association, Association of California Water Agencies, Rural Community Assistance Program, State departments of environmental protection, State health departments, State drinking water programs, and a tribe.

The Agency convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns. Two of the small entities represented small local governments. In addition, EPA officials presented a summary of the rule to the National Governor's Association in a meeting on May 24, 2000. EPA also scheduled a one-day stakeholders' meeting for the trade associations that represent elected officials on May 30, 2000 to discuss and solicit comment on this and other upcoming contaminant rules.

In general, comments on the proposed Arsenic Rule cited costs and funding for compliance, reducing administrative burden, and increasing flexibility as concerns. EPA's proposed and final rules reflected eased administrative burden on states based on their comments. For the final rule, EPA further revised the costs based on comments and continues to believe that there are affordable technologies.

Concentrated Animal Feeding Operations (CAFO)(Proposed Rule)

During the development of the proposed CAFO regulations, EPA consulted with private industry, and State and local government regulators. EPA also established a workgroup that included representatives from USDA and seven states, as well as EPA Regions and headquarters offices. The workgroup considered input from stakeholders in developing the regulatory options. EPA also sent a summary package outlining the proposed rule to State and local associations, including the National Governors' Association, National Conference of State Legislators, U.S. Conference of Mayors,

Council of State Governments, International City/County Management Association, National Association of Counties, National Association of Towns and Townships, and County Executives of America.

In addition, EPA met with the Local Government Advisory Committee, Small Community Advisory Subcommittee in September 1999. At this Federal Advisory Committee Act meeting, EPA described the CAFO regulatory revisions being considered, and responded to questions concerning the effect of EPA's regulatory actions on small communities. EPA also notified tribal communities about this rulemaking through a presentation of potential rule changes at the National Environmental Justice Advisory Committee meeting in Atlanta in June 2000 and through notices in tribal publications.

The proposed rule would widen the scope of animal feeding operations that require NPDES permits and strengthen the technology based regulations in these permits as they apply to CAFOs. Based on consultations with States and local governments, EPA also proposed some ways to clarify and simplify the existing requirements to make them more easily understandable and more effective in their implementation. Many of EPA's proposed CAFO requirements reflect this objective, particularly in proposed revisions to the existing regulations that pertain to applicability. In addition, many States disagree with EPA's assessment that the rule would have minimal impact on the States. In particular they are concerned that lowering the threshold that defines CAFOs would require additional entities to be permitted in States where there is already a permit backlog. To address this concern, States and several national associations representing State governments recommend that EPA provide States with the flexibility to use State programs in lieu of NPDES permits. This recommendation along with other concerns expressed by States were addressed through co-proposal of regulatory options. For example, EPA proposed to amend the current NPDES authorization to recognize State programs that can meet the requirements of a NPDES program consistent with 40 CFR Part 123. EPA also included a co-proposal to waive the co-permitting requirement in States that have a program for addressing excess manure. EPA solicited comment on these and other approaches and will evaluate a range of regulatory alternatives to grant greater flexibility to States.

For the final rule, the Agency is considering additional ways to provide increased flexibility—particularly to States with regard to existing State programs related to CAFOs—based on recommendations by States and several national associations representing State governments.

Ground Water Rule; National Primary Drinking Water Standards (Proposed Rule)

The Ground Water rule (GWR) contains a Federal mandate that may result in expenditures of $100 million or more for the private sector in any one year. A detailed description of the UMRA analysis is presented in EPA's Regulatory Impact Analysis of the

GWR which is included in the Office of Water docket for this rule. The proposed Ground Water Rule was published in the *Federal Register* on May 10, 2000.

EPA initiated consultations with the governmental entities affected by this rule. EPA held four public meetings for all stakeholders early in the rule development process as well as a public meeting after the proposal was published. In addition, EPA held three early involvement meetings with the Association of State Drinking Water Administrators. Because of the GWR's impact on small entities, the Agency convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns, including small local governments specifically. EPA consulted with small entity representatives prior to convening the Panel to get their input on the GWR. Of the 22 small entity participants, five represented small governments. EPA also made presentations on the GWR to the national and some local chapters of the American Water Works Association, the Ground Water Foundation, the National Ground Water Association, the National Rural Water Association, and the National League of Cities. Twelve State drinking water representatives also participated in the Agency's GWR workgroup.

In addition to these consultations, EPA circulated a draft of this proposed rule and requested comment from the public through an informal process. Specifically, on February 3, 1999, EPA posted on the EPA's Internet web page and mailed out over 300 copies of the draft to people who had attended the 1997 and 1998 public stakeholder meetings as well as people on the EPA workgroup. EPA received 80 letters or electronic responses to this draft.

To inform and involve tribal governments in the rulemaking process, EPA presented the GWR at the 16th Annual Consumer Conference of the National Indian Health Board, at the annual conference of the National Tribal Environmental Council, and at an EPA Office of Ground Water and Drinking Water (OGWDW)/Inter Tribal Council of Arizona, Inc. tribal consultation meeting. Over 900 attendees representing tribes from across the country attended the National Indian Health Board's Consumer Conference and over 100 tribes were represented at the annual conference of the National Tribal Environmental Council. At the OGWDW/Inter Tribal Council of Arizona meeting, representatives from 15 tribes participated. In addition, over 500 tribes and tribal organizations were sent the presentation materials and meeting summary.

On May 30, 2000 EPA held a one day stakeholders meeting for the trade associations that represent State and local elected official including the National League of Cities, The National Association of Counties, The National Governors Association, The National Association of Towns and Townships and the National Conference of State Legislators. The meeting was held to present information on the GWR and other drinking water rules that were proposed that year. Participants were encouraged to submit comments on the proposed GWR. Over 250 organizations and individuals submitted comments upon the proposed GWR including 38 State government organizations, 18 local government organizations and 1 tribal government organization.

Through these consultations, government stakeholders provided input on virtually all aspects of the Ground Water Rule. One concern most government stakeholders shared was that EPA might require across the board disinfection for all water systems. The Agency considered this concern when selecting its preferred alternative for the Ground Water Rule proposal, which is a risk-based targeting approach to identify systems requiring corrective action. Another concern common to most government stakeholders was that EPA should provide flexibility to address unique circumstances both at the State/Tribal level and the system level. In response to those concerns, the proposed GWR provides State and Tribal Primacy agencies with a high degree of flexibility by enabling these agencies to define significant deficiencies. The proposed GWR provides flexibility to the local governments which administer water utilities by permitting them to select from a range of corrective actions.

Metal Products and Machinery (MP&M) (Proposed Rule)

During the development of the proposed MP&M regulation, EPA consulted with private industry, and State and local government regulators. The proposed MP&M Rule will affect governments in two ways: (1) government-owned MP&M facilities may be directly affected by the MP&M regulation and therefore incur compliance costs; and (2) municipalities that own Publicly Owned Treatment Works (POTWs) that receive influent from MP&M facilities subject to the regulation may incur additional costs to implement the proposed rule. State and regional permitting authorities will also be affected. EPA consulted with these stakeholder groups on topics such as options development, cost models, pollutants to be regulated, cost of the regulation, and compliance alternatives. Some of the stakeholders provided helpful comments on the cost models, technology options, pollution prevention techniques, and monitoring alternatives.

In addition, because many facilities affected by this proposal are indirect dischargers, the Agency involved POTWs as they will have to implement the rule. EPA consulted with POTWs individually and through the Association of Municipal Sewerage Agencies (AMSA). EPA also consulted with pretreatment coordinators and State and local regulators. The Agency collaborated with POTWs in selecting BAT facilities for EPA wastewater sampling and, in several cases, POTWs performed wastewater sampling and submitted the data to EPA for use in developing the rule. EPA conducted the POTW survey to obtain estimates of POTW permitting costs and sludge disposal practices and costs. EPA assessed whether any impacts of the regulatory requirements in the rule might significantly or uniquely affect POTWs, especially small POTWs, and determined the degree to which POTWs would benefit from the regulation by having more options for sewage sludge disposal and decreased costs of disposing of the sludge.

EPA consulted with State and local regulators during three different public meetings. Their main comments focused on: (1) the potential burden on them to issue permits/control mechanisms for a large number of facilities that have not been permitted under effluent guidelines prior to this rule; (2) request for additional monitoring flexibilities; and (3) request to allow them to use concentration-based standards in the MP&M rule for those subcategories where it is difficult to obtain production or flow

information at the process-level. EPA incorporated many of their suggestions and addressed these concerns throughout the preamble.

EPA also consulted with State and local government representatives in developing the proposal. EPA developed and administered a survey questionnaire to collect information from POTWs on the burden of implementing permits for MP&M facilities. In addition, EPA attended several industry and professional meetings such as the National Metal Finishing Strategic Goals Summit and the annual meetings of the Association of Municipal Sewerage Authorities (AMSA) to talk to State and local governments (and other stakeholders) about the MP&M proposed rule including several possible alternative options for monitoring. State and local government representatives were also present at EPA's public meetings on the MP&M proposed rule.

Based on consultations with State and local governments, with particular consideration of Publicly Owned Treatment Works (POTWs), EPA incorporated increased flexibility into the proposed rule. As requested by local regulators, EPA proposed a flexible program for monitoring wastewater discharges from MP&M facilities. The proposed program includes the use of indicator parameters, waivers for pollutants not present, and self-certification of an organic chemicals management plan. In addition, to reduce implementation burden on POTWs, EPA proposed to exclude nearly 50,000 facilities from the MP&M rule. This was achieved by limiting the regulation to facilities with wastewater flows above a low-flow threshold. The low-flow exclusion will have an additional benefit by reducing the number of State and local government-owned facilities subject to the MP&M rule. For example, as proposed, a town's snow removal equipment facility, if it generates less than one million gallons per year of wastewater, would be excluded from the MP&M rule.

In addition, although not specifically incorporated into the proposed regulatory requirements, EPA solicited comment on additional opportunities to reduce implementation burdens for State and local regulatory authorities. For example, EPA requested comment on providing a low flow exclusion to other MP&M industry sectors. Finally, among the revisions for the final rule, EPA plans to incorporate clarifications to regulatory definitions and applicability statements suggested by State and local governments.

Office of Prevention, Pesticides, and Toxic Substances

Identification of Dangerous Levels of Lead (Final Rule)

The final regulation under section 403 of the Toxic Substances Control Act (TSCA), as amended by the Residential Lead-Based Paint Hazard Reduction Act of 1992, also known as "Title X (ten)," establishes standards for lead-based paint hazards in most pre-1978 housing and child-occupied facilities. This regulation supports the implementation of regulations already promulgated, and others under development, which deal with worker training and certification, lead hazard disclosure in real estate transactions, requirements for lead cleanup under State authorities, lead hazard evaluation and

control in Federally-owned housing prior to sale and housing receiving Federal assistance, and U.S. Department of Housing and Urban Development grants to local jurisdictions to perform lead hazard control. In addition, this action also establishes, under authority of TSCA section 402, residential lead dust cleanup levels and amendments to dust and soil sampling requirements and, under authority of TSCA section 404, amendments to State program authorization requirements.

Although the establishment of the standards contained in this rule do not, in and of themselves, mandate any action, the Agency recognizes that the existence of the hazard standards may influence the decisions or actions of State, local or tribal governmental officials as they relate to lead-based paint activities, i.e., hazard interventions and risk assessments. Because the standards established by this regulation may be adopted by any State or tribal government, EPA involved State and local governmental agencies in an extensive "dialogue" process. The Agency also consulted with interested State and tribal government representatives as part of the Forum on State and Tribal Toxics Action and EPA's Annual National Lead Meeting with States and Tribes. The Agency has also provided extensive technical and financial assistance. EPA also consulted with the states at the annual EPA meeting with State program representatives.

Due to this public input, EPA made several changes prior to finalizing this rule. One of the most significant concerned the characterization of lead hazards in soil. In answer to concerns that the "yard-wide" soil standards might be too burdensome and still not protective enough, EPA responded by setting two separate levels - a more stringent standard which would apply in play areas (this protecting children in areas where they are most likely to encounter lead-contaminated soil), and a less stringent standard which would apply in other areas (thus focusing attention on highest priority areas, while lowering the burden on other areas). This approach appears to satisfy Agency goals, and address public and State concerns about the implementation of the standards.

Office of Solid Waste and Emergency Response

Notice of Proposed Decision on Request by FMC Corporation for an Extension of the Land Disposal Restrictions Effective Date for Five Waste Streams Generated at the Pocatello, Idaho Facility; Notice; 65 FR 12233; 3/8/00, *65 FR 34694; 5/31/00*

EPA proposed to approve the request submitted by FMC Corporation (FMC) for a one-year Case-by-Case (CBC) extension of the May 26, 2000, effective date of the Resource Conservation and Recovery Act (RCRA) land disposal restrictions (LDRs). FMC requested the CBC extension due to the lack of available treatment capacity for five waste streams and the need for additional time to design, construct, and begin operation of an on-site treatment plant. For this CBC extension to be approved, FMC must make each of the seven demonstrations required in the procedures for CBC extensions to an effective date. These provisions establish that an applicant who satisfies the conditions for a CBC extension will be granted one. If this proposed action is finalized, FMC will be allowed to

continue to treat, store, or dispose of these five waste streams, as currently managed in on-site surface impoundments, until May 26, 2001, without being subject to the LDRs applicable to these wastes.

EPA consulted with the State of Idaho--Idaho Division of Environmental Quality (IDEQ) to determine if the State had any permitting, enforcement, or other concerns regarding this respective facility that EPA should take into consideration in deciding to grant or deny FMC's application for a CBC extension of the LDR effective date. The State of Idaho has indicated its support for the approval of the CBC extension requested by FMC.

EPA approved the request submitted by FMC Corporation (FMC) for a one-year case-by-case (CBC) extension of the May 26, 2000, effective date of the RCRA land disposal restrictions (LDRs) applicable to hazardous wastes generated by FMC. This action responds to the request submitted by FMC, under the procedures for CBC extensions to an effective date, which allow any person to request the Administrator to approve, on a case-by-case basis, an extension of the applicable effective date of the LDRs.

Amendments to the Corrective Action Management Unit (CAMU) Rule; NPRM; 65 FR 51079; 8/22/00

EPA proposed amendments to the existing RCRA Corrective Action Management Unit (CAMU) Regulation. CAMUs are used for managing remediation wastes, and for implementing corrective action or cleanup at a facility. CAMUs can promote cleanups by allowing a broader range of cleanup activities than are allowed under the other hazardous waste management regulations. The amendments, if finalized, will add more detail to the treatment and technical standards for management of cleanup wastes in CAMUs.

In the spirt of Executive Order 13132 on Federalism, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comments on the proposed rule from State and local officials. Prior to entering into the CAMU settlement agreement, EPA did discuss with the states potential impacts on states from amendments to the CAMU rule. During these discussions, individual states expressed concerns about potential disruption caused by the authorization process that would be required in states that are already authorized for the 1993 CAMU rule, the reduced discretion that would be available under any amendments to the CAMU rule, and the potentially more elaborate process that would be involved in making CAMU decisions.

EPA recognizes that these are valid concerns, and believes the proposal addresses them. For example, EPA has proposed a grandfathering provision, to address the issue of disrupting existing CAMUs and those that are substantially in the approval process. The proposal will also include an approach to authorization that is intended to reduce disruption for states with authorized CAMU programs, and to expedite authorization for states that have corrective action programs but are not yet

authorized for CAMU. In addition, EPA recognizes that increased process is introduced by this proposal, but, has tried to find a reasonable balance by adding sufficient detail to achieve the proposal's goals while preserving site-specific flexibility that provides incentives to cleanup. Finally, the proposal is designed to incorporate the CAMU designation process into the existing decision-making process that is typically used by states and EPA for cleanups, including that used for making CAMU determinations. For example, EPA designed the principal hazardous constituent process, and certain proposed adjustment factors to reference the overall cleanup decision-making process within which the CAMU decision is made. EPA is seeking comment on its approach to address these concerns.

Accidental Release Prevention Requirements; Risk Management Programs under the Clean Air Act Section 112(r)(7); Distribution of Off-site Consequences Analysis Information; Final
65 FR 48108; 8/4/00

In August 2000, EPA and the Department of Justice (DOJ) issued a joint rulemaking, "Accidental Release Prevention Requirements; Risk Management Programs Under the Clean Air Act Section 112(r)(7); Distribution of Off-Site Consequence Analysis Information." As required by the Chemical Safety Information, Site Security and Fuels Regulatory Relief Act (CSISSFRRA), this rule provided members of the public and government officials with access to information concerning the potential off-site consequences of hypothetical accidental chemical releases from industrial facilities. The agencies consulted with seven organizations that represent State and local elected officials in developing this rule (*i.e.*, National Governors Association, National Conference of State Legislatures, U.S. Conference of Mayors, National League of Cities, Council on State Governments, International City/County Management Association, National Association of Counties, and National Association of Towns and Townships). The agencies also consulted with State and local representatives of the Accident Prevention Subcommittee of the Clean Air Act Advisory Committee (an EPA FACA committee) about the implementation of the off-site consequence analysis (OCA) provisions of CSISSFRRA. In response to concerns some raised about the potential chilling effect of CSISSFRRA's restrictions on State and local officials' willingness to obtain OCA information and to communicate the substance of that information to the public, the rule included a provision clarifying that State and local officials can share OCA data with the public as long as they do so in a way that does not disseminate or permit mechanical replication of the OCA sections of risk management plans or provide access to EPA's OCA database. The rule also authorized some State and local officials to share OCA information themselves in certain ways.

Small Government Pilot Projects and Capacity Building

Small Community Outreach Project for the Environment (SCOPe)

EPA's Office of Policy, Economics and Innovation funds a project of the National Association of Schools of Public Affairs and Administration (NASPAA) to create a communications channel for small towns to consider complex environmental regulations. This communication is aimed at minimizing

the adverse impact of regulations on small governments through early consultation. The core effort of this project has regional schools of public administration meeting with small town leaders on a sub-State regional basis to empower themselves to become better environmental citizens and communities. This cooperative agreement is currently in its third year.

Small Town and Rural Outreach Project

The principal objective of the Small Town and Rural Outreach Project is to enable local government decision-makers to provide meaningful comment, at the pre-proposal stage, for a select number of rules that may have an impact on smaller communities. This will include development of a roadmap for local leaders to provide input into future rulemaking efforts. As its second objective, the Small Town and Rural Outreach Project will develop a replicable model to use in gathering small town comments at various stages in the making and implementation of future rules and/or programs. This project is currently in its first year of a two-year funding agreement.

Policy on Flexible State Enforcement Responses to Small Community Violations

EPA's Office of Enforcement and Compliance Assurance (OECA) issued the Policy on Flexible State Enforcement Responses to Small Community Violations in 1995. The policy establishes parameters within which a state can expect EPA to defer to the state's decision to address a small community's environmental violations with comprehensive, capacity-building compliance assistance instead of with the traditional enforcement action and penalty. The policy gives states the flexibility to help small communities address environmental problems on a "worst things first" basis. The policy also creates a new incentive for small communities to ask the state for help when they think they may have an environmental problem.

Developed as a result of the Agency's ongoing dialog with small communities, this policy is intended to address the concern that small communities that lack the technical resources needed to comply with all environmental regulations may not seek help for fear of becoming entangled in the enforcement process. Small localities making substantial progress towards compliance in accordance with a schedule developed with State assistance will generally not be subject to State or federal enforcement actions.

Based on EPA's experience so far in Oregon, the policy works as follows. Environmental Partnerships with Oregon Communities (EPOC) offers compliance assistance to a small community that requires assistance to meet its environmental obligations. A team of experts from the state performs a comprehensive review of the communities operations to identify all current environmental violations and areas of concern for future violations. If a community cannot correct all its violations quickly, the state negotiates an enforceable compliance schedule which establishes a specified time period for correcting the violations on a priority basis. The community then addresses those violations according to the schedule, beginning with those that have the greater potential impact on health and/or the environment.

The state refrains from taking enforcement actions and waives or reduces penalties that normally would be assessed for violations, so long as the small community is making "good faith" efforts towards implementing the schedule.

Of course, small communities that do not meet the negotiated compliance schedule may be faced with State or federal enforcement actions. The policy does not apply to criminal violations and EPA retains its independent authority to take immediate action in the event of any violation that represents an "imminent and substantial endangerment" to the public or the environment. More than a dozen Oregon communities have signed such agreements and others are “in the pipeline.” Nebraska conducts a similar program. Under the Nebraska Environmental Partners Program (NEPP), more than 200 communities have conducted comprehensive environmental self-assessments with the assistance of State government agencies of the state of their environmental compliance. Although no violations have been identified, NEPP has developed compliance assistance and funding strategies to address the compliance issues that have been identified through the self-assessment process.

In 2001, EPA will publish a Federal Register notice taking public comment on possible revisions to the Policy.

CHAPTER III– A REVIEW OF SIGNIFICANT REGULATORY MANDATES ISSUED IN THE PAST YEAR

Between June 2000 and May 2001, Federal agencies issued eighteen rules that contained statements noting they 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. The Environmental Protection Agency (EPA) issued six rules,[38] the Department of Energy issued six ,[39] the Department of Labor issued three, the Department of Health and Human Services issued two and the Department of Transportation issued one. There were two 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. These were: the HHS final rule, Standards for Privacy of Individually Identifiable Health Information, and the EPA rule, National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, and the remaining rules were covered by the Act either because of expected expenditures exclusively by the private sector, or expected aggregate expenditures by State, local or tribal governments combined with expenditures by the private sector greater than $100 million.

The individual rules along with a brief description of the rule, and a summary of the costs of the rule are listed below. As mentioned above, these are the rules that the agencies certified as meeting the strict requirements of the Unfunded Mandates Reform Act. There are clearly many other rules which have important impacts on State, local, and tribal governments (many of which are discussed in chapter two). Some of these may be considered to be unfunded mandates using a broader and less literal reading of the Act. We welcome comments on which rules issued between June 2000 and May 2001 are not included in the list below but which State, local or tribal governments believe should be considered unfunded mandates.

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy – Energy Conservation Program for Consumer Products: Central Air Conditioners and Heat Pumps Energy Conservation Standards (Proposed Rule, October 2000; Final Rule, January 2001)

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[38] The six EPA rules counts the National Primary Drinking Water Regulation on Arsenic twice because it was issued both as a final rule and a proposed rule within the year covered by this report.

[39] The sis DOE rules count the Energy efficiency standards for air conditioners and clothes washers twice each since both a proposed rule and a final rule were issued within the year covered by this report in both cases.

This rule amends the energy efficiency standards for central air conditioners and heat pumps. The rule impacts the private sector. Including the costs and markups of a central air conditioning until or heat pump under the new standards, the range of cost to the consumer would be from $1279 to $2280, with an overall impact of over $100 million.

DOE states that this rule establishes energy conservation standards for central air conditioners and heat pumps that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified.

Office of Energy Efficiency and Renewable Energy – Energy Conservation Program for Consumer Products: Clothes Washer Energy Conservation Standards (Proposed Rule, October 2000; Final Rule, January 2001)

This rule amends the energy conservation standards for clothes washers and compact clothes washers, and makes amendments to the test procedure for measuring the energy efficiency for clothes washers. This rule impacts the private sector. The price of the average clothes washer is expected to rise from about $400. 25 to $421.10 for consumers, based on the new energy conservation standards, with a total impact of over $100 million.

DOE states that the final rule establishes energy conservation standards for clothes washers that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and are economically justified.

Office of Energy Efficiency and Renewable Energy – Energy Conservation Program for Consumer Products: Energy Conservation Standards for Water Heaters (Final Rule)

This rule increases the energy conservation standards for water heaters. This rule affects the private sector. Due to the wide range of types, manufacturers and models of water heaters, an overall cost is difficult to pin down, but it will be over $100 million per year.

In the preamble to the final rule, DOE states that the final rule establishes energy conservation standards for water heaters that are designed to achieve the maximum improvement in energy efficiency that DOE has determined is both technologically feasible and economically justified.

Office of Energy Efficiency and Renewable Energy – Energy Conservation Program for Consumer Products: Fluorescent Lamp Ballasts Energy Conservation Standards (Final Rule)

This rule amends existing energy conservation standards for fluorescent lamp ballasts as proposed and recommended by stakeholders because the Department of Energy has determined that such revised standards will result in significant conservation of energy, are technologically feasible, and are economically justified.

This rule impacts the private sector. The total benefit is expected to be between $1.22 billion and $7.18 billion in 1997 dollars, while the total equipment cost will range between $0.45 billion and $1.76 billion. Thus, the Net Present Value will range between $1.40 billion and $5.42 billion. DOE states that this rule establishes energy conservation standards for fluorescent lamp ballasts that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Insurance Reform: Standards for Electronic Transfers (Final Rule)

This rule sets standards for electronic transmission of health information, which is required to be set by Title II of the Health Insurance Portability and Accountability Act (HIPAA). Standard electronic codes must be established for data sets such as national standard health care provider identifier and national standard employer identifier, and other standards such as security and electronic signatures.

This rule will impact the private sector, primarily health plans and health care providers, as well as State and local governments and tribal organizations. Savings will outweigh the costs to the private sector by the fourth year of the standards, and the total net savings for the period 2001 – 2011 will be $29.8 billion. The cost to State and local government and tribal organizations cannot be fully determined, since the federal government only has enough information on Medicaid programs to make an estimate of costs. The net effect may be that some states have to pay up to $1 million to comply. The Department states that the selection of this standard (from 10 options) does not impose a greater burden on the industry than the non-selected options. This is because the non-selected formats are not used in a standard manner by the industry and they do not incorporate the flexibility necessary to adapt easily to change. The standard chosen presents significant advantages in terms of universality and flexibility.

Office of the Assistant Secretary for Planning and Evaluation – Standards for Privacy of Individually Identifiable Health Information (Final Rule)

This rule heightens standards and provides enhanced protection of individually identifiable health information, and would apply to health plans, health care clearinghouses and some health care providers. This rule intends to protect those individuals who are the subject of such information, and how such information may be used and disclosed.

HHS states that the Department adopted the least burdensome alternatives, consistent with achieving the rule's goals." This rule would affect State and local governments. The cost to State and local governments will be approximately $360 million in 2003 and $2.4 billion over ten years. The rule will also affect the health care industry, and may cost that industry $30 billion over ten years.

DEPARTMENT OF LABOR

Occupational Safety and Health Administration – Ergonomics Program (Final Rule)

This rule would have created standards whose aim is the reduction in musculoskeletal disorders (MSDs) in the work place that are the result of ergonomic risk factors such as repetitive motion, force, awkward posture and vibration. The final ergonomics rule was a program standard that requires employers whose employees experience MSD incidents in jobs determined to be higher-risk jobs to implement a program that includes the elements of any sound safety and health program.

This rule would have affected both the private sector and government entities. The annualized benefits accruing in the first ten years the standard would have been in effect were estimated to be $9.1 billion. The estimated cost to all affected sectors per year was expected to be $4.5 billion. The DOL stated that options for improving the operation of markets include dissemination programs, tort liability options, and workers' compensation programs. After considering each of these options, OSHA concluded that none of them will provide the level of social benefits or employee protection achievable by the final ergonomics program standard.

This rule was overturned by Congress according to the terms of the Congressional Review Act on March 20, 2001.

Pension and Welfare Benefits Administration – Amendments to Summary Plan Description Regulations (Final Rule)

This rule amends the regulations governing the content of the Summary Plan Description (SPD), which is required to be furnished to employee benefit plan participants and beneficiaries under the Employee Retirement Income Security Act of 1974 (ERISA). The amendments clarify benefit, medical provider and other information required to be disclosed in the SPD of a group health plan and repeal the limited exemption with respect to SPD's of welfare plans providing benefits through qualified HMO's.

The rule will affect private companies, and the estimated cost associated with these amendments will peak at $208 million for 2002, the year most of the amendments will become applicable. DOL states that it has adopted the least burdensome method of achieving the rule's objective of improving the information that participants and beneficiaries receive about their ERISA covered pension and welfare plans.

Pension Welfare Benefits Administration – Employee Retirement Income Security Act of 1974; Rules and Regulations for Administration and Enforcement; Claims Procedure (Final Regulation)

This regulation revises the minimum requirements for benefit claims procedures of employee benefit plans covered by Title I of the Employee Retirement Income Security Act of 1974 (ERISA). The regulation establishes new standards for the processing of claims under group health plans and plans providing disability benefits and further clarifies existing standards for all other employee benefit plans.

This regulation impacts the private sector. DOL states that they selected the least costly alternative as required by UMRA. There is a total cost in years 2001-2002 of $518 million. The reported benefits of the regulation include ensuring the prompt approval of some health and disability claims that otherwise would have been wrongly denied.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration – Federal Motor Vehicle Safety Standards; Head Restraints (Proposed Rule)

This rule would upgrade the standard for head restraints for passenger cars and light multi-purpose vehicles, trucks and buses. The rule would establish higher minimum height requirements for head restraints, and add a requirement limiting the distance between a person's head and the head restraint.

The total cost per year (in 1998 dollars) is expected to be $160.5 million, while the rule is expected to reduce the number of whiplash injuries suffered by 14,247 per year. The rule would affect the private sector, specifically, motor vehicle manufacturers. The Department states that this rule would be consistent with its policy of producing the highest benefits at a reasonable cost.

ENVIRONMENTAL PROTECTION AGENCY

Office of Ground Water and Drinking Water – National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring (Proposed Rule, June 2000; Final Rule, January 2001)

This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 mg/liter to 10 mg/liter. 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 $181 million.

The EPA claims that it selected an MCL of 10 mg/L because it is the most cost-effective alternative, because it maximizes benefits.

Office of Transportation and Air Quality – Control of Emissions of Air Pollution from Highway Heavy-Duty Engines (Final Rule)

This rule updates the emissions standards for heavy-duty diesel and auto-cycle vehicles and engines. The total annual cost of improved heavy-duty vehicles for the year 2004 (in 1999 dollars) will be $479 million. The aggregate cost to society of the new heavy-duty Otto-cycle requirements will be $110 million in 2005. The 20-year annualized cost for the regulation is $379 million.

This rule will affect the private sector. The EPA stated that it believes that the final rule represents the least costly, most cost-effective approach to achieve the air quality goals of the rule.

Office of Transportation and Air Quality - Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements (Final Rule)

This rule sets new federal emissions standards for heavy-duty vehicles and places limits on the level of sulfur in diesel fuel.

This rule impacts the private sector. The annual compliance costs will be $4.2 billion in 1999 dollars, while the net benefits are expected to be at least $66.2 billion. The EPA stated that it believes the rule represents the least costly, most cost-effective approach to achieve the air quality goals of the rule.

Office of Water - Metal Products and Machinery Efficient Guidelines (Proposed Rule)

This proposed regulation will apply to process wastewater discharges from Metal Products and Machinery (MP&M) facilities performing manufacturing, rebuilding or maintenance on a metal part, product, or machine using an MP&M operation and discharging process wastewater either directly or indirectly to surface waters.

This regulation would impact both the private sector and State and local government or tribal organizations. The estimated total annualized before-tax compliance costs are $2.1 billion in 1999 dollars. Of that total, $2.095 billion is expected to be borne by the private sector, and $0.014 is expected to be borne by governments. The EPA stated that it believes that the proposed rule is the least burdensome of the regulatory alternatives considered that still meets EPA's objectives.

Office of Water – National Pollutant Discharge Elimination System Regulations and Effluent Limitations Guidelines and Standards for Concentrated Animal Feeding Operations (Proposed Rule)

This regulation seeks to ensure that manure, wastewater and other process waters generated by concentrated animal feeding operations do not impair water quality. EPA is revising the old standards in these areas, which were established in the 1970s. This rule will impact the private sector. Total

annual compliance cost is projected at $925 million. Estimates of this rule's benefits range from $163 million to $182 million annually. The EPA stated that it has selected the least costly, most cost-effective and least burdensome alternative that was consistent with the requirements of the CWA.