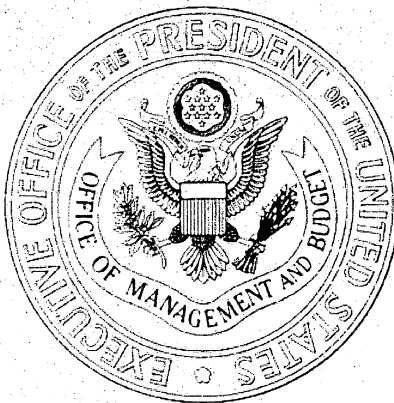


**Stimulating Smarter Regulation:
2002 Report to Congress on the
Costs and Benefits of Regulations
and Unfunded Mandates on
State, Local, and Tribal Entities**



2002

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

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Stimulating Smarter Regulation:

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

EXECUTIVE SUMMARY

This Final Report to Congress on regulatory policy was prepared in response to the Regulatory Right-to-Know Act¹ and the Unfunded Mandates Reform Act². The Report provides: (a) a summary of Federal regulatory actions taken due to the tragic events of September 11th and their aftermath, (b) an overview of the Office of Information and Regulatory Affairs' (OIRA) activities; (c) an accounting statement of the costs and benefits of Federal regulations, including assessments of their impact on State, local and tribal governments, small businesses, wages and economic growth; (d) a summary of regulatory reform activities in other developed countries, with a particular focus on the European Union; and (e) a discussion of nominations of regulatory improvements from approximately 1,700 public comments. This Final Report reflects revisions made to a Draft Report that was subjected to public comment, external peer review, and interagency review.

The major features and findings of the Report include:

1. Since September 11th, OIRA has cleared 58 significant Federal regulations aimed at responding to the terrorist attacks. These rules addressed urgent matters such as homeland security, immigration control, airline safety, and the need for assistance to businesses harmed by the resulting economic disaster.
2. OIRA's goals in regulatory oversight include openness, promptness, and analytic rigor. OIRA's website has regular updates on rules under review, meetings with outside parties, and key letters and memoranda to agencies. The number of OIRA reviews consuming more than the allotted 90 days has declined from what had regularly been 15-20 rules at any given time to near zero in recent months. From July 1, 2001, to March 1, 2002, OIRA returned more than 20 rules to agencies for reconsideration, more than the total number of rules returned to agencies during the entire Clinton Administration. Inadequate analysis by agencies was the most common reason for returns. The absence of returns in recent months (March 2002 to September 2002) reflects better communication between OMB and agencies and increased quality in rulemaking packages.
3. OIRA has developed the "prompt letter" for suggesting promising regulatory and informational priorities for agency consideration. OIRA's initial six prompt letters have addressed a range of issues at five different agencies, including the use of lifesaving defibrillators in the workplace, food labeling requirements for trans-fatty acids, and better

¹31 U.S.C. § 1105 note, Pub. L. 106-554, § 1(a) (3) [Title VI, § 624], Dec. 21, 2000, 114 Stat. 2763, 2763A-161

²P.L. 104-4, Title II

information regarding the environmental performance of industrial facilities. Agencies have performed independent assessments of each of these suggestions and adopted reasonable responses.

4. Pursuant to statutory mandate, OIRA has issued government-wide guidelines to enhance the quality of information that Federal agencies disseminate to the public. OIRA worked with agencies to finalize their guidelines prior to the October 1, 2002, statutory deadline. These guidelines offer a new opportunity for affected members of the public to request corrections when poor quality information is disseminated or used to justify new regulations or other policies. OMB has directed each agency to develop an administrative mechanism to resolve these requests, including an independent appeals mechanism.

5. The report summarizes regulatory reform activities now underway in developed countries throughout the world, with special focus on the European Union. The European Commission has recently issued an Action Plan for Better Regulation that includes expanded transparency, consultation with stakeholders, and more rigorous regulatory impact analysis.

6. OIRA examined major Federal regulations cleared from April 1, 1995 to September 30, 2001 to determine their quantifiable benefits and costs. The estimated annual benefits range from \$48 billion to \$102 billion, while the estimated costs range from \$50 billion to \$53 billion. Based on the information released in previous reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits reported here. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program. OMB's examination of the benefits and costs of Federal regulation supports the need for a common-sense approach to modernizing Federal regulation that involves the expansion, modification, and rescission of regulatory programs, as appropriate.

7. In response to an open, invitational process of regulatory reform proposals, OIRA received public suggestions on 316 regulations and guidance documents covering 26 Federal agencies. This number of public nominations is over four times larger than the 71 nominations received in 2001 and covers a broader range of topics. This year's commenters are also more diverse in organizational affiliation. As requested, this year's public reform nominations include suggestions to review existing paperwork requirements and guidance documents, as well as to add, modify, or rescind regulations. This report provides a summary of these nominations and describes a review process in which agencies should consider the nominations and identify those that are worthy reforms. This year's review process is different from last year's process, when OIRA identified high priority reform candidates. Rather than suggest any specific agency priorities, OIRA is forwarding all of the public's suggestions, with the expectation that agencies will make decisions about which, if any, reforms to pursue based on their assessment of the prospects and practicality of achieving regulatory improvements.

8. The Bush Administration is concerned about unfunded mandates that impact State and local governments. The scope of consultation activities undertaken by Federal agencies such as Agriculture and Justice demonstrate the Bush Administration's commitment to building strong relationships with our governmental partners. Federal agencies are now actively consulting with States, localities, and tribal governments.

9. Small businesses play a vital role in creating jobs and stimulating growth despite their disproportionate share of regulatory costs and burdens. The report contains numerous constructive suggestions on how agencies can reduce unnecessary regulations and paperwork requirements that impose especially large burdens on small business.

OMB has already begun to prepare the 2003 Report to Congress on the Costs and Benefits of Regulation. Our objective is to publish the draft 2003 Report to Congress with the new Federal budget, thereby starting earlier the annual processes of public comment, external peer review, and interagency review.

Circular A-4

September 17, 2003

TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS

Subject: Regulatory Analysis

This Circular provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order 12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This Circular refines OMB's "best practices" document of 1996 (<http://www.whitehouse.gov/omb/inforeg/riaguide.html>), which was issued as a guidance in 2000 (<http://www.whitehouse.gov/omb/memoranda/m00-08.pdf>), and reaffirmed in 2001 (<http://www.whitehouse.gov/omb/memoranda/m01-23.html>). It replaces both the 1996 "best practices" and the 2000 guidance.

In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review. Peer reviewers included Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; and W. Kip Viscusi, Harvard Law School. Although these individuals submitted comments, OMB is solely responsible for the final content of this Circular.

A. Introduction

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis – called either "regulatory analysis" or "analysis" for brevity – and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

The Need for Analysis of Proposed Regulatory Actions¹

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects –

¹ We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

good and bad – of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Benefit-cost analysis is a primary tool used for regulatory analysis.² Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a “threshold” analysis to evaluate their significance. Threshold or “break-even” analysis answers the question, “How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?” In addition to threshold analysis you should indicate, where possible, which non-quantified effects are most important and why.

Key Elements of a Regulatory Analysis

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

To evaluate properly the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a “no action” baseline: what the world will be like if the proposed rule is not adopted. Comparisons to a “next best” alternative are also especially useful.

² See Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

B. The Need for Federal Regulatory Action

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. If the regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use. Executive Order 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material

failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people”

Executive Order 12866 also states that “Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.” Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy. If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively. You should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values.

Market Failure or Other Social Purpose

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality, common property resource and public good

An externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. If bargaining were costless and all property rights were well defined, people would eliminate externalities through bargaining without the need for government regulation.³ From this perspective, externalities arise from high transactions costs and/or poorly defined property rights that prevent people from reaching efficient outcomes through market transactions.

Resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent common property resources. “Public goods,” such as defense or basic scientific research, are goods where provision of the good to some individuals cannot occur without providing the same level of benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices. They may exercise market power collectively or unilaterally. Government action can be a source of market power, such as when regulatory actions exclude low-cost imports. Generally, regulations that increase market power

³ See Coase RH (1960), *Journal of Law and Economics*, 3, 1-44.

for selected entities should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer – local gas and electricity distribution services, for example – a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and/or production decisions. Nevertheless, you should keep in mind that technological advances often affect economies of scale. This can, in turn, transform what was once considered a natural monopoly into a market where competition can flourish.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. Because information, like other goods, is costly to produce and disseminate, your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information. Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, such as a seller offering a warranty or a third party providing information.

Even when adequate information is available, people can make mistakes by processing it poorly. Poor information-processing often occurs in cases of low probability, high-consequence events, but it is not limited to such situations. For instance, people sometimes rely on mental rules-of-thumb that produce errors. If they have a clear mental image of an incident which makes it cognitively “available,” they might overstate the probability that it will occur. Individuals sometimes process information in a biased manner, by being too optimistic or pessimistic, without taking sufficient account of the fact that the outcome is exceedingly unlikely to occur. When mistakes in information processing occur, markets may overreact. When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met. However, the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In addition, Congress establishes some regulatory programs to redistribute resources to select groups. Such regulations should be examined to ensure that they are both effective and cost-effective. Congress also authorizes some regulations to prohibit discrimination that conflicts with generally accepted norms within our society. Rulemaking may also be appropriate to protect privacy, permit more personal freedom or promote other democratic aspirations.

Showing That Regulation at the Federal Level Is the Best Way to Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to Federal regulation. Alternatives to Federal regulation include antitrust enforcement, consumer-initiated litigation in the product liability system, or administrative compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

The advantages of leaving regulatory issues to State and local authorities can be substantial. If public values and preferences differ by region, those differences can be reflected in varying State and local regulatory policies. Moreover, States and localities can serve as a testing ground for experimentation with alternative regulatory policies. One State can learn from another's experience while local jurisdictions may compete with each other to establish the best regulatory policies. You should examine the proper extent of State and local discretion in your rulemaking context.

A diversity of rules may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate to address interstate commerce issues, you should try to examine whether it would be more efficient to retain or reduce State and local regulation. The local benefits of State regulation may not justify the national costs of a fragmented regulatory system. For example, the increased compliance costs for firms to meet different State and local regulations may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;

- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

C. Alternative Regulatory Approaches

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, you will be able to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider.

Different Choices Defined by Statute

When a statute establishes a specific regulatory requirement and the agency is considering a more stringent standard, you should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement.

Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. Benefits may vary significantly with different compliance dates where a delay in implementation may result in a substantial loss in future benefits (e.g., a delay in implementation could result in a significant reduction in spawning stock and jeopardize a fishery). Similarly, the cost of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and noncompliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their benefits and costs, you should identify the most appropriate enforcement framework. For example, in

some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring.

Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604).

Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation. It is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in benefits and/or costs, you should consider the possibility of setting different requirements for the different regions.

Performance Standards Rather than Design Standards

Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.

Market-Oriented Approaches Rather than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties. One example of a market-oriented approach is a

program that allows for averaging, banking, and/or trading (ABT) of credits for achieving additional emission reductions beyond the required air emission standards. ABT programs can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms. ABT can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as "hot spots" from local pollution concentration).

Informational Measures Rather than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and costs. Some effects of informational measures are easily overlooked. The costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information. The other costs also may include the effect of providing information that is ignored or misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

D. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed to represent expected health and safety outcomes. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes. In undertaking these analyses, it is important to keep in mind the larger objective of analytical consistency in

estimating benefits and costs across regulations and agencies, subject to statutory limitations. Failure to maintain such consistency may prevent achievement of the most risk reduction for a given level of resource expenditure. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA. In unusual cases where no quantified information on benefits, costs and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence.

Benefit-Cost Analysis

A distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure.⁴ By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes net benefits.

The size of net benefits, the absolute difference between the projected benefits and costs, indicates whether one policy is more efficient than another. The ratio of benefits to costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units. If it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. For more information on describing qualitative information, see the section “*Developing Benefit and Cost Estimates.*”

When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. If the non-quantified benefits and costs are likely to be important, you should recommend which of the non-quantified factors are of sufficient importance to justify consideration in the regulatory decision. This discussion should also include a clear explanation that support designating these non-quantified factors as important. In this case, you should also consider conducting a threshold analysis to help decision makers and other users of the analysis to understand the potential significance of these factors to the overall analysis.

Cost-Effectiveness Analysis⁵

⁴ Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

⁵ For a full discussion of CEA, see Gold, ML, Siegel, JE, Russell, LB, and Weinstein, MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York.

Cost-effectiveness analysis can provide a rigorous way to identify options that achieve the most effective use of the resources available without requiring monetization of all of relevant benefits or costs. Generally, cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the best option, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the "effectiveness" measure does not appropriately weight the consequences of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (e.g., different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical when there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

When constructing and comparing incremental cost-effectiveness ratios, you should be careful to determine whether the various alternatives are mutually exclusive or whether they can be combined. If they can be combined, you should consider which might be favored under different regulatory budget constraints (implicit or explicit). You should also make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration.⁶

The value of CEA is enhanced when there is consistency in the analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to carefully construct the two key components of any CEA: the cost and the "effectiveness" or performance measures for the alternative policy options.

With regard to measuring costs, you should be sure to include all the relevant costs to society – whether public or private. Rulemakings may also yield cost savings (e.g., energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred to comply with the requirements (sometimes

⁶ Gold ML, Siegel JE, Russell LB, and Weinstein MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 284-285.

called "total" costs) minus any cost savings. You should be careful to avoid double-counting effects in both the numerator and the denominator of the cost-effectiveness ratios. For example, it would be incorrect to reduce gross costs by an estimated monetary value on life extension if life-years are already used as the effectiveness measure in the denominator.

In constructing measures of "effectiveness", final outcomes, such as lives saved or life-years saved, are preferred to measures of intermediate outputs, such as tons of pollution reduced, crashes avoided, or cases of disease avoided. Where the quality of the measured unit varies (e.g., acres of wetlands vary substantially in terms of their ecological benefits), it is important that the measure capture the variability in the value of the selected "outcome" measure. You should provide an explanation of your choice of effectiveness measure.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weight the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation's different benefits, then you should do so. But in this case, you will be doing BCA, not CEA.

When you can estimate the monetary value of *some* but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. (This net cost estimate for the rule may turn out to be negative – that is, the monetized benefits exceed the cost of the rule.) If you are unable to estimate the value of some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits or costs that have not been incorporated in the net-cost estimates. You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

The Effectiveness Metric for Public Health and Safety Rulemakings

When CEA is applied to public health and safety rulemakings, one or more measures of effectiveness must be selected that permits comparison of regulatory alternatives. Agencies currently use a variety of effectiveness measures.

There are relatively simple measures such as the number of lives saved, cases of cancer reduced, and cases of paraplegia prevented. Sometimes these measures account only for mortality information, such as the number of lives saved and the number of years of life saved. There are also more comprehensive, integrated measures of effectiveness such as the number of "equivalent lives" (ELs) saved and the number of "quality-adjusted life years" (QALYs) saved.

The main advantage of the integrated measures of effectiveness is that they account for a rule's impact on morbidity (nonfatal illness, injury, impairment and quality of life) as well as premature death. The inclusion of morbidity effects is important because (a) some illnesses (e.g.,

asthma) cause more instances of pain and suffering than they do premature death, (b) some population groups are known to experience elevated rates of morbidity (e.g., the elderly and the poor) and thus have a strong interest in morbidity measurement⁷, and (c) some regulatory alternatives may be more effective at preventing morbidity than premature death (e.g., some advanced airbag designs may diminish the nonfatal injuries caused by airbag inflation without changing the frequency of fatal injury prevented by airbags).

However, the main drawback of these integrated measures is that they must meet some restrictive assumptions to represent a valid measure of individual preferences.⁸ For example, a QALY measure implicitly assumes that the fraction of remaining lifespan an individual would give up for an improvement in health-related quality of life does not depend on the remaining lifespan. Thus, if an individual is willing to give up 10 years of life among 50 remaining years for a given health improvement, he or she would also be willing to give up 1 year of life among 5 remaining years. To the extent that individual preferences deviate from these assumptions, analytic results from CEA using QALYs could differ from analytic results based on willingness-to-pay measures.⁹ Though willingness to pay is generally the preferred economic method for evaluating preferences, the CEA method, as applied in medicine and health, does not evaluate health changes using individual willingness to pay. When performing CEA, you should consider using at least one integrated measure of effectiveness when a rule creates a significant impact on both mortality and morbidity.

When CEA is performed in specific rulemaking contexts, you should be prepared to make appropriate adjustments to ensure fair treatment of all segments of the population. Fairness is important in the choice and execution of effectiveness measures. For example, if QALYs are used to evaluate a lifesaving rule aimed at a population that happens to experience a high rate of disability (i.e., where the rule is not designed to affect the disability), the number of life years saved should not necessarily be diminished simply because the rule saves the lives of people with life-shortening disabilities. Both analytic simplicity and fairness suggest that the estimated number of life years saved for the disabled population should be based on average life expectancy information for the relevant age cohorts. More generally, when numeric adjustments are made for life expectancy or quality of life, analysts should prefer use of population averages rather than information derived from subgroups dominated by a particular demographic or income group.

OMB does not require agencies to use any specific measure of effectiveness. In fact, OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives. The regulatory analysis should explain which measures were selected and why, and how they were implemented.

The analytic discretion provided in choice of effectiveness measure will create some inconsistency in how agencies evaluate the same injuries and diseases, and it will be difficult for

⁷ Russell LB and Sisk JE (2000), "Modeling Age Differences in Cost Effectiveness Analysis", *International Journal of Technology Assessment in Health Care*, 16(4), 1158-1167.

⁸ Pliskin JS, Shepard DS, and Weinstein MC (1980), "Utility Functions for Life Years and Health Status," *Operations Research*, 28(1), 206-224.

⁹ Hammitt JK (2002), "QALYs Versus WTP," *Risk Analysis*, 22(5), pp. 985-1002.

OMB and the public to draw meaningful comparisons between rulemakings that employ different effectiveness measures. As a result, agencies should use their web site to provide OMB and the public with the underlying data, including mortality and morbidity data, the age distribution of the affected populations, and the severity and duration of disease conditions and trauma, so that OMB and the public can construct apples-to-apples comparisons between rulemakings that employ different measures.

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations.

Distributional Effects

Those who bear the costs of a regulation and those who enjoy its benefits often are not the same people. The term "distributional effect" refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography). Benefits and costs of a regulation may also be distributed unevenly over time, perhaps spanning several generations. Distributional effects may arise through "transfer payments" that stem from a regulatory action as well. For example, the revenue collected through a fee, surcharge in excess of the cost of services provided, or tax is a transfer payment.

Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency. Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups. You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups. Effects on the distribution of income that are transmitted through changes in market prices can be important, albeit sometimes difficult to assess. Your analysis should also present information on the streams of benefits and costs over time in order to provide a basis for assessing intertemporal distributional consequences, particularly where intergenerational effects are concerned.

E. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order 12866 and the "Regulatory Right-to-Know Act." The discussions in previous sections will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

Regulatory Reform of the U.S. Manufacturing Sector



2005

Office of Management and Budget
Office of Information and Regulatory Affairs

Regulatory Reform of the U.S. Manufacturing Sector

A Summary of Agency Responses to Public Reform Nominations

Streamlining regulation is a key plank in the President's economic program. Because manufacturing bears a disproportionate share of overall regulatory costs in the economy,¹ in February 2004 OMB initiated a government-wide effort to reform regulation of the U.S. manufacturing sector. Since U.S. manufacturers compete with firms from both developed and developing countries in an increasingly global economy, the Administration believes it is critical that any unnecessary regulatory burdens be removed.²

In OMB's draft 2004 Report to Congress on the Costs and Benefits of Federal Regulation, OMB requested public nominations of specific regulations, guidance documents and paperwork requirements that, if reformed, could result in lower costs, greater effectiveness, enhanced competitiveness, more regulatory certainty and increased flexibility. OMB expressed particular interest in reforms that address burdens on small and medium-sized manufacturers. In developing reform nominations, commenters were asked to consider: (1) whether a benefit-cost case can be made for the reform, (2) whether the agencies have the statutory authority to implement the suggested reform, (3) whether the reform gives due consideration to fair and open trade policy objectives, and (4) whether the rule or program is important. Commenters were provided 90 days to prepare their nominations and submit them to OMB.

In response to the solicitation, OMB received 189 distinct reform nominations from 41 commenters. The materials submitted by the 41 commenters are available on OMB's web site, and the 189 reform nominations are summarized in OMB's Final 2004 Report to Congress on the Costs and Benefits of Federal Regulation.³ A majority of the reform nominations address programs administered by the Environmental Protection Agency and the Department of Labor, a pattern that reflects the large impact of environmental and labor regulation on this sector of the economy.

OMB instructed federal agencies to review the merits of each of the 189 reform nominations and prepare a response for OMB by January 24, 2005. The response was to include a determination as to whether reform action is appropriate. If the agency found that the reform was worth pursuing, they were to supply a proposed time line for action and, where appropriate, a plan for public participation. OMB evaluated the reform

¹ A study by Crain and Hopkins (2001) for the SBA Office of Advocacy found that manufacturing firms face a total regulatory burden approximately 6 times greater than the average firm, and a regulatory burden per employee approximately 2 times greater than the average firm.

² Please see the Department of Commerce's report "Manufacturing in America," (available at <http://www.manufacturing.gov>), and the Council of Economic Advisors' *Economic Report of the President*, 2004 (available at <http://www.gpoaccess.gov/eop/index.html>) for more detailed discussion of the challenges facing the U.S. manufacturing sector.

³ Both the reform nominations and the final Report to Congress are available at http://www.whitehouse.gov/omb/infoereg/pol-reports_congress.html

nominations and collaborated with federal agencies in the development of response plans. OMB also sought evaluations of the recommendations by the Advocacy Office of the US Small Business Administration and the US Department of Commerce's Office of the Assistant Secretary for Manufacturing and Services.

Overall, federal agencies and OMB have determined that 76 of the 189 nominations have potential merit and justify further action. Future actions on these reform nominations range from performing a priority investigation and reporting to OMB in order to determine appropriate next steps, to issuing modernized regulations. In several cases described below, agencies have already taken action that addresses some of the issues raised by commenters. Often these actions were taken in the time since OMB received the public reform nominations and the publication of this report.

The remainder of the report republishes OMB's summary of each priority reform nomination, including the identity of the commenter and its numerical designation. For all future actions on these reforms, we also include milestones and deadlines. OMB will oversee the reform process to make sure that agencies make adequate progress in the months and years ahead. As readers assess the information presented below, it should be emphasized that OMB and federal agencies do not necessarily agree with either the problem statement or specific solutions suggested by commenters. Before any regulatory reforms are adopted, federal agencies will suggest specific reforms through a process that entails opportunity for public participation (e.g., a notice and comment rulemaking).

Regulatory reform of the U.S. manufacturing sector is one component of OMB's multi-year effort to modernize or rescind outmoded rules. OMB's 2004 Report to Congress on the Costs and Benefits of Federal Regulation provides a progress report on the Administration's regulatory reform activities.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

M-05-03

December 16, 2004

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

FROM:

Joshua B. Bolten
Director

SUBJECT:

Issuance of OMB's "Final Information Quality Bulletin
for Peer Review"

OMB has today issued a bulletin applicable to all departments and agencies entitled "Final Information Quality Bulletin for Peer Review." This Bulletin establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. Peer review is an important procedure used by the scientific community to ensure that the quality of published information. Peer review can increase the quality and credibility of the scientific information generated across the federal government. This Bulletin is one aspect of a larger OMB effort to improve the quality of the scientific information upon which policy decisions are based.

The bulletin has benefited from extensive public and agency comments received on two prior draft versions, which were released by OMB in September 15, 2003 and April 28, 2004. The bulletin includes guidance to federal agencies on what information is subject to peer review, the selection of appropriate peer reviewers, opportunities for public participation, and related issues. The bulletin also defines a peer review planning process that will permit the public and scientific societies to contribute to agency dialogue about which scientific reports merit especially rigorous peer review.

If your staff has questions about this guidance, please contact Margo Schwab at (202) 395-5647 or mschwab@omb.eop.gov.

Attachments

OFFICE OF MANAGEMENT AND BUDGET

Final Information Quality Bulletin for Peer Review

INTRODUCTION

This Bulletin establishes that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government. We published a proposed Bulletin on September 15, 2003. Based on public comments, we published a revised proposal for additional comment on April 28, 2004. We are now finalizing the April version, with minor revisions responsive to the public's comments.

The purpose of the Bulletin is to enhance the quality and credibility of the government's scientific information. We recognize that different types of peer review are appropriate for different types of information. Under this Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism for a specific information product. The selection of an appropriate peer review mechanism for scientific information is left to the agency's discretion. Various types of information are exempted from the requirements of this Bulletin, including time-sensitive health and safety determinations, in order to ensure that peer review does not unduly delay the release of urgent findings.

This Bulletin also applies stricter minimum requirements for the peer review of highly influential scientific assessments, which are a subset of influential scientific information. A scientific assessment is an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. To ensure that the Bulletin is not too costly or rigid, these requirements for more intensive peer review apply only to the more important scientific assessments disseminated by the federal government.

Even for these highly influential scientific assessments, the Bulletin leaves significant discretion to the agency formulating the peer review plan. In general, an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s). The agency selecting peer reviewers must ensure that the reviewers possess the necessary expertise. In addition, the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency. This Bulletin requires agencies to adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS)¹ when selecting peer reviewers who are not government employees. Those that are government employees are subject to federal ethics requirements. The use of a transparent process, coupled with the selection of qualified and independent peer reviewers, should improve the quality of government science while promoting public confidence in the integrity of the government's scientific products.

PEER REVIEW

Peer review is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community. It is a form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.² Peer review involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft.

The peer reviewer's report is an evaluation or critique that is used by the authors of the draft to improve the product. Peer review typically evaluates the clarity of hypotheses,

¹ National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: <http://www.nationalacademies.org/coi/index.html>.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIR

January 20, 2006

MEMORANDUM FOR THE PRESIDENT'S MANAGEMENT COUNCIL

FROM: John D. Graham, Ph.D. *Jm*
Administrator

SUBJECT: Guidance on Agency Survey and Statistical Information Collections

The Paperwork Reduction Act of 1995 requires that Federal agency information collections employ effective and efficient survey and statistical methodologies appropriate to the purpose for which the information is to be collected. It further directs the Office of Management and Budget (OMB) to develop and oversee the implementation of Government-wide policies, principles, standards, and guidelines concerning statistical collection procedures and methods.

The attached guidance document, entitled "Questions and Answers When Designing Surveys for Information Collections" (Q&A), provides details about the OMB review process, assistance in strengthening supporting statements for information collection requests, and, most importantly, advice for improving information collection designs. The document was circulated for agency comment on December 14, 2004, and has been revised in response to comments from agencies and external peer reviewers.

The content of this document is focused on what agencies need to consider when designing information collections and preparing requests for OMB approval. The guidance addresses issues that frequently arise in OMB reviews, including topics ranging from basic procedural requirements to best practices for technical documentation of surveys. It has been written for a wide audience. We anticipate that the document will be updated and revised as developments warrant so that the guidance will remain current with professional practice and useful to the agencies. Ultimately, we hope the Q&A's will serve to improve the quality of Federal surveys and statistical information.

Please share the attached Q&A document with appropriate program managers and paperwork clearance officers in your agency.

Attachment

OFFICE OF MANAGEMENT AND BUDGET
STANDARDS AND GUIDELINES FOR STATISTICAL SURVEYS

September 2006

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LIST OF STANDARDS FOR STATISTICAL SURVEYS

SECTION 1 DEVELOPMENT OF CONCEPTS, METHODS, AND DESIGN

Survey Planning

Standard 1.1: Agencies initiating a new survey or major revision of an existing survey must develop a written plan that sets forth a justification, including: goals and objectives; potential users; the decisions the survey is designed to inform; key survey estimates; the precision required of the estimates (e.g., the size of differences that need to be detected); the tabulations and analytic results that will inform decisions and other uses; related and previous surveys; steps taken to prevent unnecessary duplication with other sources of information; when and how frequently users need the data; and the level of detail needed in tabulations, confidential microdata, and public-use data files.

Survey Design

Standard 1.2: Agencies must develop a survey design, including defining the target population, designing the sampling plan, specifying the data collection instrument and methods, developing a realistic timetable and cost estimate, and selecting samples using generally accepted statistical methods (e.g., probabilistic methods that can provide estimates of sampling error). Any use of nonprobability sampling methods (e.g., cut-off or model-based samples) must be justified statistically and be able to measure estimation error. The size and design of the sample must reflect the level of detail needed in tabulations and other data products, and the precision required of key estimates. Documentation of each of these activities and resulting decisions must be maintained in the project files for use in documentation (see Standards 7.3 and 7.4).

Survey Response Rates

Standard 1.3: Agencies must design the survey to achieve the highest practical rates of response, commensurate with the importance of survey uses, respondent burden, and data collection costs, to ensure that survey results are representative of the target population so that they can be used with confidence to inform decisions. Nonresponse bias analyses must be conducted when unit or item response rates or other factors suggest the potential for bias to occur.

Pretesting Survey Systems

Standard 1.4: Agencies must ensure that all components of a survey function as intended when implemented in the full-scale survey and that measurement error is controlled by conducting a pretest of the survey components or by having successfully fielded the survey components on a previous occasion.

SECTION 2 COLLECTION OF DATA

Developing Sampling Frames

Standard 2.1: Agencies must ensure that the frames for the planned sample survey or census are appropriate for the study design and are evaluated against the target population for quality.

Required Notifications to Potential Survey Respondents

Standard 2.2: Agencies must ensure that each collection of information instrument clearly states the reasons the information is planned to be collected; the way such information is planned to be used to further the proper performance of the functions of the agency; whether responses to the collection of information are voluntary or mandatory (citing authority); the nature and extent of confidentiality to be provided, if any, citing authority; an estimate of the average respondent burden together with a request that the public direct to the agency any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden; the OMB control number; and a statement that an agency may not conduct and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number.

Data Collection Methodology

Standard 2.3: Agencies must design and administer their data collection instruments and methods in a manner that achieves the best balance between maximizing data quality and controlling measurement error while minimizing respondent burden and cost.

SECTION 3 PROCESSING AND EDITING OF DATA

Data Editing

Standard 3.1: Agencies must edit data appropriately, based on available information, to mitigate or correct detectable errors.

Nonresponse Analysis and Response Rate Calculation

Standard 3.2: Agencies must appropriately measure, adjust for, report, and analyze unit and item nonresponse to assess their effects on data quality and to inform users. Response rates must be computed using standard formulas to measure the proportion of the eligible sample that is represented by the responding units in each study, as an indicator of potential nonresponse bias.

Coding

Standard 3.3: Agencies must add codes to collected data to identify aspects of data quality from the collection (e.g., missing data) in order to allow users to appropriately analyze the data. Codes added to convert information collected as text into a form that permits immediate analysis must use standardized codes, when available, to enhance comparability.

Data Protection

Standard 3.4: Agencies must implement safeguards throughout the production process to ensure that survey data are handled to avoid disclosure.

Evaluation

Standard 3.5: Agencies must evaluate the quality of the data and make the evaluation public (through technical notes and documentation included in reports of results or through a separate report) to allow users to interpret results of analyses, and to help designers of recurring surveys focus improvement efforts.

SECTION 4 PRODUCTION OF ESTIMATES AND PROJECTIONS

Developing Estimates and Projections

Standard 4.1: Agencies must use accepted theory and methods when deriving direct survey-based estimates, as well as model-based estimates and projections that use survey data. Error estimates must be calculated and disseminated to support assessment of the appropriateness of the uses of the estimates or projections. Agencies must plan and implement evaluations to assess the quality of the estimates and projections.

SECTION 5 DATA ANALYSIS

Analysis and Report Planning

Standard 5.1: Agencies must develop a plan for the analysis of survey data prior to the start of a specific analysis to ensure that statistical tests are used appropriately and that adequate resources are available to complete the analysis.

Inference and Comparisons

Standard 5.2: Agencies must base statements of comparisons and other statistical conclusions derived from survey data on acceptable statistical practice.

SECTION 6 REVIEW PROCEDURES

Review of Information Products

Standard 6.1: Agencies are responsible for the quality of information that they disseminate and must institute appropriate content/subject matter, statistical, and methodological review procedures to comply with OMB and agency Information Quality Guidelines.

SECTION 7 DISSEMINATION OF INFORMATION PRODUCTS

Releasing Information

Standard 7.1: Agencies must release information intended for the general public according to a dissemination plan that provides for equivalent, timely access to all users and provides information to the public about the agencies' dissemination policies and procedures including those related to any planned or unanticipated data revisions.

Data Protection and Disclosure Avoidance for Dissemination

Standard 7.2: When releasing information products, agencies must ensure strict compliance with any confidentiality pledge to the respondents and all applicable Federal legislation and regulations.

Survey Documentation

Standard 7.3: Agencies must produce survey documentation that includes those materials necessary to understand how to properly analyze data from each survey, as well as the information necessary to replicate and evaluate each survey's results (See also Standard 1.2). Survey documentation must be readily accessible to users, unless it is necessary to restrict access to protect confidentiality.

Documentation and Release of Public-Use Microdata

Standard 7.4: Agencies that release microdata to the public must include documentation clearly describing how the information is constructed and provide the metadata necessary for users to access and manipulate the data (See also Standard 1.2). Public-use microdata documentation and metadata must be readily accessible to users.

INTRODUCTION

This document provides 20 standards that apply to Federal censuses and surveys whose statistical purposes include the description, estimation, or analysis of the characteristics of groups, segments, activities, or geographic areas in any biological, demographic, economic, environmental, natural resource, physical, social, or other sphere of interest. The development, implementation, or maintenance of methods, technical or administrative procedures, or information resources that support such purposes are also covered by these standards. In addition, these standards apply to censuses and surveys that are used in research studies or program evaluations if the purpose of the survey meets any of the statistical purposes noted above. To the extent they are applicable, these standards also cover the compilation of statistics based on information collected from individuals or firms (such as tax returns or the financial and operating reports required by regulatory commissions), applications/registrations, or other administrative records.

Background

Standards for Federal statistical programs serve both the interests of the public and the needs of the government. These standards document the professional principles and practices that Federal agencies are required to adhere to and the level of quality and effort expected in all statistical activities. Each standard has accompanying guidelines that present recommended best practices to fulfill the goals of the standards. Taken together, these standards and guidelines provide a means to ensure consistency among and within statistical activities conducted across the Federal Government. Agency implementation of standards and guidelines ensures that users of Federal statistical information products are provided with details on the principles and methods employed in the development, collection, processing, analysis, dissemination, and preservation of Federal statistical information.

In 2002, the U.S. Office of Management and Budget (OMB), in response to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554), popularly known as the Information Quality Act, issued government-wide guidelines that “provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies” (67 FR 8452-8460; February 22, 2002). Federal statistical agencies worked together to draft a common framework to use in developing their individual Information Quality Guidelines. That framework, published in the June 4, 2002, *Federal Register* Notice, “Federal Statistical Organizations’ Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Disseminated Information” (67 FR 38467-38470), serves as the organizing framework for the standards and guidelines presented here.¹ The framework for these standards and guidelines includes:

¹ The *Federal Register* notice included eight areas where statistical organizations set standards for performance. The framework utilized here combines “Development of concepts and methods” with “Planning and design of surveys and other means of collecting data” into the single section on “Development of concepts, methods, and design.” The standards for these activities were closely linked and attempting to separate them into two distinct sections would have resulted in some duplication of standards between sections. The only other change is the title of Section 7, which was shortened to “Dissemination of Information Products” for convenience rather than “Dissemination of data by published reports, electronic files, and other media requested by users” as it originally appeared in the *Federal Register* notice.

- Development of concepts, methods, and design
- Collection of data
- Processing and editing of data
- Production of estimates and projections
- Data analysis
- Review procedures
- Dissemination of Information Products.

Within this framework, the 20 standards and their related guidelines for Federal statistical surveys focus on ensuring high quality statistical surveys that result in information products satisfying an agency's and OMB's Information Quality Guidelines' requirements for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by the Federal Government.

The standards and guidelines are not intended to substitute for the extensive existing literature on statistical and survey theory, methods, and operations. When undertaking a survey, an agency should engage knowledgeable and experienced survey practitioners to effectively achieve the goals of the standards. Persons involved should have knowledge and experience in survey sampling theory, survey design and methodology, field operations, data analysis, and dissemination as well as technological aspects of surveys.

Under the OMB Information Quality Guidelines, quality is an encompassing term comprising objectivity, utility, and integrity.

Objectivity refers to whether information is accurate, reliable, and unbiased, and is presented in an accurate, clear, and unbiased manner. It involves both the content of the information and the presentation of the information. This includes complete, accurate, and easily understood documentation of the sources of the information, with a description of the sources of any errors that may affect the quality of the data, when appropriate. Objectivity is achieved by using reliable information sources and appropriate techniques to prepare information products.

Standards related to the production of accurate, reliable, and unbiased information include Survey Response Rates (1.3), Developing Sampling Frames (2.1), Required Notifications to Potential Survey Respondents (2.2), Data Collection Methodology (2.3), Data Editing (3.1), Nonresponse Analysis and Response Rate Calculation (3.2), Coding (3.3), Evaluation (3.5), Developing Estimates and Projections (4.1), Analysis and Report Planning (5.1), and Inference and Comparisons (5.2).

Standards related to presenting results in an accurate, clear, and unbiased manner include: Review of Information Products (6.1), Survey Documentation (7.3), and Documentation and Release of Public-Use Microdata (7.4).

Utility refers to the usefulness of the information that is disseminated to its intended users. The usefulness of information disseminated by Federal agencies should be considered from the perspective of specific subject matter users, researchers, policymakers, and the public. Utility is

achieved by continual assessment of information needs, anticipating emerging requirements, and developing new products and services.

To ensure that information disseminated by Federal agencies meets the needs of the intended users, agencies rely upon internal reviews, analyses, and evaluations along with feedback from advisory committees, researchers, policymakers, and the public. In addition, agencies should clearly and correctly present all information products in plain language geared to their intended audiences. The target audience for each product should be clearly identified, and the product's contents should be readily accessible to that audience.

In all cases, the goal is to maximize the usefulness of information and minimize the costs to the government and the public. When disseminating their information products, Federal agencies should utilize a variety of efficient dissemination channels so that the public, researchers, and policymakers can locate and use information in an equitable, timely, and cost-effective fashion.

The specific standards that contribute directly to the utility and the dissemination of information include: Survey Planning (1.1), Survey Design (1.2), Pretesting Survey Systems (1.4), Review of Information Products (6.1), Releasing Information (7.1), Survey Documentation (7.3), and Documentation and Release of Public-Use Microdata (7.4).

Integrity refers to the security or protection of information from unauthorized access or revision. Integrity ensures that the information is not compromised through corruption or falsification.

Federal agencies have a number of statutory and administrative provisions governing the protection of information. Examples that may affect all Federal agencies include the Privacy Act; the Freedom of Information Act; the Confidential Information Protection and Statistical Efficiency Act of 2002; the Federal Information Security Management Act of 2002; the Health Insurance Portability and Accountability Act of 1996; OMB Circular Nos. A-123, A-127, and A-130; and the Federal Policy for the Protection of Human Subjects. The standards on Required Notifications to Potential Survey Respondents (2.2), Data Protection (3.4), and Data Protection and Disclosure Avoidance for Dissemination (7.2) directly address statistical issues concerning the integrity of data.

Requirements for Agencies

The application of standards to the wide range of Federal statistical activities and uses requires judgment that balances such factors as the uses of the resulting information and the efficient allocation of resources; this should not be a mechanical process. Some surveys are extremely large undertakings requiring millions of dollars, and the resulting general-purpose statistics have significant, far-reaching effects. (Examples of major Federal information programs, many based on statistical surveys, are the Principal Federal Economic Indicators.²) Other statistical activities may be more limited and focused on specific program areas (e.g., customer satisfaction surveys, program evaluations, or research).

² For the list of principal economic indicators and their release dates see <http://www.whitehouse.gov/omb/inforeg/statpolicy.html#sr>

For each statistical survey in existence when these standards are issued and for each new survey, the sponsoring and/or releasing agency should evaluate compliance with applicable standards. The agency should establish compliance goals for applicable standards if a survey is not in compliance. An agency should use major survey revisions or other significant survey events as opportunities to address areas in which a survey is not in compliance with applicable standards.

Federal agencies are required to adhere to all standards for every statistical survey, even those that have already received OMB approval. Agencies should provide sufficient information in their Information Collection Requests (ICR) to OMB under the Paperwork Reduction Act (PRA) to demonstrate whether they are meeting the standards. OMB recognizes that these standards cannot be applied uniformly or precisely in every situation. Consideration will be given to the importance of the uses of the information as well as the quality required to support those uses. If funding or other contingencies make it infeasible for all standards to be met, agencies should discuss in their ICR submissions the options that were considered and why the final design was selected.

The agency should also include in the standard documentation for the survey, or in an easily accessible public venue, such as on its web site, the reasons why the standard could not be met and what actions the agency has taken or will take to address any resulting issues.³

The following standards and guidelines are not designed to be completely exhaustive of all efforts that an agency may undertake to ensure the quality of its statistical information. Agencies are encouraged to develop additional, more detailed standards focused on their specific statistical activities.

The standards are presented in seven sections. For each standard, there is a list of key terms that are used in the standard or accompanying guidelines, and these terms are defined in the appendix to provide clarification on their use in this document. The guidelines for each standard represent best practices that may be useful in fulfilling the goals of the standard and provide greater specificity and detail than the standards. However, as noted earlier, these standards and guidelines are not intended to substitute for the extensive existing literature on statistical and survey theory, methods, and operations. Additional information relevant to the standards can be found in other more specialized publications, and references to other Federal guidance documents or resources and the work of the Federal Committee on Statistical Methodology are provided in this document.

Agencies conducting surveys should also consult guidance issued by OMB entitled *Questions and Answers When Designing Surveys for Information Collections*. That document was developed by OMB to assist agencies in preparing their Information Collection Requests for OMB review under the Paperwork Reduction Act (PRA). The PRA requires that all Federal agencies obtain approval from OMB prior to collecting information from ten or more persons.⁴

³ In cases where the agency determines that ongoing surveys are not in compliance with the standards, the documentation should be updated at the earliest possible time.

⁴ Under the PRA, "Person means an individual, partnership, association, corporation (including operations of government-owned contractor-operated facilities), business trust, or legal representative, an organized group of

OFFICE OF MANAGEMENT AND BUDGET

Final Bulletin for Agency Good Guidance Practices

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final bulletin.

SUMMARY: The Office of Management and Budget (OMB) is publishing a final Bulletin entitled, "Agency Good Guidance Practices," which establishes policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies. This Bulletin is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them.

On November 23, 2005, OMB proposed a draft Bulletin for public comment. 70 FR 71866 (November 30, 2005). Upon request, OMB extended the public comment period from December 23, 2005 to January 9, 2006. 70 FR 76333 (December 23, 2005). OMB received 31 comments on the proposal from diverse public and private stakeholders (see http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html) and input from Federal agencies. The final Bulletin includes refinements developed through the public comment process and interagency deliberations.

DATES: The effective date of this Bulletin is 180 days after its publication in the *Federal Register*.

FOR FURTHER INFORMATION CONTACT: Margaret Malanoski, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., New Executive Office Building, Room 10202, Washington, DC 20503. Telephone (202) 395-3122.

SUPPLEMENTARY INFORMATION:

Introduction

As the scope and complexity of regulatory programs have grown, agencies increasingly have relied on guidance documents to inform the public and to provide direction to their staffs. As the impact of guidance documents on the public has grown, so too, has the need for good guidance practices—clear and consistent agency practices for developing, issuing, and using guidance documents.

OMB is responsible both for promoting good management practices and for overseeing and coordinating the Administration's regulatory policy. Since early in the Bush Administration,

OMB has been concerned about the proper development and use of agency guidance documents. In its 2002 draft annual Report to Congress on the Costs and Benefits of Regulations, OMB discussed this issue and solicited public comments regarding problematic guidance practices and specific examples of guidance documents in need of reform.¹ OMB has been particularly concerned that agency guidance practices should be more transparent, consistent and accountable. Such concerns also have been raised by other authorities, including Congress and the courts.²

In its 2002 Report to Congress, OMB recognized the enormous value of agency guidance documents in general. Well-designed guidance documents

¹ U.S. Office of Management and Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, 67 FR 15,014, 15,034–35 (March 28, 2002).

² See, e.g., Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 371(h) (establishing FDA good guidance practices as law); "Food and Drug Administration Modernization and Accountability Act of 1997," S. Rep. 105–43, at 26 (1997) (raising concerns about public knowledge of, and access to, FDA guidance documents, lack of a systematic process for adoption of guidance documents and for allowing public input, and inconsistency in the use of guidance documents); House Committee on Government Reform, "Non-Binding Legal Effect of Agency Guidance Documents," H. Rep. 106–1009 (106th Cong., 2d Sess. 2000) (criticizing "back-door" regulation); the Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong., § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents); *Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as legislative rule requiring notice and comment); *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment); *Chamber of Commerce v. Dep't of Labor*, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as legislative rule requiring notice and comment); Administrative Conference of the United States, Rec. 92–2, 1 C.F.R. 305.92–2 (1992) (agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); *American Bar Association, Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting*, August 10–11, 1993, Vol. 118, No. 2, at 57 ("the American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity."); 3 American Bar Association, "Recommendation on Federal Agency Web Pages" (August 2001) (agencies should maximize the availability and searchability of existing law and policy on their Web sites and include their governing statutes, rules and regulations, and all important policies, interpretations, and other like matters on which members of the public are likely to request).

serve many important or even critical functions in regulatory programs.³ Agencies may provide helpful guidance to interpret existing law through an interpretive rule or to clarify how they tentatively will treat or enforce a governing legal norm through a policy statement. Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties.

Experience has shown, however, that guidance documents also may be poorly designed or improperly implemented. At the same time, guidance documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review.⁴ These procedures include: (1) Internal agency review by a senior agency official; (2) public participation, including notice and comment under the Administrative Procedure Act (APA); (3) justification for the rule, including a statement of basis and purpose under the APA and various analyses under Executive Order 12866 (as further amended), the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act; (4) interagency review through OMB; (5) Congressional oversight; and (6) judicial review. Because it is procedurally easier to issue guidance documents, there also may be an incentive for regulators to issue guidance documents in lieu of regulations. As the D.C. Circuit observed in *Appalachian Power*:

The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the *Federal Register* or the Code of Federal Regulations.⁵

³ See U.S. Office of Management and Budget, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities*, 72–74 (2002) (hereinafter "2002 Report to Congress").

⁴ *Id.*, at 72.

⁵ *Appalachian Power*, 208 F.3d at 1019.

Concern about whether agencies are properly observing the notice-and-comment requirements of the APA has received significant attention. The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they initially are labeled.⁶ More general concerns also have been raised that agency guidance practices should be better informed and more transparent, fair and accountable.⁷ Poorly designed or misused guidance documents can impose significant costs or limit the freedom of the public. OMB has received comments raising these concerns and providing specific examples in response to its proposed Bulletin,⁸ its 2002 request for comments on problematic guidance⁹ and its other requests for regulatory reform nominations in 2001¹⁰ and 2004.¹¹ This Bulletin and recent amendments to Executive Order 12866 respond to these problems.¹²

This Bulletin on "Agency Good Guidance Practices" sets forth general policies and procedures for developing, issuing and using guidance documents. The purpose of Good Guidance Practices (GGP) is to ensure that guidance documents of Executive Branch departments and agencies are: Developed with appropriate review and public participation, accessible and transparent to the public, of high

quality, and not improperly treated as legally binding requirements. Moreover, GGP clarify what does and does not constitute a guidance document to provide greater clarity to the public. All offices in an agency should follow these policies and procedures.

There is a strong foundation for establishing standards for the initiation, development, and issuance of guidance documents to raise their quality and transparency. The former Administrative Conference of the United States (ACUS), for example, developed recommendations for the development and use of agency guidance documents.¹³ In 1997, the Food and Drug Administration (FDA) created a guidance document distilling its good guidance practices (GGP).¹⁴ Congress then established certain aspects of the 1997 GGP document as the law in the Food and Drug Administration Modernization Act of 1997 (FDAMA; Public Law No. 105-115).¹⁵ The FDAMA also directed FDA to evaluate the effectiveness of the 1997 GGP document and then to develop and issue regulations specifying FDA's policies and procedures for the development, issuance, and use of guidance documents. FDA conducted an internal evaluation soliciting FDA employees' views on the effectiveness of GGP and asking whether FDA employees had received complaints regarding the agency's development, issuance, and use of guidance documents since the development of GGP. FDA found that its GGP had been beneficial and effective in standardizing the agency's procedures for development, issuance, and use of guidance documents, and that FDA employees had generally been following GGP.¹⁶ FDA then made some changes to its existing procedures to clarify its GGP.¹⁷ The provisions of the FDAMA and FDA's implementing regulations, as well as the ACUS recommendations, informed the development of this government-wide Bulletin.

Legal Authority for This Bulletin

This Bulletin is issued under statutory authority, Executive Order, and OMB's general authorities to oversee and coordinate the rulemaking process. In what is commonly known as the Information Quality Act, Congress

directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, utility, objectivity and integrity of information disseminated by Federal agencies."¹⁸ Moreover, Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review," recently clarified OMB's authority to oversee agency guidance documents. As further amended, Executive Order 12866 affirms that "[c]oordinated review of agency rulemaking is necessary to ensure that regulations and guidance documents are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order," and the Order assigns that responsibility to OMB.¹⁹ E.O. 12866 also establishes OMB's Office of Information and Regulatory Affairs as "the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency."²⁰ Finally, OMB has additional authorities to oversee the agencies in the administration of their programs.

The Requirements of the Final Bulletin and Response to Public Comments

A. Overview

This Bulletin establishes: a definition of a significant guidance document; standard elements for significant guidance documents; practices for developing and using significant guidance documents; requirements for agencies to enable the public to comment on significant guidance documents or request that they be created, reconsidered, modified or rescinded; and ways for making guidance documents available to the public. These requirements should be interpreted and implemented in a manner that, consistent with the goals of improving the quality, accountability and transparency of agency guidance documents, provides sufficient flexibility for agencies to take those

⁶ See, e.g., *Appalachian Power; Gen. Elec. Co.; Chamber of Commerce*; House Committee on Government Reform, "Non-Binding Legal Effect of Agency Guidance Documents"; ACUS Rec. 92-2, *supra* note 2; Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals and the Like—Should Federal Agencies Use Them to Bind the Public?" 41 Duke L.J. 1311 (1992).

⁷ See, e.g., note 2, *supra*.

⁸ U.S. Office of Management and Budget, "Proposed Bulletin for Good Guidance Practices," 70 FR 76333 (Dec. 23, 2005).

⁹ See note 1, *supra*.

¹⁰ U.S. Office of Management and Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, 66 FR 22041 (May 2, 2001).

¹¹ U.S. Office of Management and Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, 69 FR 7987 (Feb. 20, 2004); see also U.S. Office of Management and Budget, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local and Tribal Entities* 107-125 (2005).

¹² President Bush recently signed Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review." Among other things, E.O. 13422 addresses the potential need for interagency review of certain significant guidance documents by clarifying OMB's authority to have advance notice of, and to review, agency guidance documents.

¹³ See, e.g., note 2, *supra*.

¹⁴ Notice, "The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents," 62 FR 8961 (Feb. 27, 1997).

¹⁵ 21 U.S.C. 371(h).

¹⁶ See FDA, "Administrative Practices and Procedures; Good Guidance Practices," 65 FR 7321, 7322-23 (proposed Feb. 14, 2000).

¹⁷ 21 CFR 10.115; 65 FR 56468 (Sept. 19, 2000).

¹⁸ Pub. L. 106-554, § 515(a) (2000). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, which requires OMB, among other things, to "develop and oversee implementation of policies, principles, standards, and guidelines to—(1) Apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated; and (2) promote public access to public information and fulfill the purposes of this subchapter, including through the effective use of information technology." 44 U.S.C. 3504(d).

¹⁹ Executive Order 12866, as further amended, § 2(b).

²⁰ *Id.*

actions necessary to accomplish their essential missions.

B. Definitions

Section I provides definitions for the purposes of this Bulletin. Several terms are identical to or based on those in FDA's GGP regulations, 21 CFR 10.115; the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.; Executive Order 12866, as further amended; and OMB's Government-wide Information Quality Guidelines, 67 FR 8452 (Feb. 22, 2002).

Section I(1) provides that the term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.

Section I(2) provides that the term "agency" has the same meaning as it has under the Paperwork Reduction Act, 44 U.S.C. 3502(1), other than those entities considered to be independent agencies, as defined in 44 U.S.C. 3502(5).

Section I(3) defines the term "guidance document" as an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended), that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue. This definition is used to comport with definitions used in Executive Order 12866, as further amended. Nothing in this Bulletin is intended to indicate that a guidance document can impose a legally binding requirement.

Guidance documents often come in a variety of formats and names, including interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, advisories, and the like. Guidance documents include, but are not limited to, agency interpretations or policies that relate to: the design, production, manufacturing, control, remediation, testing, analysis or assessment of products and substances, and the processing, content, and evaluation/approval of submissions or applications, as well as compliance guides. Guidance documents do not include solely scientific research. Although a document that simply summarizes the protocol and conclusions of a specific research project (such as a clinical trial funded by the National Institutes of Health) would not qualify as a guidance document, such research may be the basis of a guidance document (such as the HHS/USDA "Dietary Guidelines for Americans," which provides guidance to Americans on what constitutes a healthy diet).

Some commenters raised the concern that the term "guidance document" reflected too narrow a focus on written materials alone. While the final Bulletin adopts the commonly used term "guidance document," the definition is not limited only to written guidance materials and should not be so construed. OMB recognizes that agencies are experimenting with offering guidance in new and innovative formats, such as video or audio tapes, or interactive web-based software. The definition of "guidance document" encompasses all guidance materials, regardless of format. It is not the intent of this Bulletin to discourage the development of promising alternative means to offer guidance to the public and regulated entities.

A number of commenters raised concerns that the definition of "significant guidance document" in the proposed Bulletin was too broad in some respects. In particular, the proposed definition included guidance that set forth initial interpretations of statutory and regulatory requirements and changes in interpretation or policy. The definition in the proposed Bulletin was adapted from the definition of "Level 1 guidance documents" in FDA's GGP regulations.

Upon consideration of the comments, the need for clarity, and the broad application of this Bulletin to diverse agencies, the definition of "significant guidance document" has been changed. Section I(4) defines the term "significant guidance document" as a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to: (i) Lead to 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 (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; or (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended. Under the Bulletin, significant guidance documents include interpretive rules of general applicability and statements of general policy that have the effects described in Section I(4)(i)-(iv).

The general definition of "significant guidance document" in the final Bulletin adopts the definition in

Executive Order 13422, which recently amended Executive Order 12866 to clarify OMB's role in overseeing and coordinating significant guidance documents. This definition, in turn, closely tracks the general definition of "significant regulatory action" in E.O. 12866, as further amended. One advantage of this definition is that agencies have years of experience in the regulatory context applying the parallel definition of "significant regulatory action" under E.O. 12866, as further amended. However, a few important changes were made to the definition used in E.O. 12866, as further amended, to make it better suited for guidance. For example, in recognition of the non-binding nature of guidance the words "may reasonably be anticipated to" preface all four prongs of the "significant guidance document" definition. This prefatory language makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules.

Section I(4) also clarifies what is not a "significant guidance document" under this Bulletin. For purposes of this Bulletin, documents that would not be considered significant guidance documents include: Legal advisory opinions for internal Executive Branch use and not for release (such as Department of Justice Office of Legal Counsel opinions); briefs and other positions taken by agencies in investigations, pre-litigation, litigation, or other enforcement proceedings; speeches; editorials; media interviews; press materials; Congressional correspondence; guidances that pertain to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidances that pertain to the use, operation or control of a government facility; and internal operational guidances directed solely to other Federal agencies (including Office of Personnel Management personnel issuances, General Services Administration Federal Travel Regulation bulletins, and most of the National Archives and Records Administration's records management bulletins). The Bulletin also exempts speeches of agency officials.

Information collections, discretionary grant application packages, and compliance monitoring reports also are not significant guidance documents. Though the Bulletin does not cover

guidance documents that pertain to the use, operation, or control of a Federal facility, it does cover generally applicable instructions to contractors. Section I(4) also provides that an agency head, in consultation and concurrence with the OIRA Administrator, may exempt one or more categories of significant guidance documents from the requirements of the Bulletin.

The definition of guidance document covers agency statements of "general applicability" and "future effect," and accordingly, the Bulletin does not cover documents that result from an adjudicative decision. We construe "future effects" as intended (and likely beneficial) impacts due to voluntary compliance with a guidance document. Moreover, since a significant guidance document is an agency statement of "general applicability," correspondence such as opinion letters or letters of interpretation prepared for or in response to an inquiry from an individual person or entity would not be considered a significant guidance document, unless the correspondence is reasonably anticipated to have precedential effect and a substantial impact on regulated entities or the public. Thus, this Bulletin should not inhibit the beneficial practice of agencies providing informal guidance to help specific parties. If the agency compiles and publishes informal determinations to provide guidance to, and with a substantial impact on, regulated industries, then this Bulletin would apply. Guidance documents are considered "significant" when they have a broad and substantial impact on regulated entities, the public or other Federal agencies. For example, a guidance document that had a substantial impact on another Federal agency, by interfering with its ability to carry out its mission or imposing substantial burdens, would be significant under Section I(4)(ii) and perhaps could trigger Section I(5) as well.

In general, guidance documents that concern routine matters would not be "significant." Among an agency's internal guidance documents, there are many categories that would not constitute significant guidance documents. There is a broad category of documents that may describe the agency's day-to-day business. Though such documents might be of interest to the public, they do not fall within the definition of significant guidance documents for the purposes of this Bulletin. More generally, there are internal guidance documents that bind agency employees with respect to matters that do not directly or

substantially impact regulated entities. For example, an agency may issue guidance to field offices directing them to maintain electronic data files of complaints regarding regulated entities.

Section I(5) states that the term "economically significant guidance document" means a significant guidance document that "may reasonably be anticipated to lead to" an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy. The relevant economic impacts include those that may be imposed by Federal agencies, State, or local governments, or foreign governments that affect the U.S. economy, as well as impacts that could arise from private sector conduct. The definition of economically significant guidance document tracks only the part of the definition of significant guidance document in Section I(4)(i), related to substantial economic impacts. This clarifies that the definition of "economically significant guidance document" includes only a relatively narrow category of significant guidance documents. This definition enables agencies to determine which interpretive rules of general applicability or statements of general policy might be so consequential as to merit advance notice-and-comment and a response-to-comments document—and which do not. Accordingly, the definition of economically significant guidance document includes economic impacts that rise to \$100 million in any one year or adversely affect the economy or a sector of the economy.

The definition of economically significant guidance document also departs in other ways from the language describing an economically significant regulatory action in Section 3(f)(1) of E.O. 12866, as further amended. A number of commenters on the proposed Bulletin raised questions about how a guidance document—which is not legally binding—could have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy. As other commenters recognized, although guidance may not be legally binding, there are situations in which it may reasonably be anticipated that a guidance document could lead parties to alter their conduct in a manner that would have such an economically significant impact.

Guidance can have coercive effects or lead parties to alter their conduct. For example, under a statute or regulation that would allow a range of actions to be eligible for a permit or other desired agency action, a guidance document

might specify fast track treatment for a particular narrow form of behavior but subject other behavior to a burdensome application process with an uncertain likelihood of success. Even if not legally binding, such guidance could affect behavior in a way that might lead to an economically significant impact. Similarly, an agency might make a pronouncement about the conditions under which it believes a particular substance or product is unsafe. While not legally binding, such a statement could reasonably be anticipated to lead to changes in behavior by the private sector or governmental authorities such that it would lead to a significant economic effect. Unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures of section IV.

In recognition of the non-binding nature of guidance documents, the Bulletin's definition of economically significant guidance document differs in key respects from the definition of an economically significant regulatory action in section 3(f)(1) of E.O. 12866, as further amended. First, as described above, the words "may reasonably be anticipated to" are included in the definition. Second, the definition of economically significant guidance document contemplates that the guidance document could "lead to" (as opposed to "have") an economically significant effect. This language makes clear that the impacts of guidance documents often will be more indirect and dependent on third-party decisions and conduct than is the case with binding legislative rules. This language also reflects a recognition that, as various commenters noted, guidance documents often will not be amenable to formal economic analysis of the kind that is prepared for an economically significant regulatory action. Accordingly, this Bulletin does not require agencies to conduct a formal regulatory impact analysis to guide their judgments about whether a guidance document is economically significant.

The definition of "economically significant guidance document" excludes guidance documents on Federal expenditures and receipts. Therefore, guidance documents on Federal budget expenditures (e.g., entitlement programs) and taxes (the administration or collection of taxes; tax credits, or duties) are not subject to the requirements for notice and comment and a response to comments document in § IV. However, if such guidance documents are "significant," then they are subject to the other requirements of

this Bulletin, including the transparency and approval provisions.

Section I(6) states that the term "disseminated" means prepared by the agency and distributed to the public or regulated entities. Dissemination does not include distribution limited to government employees; intra-or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law.²¹

Consistent with Executive Order 12866, as further amended, Section I(7) defines the term "regulatory action" as any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of inquiry and notices of proposed rulemaking.

Section I(8) defines the term "regulation," consistent with Executive Order 12866, as further amended, as an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.

C. Basic Agency Standards

Section II describes basic agency standards for significant guidance documents.

1. Agency Approval Procedures

Section II(1)(a) directs each agency to develop or have written procedures for the internal clearance of significant guidance documents no later than the effective date of this Bulletin. Those procedures should ensure that issuance of significant guidance documents is approved by appropriate agency officials. Currently at FDA the Director in a Center or an Office of Regulatory Affairs equivalent or higher approves a significant guidance document before it is distributed to the public in draft or final form. Depending on the nature of specific agency guidance documents, these procedures may require approval or concurrence by other components within an agency. For example, if guidance is provided on compliance with an agency regulation, we would anticipate that the agency's approval procedures would ensure appropriate coordination with other agency components that have a stake in the

regulation's implementation, such as the General Counsel's office and the component responsible for development and issuance of the regulation.

Section II(1)(b) states that agency employees should not depart from significant agency guidance documents without appropriate justification and supervisory concurrence. It is not the intent of this Bulletin to inhibit the flexibility needed by agency officials to depart appropriately from significant guidance documents by rigidly requiring concurrence only by very high-level officials. Section II(1)(a) also is not intended to bind an agency to exercise its discretion only in accordance with a general policy where the agency is within the range of discretion contemplated by the significant guidance document.

Agencies are to follow GGP when providing important policy direction on a broad scale. This includes when an agency communicates, informally or indirectly, new or different regulatory expectations to a broad public audience for the first time, including regulatory expectations different from guidance issued prior to this Bulletin.²² This does not limit the agency's ability to respond to questions as to how an established policy applies to a specific situation or to answer questions about areas that may lack established policy (although such questions may signal the need to develop guidance in that area). This requirement also does not apply to positions taken by agencies in litigation, pre-litigation, or investigations, or in any way affect their authority to communicate their views in court or other enforcement proceedings. This requirement also is not intended to restrict the authority of agency General Counsels or the Department of Justice Office of Legal Counsel to provide legal interpretations of statutory and regulatory requirements.

Agencies also should ensure consistent application of GGP. Employees involved in the development, issuance, or application of significant guidance documents should be trained regarding the agency's GGP, particularly the principles of Section II(2). In addition, agency offices should

monitor the development, issuance and use of significant guidance documents to ensure that employees are following GGP.

2. Standard Elements

Section II(2) establishes basic requirements for significant guidance documents. They must: (i) Include the term "guidance" or its functional equivalent; (ii) Identify the agency(ies) or office(s) issuing the document; (iii) Identify the activity to which and the persons to whom the document applies; (iv) Include the date of issuance; (v) Note if it is a revision to a previously issued guidance document and, if so, identify the guidance that it replaces; (vi) Provide the title of the guidance and any document identification number, if one exists; and (vii) include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets.

In implementing this Bulletin, particularly Section II(2)(e), agencies should be diligent to identify for the public whether there is previous guidance on an issue, and, if so, to clarify whether that guidance document is repealed by the new significant guidance document completely, and if not, to specify what provisions in the previous guidance document remain in effect. Superseded guidance documents that remain available for historical purposes should be stamped or otherwise prominently identified as superseded. Draft significant guidance documents that are being made available for pre-adoption notice and comment should include a prominent "draft" notation. As existing significant guidance documents are revised, they should be updated to comply with this Bulletin.

Finally, Section II(2)(h) clarifies that, given their legally nonbinding nature, significant guidance documents should not include mandatory language such as "shall," "must," "required" or "requirement," unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose consideration by the agency of positions advanced by affected private parties.²³ For example, a guidance document may explain how the agency believes a statute or

²² See FDA's Good Guidance Practices, 21 CFR 10.115(e): "Can FDA use means other than a guidance document to communicate new agency policy or a new regulatory approach to a broad public audience? The agency must not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGPs must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience."

²³ As the courts have held, *see supra* note 2, agencies need to follow statutory rulemaking requirements, such as those of the APA, to issue documents with legally binding effect, i.e., legislative rules. One benefit of GGP for an agency is that the agency's review process will help to identify any draft guidance documents that instead should be promulgated through the rulemaking process.

²¹ See U.S. Office of Management and Budget's Government-wide Information Quality Guidelines, 67 FR 8452, 8454, 8460 (Feb. 22, 2002).

regulation applies to certain regulated activities. Before a significant guidance document is issued or revised, it should be reviewed to ensure that improper mandatory language has not been used. As some commenters noted, while a guidance document cannot legally bind, agencies can appropriately bind their employees to abide by agency policy as a matter of their supervisory powers over such employees without undertaking pre-adoption notice and comment rulemaking. As a practical matter, agencies also may describe laws of nature, scientific principles, and technical requirements in mandatory terms so long as it is clear that the guidance document itself does not impose legally enforceable rights or obligations.

A significant guidance document should aim to communicate effectively to the public about the legal effect of the guidance and the consequences for the public of adopting an alternative approach. For example, a significant guidance document could be captioned with the following disclaimer under appropriate circumstances:

"This [draft] guidance, [when finalized, will] represent[s] the [Agency's] current thinking on this topic. It does not create or confer any rights for or on any person or operate to bind the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach (you are not required to do so), you may contact the [Agency] staff responsible for implementing this guidance. If you cannot identify the appropriate [Agency] staff, call the appropriate number listed on the title page of this guidance."

When an agency determines it would be appropriate, the agency should use this or a similar disclaimer. Agency staff should similarly describe the legal effect of significant guidance documents when speaking to the public about them.

D. Public Access and Feedback

Section III describes public access procedures related to the development and issuance of significant guidance documents.

1. Internet Access

Section III directs agencies to ensure that information about the existence of significant guidance documents and the significant guidance documents themselves are made available to the public in electronic form. Section III(1) enables the public to obtain from an agency's Web site a list of all of an agency's significant guidance documents. Under section III(1)(a), agencies will maintain a current electronic list of all significant guidance

documents on their Web sites in a manner consistent with OMB policies for agency public Web sites and information dissemination.²⁴ To assist the public in locating such electronic lists, they should be maintained on an agency's Web site—or as a link on an agency's Web site to the electronic list posted on a component or subagency's Web site—in a quickly and easily identifiable manner (e.g., as part of or in close visual proximity to the agency's list of regulations and proposed regulations). New documents will be added to this list within 30 days from the date of issuance. The agency list of significant guidance documents will include: the name of the significant guidance document, any docket number, and issuance and revision dates. As agencies develop or revise significant guidance documents, they should organize and catalogue their significant guidance documents to ensure users can easily browse, search for, and retrieve significant guidance documents on their Web sites.

The agency shall provide a link from the list to each significant guidance document (including any appendices or attachments) that currently is in effect. Many recently issued guidance documents have been made available on the Internet, but there are some documents that are not now available in this way. Agencies should begin posting those significant guidance documents on their Web sites with the goal of making all of their significant guidance documents currently in effect publicly available on their Web sites by the effective date of this Bulletin.²⁵ Other requirements of this Bulletin, such as section II(2) (Standard Elements), apply only to significant guidance documents issued or amended after the effective date of the Bulletin. For such significant guidance documents (including economically significant guidance documents), agencies should provide, to the extent appropriate and feasible, a Web site link from the significant guidance document to the public comments filed on it. This would enable interested stakeholders and the general

public to understand the various viewpoints on the significant guidance documents.

Under section III(1)(b), the significant guidance list will identify those significant guidance documents that were issued, revised or withdrawn within the past year. Agencies are encouraged, to the extent appropriate and feasible, to offer a list serve or similar mechanism for members of the public who would like to be notified by e-mail each time an agency issues its annual update of significant guidance documents. To further assist users in better understanding agency guidance and its relationship to current or proposed Federal regulations, agencies also should link their significant guidance document lists to Regulations.gov.²⁶

2. Public Feedback

Section III(2) requires each agency to have adequate procedures for public comments on significant guidance documents and to address complaints regarding the development and use of significant guidance documents. Not later than 180 days from the publication of this Bulletin, each agency shall establish and clearly advertise on its Web site a means for the public to submit electronically comments on significant guidance documents, and to request electronically that significant guidance documents be issued, reconsidered, modified or rescinded. The public may state their view that specific guidance documents are "significant" or "economically significant" and therefore are subject to the applicable requirements of this Bulletin. At any time, the public also may request that an agency modify or rescind an existing significant guidance document. Such requests should specify why and how the significant guidance document should be rescinded or revised.

Public comments submitted under these procedures on significant guidance documents are for the benefit of the agency, and this Bulletin does not require a formal response to comments (of course, agencies must comply with any applicable statutory requirements to respond, and this Bulletin does not alter those requirements). In some cases, the agency, in consultation with the Administrator of OMB's Office of Information and Regulatory Affairs, may in its discretion decide to address public comments by updating or altering the significant guidance document.

²⁴ U.S. Office of Management and Budget, Memorandum M-05-04, "Policies for Federal Agency Public Web sites" (Dec. 17, 2004), available at: <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-04.pdf>; U.S. Office of Management and Budget, Memorandum M-06-02, "Improving Public Access to and Dissemination of Government Information and Using the Federal Enterprise Architecture Data Reference Model" (Dec. 16, 2005), available at: <http://www.whitehouse.gov/omb/memoranda/fy2006/m06-02.pdf>.

²⁵ In this regard, we note that under the Electronic Freedom of Information Act Amendments of 1996, agencies have been posting on their Web sites statements of general policy and interpretations of general applicability. See 5 U.S.C. 552(a)(2).

²⁶ Regulations.gov is available at <http://www.Regulations.gov/fdmspublic/component/main>.

Although this Bulletin does not require agencies to provide notice and an opportunity for public comment on all significant guidance documents before they are adopted, it is often beneficial for an agency to do so when they determine that it is practical. Pre-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial. Agencies also are encouraged to consider observing notice-and-comment procedures for interpretive significant guidance documents that effectively would extend the scope of the jurisdiction the agency will exercise, alter the obligations or liabilities of private parties, or modify the terms under which the agency will grant entitlements. As it does for legislative rules, providing pre-adoption opportunity for comment on significant guidance documents can increase the quality of the guidance and provide for greater public confidence in and acceptance of the ultimate agency judgments. For these reasons, agencies sometimes follow the notice-and-comment procedures of the APA even when doing so is not legally required.²⁷ Of course, where an agency provides for notice and comment before adoption, it need not do so again upon issuance of the significant guidance document.²⁸

Many commenters expressed the desire for a better way to resolve concerns about agency guidance documents and adherence to good guidance practices. To help resolve public concerns over problematic guidance documents, section III(2)(b) requires each agency to designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a guidance document as a binding requirement. The public also could turn to this office to request that the agency classify a guidance as "significant" or "economically significant" for purposes of this Bulletin. The agency shall provide the name and contact

information for the office(s) on its Web site.

E. Notice and Comment on Economically Significant Guidance Documents

Under section IV, after the agency prepares a draft of an economically significant guidance document, the agency must publish a notice in the **Federal Register** announcing that the draft guidance document is available for comment. In a manner consistent with OMB policies for agency public Web sites and information dissemination, the agency must post the draft on its Web site, make it publicly available in hard copy, and ensure that persons with disabilities can reasonably access and comment on the guidance development process.²⁹ If the guidance document is not in a format that permits such electronic posting with reasonable efforts, the agency should notify the public how they can review the guidance document. When inviting public comments on the draft guidance document, the agency will propose a period of time for the receipt of comments and make the comments available to the public for review. The agency also may hold public meetings or workshops on a draft guidance document, or present it for review to an advisory committee or, as required or appropriate, to a peer review committee.³⁰ In some cases, the agency may, in its discretion, seek early public input even before it prepares the draft of an economically significant guidance document. For example, the agency could convene or participate in meetings or workshops.

After reviewing comments on a draft, the agency should incorporate suggested changes, when appropriate, into the final version of the economically significant guidance document. The agency then should publish a notice in the **Federal Register** announcing that the significant guidance document is available. The agency must post the significant guidance document on the Internet and make it available in hard copy. The agency also must prepare a robust response-to-comments document and make it publicly available. Though these procedures are similar to APA notice-and-comment requirements, this Bulletin in no way alters (nor is it

intended to interpret) the APA requirements for legislative rules under 5 U.S.C. 553.

Prior to or upon announcing the availability of the draft guidance document, the agency should establish a public docket. Public comments submitted on an economically significant guidance document should be sent to the agency's docket. The comments submitted should identify the docket number on the guidance document (if such a docket number exists), as well as the title of the document. Comments should be available to the public at the docket and, when feasible, on the Internet. Agencies should provide a link on their Web site from the guidance document to the public comments as well as the response to comments document.

After providing an opportunity for comment, an agency may decide, in its discretion, that it is appropriate to issue another draft of the significant guidance document. The agency may again solicit comment by publishing a notice in the **Federal Register**, posting a draft on the Internet and making the draft available in hard copy. The agency then would proceed to issue a final version of the guidance document in the manner described above. Copies of the **Federal Register** notices of availability should be available on the agency's Web site. In addition, the response-to-comments document should address the additional comments received on the revised draft.

An agency head, in consultation and concurrence with the OIRA Administrator, may identify a particular significant guidance document or class of guidance documents for which the procedures of this Section are not feasible and appropriate. Under § IV, the agency is not required to seek public comment before it implements an economically significant guidance document if prior public participation is not feasible or appropriate. It may not be feasible or appropriate for an agency to seek public comment before issuing an economically significant guidance document if there is a public health, safety, environmental or other emergency requiring immediate issuance of the guidance document, or there is a statutory requirement or court order that requires immediate issuance. Another type of situation is presented by guidance documents that, while important, are issued in a routine and frequent manner. For example, one commenter raised concerns that the National Weather Service not only frequently reports on weather and air conditions but also gives consumers guidance, such as heat advisories, on the best course of action to take in

²⁷For example, in developing its guidelines for self-evaluation of compensation practices regarding systemic compensation discrimination, the Department of Labor provided for pre-adoption notice and opportunity for comment. See Office of Federal Contract Compliance Programs,

"Guidelines for Self-Evaluation of Compensation Practices for Compliance with Nondiscrimination Requirements of Executive Order 11246 with Respect to Systemic Compensation Discrimination," 69 FR 67,252 (Nov. 16, 2004).

²⁸See, e.g., Office of Federal Procurement Policy Act, 41 U.S.C. 418(b) (providing for pre-adoption notice and comment for procurement policies with a significant effect or cost).

²⁹Federal agency public Web sites must be designed to make information and services fully available to individuals with disabilities. For additional information, see: <http://www.access-board.gov/index.htm>; see also Rehabilitation Act, 29 U.S.C. 701, 794, 794d.

³⁰See U.S. Office of Management and Budget, "Final Information Quality Bulletin For Peer Review," 70 FR 2664 (Jan. 14, 2005).

severe weather conditions. Even if such notices or advisories had an economically significant impact, subjecting them to the notice-and-comment procedures of Section IV would not be feasible or appropriate. An agency may discuss with OMB other exceptions that are consistent with section IV(2).

Though economically significant guidance documents that fall under the exemption in section IV(2) are not required to undergo the full notice-and-comment procedures, the agency should: (a) Publish a notice in the **Federal Register** announcing that the guidance document is available; (b) post the guidance document on the Internet and make it available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts); and (c) seek public comment when it issues or publishes the guidance document. If the agency receives comments on an excepted guidance document, the agency should review those comments and revise the guidance document when appropriate. However, the agency is not required to provide post-promulgation notice-and-comment if such procedures are not feasible or appropriate.

F. Emergencies

In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with this Bulletin. For those significant guidance documents that are governed by a statutory or court-imposed deadlines, the agency shall, to the extent practicable, schedule its proceedings so as to permit sufficient time to comply with this Bulletin.

G. Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.³¹

H. Effective Date

The requirements of this Bulletin shall take effect 180 days after publication in the **Federal Register**.

³¹ The provisions of this Bulletin, and an agency's compliance or noncompliance with the Bulletin's requirements, are not intended to, and should not, alter the deference that agency interpretations of laws and regulations should appropriately be given.

except that agencies will have 210 days to comply with requirements for significant guidance documents promulgated on or before the date of publication of this Bulletin.

Bulletin for Agency Good Guidance Practices

I. Definitions

For purposes of this Bulletin—

1. The term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

2. The term "agency" has the same meaning it has under the Paperwork Reduction Act, 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5).

3. The term "guidance document" means an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended, section 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue.

4. The term "significant guidance document"—

a. Means (as defined in Executive Order 12866, as further amended, section 3(h)) a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

(i) Lead to 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;

(ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.

b. Does not include legal advisory opinions for internal Executive Branch use and not for release (such as Department of Justice Office of Legal Counsel opinions); briefs and other positions taken by agencies, in investigations, pre-litigation, litigation, or other enforcement proceedings (nor does this Bulletin in any other way affect an agency's authority to

communicate its views in court or in other enforcement proceedings); speeches; editorials; media interviews; press materials; Congressional correspondence; guidance documents that pertain to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidance documents that pertain to the use, operation or control of a government facility; internal guidance documents directed solely to other Federal agencies; and any other category of significant guidance documents exempted by an agency head in consultation with the OIRA Administrator.

5. The term "economically significant guidance document" means a significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant guidance documents do not include guidance documents on Federal expenditures and receipts.

6. The term "disseminated" means prepared by the agency and distributed to the public or regulated entities. Dissemination does not include distribution limited to government employees; intra- or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar laws.

7. The term "regulatory action" means any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of inquiry and notices of proposed rulemaking (see Executive Order 12866, as further amended, section 3).

8. The term "regulation" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency (see Executive Order 12866, as further amended, section 3).

II. Basic Agency Standards for Significant Guidance Documents

1. Approval Procedures:

a. Each agency shall develop or have written procedures for the approval of significant guidance documents. Those procedures shall ensure that the issuance of significant guidance documents is approved by appropriate senior agency officials.

b. Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence.

2. *Standard Elements:* Each significant guidance document shall:

a. Include the term "guidance" or its functional equivalent;

b. Identify the agency(ies) or office(s) issuing the document;

c. Identify the activity to which and the persons to whom the significant guidance document applies;

d. Include the date of issuance;

e. Note if it is a revision to a previously issued guidance document and, if so, identify the document that it replaces;

f. Provide the title of the document, and any document identification number, if one exists;

g. Include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets; and

h. Not include mandatory language such as "shall," "must," "required" or "requirement," unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties.

III. Public Access and Feedback for Significant Guidance Documents

1. Internet Access:

a. Each agency shall maintain on its Web site—or as a link on an agency's Web site to the electronic list posted on a component or subagency's Web site—a current list of its significant guidance documents in effect. The list shall include the name of each significant guidance document, any document identification number, and issuance and revision dates. The agency shall provide a link from the current list to each significant guidance document that is in effect. New significant guidance documents and their Web site links shall be added promptly to this list, no later than 30 days from the date of issuance.

b. The list shall identify significant guidance documents that have been added, revised or withdrawn in the past year.

2. Public Feedback:

a. Each agency shall establish and clearly advertise on its Web site a means

for the public to submit comments electronically on significant guidance documents, and to submit a request electronically for issuance, reconsideration, modification, or rescission of significant guidance documents. Public comments under these procedures are for the benefit of the agency, and no formal response to comments by the agency is required by this Bulletin.

b. Each agency shall designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a significant guidance document as a binding requirement. The agency shall provide, on its Web site, the name and contact information for the office(s).

IV. Notice and Public Comment for Economically Significant Guidance Documents

1. *In General:* Except as provided in Section IV(2), when an agency prepares a draft of an economically significant guidance document, the agency shall:

a. Publish a notice in the **Federal Register** announcing that the draft document is available;

b. Post the draft document on the Internet and make it publicly available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts);

c. Invite public comment on the draft document; and

d. Prepare and post on the agency's Web site a response-to-comments document.

2. *Exemptions:* An agency head, in consultation with the OIRA Administrator, may identify a particular economically significant guidance document or category of such documents for which the procedures of this Section are not feasible or appropriate.

V. Emergencies

In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with this Bulletin. For those significant guidance documents that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule its proceedings so as to permit sufficient time to comply with this Bulletin.

VI. Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

VII. Effective Date

The requirements of this Bulletin shall take effect 180 days after its publication in the **Federal Register** except that agencies will have 210 days to comply with requirements for significant guidance documents promulgated on or before the date of publication of this Bulletin.

Dated: January 18, 2007.

Steven D. Aitken,

Acting Administrator, Office of Information and Regulatory Affairs.

[FR Doc. E7-1066 Filed 1-24-07; 8:45 am]

BILLING CODE 3110-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 27668; 812-13201]

Hercules Technology Growth Capital, Inc.; Notice of Application

January 19, 2007.

AGENCY: Securities and Exchange Commission (the "Commission").

ACTION: Notice of an application for an order under section 61(a)(3)(B) of the Investment Company Act of 1940 (the "Act").

SUMMARY OF APPLICATION: Applicant, Hercules Technology Growth Capital, Inc. ("HTGC"), requests an order approving a proposal to issue options to purchase HTGC's common stock ("Common Stock") to directors who are not officers or employees of HTGC ("Eligible Directors") pursuant to HTGC's 2006 Non-employee Director Plan (the "Plan").

FILING DATES: The application was filed on June 21, 2005 and amended on December 12, 2006.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 13, 2007, and



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

April 25, 2007

M-07-13

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES,
AND INDEPENDENT REGULATORY AGENCIES

FROM: Rob Portman *Rob Portman*

SUBJECT: Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices

On January 18, 2007, the President issued Executive Order (EO) 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review." On the same day, and in connection with EO 13422, I issued an Office of Management and Budget (OMB) Bulletin on Agency Good Guidance Practices (Bulletin).

The primary focus of EO 13422 and the Bulletin is on improving the way the Federal government does business with respect to guidance documents – by increasing their quality, transparency, accountability, and coordination. Guidance documents, used properly, can have important benefits. These include, for example, advising and assisting individuals, small businesses and other regulated entities in their compliance with agency regulations. When an agency issues a guidance document that has a significant impact on society, the guidance document should be subject to an appropriate level of review – by the public, within an agency, and by other Federal agencies.

Within OMB, the Office of Information and Regulatory Affairs (OIRA) has primary responsibility for implementing EO 12866, as amended by EO 13422, and the Bulletin. To assist your agencies in implementing EO 13422 and Bulletin, OIRA has prepared the attached compliance assistance memorandum which describes what agencies should do to comply with the EO and the Bulletin. Please circulate this memorandum to the appropriate officials within your agency for immediate attention.

OMB looks forward to working with your agencies in the implementation of EO 12866, as amended, and the Bulletin.

Attachment



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

April 25, 2007

MEMORANDUM FOR REGULATORY POLICY OFFICERS

FROM: Susan E. Dudley *SED*
Administrator
Office of Information and Regulatory Affairs

SUBJECT: Implementation of the OMB Bulletin on Good Guidance Practices and Executive Order 13422 (amending Executive Order 12866)

On January 18, 2007, the President issued Executive Order (EO) 13422, "Amendment to Executive Order 12866 for Regulatory Planning and Review." On that same day, the OMB Director issued a related document, the OMB Bulletin on Agency Good Guidance Practices (the Bulletin). The primary focus of the Executive Order and the Bulletin is on improving the way the Federal government does business with respect to guidance documents – by increasing their quality, transparency, accountability, and coordination.

The Bulletin, which OMB issued after seeking public comment on a proposed version, establishes policies and procedures for agencies to apply in their development and issuance of "significant" and "economically significant" guidance documents. The Bulletin will ensure that guidance documents are of high quality, developed with appropriate agency review and public participation, and readily accessible by the public.

The principal change made by EO 13422 is that it amends EO 12866 to establish a process that will provide an opportunity for interagency coordination and review of significant guidance documents prior to their issuance. EO 13422 also amends EO 12866 in several other ways. To ensure appropriate accountability, the EO modifies the procedures for an agency's adoption of its annual Regulatory Plan and requires that an agency's Regulatory Policy Officer be a Presidential appointee. The EO also updates the Principles of Regulation in EO 12866 to reflect the guidance-coordination provisions that are added by EO 13422 as well as pre-existing OMB guidance. Finally, the EO invites agencies to consider whether they would want to rely on formal rulemaking procedures for resolving complex determinations.

Within OMB, the Office of Information and Regulatory Affairs (OIRA) has primary responsibility for implementing EO 12866, as amended, and the Bulletin. To assist agencies in their implementation of the EO and Bulletin, OIRA has prepared and is now issuing this memorandum that provides answers to a number of questions. Agencies should also consult the preamble to the Bulletin for additional implementation assistance.

If your agencies have any questions about the attached implementation assistance, or about the EO or the Bulletin, they may contact Margaret Malanoski at (202) 395-3122 or [Margaret A. Malanoski@omb.eop.gov](mailto:Margaret_A_Malanoski@omb.eop.gov).

OIRA looks forward to working with your agencies in implementing the EO and Bulletin.

Attachment

A. General Information.....	1
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A. General Information

1. When do Executive Order 13422 and the Agency Good Guidance Practices Bulletin take effect?

Executive Order 13422 (Executive Order) became effective when it was signed by the President, on January 18, 2007.

The requirements of the Agency Good Guidance Practices Bulletin (Bulletin) will take effect on July 24, 2007. However, for significant guidance documents promulgated prior to January 25, 2007, agencies have until August 23, 2007 to comply with the requirements of Section III of the Bulletin. For documents promulgated after January 25, 2007, agencies should comply with the requirements of Section III of the Bulletin by July 24, 2007 or within thirty (30) days of issuance of the guidance document, whichever is later.

Agencies are encouraged to comply with the provisions of the Bulletin sooner if possible.

2. What agencies are covered by the Executive Order and the Bulletin?

The Executive Order and the Bulletin as a whole apply to all Federal agencies, except for the independent regulatory agencies as defined in 44 U.S.C. § 3502. (Sec. 3(b) of the Executive Order). The scope of agencies covered by the Bulletin and the Executive Order does not differ from the scope of agencies covered by Executive Order 12866.

The independent regulatory agencies are included in provisions concerning the "Unified Regulatory Agenda" (Sec. 4(b) of the Executive Order) and "The Regulatory Plan" (Sec. 4(c) of the Executive Order) and they must comply with the new requirements for the "Unified Regulatory Agenda" (Sec. 4(b) of the Executive Order) contained in the Executive Order. As OMB requested in 1993 following the issuance of Executive Order 12866, the independent agencies are requested on a voluntary basis to adhere to the provisions of the Executive Order that may be pertinent to their activities.

B. Guidance Questions -- Applicable to Both the Bulletin and the Executive Order

3. What types of guidance documents are covered by the Bulletin and by the Executive Order?

Both the Executive Order and the Bulletin define "guidance documents" as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue."

The definition is not limited to written guidance materials; it encompasses all guidance materials regardless of format, including guidance offered through video, audio tapes, interactive web-based software, or other innovative formats. Guidance documents may be currently referred to by a variety of names, such as interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, or advisories.

4. What types of guidance documents are not covered by the Bulletin and by the Executive Order?

Guidance documents that are not significant are not covered by the Bulletin or the Executive Order. Further, Section I(4) of the Bulletin clarifies what is not a significant guidance document.

5. What is a “significant” guidance document?

Both the Bulletin (Sec. I(4)) and the Executive Order (Sec. 3(h)) define a “significant” guidance document as a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

- (1) lead to an annual effect 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;
- (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) materially alter the budgetary impacts of entitlements, grants, user fees or loan programs or the rights or obligations of recipients thereof; or
- (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.

OIRA will work with agencies in applying the definition of “significant guidance” to the agency’s guidance documents.

6. What is an “economically significant” guidance document and how is it related to a “significant” guidance document?

The Bulletin defines an “economically significant guidance document” as a “significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant documents do not include guidance documents on Federal expenditures and receipts.” Therefore, economically significant guidance documents are a subset of significant guidance documents.

The Executive Order does not define “economically significant” guidance documents nor does it impose a separate process for “economically significant” guidance documents. Therefore, guidance documents that meet the definition of “economically significant” in

the Bulletin will be a “significant” guidance document for the purposes of the Executive Order.

If agency staff are uncertain about whether a guidance document should be classified as economically significant, they may contact OIRA for assistance.

7. Does either the Executive Order or the Bulletin require agencies to prepare a benefit-cost analysis for guidance documents as agencies are required to do for regulations?

No. The amendments to Executive Order 12866 did not alter the Section 6 requirements for analysis of regulations – specifically Sec. 6 (a)(3)(B)-(C) – to include guidance documents. The requirements for significant guidance documents (Sec. 9 of the Executive Order) do not impose similar analytical requirements.

In determining whether a guidance document is economically significant, agencies are not expected to complete a benefit-cost analysis or to do more than they currently do when they make preliminary recommendations to OIRA about the designation of regulations under Executive Order 12866. Rather, we expect agencies to use common-sense principles and readily available facts and assumptions in making their evaluation of whether a guidance document is reasonably likely to have an impact of \$100 million or more annually. We recommend that the agency as part of its determination, consider both the expected adoption rate of guidance, in whole or in part, and the potential benefits that would occur with such adoption. If information to make reasonable assumptions is not available, we suggest that the agency consider the effect of the guidance as if it were adopted widely by all affected parties.

C. Guidance Questions -- Applicable to Requirements specific to the Bulletin

8. Under the Bulletin, what are the requirements for the content of “significant” guidance documents?

The Bulletin requires that significant guidance documents: (i) include the term “guidance” or its functional equivalent; (ii) identify the agenc(ies) or office(s) issuing the document; (iii) identify the activity to which and the persons to whom the document applies; (iv) include the date of issuance; (v) note if it is a revision to a previously issued guidance document and, if so, identify the guidance that it revises or replaces; (vi) provide the title of the guidance and any document identification number, if one exists; and (vii) include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets.

9. Under the Bulletin, what information are agencies required to post on their Web sites?

The Bulletin requires each agency to maintain a current electronic list of all significant guidance documents in effect on its Web site – or as a link on an agency's Web site to the electronic list posted on a component or subagency's Web site. The agency must provide a link from the current list to each significant guidance document that is in effect.

The agency list of significant guidance documents must include: the name of the significant guidance document, any document identification number, and issuance and revision dates and must identify significant guidance documents that have been added, revised or withdrawn in the past year. New significant guidance documents and their links should be added to this list within 30 days from the date of their issuance, but ideally as soon as possible. (Sec. III(1) of the Bulletin).

The lists should be maintained in a manner consistent with OMB policies for agency public Web sites and information dissemination. As agencies develop or revise significant guidance documents, they should organize and catalogue their significant guidance documents to ensure users can easily browse, search for, and retrieve significant guidance documents on agency Web sites. To further assist users in understanding agency guidance documents and the relationship of the guidance documents to current or proposed Federal regulations, agencies should also link their significant guidance document lists to Regulations.gov.

The agency must also provide, on its Web site, the name and contact information for the office or offices designated by the agency to receive and address complaints by the public that the agency is not following the procedures in the Bulletin or is improperly treating a significant guidance document as a binding requirement. (Sec. III(2)(b) of the Bulletin). The agency's Regulatory Policy Officer should ensure that these individuals respond promptly and appropriately to any such complaints.

10. Can a subcomponent of an agency establish a separate Web site listing guidance documents and/or designate more than one office to receive and address complaints from the public on the guidance documents?

The Bulletin allows for an electronic list of significant guidance documents to be posted on a component or subagency Web site as long as the agency maintains a link to this list on its Web site. In this case, both the component or subagency Web site and the agency Web site must be maintained in a manner consistent with OMB policies for public Web sites and information dissemination.

The Bulletin requires the agency to designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in the Bulletin or is improperly treating a guidance document as a binding requirement. Accordingly, the Bulletin permits an agency to establish one or more such offices, at its discretion. The agency shall provide the name and contact information for the office(s) on its Web site.

11. What requirements does the Bulletin establish -- for public comments and for Agency responses to those comments -- for “economically significant” guidance documents?

When the agency prepares a draft of an economically significant guidance document, the agency must publish a notice in the Federal Register announcing that the draft guidance document is available for comment and otherwise make it publicly available (e.g., by maintaining a hard copy, posting the draft on its Web site and ensuring that persons with disabilities can reasonably access and comment on the guidance). The Federal Register notice should explain how to submit comments and establish a period of time for the receipt of comments. Prior to or upon announcing availability of the draft guidance document, the agency should establish a public docket. Agencies should provide a link on their Web site from the guidance document to the public comments. In response to comments received on economically significant guidance documents, the agency also must prepare a response-to-comments document and make it publicly available in hard copy and on its Web site. (Sec. IV of the Bulletin). Further, in their requests for public comment, agencies should state that the guidance document does not have the force and effect of law.

12. What requirements does the Bulletin establish -- for public comments and for Agency responses to those comments -- for “significant” guidance documents?

The Bulletin does not require agencies to publish draft significant guidance documents for public comment prior to final issuance. However, each agency should have adequate procedures for handling public comments on significant guidance documents after they are published. Each agency must establish and clearly advertise on its Web site a means for the public to submit comments electronically and to provide a way for the public to request electronically that significant guidance documents be issued, reconsidered, modified or rescinded. However, unlike for economically significant guidance documents, the agency is not required to prepare a formal response-to-comments document. (Sec. III(2)(a) of the Bulletin).

The agency should provide, to the extent appropriate and feasible, a Web site link from the significant guidance document to the public comments filed on it. While agencies must comply with the Federal Records Act, agencies are not required to display public comments on their Web sites indefinitely. Accordingly, it would be appropriate for agencies to develop procedures for posting and maintaining the comments on the agency’s Web site for a specified and reasonable period of time so as to enable interested members of the public to view the comments (and perhaps to offer their own comments in reply), and then to withdraw the comments from the Web site.

Should an agency determine that publishing a draft for public comment would be beneficial, they should provide a link from the significant guidance document to the public comments filed on it.

13. Should agencies use Regulations.gov to process public comments for guidance documents?

Yes. Agencies must use Regulations.gov to process public comments for economically significant guidance documents. Regulations.gov may also be used to process public comments for significant guidance documents. If your agency has not yet migrated to Regulations.gov, your agency can utilize existing processing capabilities. Your agency's Chief Information Officer can assist in scheduling and obtaining this service.

14. Under the Bulletin, what should an agency do if it believes that it would not be feasible or appropriate for the agency to provide the public with advance notice of, and an opportunity to comment on, an economically significant guidance document before the agency issues the guidance in final form?

An agency head or the Regulatory Policy Officer, in consultation with the OIRA Administrator, may identify a particular economically significant guidance document or class of economically significant guidance documents for which the procedures of Section IV of the Bulletin are not feasible and appropriate. In these circumstances, the agency should nonetheless: (a) publish a notice in the Federal Register announcing that the guidance document is available; (b) post the guidance document on its Web site and make it available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts); and (c) seek public comment when it issues or publishes the guidance document. If the agency receives comments on an excepted guidance document, the agency should review those comments and revise the guidance document as appropriate.

15. Under the Bulletin, what should an agency do if it needs to issue a significant guidance document to address an emergency situation?

The Bulletin expressly provides for emergency situations or when an agency is obligated by law to act more quickly than would occur under normal review procedures. In those cases, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with the Bulletin. (See also the question in D(22) below concerning how the agency should proceed under the Executive Order when issuing guidance to address an emergency situation.)

16. What are the timelines for meeting the requirements of the Bulletin?

No later than July 24, 2007, agencies must:

- Have developed procedures for the approval of significant guidance documents. Those procedures should ensure that the issuance of a significant guidance document is approved by appropriate senior agency officials (Sec. II(1) of the Bulletin);

- Comply with the standards for guidance documents contained in Section II(2) of the Bulletin;
- Provide for public comment on new economically significant guidance documents and otherwise meet the requirements of Section IV of the Bulletin.
- In accordance with Section III(1) of the Bulletin, provide on their Web sites a list of significant guidance documents promulgated after January 25, 2007.
- Advertise on the Web site a means for public feedback (Sec. III(2)(a) of the Bulletin); and
- Designate an office (or offices) to receive and address complaints by the public. The designated office should be clearly identified on the agency Web site, along with the contact information for the office. (Sec. III(2)(b) of the Bulletin)

No later than August 23, 2007, agencies must:

- Provide a list of significant guidance documents currently in effect and promulgated on or before January 25, 2007 on their agency Web site in accordance with Section III(1) of the Bulletin (and new significant guidance documents and their Web site links shall be added promptly to this list, no later than 30 days from the date of issuance); and
- Identify (and update at the beginning of each calendar year) significant guidance documents on the list that have been added, revised, or withdrawn within the past year, in accordance with Sec. III(1)(b) of the Bulletin.

We encourage the agencies to implement the requirements of the Bulletin sooner, if practicable.

D. Guidance Questions – Applicable to Requirements specific to the Executive Order

17. Under the Executive Order, what is an agency required to do when it wants to issue a “significant” guidance document?

Before an agency promulgates a significant guidance document, the agency must:

- (1) Provide to OIRA advance notification of any significant guidance documents; and
- (2) Upon the Administrator’s request, provide to OIRA the content of the draft guidance, together with a brief explanation of the need for the guidance document and how it will meet that need.

Within ten (10) days of providing such notice to OIRA, OIRA will notify the agency if additional consultation will be required before issuing the guidance. (Sec. 9 of the Executive Order)

The Executive Order assigns responsibility for ensuring compliance with these requirements to the Regulatory Policy Officer.

18. Under the Executive Order, how should an agency provide advance notification to OIRA of a significant guidance document?

As a general rule, no less than 10 days prior to intended dissemination of a significant guidance document, including draft documents that an agency may disseminate for public comment, the appropriate personnel at the agency should work with the OIRA desk officer who handles review of that agency's rules pursuant to Executive Order 12866. At a minimum, for each significant guidance document, the agency should provide the following information to OIRA:

- DEPARTMENT/Subcomponent;
- Title;
- Planned Publication Date;
- Name and Telephone number of the agency official who can answer detailed questions about the guidance document and;
- A brief description of what the agency is intending to do and why, issues associated with the guidance, time pressures, and why the action is important. If the agency received comment on a draft guidance document, include a brief statement of the nature and extent of public comment and the nature and extent of changes made in response to the public comment.

Lengthy or detailed descriptions of the issues listed above are not necessary. Based on these descriptions, OIRA will determine whether the agency should submit the content of the draft guidance.

Please note that these summaries are required only for "significant" guidance documents, which includes "economically significant" guidance documents.

An agency should provide this information to OIRA using the same process that the agency uses to request significance determinations for regulations.

19. What is the next step when the OIRA Administrator determines that additional consultation under the Executive Order is warranted?

If the Administrator determines that additional consultation is warranted, OIRA will review the guidance to ensure that it is consistent with the philosophy and principles of Executive Order 12866, as amended, and will also coordinate review among appropriate Executive branch departments and agencies. Additionally, OIRA will discuss with the agency its compliance with the requirements in the Bulletin that apply to "significant" and/or "economically significant" guidance documents. OIRA will remain in close consultation with the agency until the review is completed and will conduct the review in as expedited a manner as is possible. OIRA will complete its consultative process within 30 days or, at that time, advise the agency when consultation will be complete.

20. How will the OIRA Administrator determine which significant guidance documents are exempt from review under the Executive Order?

The Executive Order gives the OIRA Administrator the authority to exempt any category of agency guidance documents from centralized review. If an agency wishes to request an exemption, it should make such a request to the Administrator who will consider the request in consultation with the agency.

21. What is the time period for consultation with OIRA on significant guidance documents under the Executive Order?

The Executive Order does not specify a time period for review of significant guidance documents. However, as noted above, OIRA will remain in close consultation with the agency until the review is completed and will conduct the review in as expedited a manner as is possible. OIRA will complete its consultative process within 30 days or, at that time, advise the agency when consultation will be complete.

22. What should an agency do, under the Executive Order, if the agency needs to issue a significant guidance document to address an emergency situation?

If an agency needs to issue a significant guidance document to address an emergency situation, the agency should notify OIRA as soon as possible. After the emergency has been addressed, OIRA and the agency will consult on whether further review, including interagency review, is warranted under the Executive Order.

23. How were the Regulatory Principles of Executive Order 12866 amended to apply to guidance documents?

The Executive Order amends the Principles of Regulation (Sec. (1)(b) of the Executive Order) to ensure guidance documents are consistent with the philosophy of Executive Order 12866. Four of the principles are revised to clarify that they apply to guidance. Specifically, the principles, as amended, state [changes in italics]:

- Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of the intended regulation *or guidance document* (Sec. (1)(b)(7) of the Executive Order);
- Each agency shall avoid regulations *or guidance documents* that are inconsistent, incompatible, or duplicative with its other regulations *or guidance documents* or those of other Federal agencies (Sec. (1)(b)(10) of the Executive Order);

- Each agency shall tailor its regulations *and guidance documents* to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the cost of cumulative regulations (Sec. (1)(b)(11) of the Executive Order); and
- Each agency shall draft its regulations *and guidance documents* to be simple and easy to understand with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty (Sec. (1)(b)(12) of the Executive Order).

E. Non-Guidance provisions in Executive Order 13422

24. When does an agency head need to designate its Regulatory Policy Officer?

Under the Order, each agency head was required to designate the agency's Regulatory Policy Officer no later than March 19, 2007. If your agency has not done so, please notify Margaret Malanoski at (202) 395-3122 or mmalanos@omb.eop.gov of this designation immediately. Further, the agency head must annually update OMB on the status of this designation.

Independent agencies are encouraged to appoint a Regulatory Policy Officer.

25. What changes does the Executive Order make to the appointment of the Regulatory Policy Officer?

The Order requires the Regulatory Policy Officer to be one of the agency's Presidential appointees. (Sec.6(a)(2) of the Executive Order) For many agencies, this will not be a change, because their Regulatory Policy Officers have already been Presidential appointees. These Presidential appointees will report to the heads of their agencies in carrying out their role as the agency's Regulatory Policy Officer, as they do when carrying out their other responsibilities and as the Regulatory Policy Officers have previously done.

26. Can the agency head designate as the Regulatory Policy Officer an agency employee who serves in a position for which the agency head (not the President) is the appointing official?

No. The agency head may designate the agency's Regulatory Policy Officer from among those agency positions whose appointment is vested by law in the President. Such "political appointees" as Schedule C and non-career SES employees are appointed by the agency head, not by the President, and thus they may not be designated as the agency's Regulatory Policy Officer.

27. If there is a vacancy in the Presidentially-appointed position that the agency head has designated as the Regulatory Policy Officer, may the person who is serving in an "acting" capacity in that position be the Regulatory Policy Officer?

Yes. If a person who is not a Presidential appointee is serving in the acting capacity in a position that is Presidentially-appointed (PA), the amended Executive Order does not require an agency head to designate another official to serve as the Regulatory Policy Officer when a vacancy exists in the PA position that is designated as the Regulatory Policy Officer. Such a requirement to change the designation would be disruptive of agency operations.

28. Are independent regulatory agencies required to designate a Presidential appointee as a Regulatory Policy Officer?

No. Independent regulatory agencies are not subject to the requirement in Section 6(a)(2) of the Executive Order regarding the designation of Regulatory Policy Officers. However, the heads of independent regulatory agencies may decide to designate a Regulatory Policy Officer in order to meet the requirements for the Regulatory Plan (Sec. 4(c) of the Executive Order). We encourage independent agencies to do so.

29. Will the Regulatory Policy Officers continue to report to their agency heads, as they did under Executive Order 12866 prior to its recent amendment?

Yes. The deletion of the "report to the agency head" language by the recent Executive Order does not change the fact that the Regulatory Policy Officer reports to the agency head. As before, the agency head continues to be the official who designates the agency's Regulatory Policy Officer. The Regulatory Policy Officer will continue to report to the agency head in performing that role, as well as in performing his or her other responsibilities.

30. Does the agency need to establish a Regulatory Policy Office, in addition to the agency head designating a Regulatory Policy Officer?

No. The reference in Executive Order 13442 to a Regulatory Policy "Office" was a typographical error. This is in fact another reference to the Regulatory Policy Officer.

31. What changes does the Executive Order make to the responsibilities of the Regulatory Policy Officer?

Under the Executive Order, the Regulatory Policy Officer must:

- Personally authorize the commencement of rulemakings and the inclusion of rulemakings on the Regulatory Plan, unless they are otherwise authorized by the head of the agency. (Sec. 4(c) of the Executive Order); and

- Ensure that the agency provides OIRA with advance notification of and an opportunity to review any significant guidance documents prior to their promulgation. (Sec. 9 of the Executive Order).

Of course, it is assumed that these requirements will be implemented in a way that complies with all applicable laws.

32. When does a rulemaking "commence" for the purpose of meeting the new requirement for the Regulatory Policy Officer's (or the agency head's) authorization of the agency's "commencement of a rulemaking"?

The point at which a rulemaking commences may vary from one agency to the next, depending on each agency's procedures and practices, and may vary from rulemaking to rulemaking. As a general matter, a rulemaking commences when the agency has decided as an institutional matter that it will engage in a rulemaking. At the latest, the rulemaking will commence when the rulemaking receives a Regulation Identification Number (RIN).

33. What are the new requirements for the Regulatory Plan?

As noted above, the Executive Order requires the Regulatory Policy Officer (or the head of the agency) personally to authorize the commencement of rulemakings and the inclusion of rulemakings on the *Regulatory Plan*.

As has always been the case under Executive Order 12866, regulations identified in Part II of the *Plan* should, to the extent possible, include preliminary estimates of the anticipated costs and benefits of each rule. The change made by Executive Order 13422 is that each agency providing such estimates must sum-up these individual rule-by-rule estimates into a combined aggregate estimate of the costs and benefits of all its regulations planned for each calendar year or thereafter. (Sec. 4(c) of the Executive Order). The summation methodology should be internally consistent and transparent. The aggregate figures should be provided in a manner that allows for the public to easily understand the overall impact of the planned regulatory actions.

In summarizing the legal basis for each action, agencies must provide a specific citation for the statute, order, or other legal authority for each planned regulation. In particular, with regard to legal deadlines for completion of rulemakings, it will be necessary for agencies to provide full and specific information sufficient to identify in detail the source of any deadline requirements.

34. Do the revisions to the Principles of Regulation, specifically those in Section 1(b)(1) related to "market failure," require agencies to provide more or different information to OIRA when submitting a regulation for review?

The Executive Order clarifies in the Principles of Regulation (Sec. 1(b)(1) of the Executive Order) that: "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it

intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem.”

This is not a substantive change to the Regulatory Principles of Executive Order 12866. Rather, this change makes clear that agencies must state “in writing” the problem the regulation seeks to address. Many agencies already provide this information in their preambles and, for those agencies, this should not represent any change.

Please note that the revision to the principle does not prescribe or limit the agencies’ written rationale exclusively to “market failure, though that issue should be addressed where it is applicable. The language from the principle explicitly recognizes that there may be other “specific problems that [an agency] intends to address...that warrant new agency action.” In addition, the language that expressly directs Federal agencies to “promulgate . . . such regulations as are required by law, [or] are necessary to interpret the law” has not been amended and so it continues to apply. Agencies should continue to set forth the appropriate basis for any proposed regulatory action.

35. Does the Executive Order require an agency to consider the use of formal rulemaking?

No. The Executive Order instead reminds agencies that they may, in consultation with OIRA, consider whether to use formal rulemaking procedures under the Administrative Procedure Act (APA) for the resolution of complex determinations. This is a reminder to agencies of an authority that they have long had, and that remains available to them, under the APA. Some agencies have utilized this authority and may want to consider doing so in the future, and other agencies may identify situations in which it could be beneficial.

* * * *

Further Questions

With whom should agency staff consult about questions concerning the Executive Order and the Bulletin?

If your staff has questions concerning the Executive Order or the Bulletin, please contact Margaret Malanoski in OIRA ((202) 395-3122 and mmalanos@omb.eop.gov.)



Federal Register

Friday,
June 15, 2007

Part IV

Office of Management and Budget

Implementation Guidance for Title V of
the E-Government Act, Confidential
Information Protection and Statistical
Efficiency Act of 2002 (CIPSEA); Notice

OFFICE OF MANAGEMENT AND BUDGET

Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of decision.

SUMMARY: The Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) can provide strong confidentiality protections for statistical information collections, such as surveys and censuses, as well as for other statistical activities, such as data analysis, modeling, and sample design, that are sponsored or conducted by Federal agencies. The Office of Management and Budget (OMB) is issuing Implementation Guidance for Title V of the E-Government Act, the Confidential Information Protection and Statistical Efficiency Act of 2002 (Pub. L. 107-347). The purpose of the CIPSEA implementation guidance is to inform agencies about the requirements for using CIPSEA and to clarify the circumstances under which CIPSEA can be used.

Authority: 31 U.S.C. 1104(d); 44 U.S.C. 3504 (specifically (a)(1)(B)(iii) and (v), (e)(1), (3) and (5), and (g)(1)); Pub. L. 107-347 section 503(a), 44 U.S.C. 3501 note.

FOR FURTHER INFORMATION CONTACT: Brian Harris-Kojetin, Ph.D., Statistical and Science Policy Office, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10201, 725 17th Street, NW., Washington, DC 20503. Telephone: 202-395-3093.

SUPPLEMENTARY INFORMATION:

A. Background

Statistics collected and published by the Federal Government constitute a significant portion of the available information about the United States' economy, population, natural resources, environment, and public and private institutions. There are more than 70 Federal agencies or organizational units that carry out statistical activities as their principal mission or in conjunction with other program missions, such as providing services or enforcing regulations. In addition to these 70 agencies, many other Federal agencies or units may collect statistical information to use for specific program needs.

Prior to the enactment of CIPSEA, a patchwork of legislative protections governed the confidentiality of data

gathered for statistical purposes by the different agencies and units. Some agencies had strong statutory authority to protect the confidentiality of the data they gathered for statistical purposes, while other agencies had weak or no legislative authority to protect confidentiality. In addition, the ability of the designated statistical agencies to share information to improve the efficiency of the Federal statistical system was limited by statutory constraints affecting those agencies.

By establishing a uniform policy for all Federal statistical collections, this law will reduce public confusion, uncertainty, and concern about the treatment of confidential statistical information by different Federal agencies. By establishing consistent rational principles and processes to buttress confidentiality pledges, the guidance that implements the law will harmonize confidentiality claims and set minimum standards for safeguarding confidential statistical information. Such consistent protection of confidential statistical information will, in turn, reduce the perceived risks of more efficient working relationships among statistical agencies, relationships that can reduce both the cost and reporting burden imposed by statistical programs.

B. Development and Review

In 2003, OMB and the other members of the Interagency Council on Statistical Policy (ICSP) formed an interagency group to discuss issues that OMB and the agencies anticipated would arise in the implementation of CIPSEA. OMB was particularly interested in understanding the questions and concerns that these statistical agencies had about the new law and how it would affect their activities. OMB also sought to incorporate the best practices of these agencies for handling confidential statistical information.

An initial draft of this implementation guidance was reviewed by the ICSP members, and OMB revised the draft guidance in response to the comments that we received. Based on the use of the law by agencies over the past three years, OMB has also addressed in the guidance specific issues that have arisen, such as nonstatistical agencies' use of CIPSEA.

C. Summary of and Response to Comments Received in Response to the October 16, 2006 Federal Register Notice

OMB issued proposed Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical

Efficiency Act of 2002 (CIPSEA)(Pub. L. 107-347) in October 2006 (71 FR 60,772-60,773). Five public comments were received in response to OMB's request. OMB reviewed the public comments on the guidance and made some modifications in response to the comments. The complete text of the public comments and this document are available on the OMB Web site at <http://www.whitehouse.gov/omb/inforeg/statpolicy.html>.

General Comments

One commenter expressed support for the guidance and stated that "the proposed guidelines establish principles and policies that will protect the confidentiality of the data provided by respondents to federal statistical surveys" and noted that the guidance provides "reasonable approaches to protecting confidentiality, and thereby will reduce the costs and reporting burdens imposed by statistical programs." The commenter also noted that it was "especially useful to see guidelines for statistical agency interactions with outside analysts (e.g., contractors) authorized to see the confidential data."

I. Introduction

Identifiability

One commenter believed the discussion of the identifiability of personal information in the proposed guidance was insufficient. Although the commenter noted the technical references to Statistical Policy Working Paper #22¹ and to the Federal Committee on Statistical Methodology's Confidentiality and Data Access Committee's disclosure review checklist,² she asked for "more specific guidance about the meaning of the terms *reasonably inferred* and *direct or indirect means*" [emphasis in original] and "how the CIPSEA standard specifically relates to the HIPAA standards of *no reasonable basis to believe* and *risk is very small*" [emphasis in original] * * * "whether a risk assessment is required, how to conduct that risk assessment, what data sources (public and private) must be considered in assessing identifiability" as well as how much effort and cost are reasonable.

In response to this comment, OMB has included a definition of "personally identifiable information" in footnote 21 and provided an example of indirect identification in footnote 23, as follows:

¹ Available at <http://www.fcsm.gov/reports/>.

² Available at <http://www.fcsm.gov/committees/cdac/cdac.html>.

²¹ "personally identifiable information" refers to information which can be used to distinguish or trace an individual's identity, such as his or her name, social security number, biometric records, etc., alone, or when combined with other personal or identifying information that is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc.

²³ Indirect identification refers to using information in conjunction with other data elements to reasonably infer the identity of a respondent. For example, data elements such as a combination of gender, race, date of birth, geographic indicators, or other descriptors may be used to identify an individual respondent.

However, it is beyond the scope of this implementation guidance to provide lists of other data sources that could be used to reidentify respondents or specific risk assessment techniques agencies must employ. As the commenter noted, OMB does provide references to more technical resources that address these issues, such as Statistical Policy Working Paper #22, and a citation to the HIPAA privacy rule has been added. Federal statistical agencies are in the best position to know about the sensitivity of their confidential statistical information and to take appropriate steps to assess and mitigate the risks of reidentification. Because this area is a "moving target," as the commenter noted, OMB, through its Federal Committee on Statistical Methodology, sponsors the Confidentiality and Data Access Committee, which facilitates the sharing and adoption of best practices and latest techniques in disclosure avoidance across Federal agencies.

Relation of CIPSEA to Other Laws

One commenter noted that "subsection (b) of the Privacy Act of 1974 authorizes numerous disclosures, many of which are inappropriate for CIPSEA records. For example, disclosures for law enforcement purposes" as well as many routine uses. The commenter asked OMB to "elaborate on the intersection between CIPSEA and the Privacy Act of 1974."

As OMB has noted in the guidance, agencies are responsible for ensuring that information protected under CIPSEA is used exclusively for statistical purposes. OMB recognizes that the Privacy Act does permit routine uses that are nonstatistical; these uses are not permitted for CIPSEA-protected information. OMB believes that the minimum standards in the guidance for safeguarding confidential information make clear that agencies need to develop appropriate policies and procedures for CIPSEA-protected

information that go beyond those that exist for Privacy Act systems of records; however, we have added the following language to make this explicit in Part I.F. of the guidance:

On the other hand, if an agency pledges to use the information for only for statistical purposes, then the agency shall not use any other authorities it has available to use the information for non-statistical purposes, because those uses would be contrary to the agency's pledge. For example, if information is protected by CIPSEA and the Privacy Act, some of the routine uses permitted under the Privacy Act would no longer be allowed because they are not for statistical purposes.

Agencies Authorized To Designate Agents

One commenter cited Footnote 31 on page 11 of the proposed guidance³ that tells agencies that they should consult with OMB regarding use of agents and stated that the use of agents should be subject to public notice and comment. In this footnote, OMB was referring specifically to the review and legal interpretation of a nonstatistical agency's statute and whether that would meet the requirements of CIPSEA and permit the agency to designate agents under CIPSEA. Generally, legal analysis and interpretation are accomplished by the agency. However, when agencies are applying a new statute that OMB has responsibility for, agencies should consult with OMB to ensure a government-wide perspective.

Commenters also had questions about other specific matters that will be addressed during implementation.

II. Requirements for Agencies Collecting or Acquiring Information Protected Under CIPSEA

Non-CIPSEA Pledges

One commenter objected to agencies being restricted from using both the terms "confidential" and "statistical purposes" together if CIPSEA did not cover the collection. The commenter noted that these terms have meaning independent of CIPSEA and agencies should be able to use them as they see fit. The commenter suggested that "Rather than prohibit the use of the terms 'confidential' and 'exclusively statistical purposes,' we suggest that OMB advise agencies, as it has in prior guidance, to ensure that they do not use terms that are confusing. OMB could also prohibit the mention of CIPSEA when it is not applicable and require that agencies invoke coverage by CIPSEA only by the mention of that law directly to survey respondents."

³ This footnote appears as footnote 40 in this final document.

OMB agrees that the terms "confidential" and "statistical purposes" have meaning independent of CIPSEA; however, when used together in a pledge to respondents, they clearly meet the requirements of CIPSEA and the protection of this law. Sec. 512 of CIPSEA simply requires that the information be "acquired by an agency under a pledge of confidentiality and for exclusively statistical purposes." The law does not require that CIPSEA be mentioned explicitly, and OMB would certainly prohibit an agency from mentioning the law if it did not apply. It would clearly be confusing to respondents for different protections to be implied by two different agencies both pledging that the information would be confidential and used for exclusively statistical purposes. Thus, it is necessary to ensure that CIPSEA protections or greater protections apply when an agency makes this pledge to respondents.

CIPSEA Pledges

One commenter supported the shorter version of the pledge, but expressed concerns about its comprehensibility. The commenter then suggested that OMB consider developing a formal statistical confidentiality seal that would provide an identifiable marker that would tell individuals what level of protection the information they provide will receive under the law. Specifically the commenter suggested as an example that OMB consider a green-yellow-red color scheme: Green would mean respond with confidence because answers receive the highest level of legal confidentiality protection; yellow would mean respond with caution because answers receive some confidentiality protection but less than the highest level of legal protection; and red would mean no legal confidentiality protections at all.

The CIPSEA pledge was based on a pledge that was thoroughly tested; however, OMB has encouraged further cognitive testing of this pledge by agencies. OMB agrees that it would also be helpful to have more testing on a shortened version. OMB also appreciates the commenter's suggestions regarding potential "seals" that would be easy for respondents to understand and recognize, and agrees that this idea is worthy of further investigation and testing. We also agree that this will require a considerable amount of research not only to develop a recognizable seal but also to figure out appropriate ways to present it in different modes. If this research proves fruitful, OMB will consider revising this

implementation guidance and/or issuing other guidance for use of a seal.

III. Minimum Standards for Safeguarding Confidential Information Acquired Under CIPSEA

Costs and Burden of Security Requirements

One commenter noted that during a time of reduced funding resources the implementation requirements call for annual recertification of employees, increased physical and information security, additional record keeping requirements, and additional staff time (to ensure that appropriate confidentiality and security protocols are followed). Providing appropriate security for agency information and information systems does require resources. As with any ongoing program, agencies need to incorporate into their budgets the costs for protecting confidential information throughout the lifecycle of the statistical activities.

Security of Confidential Information in Laptop Computers

One commenter noted that "recent events have highlighted the particular vulnerability of laptop computers to loss and theft," and suggested that additional information be included in the guidance about the security of laptops, PDAs, or other types of devices. OMB agrees with the comment and has modified language in the section on physical and information systems security in Part III. B, which also applies to Part IV. D of the proposed guidance referenced on page 22, so that it now reads:

Agencies are required to establish appropriate administrative and technical safeguards to ensure that the security of all media containing confidential information is protected against unauthorized disclosures and anticipated threats or hazards to their security or integrity. For example, agencies must ensure that security requirements are followed for reports, documents, printouts, information collection instruments, laptops, PDA's, zip drives, floppy disks, CD-ROMs, or any other IT devices that contain confidential information to prevent access by unauthorized persons.

VII. Data Sharing Under Subtitle B of CIPSEA

Data Linking and Data Sharing

One comment requested that OMB include administrative data as well as other agencies under the data sharing provisions of Subtitle B of CIPSEA to further improve efficiency. OMB notes that Subtitle B is limited in statute to the three designated statistical agencies (BLS, BEA, and Census) and applies

only to business data. While OMB appreciates the potential benefits suggested in this comment, CIPSEA does not authorize any other data sharing or authorize additional agencies to share data. However, CIPSEA did not alter other existing authorities for data sharing among Federal agencies.

VIII. Annual Reporting and Review Requirements

Annual Reports to OMB

One commenter requested that the annual reports that agencies provide to OMB be made public and posted on agency Web sites. In the interest of transparency, agencies will now be required to post their reports on their Web sites.

Susan E. Dudley,

Administrator, Office of Information and Regulatory Affairs.

Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)

I. Introduction

A. Overview

Issues of privacy and confidentiality are of increasing concern to respondents to Federal government surveys. Agencies often seek to assuage these concerns by pledging to respondents that the agency will protect the information that respondents provide, and by using whatever statutory authority that the agency has to substantiate this pledge. However, many agencies do not have strong confidentiality provisions in their authorizing statutes. In this case, agencies may be able to use government-wide statutes such as the Privacy Act or exemptions under the Freedom of Information Act as the basis for a pledge to respondents, but these statutes still do not apply to many Federal surveys.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) is a new government-wide law that can provide strong confidentiality protections to many Federal agencies conducting statistical information collections, such as surveys and censuses as well as other statistical activities including data analysis and modeling, sample design, etc. The purpose of this guidance is to inform agencies about the requirements for using CIPSEA and clarify the circumstances under which CIPSEA can be used.

There are several key definitions and distinctions in CIPSEA regarding statistical and nonstatistical agencies, and statistical and nonstatistical

purposes, that affect whether CIPSEA can be used by an agency to acquire and protect information. Below is a brief description of these major definitions and distinctions, as well as of issues related to data sharing under CIPSEA, and additional requirements for using CIPSEA that are addressed in greater detail in this guidance.

1. *Is the agency a statistical or nonstatistical agency?* CIPSEA distinguishes between statistical and nonstatistical agencies or units and imposes different requirements and privileges on these different types of agencies. Briefly, statistical agencies or units are those whose activities are predominantly the collection, compilation, processing, or analysis of information for statistical purposes. More detail and a listing of statistical agencies and units is provided in section I., part G of this section of the guidance.

2. *Is the information used for statistical or nonstatistical purposes?* CIPSEA provides protection for information acquired for statistical purposes under a pledge of confidentiality. Under CIPSEA, a statistical purpose includes the description, estimation, or analysis of the characteristics of groups, without identifying the individuals or organizations that comprise such groups, while nonstatistical purposes include any administrative, regulatory, law enforcement, adjudicatory, or other purpose that affects the rights, privileges, or benefits of a particular respondent. Information acquired and protected under CIPSEA may only be used for statistical purposes.

3. *Is the information being acquired by the Federal agency itself?* Agencies acquire information in different ways from a wide variety of respondents. Agencies often acquire information directly from a respondent to a Federal survey. In some cases, these respondents are local or State governments that have themselves collected the information from a respondent. Any agency that directly acquires information from a respondent, including a local or State government, under a pledge of confidentiality for exclusively statistical purposes, is bound by CIPSEA. However, CIPSEA does not restrict or diminish confidentiality protections in law that otherwise apply to a collection of statistical data or information. Agencies protecting information under CIPSEA must follow the requirements specified in section II of this guidance and include an appropriate pledge to respondents. All agencies that have information protected under CIPSEA

must also follow the procedures in section III for safeguarding the security of this information.

4. *Is the information being acquired for the Federal agency by contractors or others acting on behalf of the agency?* Many agencies acquiring information from respondents do not directly collect the information themselves from respondents but do so through intermediaries such as contractors or researchers who are operating under cooperative agreements or grants at the direction of the agency. CIPSEA defines contractors and their employees, researchers, and employees of private organizations or institutions of higher learning who have a contract or agreement with a Federal agency as "agents" and authorizes only some agencies to use agents to acquire information that will be protected under CIPSEA or access CIPSEA-protected information.

5. *How can statistical agencies use CIPSEA?* Statistical agencies or units that directly acquire information from respondents, including State and local governments, may protect the confidentiality of that information under CIPSEA. Statistical agencies or units may also designate agents to acquire information for the agency under CIPSEA as well as perform other exclusively statistical activities for the agency on CIPSEA-protected information. Statistical activities include the collection, compilation, processing, or analysis of data for the purposes of describing or making estimates concerning the whole, or relevant groups or components within, the economy, society, or the natural environment. Statistical activities also include the development of methods or resources that support these activities, such as measurement methods, models, statistical classifications, or sampling frames. More information is provided in section IV about the requirements for statistical agencies designating agents under CIPSEA.

6. *How can nonstatistical agencies use CIPSEA?* Nonstatistical agencies can use CIPSEA to protect information they are authorized to acquire directly themselves from respondents, including State and local governments. However, nonstatistical agencies or units are not permitted to designate agents under CIPSEA. Therefore, nonstatistical agencies or units may not protect information under CIPSEA if they are using a contractor or other persons who fall under the CIPSEA definition of agents to acquire that information unless they have the authority to designate agents to collect information or perform other statistical activities

under some other statute. More information on how nonstatistical agencies can acquire and protect information under CIPSEA is provided in section VI of this guidance.

7. *What if a statistical agency acquires information for nonstatistical purposes?* OMB expects that the vast majority of information collections conducted by statistical agencies or units will be subject to CIPSEA because these agencies generally collect information for exclusively statistical purposes and pledge confidentiality. Statistical agencies or units that are collecting information that may be used for nonstatistical purposes need to ensure that respondents understand these nonstatistical uses and that CIPSEA does not apply to the specific collection. Requirements for statistical agencies collecting information that may be used for nonstatistical purposes are covered in section V.

8. *What data sharing does CIPSEA authorize?* Subtitle B of CIPSEA explicitly provides the ability for three designated statistical agencies, the Bureau of Economic Analysis, the Bureau of Labor Statistics, and the Bureau of the Census to share business data. Requirements for data sharing among these designated statistical agencies are outlined in section VII.

9. *What other requirements are there for using CIPSEA?* Agencies should carefully review this guidance to determine whether CIPSEA applies to any of their information collections or statistical activities. Agencies using CIPSEA are responsible for following all requirements in this guidance. In addition, OMB is requiring agencies that use CIPSEA to report annually to OMB on their use of this law in order to effectively monitor the implementation of CIPSEA across Federal agencies. All agencies that use CIPSEA for their collections are asked to report to OMB annually the information collections CIPSEA applies to and affirm that all of the requirements in this guidance are being met. Statistical agencies protecting information under CIPSEA are further required to report on their use of agents, and the three designated statistical agencies in Subtitle B of CIPSEA are required to report annually on their data sharing activities under CIPSEA. Further information on the reporting requirements is in section VIII of this guidance.

B. Purposes of CIPSEA

The Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), Title V of the E-Government Act of 2002 (Pub. L. 107-347), has two subtitles.

Subtitle A, Confidential Information Protection, concerns confidentiality and statistical uses of information. The purposes of Subtitle A are:

1. To ensure that information supplied by individuals or organizations to an agency for statistical purposes under a pledge of confidentiality is used exclusively for statistical purposes;
2. To ensure that individuals or organizations who supply information under a pledge of confidentiality to agencies for statistical purposes will neither have that information disclosed in identifiable form to anyone not authorized by this title nor have that information used for any purpose other than a statistical purpose; and
3. To safeguard the confidentiality of individually identifiable information acquired under a pledge of confidentiality for statistical purposes by controlling access to, and uses made of, such information.⁴

CIPSEA Subtitle A protects information that is acquired for exclusively statistical purposes under a pledge of confidentiality. This subtitle of the law applies to all Federal agencies that acquire information under these carefully prescribed conditions. The protection of information collected under this law is supported by a penalty of a Class E Felony for a knowing and willful disclosure of confidential information. This includes imprisonment for up to five years and fines up to \$250,000.⁵ Thus, for many agencies this law strengthens the protections afforded to confidential statistical information.

CIPSEA Subtitle B promotes statistical efficiency through limited sharing of business data among three designated statistical agencies, the Bureau of the Census (Census), the Bureau of Economic Analysis (BEA), and the Bureau of Labor Statistics (BLS). The purposes of Subtitle B are:

1. To authorize the sharing of business data among Census, BEA, and BLS for exclusively statistical purposes;
2. To reduce the paperwork burdens imposed on businesses that provide requested information to the Federal Government;
3. To improve the comparability and accuracy of Federal economic statistics by allowing Census, BEA, and BLS to update sample frames, develop consistent classifications of establishments and companies into industries, improve coverage, and reconcile significant differences in data produced by the three agencies; and

⁴ Sec. 511(b).

⁵ Sec. 513.

4. To increase understanding of the United States economy, especially for key industry and regional statistics, to develop more accurate measures of the impact of technology on productivity growth, and to enhance the reliability of the Nation's most important economic indicators, such as the National Income and Product Accounts.⁶

The remainder of this section of the guidance provides background information on CIPSEA and its applicability to Federal agencies. Sections II through VI provide implementation guidance on CIPSEA Subtitle A, and Section VII provides implementation guidance on Subtitle B. Section VIII covers agency reporting requirements to OMB on the implementation of CIPSEA.

C. Background

There are more than 70 Federal agencies or organizational units that carry out statistical activities as their principal mission or in conjunction with other program missions, such as providing services or enforcing regulations.⁷ In addition to these 70 agencies, many other Federal agencies or units may collect statistical information to use for specific program needs. Prior to the enactment of CIPSEA, a patchwork of legislative protections governed the confidentiality of data gathered for statistical purposes by the different agencies and units. Some agencies had strong statutory authority to protect the confidentiality of the data they gathered for statistical purposes, while other agencies had weak or no legislative authority to protect confidentiality. In addition, the ability of the designated statistical agencies to share information to improve the efficiency of the Federal statistical system was limited by statutory constraints affecting those agencies.

Over the years, there have been numerous attempts both to shore up legal protection for the confidentiality of statistical information, and to permit some limited sharing of data for statistical purposes. Strengthening and standardizing statutory protections for the confidentiality of individually identifiable data that are collected for statistical purposes as well as enhancing the capability of Federal agencies to share information for exclusively statistical purposes have always been goals.

In 1971, the President's Commission on Federal Statistics recommended that the term *confidential* should always mean that disclosure of data in a manner that would allow public identification of the respondent or would in any way be harmful to him should be prohibited. In addition, the Commission recommended that a promise to hold data in confidence should not be made unless the agency has legal authority to uphold such a promise, and that legislation should be enacted authorizing agencies collecting data for statistical purposes to promise confidentiality as the term was defined by the Commission.⁸

In July 1977, the Privacy Protection Study Commission stated that "no record or information * * * collected or maintained for a research or statistical purpose under Federal authority * * * may be used in individually identifiable form to make any decision or take any action directly affecting the individual to whom the record pertains * * *"⁹

In October 1977, the President's Commission on Federal Paperwork endorsed the confidentiality and "functional separation" concepts, but applied them directly and simply to statistical programs, saying that:

- Information collected or maintained for statistical purposes must never be used for administrative or regulatory purposes or disclosed in identifiable form, except to another statistical agency with assurances that it will be used solely for statistical purposes; and
- Information collected for administrative and regulatory purposes must be made available for statistical use, with appropriate confidentiality and security safeguards, when assurances are given that the information will be used solely for statistical purposes.¹⁰

The policy discussions generated by the three Commissions came together in a bipartisan outpouring of support for the Paperwork Reduction Act of 1980, which largely addressed the efficiency recommendations of the Paperwork Commission. The legislative history of that Act recognized the unfinished work of fitting the "functional separation" of statistical information into the overall scheme.

In 1993, a National Academy of Sciences panel on confidentiality and data access recommended that "Statistical records across all federal

agencies should be governed by a consistent set of statutes and regulations meeting standards for the maintenance of such records, including the following features of fair statistical information practices: (a) A definition of statistical data that incorporates the principle of functional separation as defined by the Privacy Protection Study Commission, (b) a guarantee of confidentiality for data, * * * (g) legal sanctions for those who violate confidentiality requirements."¹¹

To clarify and make consistent government policy protecting the privacy and confidentiality interests of individuals and organizations who furnish data for Federal statistical programs, OMB issued an "Order Providing for the Confidentiality of Statistical Information" in June 1997.¹² This order applied the principles of functional separation and protection of confidential information gathered for statistical purposes to twelve principal statistical agencies.

CIPSEA builds upon these and other efforts of the Executive and Legislative branches including H.R. 2885 (the Statistical Efficiency Act of 1999, originally offered by Representative Stephen Horn, and unanimously passed by the House of Representatives) and H.R. 2136 (the Confidential Information Protection Act, originally offered by Representative Tom Sawyer in 2001). Introducing CIPSEA, H.R. 5215, on July 25, 2002, Representative Horn indicated,

"The bill's enhanced confidentiality protections will improve the quality of Federal statistics by encouraging greater cooperation on the part of respondents. Even more important, these protections ensure that the Federal Government does not abuse the trust of those who provide data to it under a pledge of confidentiality. * * * the Confidential Information Protection and Statistical Efficiency Act of 2002 makes important, common sense and long overdue improvements in our Nation's statistical programs. It is a bipartisan, good Government measure that has the Administration's strong support. I urge my colleagues to join with us to achieve prompt enactment of the bill."¹³

In this guidance, OMB is establishing a uniform policy for all Federal statistical collections to reduce public confusion, uncertainty, and concern about the application of the newly-enacted confidentiality requirements associated with protected statistical information acquired by different Federal agencies. By establishing consistent rational principles and

⁸ *Federal Statistics—Report of the President's Commission*, Volume 1, p. 222, September, 1971.

⁹ *Personal Privacy in an Information Society—Report of the Privacy Protection Study Commission*, p. 574, July, 1977.

¹⁰ *Statistics—A Report of the Commission on Federal Paperwork*, p. 128, October, 1977.

¹¹ *Private Lives and Public Policies*, 1993, National Academy Press, Washington, DC.

¹² 62 FR 35,044–35,050.

¹³ *Congressional Record*, July 25, 2002, p. E1397.

⁶ Sec. 521(b).

⁷ *Statistical Programs of the U.S. Government FY 2007*, Office of Management and Budget, Washington, DC.

processes to buttress confidentiality pledges, the law codifies confidentiality claims and sets minimum standards for safeguarding confidential statistical information. Establishing consistent protection of confidential statistical information will, in turn, reduce the perceived risks of more efficient working relationships among statistical agencies, relationships that can reduce both the cost and reporting burden imposed by statistical programs.

D. Authority

The Paperwork Reduction Act (PRA) of 1980 (as amended in 1986 and 1995) requires the Office of Information and Regulatory Affairs (OIRA) within OMB to develop policies, principles, standards, and guidelines for privacy and confidentiality generally; the integrity of confidentiality pledges; and the confidentiality of information collected for statistical purposes.¹⁴ In addition, the Act tasks OIRA to oversee agency compliance with related requirements of the Act and with the policies referenced above.¹⁵ For example, agencies are required to "inform respondents fully and accurately about the sponsors, purposes, and uses of statistical surveys and studies."¹⁶

With respect to statistical policy and coordination, the PRA directs OMB to:

- Coordinate the activities of the Federal statistical system to ensure—
 - The efficiency and effectiveness of the system; and
 - The integrity, objectivity, impartiality, utility, and confidentiality of information collected for statistical purposes; * * *
- Develop and oversee the implementation of Governmentwide policies, principles, standards, and guidelines * * *
- Promote the sharing of information collected for statistical purposes consistent with privacy rights and confidentiality pledges;¹⁷

In addition, Title V of the E-Government Act of 2002 authorizes the Director of the Office of Management and Budget to coordinate and oversee the confidentiality and disclosure policies established by CIPSEA. The Director is authorized to promulgate rules or provide other guidance to ensure the consistent interpretation of this title by the affected agencies.¹⁸

E. Affected Agencies

Executive agencies as defined in 31 U.S.C. 102 or 44 U.S.C. 3502¹⁹ are subject to the provisions and penalties in CIPSEA Subtitle A if they (1) Acquire information for exclusively statistical purposes under a pledge of confidentiality, or (2) they possess or access information protected by CIPSEA, unless even stronger confidentiality protections apply.²⁰ CIPSEA also imposes additional requirements on statistical agencies or units, which are defined to include "an agency or organizational unit of the executive branch whose activities are predominantly the collection, compilation, processing, or analysis of information for statistical purposes."²¹ CIPSEA Subtitle B applies only to the designated statistical agencies, i.e., the Bureau of the Census of the Department of Commerce, the Bureau of Economic Analysis of the Department of Commerce, and the Bureau of Labor Statistics of the Department of Labor.²²

F. Applicability of CIPSEA

Federal agencies collect and acquire information for a wide variety of purposes and uses, including benefit determinations, program planning and management, program evaluation, measurement of compliance with laws and regulations, and research, as well as for general purpose statistics. When acquiring information, an agency must inform the person or organization being asked to provide information whether or not it will be treated as confidential and the purpose(s) for which the information will be used.²³

CIPSEA protection applies to any identifiable information acquired by the agency under a pledge of confidentiality for exclusively statistical purposes. For purposes of CIPSEA, this information includes personally identifiable information²⁴ as well as information that permits the identity of any respondent, such as business establishments, institutions, or State or

local governments,²⁵ to be reasonably inferred by either direct or indirect means.²⁶ In this guidance, the terms confidential information and confidential data refer to information that is protected by CIPSEA.

CIPSEA can apply only when an agency pledges both to protect the confidentiality of the information it acquires and to use the information only for statistical purposes. CIPSEA defines a statistical purpose to include the description, estimation, or analysis of the characteristics of groups, without identifying the individuals or organizations that comprise such groups and includes the development, implementation, or maintenance of methods, technical or administrative procedures, or information resources that support the above purposes.²⁷ If information is collected or acquired for any nonstatistical purpose, then CIPSEA shall not be used to protect the confidentiality of the information.²⁸

A nonstatistical purpose means the use of information in identifiable form for anything other than a statistical

²⁵ Statistical agencies may collect information from a State or local government that is in the public domain, and, therefore, the statistical agency would typically not pledge to keep that information confidential under CIPSEA or other legal authorities.

²⁶ Sec. 502(4). Indirect identification refers to using information in conjunction with other data elements to reasonably infer the identity of a respondent. For example, data elements such as a combination of gender, race, date of birth, geographic indicators, or other descriptors may be used to identify an individual respondent.

²⁷ Sec. 502(9).

²⁸ There are some authorized, nonstatistical uses of information collected for statistical purposes, such as the use of Decennial Census information for genealogical research, that are noted in Section 504 of CIPSEA. CIPSEA was intended to apply to these collections that are intended for statistical purposes and have only very narrow exceptions for specific nonstatistical uses that do not result in any actions directly affecting the respondent. Agencies acquiring or protecting information under CIPSEA with similar nonstatistical uses of the information should consult with OMB on the applicability of CIPSEA for the information collection. Unless there is a specific exception noted in Section 504 of CIPSEA, CIPSEA clearly prohibits disclosures for administrative, regulatory, law enforcement, or adjudicatory purposes that affect the rights, privileges, or benefits of a particular identifiable respondent absent informed consent. Since some State or Federal laws may require notification of authorities if, for example, child abuse is reported by the respondent, agencies collecting such information shall inform respondents at the time of collection that revelations of this type of information must be reported to legal authorities. Agencies may conduct these collections under CIPSEA if any such nonstatistical uses are clearly described in advance to the respondent (with the respondent providing informed consent), and these procedures are clearly stated in the notices and supporting materials described in Section II. Agencies should also consult with their institutional review boards to determine circumstances when informed consent is appropriate or necessary.

¹⁹ Sec. 502(1).

²⁰ Sec. 512(a) and 512(b). Agencies may also be governed by other statutes that may have additional restrictions on the use and disclosure of confidential statistical information that apply beyond CIPSEA (Sec. 504(h); Sec. 512(b)(3)).

²¹ Sec. 502(8).

²² Sec. 522.

²³ 5 CFR 1320.8(b)(3).

²⁴ The term "personally identifiable information" refers to information that can be used to distinguish or trace an individual's identity, such as his or her name, social security number, biometric records, etc., alone, or when combined with other personal or identifying information that is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc.

¹⁴ 44 U.S.C. 3504(e)(1), 3504(e)(5), and 3504(g)(1).

¹⁵ 44 U.S.C. 3506(b)(1)(C), 3506(e)(2)–(4), and 3506(g)(1).

¹⁶ 44 U.S.C. 3506(e)(2).

¹⁷ 44 U.S.C. 3504(e).

¹⁸ Sec. 503(a).

purpose, including any administrative, regulatory, law enforcement, adjudicative, or other purpose that affects the rights, privileges or benefits of a particular identifiable respondent. Providing confidential information in response to a Freedom of Information Act (FOIA) request is also considered a nonstatistical purpose.²⁹ Since the CIPSEA statute is a (b)(3) statute under FOIA, confidential information covered under CIPSEA is exempt from release pursuant to a FOIA request (5 U.S.C. 552(b)(3)).

Agencies acquire information in different ways from a wide variety of respondents. An agency may collect information directly (e.g., surveys) from individuals, households, businesses, organizations, or institutions, or the agency may acquire information through secondary sources (e.g., from State government agencies).³⁰ This guidance, in accordance with the law, will use as the more general term, "acquire," to include both agency collections of information directly from respondents, and acquisitions of information from secondary sources.

In many cases, agencies acquire information directly from respondents (including local or State governments) to a Federal survey; in other cases, agencies do not themselves directly acquire information from respondents but do so through intermediaries, such as contractors or researchers who are operating under cooperative agreements or grants at the direction of the agency. CIPSEA defines contractors and their employees, researchers, and employees of private organizations or institutions of higher learning that have a contract or agreement with a Federal agency as "agents."³¹

Any agency that directly acquires information from a respondent, including a local or State government, under a pledge of confidentiality for exclusively statistical purposes, can use CIPSEA to protect the information. However, if an agency is using an agent, such as a contractor, to acquire information for exclusively statistical purposes, the agency may not be able to protect the information under CIPSEA unless it is a statistical agency (see part G). In these situations, nonstatistical agencies should use their existing statutory authority to protect the confidentiality of this information.

Generally, the applicable statute with the strongest confidentiality protections for the information governs the use and disclosure of the information. CIPSEA

does not restrict or diminish any other confidentiality protections or penalties for unauthorized disclosure that an agency may otherwise have for information collected for statistical purposes.³² Accordingly, if an agency has any stronger protections in its statutes, these protections would remain in effect. For example, the more restrictive use and disclosure provisions of the Census Act and the International Investment and Trade in Services Survey Act would take precedence over the broader statistical uses permitted under CIPSEA. In another example, if an agency's authorizing statute prohibited disclosure with informed consent, the agency would not be able to disclose the information with informed consent, which could be permissible under CIPSEA under certain circumstances.³³

On the other hand, if an agency pledges to use the information for only statistical purposes, then the agency shall not use any other authorities it has available to use the information for nonstatistical purposes, because those uses would be contrary to the agency's pledge. For example, if information is protected by CIPSEA and the Privacy Act, some of the routine uses permitted under the Privacy Act would no longer be allowed because they are not for statistical purposes.

G. Use of CIPSEA by Statistical and Nonstatistical Agencies or Units

Although any Federal agency can acquire and protect information under CIPSEA, CIPSEA provides additional authority and imposes additional requirements on statistical agencies or units. These additional provisions have implications for how and whether an agency can use CIPSEA to acquire information; these provisions are discussed in later sections of this guidance.

CIPSEA defines a statistical agency or unit as "an agency or organizational unit of the executive branch whose activities are predominantly the collection, compilation, processing, or analysis of information for statistical purposes."³⁴

OMB shall determine whether an agency or unit can be considered a statistical agency or unit for purposes of CIPSEA.

OMB recognized 12 statistical agencies or units in its 1997

Confidentiality Order:³⁵

- Department of Agriculture
- Economic Research Service

- National Agricultural Statistics Service

- Department of Commerce
- Bureau of Economic Analysis
- Census Bureau

- Department of Education
- National Center for Education

Statistics

- Department of Energy
- Energy Information Administration
- Department of Health and Human

Services

- National Center for Health Statistics
- Department of Justice
- Bureau of Justice Statistics
- Department of Labor
- Bureau of Labor Statistics
- Department of Transportation
- Bureau of Transportation Statistics
- Department of the Treasury
- Statistics of Income Division of the

Internal Revenue Service

- National Science Foundation
- Division of Science Resources

Statistics

Since this guidance was issued in proposed form in October 2006, OMB has recognized two statistical organizational units: the Office of Applied Studies within the Substance Abuse and Mental Health Services Administration in the Department of Health and Human Services, and the Microeconomic Surveys Unit of the Board of Governors of the Federal Reserve. Other agencies or units that wish to be recognized as statistical agencies or units for purposes of CIPSEA must send a request to the Chief Statistician at OMB. The request must come from the head of the agency or unit and have the concurrence of the larger organization within which the agency or unit resides. This request should include a statement of the organizational definition of the agency or unit, its mission, statistical activities, and any nonstatistical activities, and demonstrate that its activities are predominantly statistical. Statistical activities include the collection, compilation, processing, or analysis of data for the purpose of describing the characteristics of groups or making estimates concerning the whole or relevant groups, or components within, the economy, society, or the natural environment. Statistical activities also include the development of methods or resources that support these activities, such as measurement methods, models, statistical classifications, or sampling frames. A listing of OMB recognized statistical agencies and units will be posted and maintained on OMB's Web site.

Both statistical and nonstatistical agencies can use CIPSEA to protect information they acquire directly from

²⁹ Sec. 502(5)(B).

³⁰ Sec. 502(6).

³¹ Sec. 502(2).

³² Sec. 504(h); Sec. 512(b)(3).

³³ Sec. 512(b).

³⁴ Sec. 502(8).

³⁵ 62 FR 35,044–35,050.

respondents, including State and local governments. However, only statistical agencies or units are authorized under CIPSEA to designate agents to perform exclusively statistical activities, which include data collection, subject to CIPSEA limitations and penalties.³⁶ Because data collection contractors are agents under CIPSEA,³⁷ only statistical agencies may designate contractors to acquire information that will be protected under CIPSEA. In order for the collections of nonstatistical agencies to fall within the protections of CIPSEA, nonstatistical agencies must acquire the information themselves directly from respondents. Nonstatistical agencies cannot empower contractors or other agents to acquire information or carry out any other statistical activities for the agency under CIPSEA.³⁸

The following sections II and III of this guidance describe in detail the requirements for all agencies using CIPSEA. Additional requirements for statistical agencies or units designating agents are covered in section IV. Because it is generally expected that statistical agencies or organizational units will be collecting information for exclusively statistical purposes under a pledge of confidentiality, statistical agencies or units that conduct or sponsor a collection that will not be for exclusively statistical purposes must follow additional requirements as described in section V. Additional requirements for nonstatistical agencies or units are provided in section VI.

II. Requirements for Agencies Collecting or Acquiring Information Protected Under CIPSEA

CIPSEA provides strong protection for information obtained for exclusively statistical purposes under a pledge of confidentiality. For CIPSEA to have its intended effect of reinforcing public confidence in Federal confidentiality pledges, all Federal agencies that make the CIPSEA pledge must provide CIPSEA protection to that information. A Federal agency should not make a CIPSEA pledge unless the agency is fully committed to taking all the actions that are necessary to provide CIPSEA

level protection; making the CIPSEA pledge means giving CIPSEA level protection to the collected information.

To faithfully maintain this commitment requires that agencies meet a number of minimum requirements that are described in detail in the remainder of this guidance. Specifically, agencies must:

- Inform the respondents about the confidentiality protection and use of the information (section II.);
- Collect and handle confidential information to minimize risk of disclosure, including properly training employees (section III.);
- Ensure the information is used only for statistical purposes (section III. A.);
- Review information to be disseminated to prevent identifiable information from being reasonably inferred by either direct or indirect means (section III. F.); and
- Supervise and control agents who have access to confidential information (section IV.).

A. Requirements for Public Notice Prior to Data Collection

Agencies are required under the PRA to:

- Publish a notice in the **Federal Register** allowing 60 days for the public to comment on information collections and otherwise consult with members of the public and affected agencies concerning each proposed collection of information;³⁹
- Publish a notice in the **Federal Register** at the time OMB approval is being sought, and allow the public 30 days to comment; and
- "Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy" in their PRA supporting statements submitted to OMB.⁴⁰

When agencies are acquiring information that will be protected under CIPSEA, they shall:⁴¹

³⁹ 5 CFR 1320.8(d)(1).

⁴⁰ Instructions for Supporting Statement for Paperwork Reduction Act submissions and 5 CFR 1320.8(b)(3).

⁴¹ Agencies conducting an OMB-approved information collection prior to passage of CIPSEA or issuance of this guidance, such as a periodic or longitudinal survey, can also protect that collection under CIPSEA if the collection is intended for exclusively statistical purposes, the agency pledges confidentiality, and the agency will follow this guidance in implementing CIPSEA. In this case, the agency should consult with OMB about the change in confidentiality protection for the collection and plan appropriate consultation with stakeholders and respondents. OMB may require agencies to provide **Federal Register** notices concerning the change in policy and to contact respondents for comments before the agency can make a CIPSEA pledge.

- State that the information will be protected under CIPSEA, and cite any other authority they have to protect the confidentiality of the data in their PRA supporting statements; and

- State in their **Federal Register** notices if there is a substantive change in the confidentiality protection of the information being collected, such as using CIPSEA to protect the information for an ongoing collection when similar protection was not available previously.

B. Requirements for Informing Respondents at the Time of Information Collection

At the time of the information collection, agencies are required under the PRA to adequately inform potential respondents about the uses of the information they provide.⁴² This description must include the following information related to the confidentiality of their responses:

- The reasons the information is planned to be and/or has been collected;
- The way such information is planned to be and/or has been used to further the proper performance of the functions of the agency; and
- The nature and extent of confidentiality protection to be provided, if any.⁴³

When agencies are collecting information that they want to be protected under CIPSEA, they are required by law at the time of collection to do the following:⁴⁴

- Pledge to keep the data or information confidential, and
- Pledge that the information will be used for exclusively statistical purposes.

Agencies that are not protecting information under CIPSEA must ensure that the public is able to distinguish easily between pledges that reflect the protections provided by CIPSEA and those affording less protection than CIPSEA. In particular, the pledge for collections not protected to the extent afforded by CIPSEA shall not contain all the elements related to CIPSEA found in the pledges below—specifically, the pledge shall not state both that the data are confidential and that they are for exclusively statistical use (in such cases CIPSEA would apply even if not stated).⁴⁵ The degree to which the

⁴² 5 CFR 1320.8(b)(3); Additional requirements are imposed if the collection involves a Privacy Act system of records (5 U.S.C. 552(a)(3) as amended).

⁴³ 5 CFR 1320.8(b)(3).

⁴⁴ Sec. 512(a).

⁴⁵ As noted at the end of this subsection (and in footnote 17), CIPSEA does not restrict or diminish any other confidentiality protections or penalties for unauthorized disclosure that an agency may otherwise have for information collected for

Continued

³⁶ Sec. 512(d).

³⁷ Sec. 502(2)(iii).

³⁸ Some nonstatistical agencies may have specific statutory authority to designate agents that meets the requirements of CIPSEA, allowing the agency to use agents to perform exclusively statistical activities, including data collection, for the agency. Agencies should consult with OMB on the applicability of their statute for purposes of using CIPSEA before making plans to designate agents. Agencies should also clearly describe how their authority meets the requirements for CIPSEA designation of agents in their information collection requests to OMB.

pledge differs from the CIPSEA pledge needs to be based on the laws and regulations governing the collection and determined in collaboration with the agency legal staff, agency confidentiality officer, and PRA clearance officer. A pledge of confidentiality for collections not protected by CIPSEA must specifically cite the statutory authorization protecting the confidentiality of the data being collected and accurately describe the extent of that protection. If an agency elects to collect information under laws affording less protection than CIPSEA, OMB will not approve an agency's proposed non-CIPSEA pledge that is too similar to the CIPSEA pledge (e.g., one that includes the term 'confidential' and states that the information will be used for exclusively statistical purposes).

The following examples of confidentiality pledges under CIPSEA are sufficient to inform respondents of the protections afforded. Agencies shall use the following model and customize the wording in accordance with their needs. Parentheses indicate options and italics are instructions. Comparable pledge language may be substituted, but that alternative wording shall be included in the PRA supporting statements to OMB and should be cognitively tested. A complete confidentiality pledge shall be developed from the following:

The information (*choose one*—you, your household, your establishment—as needed) provide(s) will be used for statistical purposes only. In accordance with the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107-347 (*option to add or substitute laws that are stronger or more restrictive than CIPSEA*) and other applicable Federal laws (*option to list them, but it is not necessary to be exhaustive*), your responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees (*option to add "or agents" if applicable, or another term the agency uses*) (*option to add—without your consent*).⁴⁶ By law, every (your agency here) employee (*optional—including the Director*), (if applicable, *option to add "as well as every agent such as then list as appropriate—contractors, field representatives,*

telephone interviewers, authorized researchers,⁴⁷ etc."⁴⁸), (*optional—has taken an oath and*) is subject to a jail term (*optional—of up to 5 years*), a fine (*optional—of up to \$250,000*), or both if he or she willfully discloses ANY identifiable information about (*choose one*—you, your household, your establishment).

The above pledge may be placed on the survey instrument (e.g., form), in the instructions, or on the back side of the cover letter. A shorter, more user-friendly version may be used in introductory statements, on the cover of the instrument, or in the body of the cover letter as long as there is a reference to the full pledge. In addition, the agency may place the full pledge on the agency's web site and point respondents to that site.

To illustrate the actual pledge wording, an agency could implement this pledge as follows:

The information you provide will be used for statistical purposes only. In accordance with the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107-347 and other applicable Federal laws, your responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees or agents. By law, every ABC employee as well as every agent has taken an oath and is subject to a jail term of up to 5 years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you.

Agencies may choose to employ a shortened version of the pledge, such as the following, when conducting telephone surveys or in other similar circumstances as long as respondents are given access to the longer version in some other manner such as posting on the agency's Web site:

The information you provide about (*choose one*—yourself, household, establishment) will be used for statistical purposes only. In accordance with the Confidential Information Protection provisions in Public Law 107-347 (*option to add or other applicable Federal laws*), your responses will be kept confidential and will not be disclosed in identifiable form (*optional—without your consent*).⁴⁹ By law, everyone working on this (*your agency here*) survey is subject to a jail term, a fine, or both if he or she willfully discloses ANY information that could identify you.

⁴⁷ Agencies that plan to provide access to confidential information for statistical purposes should include mention of this in their pledge.

⁴⁸ Designated statistical agencies (as defined under CIPSEA Subtitle B) may include "employees of partner statistical agencies" for collections of confidential business information that may be used in data sharing agreements as authorized under that Subtitle.

⁴⁹ Use "without your consent" only if consent is asked or may be in the future—omitting this phrase could create difficulties if the agency later wants to ask for consent.

Agencies whose statutory authority provides confidentiality protections more restrictive than CIPSEA for information acquired for exclusively statistical purposes under a pledge of confidentiality may use the CIPSEA pledge or their existing pledges that are similar as long as they make clear what confidentiality protections cover the information and the statutory authority for those protections. In such cases, the resemblance of an agency's pledge to the CIPSEA pledge does not imply that any provisions in CIPSEA would overrule the agency's stronger confidentiality statute. CIPSEA does not restrict or diminish any other confidentiality protections or penalties for unauthorized disclosure that an agency may otherwise have for information collected for statistical purposes, and any stronger protections would remain in effect.⁵⁰

III. Minimum Standards for Safeguarding Confidential Information Acquired Under CIPSEA

These standards for safeguarding confidential information apply to information protected under CIPSEA. Federal agencies shall follow the minimum standards in this section. In addition, some best practices are provided that agencies are encouraged to adopt but are not required to implement.⁵¹

The central objective of these standards is to ensure that a Federal agency that pledges confidentiality for statistical information honors that pledge. Each Federal agency remains ultimately responsible and accountable for the confidential information that the agency acquires under a CIPSEA pledge. Any inappropriate use or disclosure of CIPSEA-protected information violates the law and can undermine public trust. Therefore, there is no "acceptable" level of non-compliance with the CIPSEA pledge.

These minimum standards have been developed according to the principle of disclosure risk, which considers both the probability of an unauthorized disclosure and the expected harm from such a disclosure. These minimum standards apply to data for which the disclosure risk has been deemed relatively low by the Federal agency responsible for the information. Federal agencies shall set higher standards as the disclosure risk increases.

At a minimum, such standards shall make clear that each person having

⁵⁰ Sec. 504(h); Sec. 512(b)(3).

⁵¹ Best practices that agencies are encouraged but not required to implement are designated as items that agencies "may" do, while requirements are noted as items that agencies "shall" do.

statistical purposes, and any stronger protections would remain in effect (Sec. 504(h); Sec. 512(b)(3)).

⁴⁶ Use the phrase "without your consent" only in cases where an agency can reasonably anticipate such consent will be requested.

access to confidential information understands his/her responsibility related to maintaining the confidentiality of that information. In addition, these standards shall make clear who is accountable for each part of the information protection, including:

- Determining and monitoring procedures for collection and release;
- Evaluating the reason for accessing the information and controlling access to the information; and
- Maintaining physical and information systems security.

A. Principles and Procedures for Protecting Confidential Information

Agencies or organizational units protecting information under CIPSEA shall incorporate the costs for protecting confidential information throughout the lifecycle of the statistical activity. This will ensure that sufficient resources are available to develop and implement procedures to ensure that:

- The confidentiality of the information is protected;
- Confidential information is used exclusively for statistical purposes;
- Access to confidential information is controlled, and only authorized persons have access to the information;
- All persons having access to confidential information understand
 - The obligations of confidentiality protection,
 - That unauthorized access to confidential information is prohibited, and
 - The penalties for unauthorized access to and unauthorized use of confidential information; and
- A person or persons are designated to oversee all procedures for handling confidential information, and that such persons are responsible for all agency confidentiality procedures, reviews, and compliance with confidentiality laws.

B. Physical and Information Systems Security

Each agency shall ensure the physical security and information systems security where data protected under CIPSEA are accessed and stored.

Agencies are required to establish appropriate administrative and technical safeguards to ensure the security of all media containing confidential information is protected against unauthorized disclosures and anticipated threats or hazards to their security or integrity. For example, agencies must ensure that security requirements are followed for reports, documents, printouts, information collection instruments, laptops, PDA's, zip drives, floppy disks, CD-ROMs, or any other IT devices that contain

confidential information to prevent access by unauthorized persons. Agencies must also ensure that only persons authorized by the head of the statistical agency or unit are permitted access to confidential information stored in information systems.

Agencies are required to assess and secure their information and information systems in accord with the Federal Information Security Management Act (FISMA) which appears as Title III of the E-Government Act of 2002. OMB has issued guidance on implementing FISMA, and the National Institute of Standards and Technology (NIST) has issued compulsory and binding standards used to identify the level of impact and controls for maintaining the confidentiality, integrity, and availability of all information collected or maintained on behalf of an agency.⁵²

One of three security objectives for information and information systems that FISMA defines is confidentiality. The security category of an information type is determined by its potential impact on agencies should there be a breach of security, i.e., a loss of confidentiality.⁵³ Because agencies handle many different types of information, an agency should determine what the potential impact of a security breach on the agency is (including mission, function, image, and reputation), and take into account CIPSEA requirements that the information be used for exclusively statistical purposes as well as the penalties that CIPSEA imposes for disclosure.

Privacy Impact Assessments (PIAs) are also required of agencies developing or procuring information systems or projects that maintain or handle confidential information in identifiable form about members of the public, and agencies initiating new electronic collections of information in identifiable form.⁵⁴

C. Confidentiality Training

Each agency with information protected under CIPSEA shall ensure

⁵² For more information about existing security and privacy requirements, see <http://www.whitehouse.gov/omb/inforeg/infopoltech.html>. FIPS PUB 199, *Standards for Security Categorization of Federal Information and Information Systems*, Gaithersburg, MD:U.S. Department of Commerce, and related publications.

⁵³ See FIPS PUB 199, *Standards for Security Categorization of Federal Information and Information Systems*, Gaithersburg, MD:U.S. Department of Commerce; and related publications such as NIST Special Publication 800-60.

⁵⁴ See OMB Memorandum M-03-22, September 26, 2003, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*.

that all individuals having access to such confidential information have a current understanding of confidentiality rules and procedures. Confidentiality training shall include at a minimum:

- An overview of information protection procedures,
- The importance of "need to know" for an authorized purpose in accessing confidential information,
- Physical and information systems security procedures, and
- The penalties for unauthorized access, use and disclosures.

Employees who have access to confidential information shall be recertified annually to ensure their understanding of confidentiality requirements.

D. Record Keeping

Agencies shall establish and maintain a system of records⁵⁵ that identifies individuals accessing confidential information. Agencies shall also be prepared to document their compliance with the safeguard principles to OMB.⁵⁶

E. Information Collection, Processing, or Analysis Contracts

Prior to award, agencies shall review any contracts that involve CIPSEA protected information to ensure language is included that informs the contractor of the requirements of CIPSEA and of the contractor's obligations under the law and penalties for noncompliance (see Section IV).

F. Guidelines for Review of Information Prior to Dissemination

For CIPSEA protected information, the agency as well as any agent accessing the information shall ensure that any dissemination of information based on confidential information is done in a manner that preserves the confidentiality of the information. To accomplish this, agencies shall:

- Review their information products prior to public release for disclosures of confidential information, and
- Apply appropriate statistical disclosure limitation (SDL) techniques

⁵⁵ Agencies should assess for themselves the nature of these records and requirements for record keeping, including whether what an agency does for this purpose qualifies as a system of records under the Privacy Act. OMB is not implying in this guidance what form these record keeping systems should take and is leaving that determination to the agency.

⁵⁶ OMB recognizes that in some cases agencies have very detailed documentation on access to confidential information that itself is treated as confidential by the agency. In this case, it is sufficient for the agency simply to demonstrate that the basic safeguard principles are being followed; agencies should not reveal specific individuals or specific procedures that would compromise the protection of the information.

to preserve the confidentiality of the information.

For further guidance on SDL techniques, agencies can refer to practices described in *Statistical Policy Working Paper #22, Report on Statistical Disclosure Limitation Methodology*⁵⁷ and utilize other resources such as the disclosure review checklist provided by the Federal Committee on Statistical Methodology's Confidentiality and Data Access Committee.⁵⁸

Additional guidelines are provided below for handling confidential information protected under CIPSEA in conjunction with information not protected by CIPSEA.

Tabular Information

When a table includes both data protected under CIPSEA and other data not protected under CIPSEA, all data shall be treated as confidential, and identifiable respondent information shall not be present in the table.

When a table includes both data protected under CIPSEA and nonconfidential data, the agency:

- Shall apply SDL techniques to ensure protection of any table cells based on information protected under CIPSEA;
- May have a table cell that reveals nonconfidential identifiable respondent information. However, the agency shall take special care to ensure that the presentation of the nonconfidential information in no way jeopardizes confidential information.
 - If the table includes any identifiable nonconfidential respondent information, the agency shall distinguish what information is protected under CIPSEA in the accompanying text or notes to the table.
 - If the table does not include any identifiable nonconfidential respondent information, there is no need to distinguish these data from those protected under CIPSEA.
- A special case exists when a table cell value reflects a combination of CIPSEA protected data and nonconfidential data (e.g., a ratio or weighted average). In this case, these data elements are considered confidential and shall not be disseminated in a manner where any respondent could be identified.

The agency shall determine how the disclosure limitation methods used on the data affect the users and thus what information about confidentiality

protection shall be included with tabular presentation.

Microdata⁵⁹

The confidentiality provisions and limits on uses of microdata shall be completely discussed in the documentation or mentioned with a reference for details. For microdata protected under CIPSEA, SDL techniques shall be applied prior to public release.

There are two possible scenarios to consider for the dissemination of microdata in which some elements are protected under CIPSEA and other elements are not (e.g., not confidential or confidential under other laws/authorities).

- If variables protected under CIPSEA are linked to other variables that are not, the most restrictive law (in terms of promising confidentiality and limiting the use of the information) shall apply. For example:

- If an agency links data protected under CIPSEA with nonconfidential administrative data from another source and releases a linked public use microdata file, the restrictions of CIPSEA apply.

- If an agency links data protected under CIPSEA with confidential administrative data from another source (e.g., IRS data) and releases a linked public use microdata file, the most restrictive law (in terms of promising confidentiality and limiting the use of the information) shall prevail.

- If data from some respondents are protected under CIPSEA and data from other respondents are not, an agency may keep the data in separate files or combine the data sets and include a variable that tells the source for each record. Keeping the data in separate files may be the best choice because it would help highlight the difference in confidentiality provisions and limits on uses.

IV. Requirements and Guidelines for Statistical Agencies or Organizational Units When Designating Agents to Acquire or Access Confidential Information Protected Under CIPSEA

Statistical agencies or organizational units may under CIPSEA designate agents by contract or by entering into a special agreement to perform exclusively statistical activities that are subject to CIPSEA limitations and penalties.⁶⁰ To ensure that the protections of CIPSEA apply to the

information that a statistical agency or unit acquires, the agency shall follow the requirements in this section when designating agents to acquire information for the agency for exclusively statistical purposes under a pledge of confidentiality.

Because CIPSEA has a broad definition of agents, statistical agencies and organizational units may use CIPSEA to designate a variety of individuals as agents to allow them to access confidential information for exclusively statistical purposes.⁶¹ A statistical agency may designate agents to perform exclusively statistical activities, at its discretion, subject to the agency's needs, resources, and other requirements. The agency that possesses the confidential information shall ensure that all agents comply with the agency's confidentiality procedures and shall follow the requirements in this section when designating agents to access confidential information for exclusively statistical purposes.

Information protected under CIPSEA must be used only for statistical purposes. When entering into contracts or special agreements with agents to acquire or access confidential information, an agency shall consider:

- The sensitivity of the confidential information,
- The risk of disclosure, and
- The resources required to maintain supervision and control of agents.

Agencies are responsible for protecting the confidentiality of their data and may establish standards beyond those in this guidance. This section thus provides the minimum requirements as well as additional guidelines for statistical agencies or units to designate agents to perform exclusively statistical activities, including data collection.

It is important to note that neither CIPSEA nor this guidance requires any statistical agency or unit to designate agents; the decision to enter into these agreements is at the discretion of the statistical agency or unit. Therefore, an agency may decline to designate agents in accordance with its authorities or practices.⁶² If a statistical agency or unit chooses to designate agents, the agency remains responsible for all confidential information protected under CIPSEA, and statistical agencies or units should not designate agents unless the agencies

⁶¹ Sec. 512(a).

⁶² An example is the authority granted the Census Bureau under Title 13, Section 23(c) that permits the use of temporary staff to assist in the performance of work authorized by Title 13. Whereas CIPSEA puts no limits on the statistical uses made by agents, Title 13 limits the statistical uses to those that support the work of the agency.

⁵⁷ Available at <http://www.fcs.gov/reports/>.

⁵⁸ See <http://www.fcs.gov/committees/cdac/cdac.html>. Agencies may also wish to consult HIPAA standards for deidentification of protected health information at 45 CFR 164.514.

⁵⁹ Microdata are data about individual respondents (e.g., persons, households, organizations, companies, farms, etc.)

⁶⁰ Sec. 512(d).

or units are able to ensure that all CIPSEA requirements in this guidance will be met and faithfully carried out by their agents. Carrying out these responsibilities will take agency resources, and thus, will limit the extent to which a statistical agency or unit should consider designating agents.

A. Designating Agents

Under CIPSEA, a statistical agency or unit may designate as an agent⁶³ any of the following:

- An employee of a private organization or a researcher affiliated with an institution of higher learning;
- Someone who is working under the authority of a government entity;
- Someone who is a self-employed researcher, a consultant, a contractor, or an employee of a contractor; or
- Someone who is a contractor or an employee of a contractor, and who is engaged by the agency to design or maintain the systems for handling or storage of data received under this title.⁶⁴

Statistical agencies or units designating agents must do so through contracts or other agreements that require the agent to agree in writing to comply with all provisions of law that affect information acquired by that agency.⁶⁵ Any statistical agencies or units that designate agents shall exercise supervision and/or control of the agents to ensure the confidentiality and appropriate use of the information.

B. Requirements for Agents To Request Access to Confidential Information Protected Under CIPSEA

Some statistical agencies and units receive requests from outside researchers and others who wish to obtain access to confidential data for statistical purposes as agents of the statistical agency. Most agencies that receive these kinds of requests have found it useful to first obtain a written proposal from the prospective agent. Agencies may require prospective agents to submit a proposal that includes some or all of the following in order to properly evaluate the proposed access and use of their confidential data:

- A clear and detailed description of the purpose of the access;
- The specific confidential information needed;
- How the information will be used;
- Plans for disseminating information as well as the products planned for public distribution;
- A list of persons involved in the project who will have access to the information;
- A security plan (information systems and physical security) for protecting the information [applicable only for off-site access arrangements], and
- A timeframe for access.

After an agency receives the proposal and reviews it, the agency may provide comments and may request changes or may request the prospective agent to complete a written agreement (see section IV.C).⁶⁶ Agencies shall deny any proposal that does not meet the requirements described in this guidance.

Whether or not a prospective agent has submitted a proposal to an agency, access to confidential information shall not be granted until the agency has entered into a written agreement with the agent, and the agent has met the requirements contained in this guidance and in agency standards for accessing the data.

Prior to the enactment of CIPSEA, some statistical agencies and units had statutory authority to authorize agents to access confidential information. Agencies have developed a variety of mechanisms that balance permitting access to confidential data, while controlling that access. This area is evolving rapidly, and the following examples are included only as illustrations:

- *Onsite at Agency:* An external analyst works at an agency as an agent to participate in statistical activities involving confidential data. This work shall be done either in collaboration with or otherwise under the direct control and supervision of agency staff, per the terms of a written agreement. The agent's work is subject to review by the supervising staff.
- *Data Center:* An agent visits a controlled access secure facility maintained by the agency or unit to conduct analyses on confidential data held by the agency. The facility must be equipped with secure computers and staffed by agency personnel who review all outputs for the purposes of confidentiality. There may be additional

constraints on what the agent may bring to or remove from the center.

- *Off-site License Agreement:* An agent is granted access to confidential information from an agency or unit for use at the agent's facility. The organization the agent is affiliated with shall enter into a legally binding written agreement as described in section IV.C with the agency that possesses the confidential information.

C. Written Agreements for Agent Access to Confidential Information Protected Under CIPSEA

Some statistical agencies or units use contractors to acquire information and/or perform other statistical activities. Under CIPSEA, the contractor and the contractor's employees are considered agents. For any data that will be acquired by the contractor under CIPSEA, or if the contractor will have access to any confidential information protected by CIPSEA, the legally binding contract shall include the provisions shown in the Appendix.

If a statistical agency or unit provides designated agents access to confidential information protected under CIPSEA for exclusively statistical purposes, then all such access shall require a written, legally binding contract or other agreement between the agency and the responsible management level official from the institution with which the agent(s) is(are) affiliated.⁶⁷ The information required as part of that written agreement is shown in the Appendix.

D. Physical and Information Systems Security for Confidential Information Protected Under CIPSEA: On-Site and Off-Site

Agencies have the responsibility to ensure the security of physical and information systems for on-site as well as off-site access (if applicable) to confidential information and must follow applicable OMB Guidance and NIST standards and publications.⁶⁸ In addition to the security requirements described in section III.B, agencies allowing agents access to confidential information protected under CIPSEA

⁶³ Sec. 502(2)(A); Sec. 512(d).

⁶⁴ CIPSEA includes as agents contractors maintaining systems for handling or storage of data. Such information technology personnel provide support and have direct contact with confidential information not because they would necessarily use the information for statistical purposes, but because they would be responsible for the protection of the information from use for nonstatistical purposes and for ensuring appropriate security. As agents, these contractors and their employees are bound by CIPSEA to protect the confidentiality of the information.

⁶⁵ Sec. 502(2)(B).

⁶⁶ If the agency chooses, the agent may submit the proposal in conjunction with a completed written agreement.

⁶⁷ For situations in which agents are not affiliated with an institution, the agreement will be signed as legally binding by the agent(s). The latter arrangements would include those with a single agent operating independently as a sole proprietor as well as those with multiple agents operating independently.

⁶⁸ For more information about existing security and privacy requirements, see <http://www.whitehouse.gov/omb/inforeg/infopoltech.html>, FIPS PUB 199, *Standards for Security Categorization of Federal Information and Information Systems*, Gaithersburg, MD:U.S. Department of Commerce, and related publications.

outside of the collecting agency or a facility under the agency's control shall require that the written access agreement, described in section IV.C, stipulate the agency's right to conduct inspections of the off-site facility.

In order to ensure the physical and information systems security of the confidential information, agencies shall conduct inspections of any off-site facility that harbors confidential information protected under CIPSEA. (If the off-site facility is another Federal statistical agency or unit, agencies may at their option conduct inspections but are not required to inspect these facilities.) These inspections shall be conducted according to the following principles:

- The inspections shall assess and document whether the protection procedures outlined in the written agreement and in the agent's security plan are being implemented.
- While an inspection of the off-site facility is encouraged prior to release of the information to the agent, it is not required. (The inspection may occur any time during the access agreement period, preferably as soon as possible.)
- Inspections shall be conducted at all off-site facilities at some time during the timeframe of access. Agencies may prioritize their selection of sites for inspections based on risk, but must still inspect all off-site facilities; however, agencies may coordinate and collaborate on inspections of off-site facilities that harbor confidential data from multiple agencies. Agencies may choose not to inform the agent of the timing of such inspections.

E. Confidentiality Training

All persons with access to confidential information protected under CIPSEA shall participate in agency-provided confidentiality training (see section III.(C)) prior to accessing the confidential information as stipulated in the written agreement (section IV.C) between the agency and the agent's organization or institution.⁶⁹

The agency possessing the confidential data shall certify or receive notification that each project staff member has undergone the training. Agents shall also be required to be recertified annually.

F. Record Keeping

Agencies shall establish and maintain a system of records⁷⁰ that identifies

designated agents accessing confidential information protected under CIPSEA and the project for which the information was authorized.

V. Requirements for Statistical Agencies or Organizational Units Acquiring Information That May Be Used for Nonstatistical Purposes

CIPSEA defines a statistical agency or unit to be "an agency or organizational unit of the executive branch whose activities are predominantly the collection, compilation, processing, or analysis of information for statistical purposes."⁷¹

Because the public should expect that a statistical agency or unit will be collecting information for exclusively statistical purposes, CIPSEA requires a statistical agency to "clearly distinguish any data or information it collects for nonstatistical purposes (as authorized by law) and provide notice to the public, before the data or information is collected, that the data or information could be used for nonstatistical purposes."⁷²

A. Requirements for Public Notice

If a statistical agency or unit will collect information that may be subject to use for nonstatistical purposes, the statistical agency or unit shall use the notices in the **Federal Register** that are required under the PRA to inform the public about the nonstatistical uses of the information during the process of requesting OMB approval of the information collection.

As noted in section II.A, OMB's regulations for Controlling Paperwork Burdens on the Public⁷³ set forth public notification requirements for agencies conducting or sponsoring an information collection. Agencies are required under the PRA to:

- Publish a notice in the **Federal Register** allowing 60 days for the public to comment on information collections and otherwise consult with members of the public and affected agencies concerning each proposed collection of information;⁷⁴
- Publish a notice in the **Federal Register** at the time OMB approval is being sought, and allow the public 30 days to comment; and
- "Describe any assurance of confidentiality provided to respondents

this purpose qualifies as a system of records under the Privacy Act. OMB is not implying in this guidance what form these record keeping systems should take, and is leaving that determination to the agency.

⁷¹ Sec. 502(8).

⁷² Sec. 512(c).

⁷³ 5 CFR 1320.

⁷⁴ 5 CFR 1320.8(d)(1).

and the basis for the assurance in statute, regulation, or agency policy" in their PRA supporting statements submitted to OMB.⁷⁵

Both **Federal Register** notices (*i.e.*, the initial one seeking public comments for consideration by the agency and the later one seeking public comments for consideration by OMB) must explicitly address what information the statistical agency or unit plans to collect (that may be used for nonstatistical purposes).

B. Requirements for Informing and Making Pledges to Respondents

As noted in section II.B, at the time of the information collection, agencies are required under the PRA to adequately inform potential respondents about the uses of the information they provide.⁷⁶

This description must include the following information related to the confidentiality of their responses:

- The reasons the information is planned to be and/or has been collected;
- The way such information is planned to be and/or has been used; and
- The nature and extent of confidentiality to be provided, if any.⁷⁷

The statistical agency or unit must clearly explain the confidentiality provisions, if any, for all information not protected under CIPSEA. As appropriate, the explanation shall include:

- What information will be treated as confidential and the basis (*e.g.*, laws) for any confidentiality pledge;
- What information will be treated as nonconfidential;
- What information, if any, is limited to use for exclusively statistical purposes and the agency's basis (*e.g.*, laws) for such assurances;
- What information, if any, is not limited to use for exclusively statistical purposes and may be used for nonstatistical purposes; and
- Any limitations on the confidentiality provisions (*e.g.*, the information will be kept confidential only to the extent that it satisfies a criterion for exemption in the Freedom of Information Act (FOIA), the information may be shared with other Federal government agencies for official uses, etc.).

Agencies must ensure that the public is able to distinguish easily between their CIPSEA pledge and any non-CIPSEA pledge covering information

⁷⁵ Instructions for Supporting Statement for Paperwork Reduction Act submissions and 5 CFR 1320.8(b)(3).

⁷⁶ 5 CFR 1320.8(b)(3); Additional requirements are imposed if the collection involves a Privacy Act system of records (5 U.S.C. 552a(e)(3) as amended).

⁷⁷ 5 CFR 1320.8(b)(3).

⁶⁹ For situations in which agents are not affiliated with an institution, the agreement will be signed as legally binding by the agent(s).

⁷⁰ Agencies should assess for themselves the nature of these records and requirements for record keeping, including whether what an agency does for

that will be used for nonstatistical purposes. The degree to which the pledge differs from the CIPSEA pledge needs to be based on the laws and regulations governing the collection and determined in collaboration with the agency legal staff, agency confidentiality officer, and PRA clearance officer. The pledge shall be in compliance with section 512(c) of CIPSEA—requiring notice that any data could be used for nonstatistical purposes. The approach a statistical agency or unit uses in crafting wording for confidentiality pledges for information not protected under CIPSEA must be done with care and take into account the laws governing the particular agency, and the agency is strongly encouraged to test changes from currently used wording. In particular, the pledge for collections not protected under CIPSEA (because, for example, the information would be used for nonstatistical purposes) shall not contain all the elements related to CIPSEA found in the pledges given in section II—for example, the pledge shall not state both that the data are confidential and that they are for exclusively statistical use (in such cases CIPSEA would apply even if not stated).

For example, a pledge for data that are legally permitted to be accessed for nonstatistical purposes may state:

The information you provide will be protected to the fullest extent allowable under (name the law). This law allows for the (name specific nonstatistical uses). Information will be protected from public disclosure by (your agency). Results from this survey will be reported publicly only in statistical summaries, so that individuals cannot be identified.

To illustrate the actual pledge wording, an agency could implement this pledge as follows:

The information you provide will be protected and will not be disclosed to the public to the extent that it satisfies the criteria for exemption under the Freedom of Information Act (FOIA), 5 U.S.C. Sec. 552, and the Trade Secrets Act, 18 U.S.C. Sec. 1905.

To ensure public understanding and avoid confusion (about whether the agency will provide CIPSEA protection to the data), the above pledges do not use the word "confidential" because use of this term could give rise to confusion.

VI. Requirements and Guidelines for Nonstatistical Agencies or Units Acquiring and Handling Information Protected Under CIPSEA

Nonstatistical agencies seeking to acquire information that will be protected under CIPSEA can take two general approaches: (1) They can directly acquire the information

themselves from respondents, or (2) they can enter into an agreement with a statistical agency to acquire the information.

As noted in Section I. G., Subtitle A of CIPSEA may be used by any Federal agency that directly acquires information from respondents for exclusively statistical purposes under a pledge of confidentiality. Nonstatistical agencies that acquire information in this manner must follow all of the requirements in sections II and III of this guidance for confidential information protected by CIPSEA.

Nonstatistical agencies or units that will not collect the information themselves directly from respondents will need to carefully consider their plans for acquiring and using information if they want to use CIPSEA to protect the information. Although nonstatistical agencies and units do acquire information directly from respondents, they frequently use contractors or other agencies to acquire information for them that is used for statistical purposes. CIPSEA did not authorize nonstatistical agencies or units to designate agents, such as contractors, university researchers, or others included within the definition of agents,⁷⁸ to perform exclusively statistical activities, including data collection. Because nonstatistical agencies or units are not empowered under CIPSEA to designate agents, who are subject to CIPSEA limitations and penalties, they will not be able to protect the information under CIPSEA if they employ contractors or other agents to acquire the information or if they plan to allow access to the information by anyone outside of authorized agency employees, even if they intend to use the information for exclusively statistical purposes and want to keep it confidential.⁷⁹

As an alternative to collecting the data directly themselves, nonstatistical agencies or units that wish to acquire information with CIPSEA protection may want to consider entering into an agreement with a Federal statistical agency or unit. Because the statistical agency or unit would be responsible for protecting all confidential information

acquired under the CIPSEA pledge, carrying out these responsibilities will take resources that non-statistical agencies should be prepared to provide to the statistical agency. Statistical agencies or units may designate agents under CIPSEA, but must follow the requirements in Section IV of this guidance to do so. Employees within a nonstatistical agency or unit may serve as agents for a statistical agency or unit to perform exclusively statistical activities on confidential information and be bound by CIPSEA provided that the statistical agency or unit and the agents have followed all of the requirements given in section IV.

An agreement between the statistical agency and the nonstatistical agency could be used to make the statistical agency or unit responsible for the control of the confidential information. The statistical agency could then designate a contractor to acquire the information and perform other exclusively statistical activities. The statistical agency could also designate as agents select employees of the nonstatistical agency or unit to have access to the information for exclusively statistical purposes. As noted earlier, all requirements in sections II, III, and IV would have to be met; and, therefore, all agents would be subject to penalties under CIPSEA for any disclosure.

VII. Data Sharing Under Subtitle B of CIPSEA

Subtitle B, Statistical Efficiency, provides only for the sharing of business data for exclusively statistical purposes and provides for that sharing only among three statistical agencies designated in Subtitle B. Subtitle B of CIPSEA does not authorize the sharing of confidential business data among any Federal agencies other than the three designated statistical agencies, nor does it authorize any sharing of demographic or other types of data among any Federal agencies.⁸⁰

The following brief guidance in this section applies to the three designated statistical agencies sharing business data. These three agencies are currently working to implement the data sharing provisions of CIPSEA. OMB is working closely with them and may issue additional guidance to these three agencies as needed to implement the data sharing provisions of CIPSEA.

⁷⁸ See Sec. 502(2)(A).

⁷⁹ Some nonstatistical agencies may have specific statutory authority to designate agents that meets the requirements of CIPSEA, allowing the agency to use agents to perform exclusively statistical activities, including data collection, for the agency. Agencies should consult with OMB on the applicability of their statute for purposes of using CIPSEA before making plans to designate agents. Agencies should also clearly describe how their authority meets the requirements for CIPSEA designation of agents in their information collection requests to OMB.

⁸⁰ Although CIPSEA Subtitle B only authorizes the sharing of confidential business information among BEA, BLS, and the Census Bureau, CIPSEA did not alter other existing authorities for data sharing among Federal agencies (see Sec. 504(a)).

A. Designated Statistical Agencies

The three designated statistical agencies permitted by Subtitle B to share business data for exclusively statistical purposes are the Bureau of the Census, the Bureau of Economic Analysis, and the Bureau of Labor Statistics.⁸¹

B. Requirements When the Designated Statistical Agencies Share Data

Prior to sharing any business data under CIPSEA, the designated statistical agencies shall inform respondents about their intentions to share the business data. If, prior to collection, the designated agencies anticipate that they will share business data, the agencies shall:

- Include in their **Federal Register** notices required under the PRA notification that the business data may be shared with designated statistical agencies, and
- Also include in their CIPSEA confidentiality pledges notification that the data may be shared with designated statistical agencies.

When a designated statistical agency plans to share data that was collected under a legal requirement to supply the information without notice of the intent to share that information with one or more designated statistical agencies, the agency shall publish a notice of the proposed data sharing activity in the **Federal Register** and specify the business data to be shared and the statistical purposes for which the business data are to be used. This notice shall allow a minimum of 60 days for public comment,⁸² and a copy of this notice shall be sent to OMB when it is published.

C. Requirements for Written Agreements for Data Sharing Among Designated Statistical Agencies

Designated statistical agencies shall enter into a written agreement before sharing any business data. The written agreement shall specify:

- The business data to be shared;
- The statistical purposes for which the business data are to be used;
- The officers, employees, and agents authorized to examine the business data to be shared; and
- Appropriate security procedures to safeguard the confidentiality of the business data.

A copy of the written agreement shall be provided to OMB ten days prior to execution.

VIII. Annual Reporting and Review Requirements

A. Reporting Requirements

To coordinate and oversee the confidentiality and disclosure policies established under CIPSEA, the Office of Management and Budget is authorized under CIPSEA to require reports and other information regarding the implementation of this legislation by Federal agencies.⁸³ In order to effectively monitor Federal agencies' use of the different provisions in CIPSEA, all agencies shall report to OMB on (1) The use of the CIPSEA pledge, (2) the use of the CIPSEA agents provision, and (3) data sharing activities under Subtitle B.

Use of the CIPSEA pledge. Any Federal agency acquiring data under CIPSEA Subtitle A shall report to OMB on an annual basis on those collections it has conducted under CIPSEA and affirm that the agency has followed the procedures in this guidance to ensure the confidentiality of the information is protected.

Use of the agents provision in CIPSEA. Statistical agencies and units are authorized under Subtitle A of CIPSEA to designate agents, who may perform exclusively statistical activities, including data collection, and are bound to the same legal requirements as agency employees for maintaining the confidentiality of the information. Statistical agencies or units that choose to designate agents shall report to OMB on an annual basis on the number of agents designated; the kinds of statistical activities performed by agents, e.g., data collection, analysis, etc.; the different types of arrangements for access to confidential information (if applicable), e.g., on-site at the statistical agency, through an agency-controlled research data center, or off-site licensing agreement; and the kind of written agreement that is required for each type of access.

Use of data sharing provisions under Subtitle B of CIPSEA. CIPSEA directs that the three designated agencies shall report annually to the Director of the Office of Management and Budget, the Committee on Government Reform of the House of Representatives, and the Committee on Governmental Affairs of the Senate on the actions taken to implement the sections of the law on sharing of business data. Designated agency reports shall be prepared on a calendar year basis, and shall include a summary of activities carried out under this law including the statistical purposes for sharing, any anticipated

improvements to quality, and any anticipated or achieved reductions in cost or respondent burden due to the sharing of business data. The report shall include copies of each written agreement for the sharing of business data for the applicable year.

The initial report to OMB shall cover any collections since the enactment of the legislation in December 2002 through December 2006, and subsequent reports shall cover a calendar year. Agencies shall submit their initial reports to OMB by May 30, 2007. Subsequent reports shall be submitted annually to OMB by April 30th of each year. Agencies shall also post copies of this report on their Web sites.

B. OMB Review of Agency Rules

Agencies are authorized to promulgate rules to implement CIPSEA.⁸⁴ Agencies proposing rules to implement CIPSEA shall submit these proposed rules to OMB for review and approval.⁸⁵

Appendix Requirements for Contracts and Written Agreements for Agents Acquiring or Accessing Confidential Information Under CIPSEA

The following information shall be included in the contract or written agreement:

- The identity and affiliation of both the legally responsible agent (e.g., contractor or requestor seeking access to confidential data) and agency official signing the agreement;
- Whether the agent will be acquiring confidential information on behalf of the agency or only accessing confidential information the agency possesses;
- A clear and detailed description of the purpose of the access;
- The specific confidential information needed;
- How the information will be used;
- Any plans for disseminating information as well as the products planned for public distribution;
- Legally binding signature lines for the agency, and the responsible management level official from the institution with which the agent(s) is (are) affiliated. When the agent is operating independently for these purposes and is unaffiliated with an institution, the agent will sign;
- The legal authority under which the information was collected or acquired;
- The legal authority from CIPSEA and other laws for providing the agent the ability to acquire or to access the information;

⁸¹ Sec. 522.

⁸² Sec. 524(d).

⁸³ Sec. 503.

⁸⁴ Sec. 503(b).

⁸⁵ Sec. 503(c).

- Penalties for violating confidentiality or unauthorized use of the information;
- The timeframe for access;
- A requirement that the agent provide and update as necessary a list of persons involved in the project who will have access to the information;
- The agent's responsibility to notify agency when
 - The agent no longer needs the information,
 - The agent plans a change in site access, and/or
 - The project purpose changes (agency approval must be obtained first);
- Confidentiality training requirement for all persons who have access to confidential information;
- The requirement that each person with access to confidential information sign a non-disclosure form that signifies an understanding of and agreement to the terms of access and agreement to comply with CIPSEA and any other applicable laws (see below for options on where to include this information);
- The requirement that the agent submit any project information products to the agency for disclosure review (agencies may also include or reference reporting requirements or standards);

- For off-site access arrangements
 - A security plan (information systems and physical security) for protecting the information,
 - Procedures regarding the return or destruction of information when access is no longer necessary (may precede project's end), and
 - The requirement that the agent allows the agency to carry out a physical and IT security inspection of the agent's workplace;
- Conditions requiring modification of the agreement;
- Termination clause for the agreement;
- Listing of contact persons for the agency and the responsible management level official from the institution with which the agent is affiliated. (When the agent is operating independently and is unaffiliated with an institution, the agent will designate a contact person.); and
- As applicable, information on funding of project work, including any between the agency, agent(s), and/or agents' institution.

The following information may be included in the body of the agreement, added to the agreement as appendices, or made part of the agency's official files for the actual agreement:

- Copy of the agency-approved proposal (if required);
- Copies of all laws cited in the agreement;
- The list of persons with access to confidential information;
- Certification that all persons who have access to confidential information have completed confidentiality training;
- Signed non-disclosure forms for all persons with access to confidential information; and
- For each person with data access, a copy of the background certification supporting such access—details to be determined by agency (options could include fingerprinting, a sworn affidavit of nondisclosure, work history checks, etc.).

Agencies may also include additional requirements in their written agreements. Examples of written agreements used by some agencies that conform to the above requirements will be available on the OMB Web site.⁸⁶

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BILLING CODE 3110-01-P

⁸⁶ <http://www.whitehouse.gov/omb> go to "Statistical Programs and Standards."

CANADA/UNITED STATES/ MEXICO SPP REGULATORY COOPERATION FRAMEWORK

On March 23, 2005, the Leaders of the United States, Canada and Mexico, announced the Security and Prosperity Partnership of North America (SPP). The "Prosperity Agenda" of the SPP seeks to enhance the competitive position of North American industries in the global marketplace and to provide greater economic opportunity for all of our societies, while maintaining high standards of health and safety for our people.

Improving trilateral regulatory cooperation is a key element of the Prosperity Agenda. By increasing regulatory cooperation, the federal governments of the United States, Canada and Mexico (the Partners) aim to lower costs for North American businesses, producers, governments and consumers; maximize trade in goods and services across our borders; and protect health, safety, and the environment.

This voluntary Framework sets out steps to improve regulatory cooperation, where appropriate and feasible, while in no way diminishing the sovereignty of each Partner to carry out its regulatory functions according to its domestic legal and policy requirements. This framework is not meant to replace or duplicate ongoing regulatory cooperation undertaken by existing mechanisms.

I. Framework Goals

While maintaining high standards of health and safety, and environmental protection, the Partners strive to achieve the goals set out below.

1. **To strengthen regulatory cooperation, including at the outset of the regulatory process:** Regulatory cooperation should be strengthened on a systematic basis through increased transparency in the rulemaking process, exchanges of best practices, and information sharing among regulators.
2. **To streamline regulations and regulatory processes:** Regulations and regulatory processes can be streamlined through the increased use of joint analysis or evaluation of regulatory issues of mutual interest, information exchange on implementation approaches, or work-sharing, as well as through existing mechanisms, such as the SPP Prosperity Working Groups, North America Free Trade Agreement (NAFTA) working groups, and bilateral and/or trilateral undertakings among the Partners.
3. **To encourage compatibility of regulations, promote the use or adoption of relevant international standards, as well as domestic voluntary consensus standards, in regulations, and eliminate redundant testing and certification requirements, consistent with our World Trade Organization (WTO) obligations:** These goals will be pursued through, for example, the work of the SPP Prosperity Working Groups, NAFTA working groups and bilateral and/or trilateral undertakings among the Partners.

The objectives and measures outlined in the Action Plan, Part III, are aimed at achieving these goals.

II. Trilateral Regulatory Cooperation

1. The Partners hereby establish a Coordinating Committee to ensure the effectiveness and accountability of this Framework. The Coordinating Committee is to include participants from central agencies, regulatory agencies and trade/foreign relation agencies. The nature of this coordination should depend on the specific Framework objective being addressed.
2. The Coordinating Committee is to develop an annual work-plan to implement the Action Plan set out in Part III that identifies areas of mutual interest for cooperation. The Coordinating Committee is to offer stakeholders an opportunity to comment as the work-plan is developed and make it available to the public.
3. The Coordinating Committee is to report annually to Leaders, Ministers and the public on regulatory cooperation and thereby increase the transparency and accountability of the process to: (a) ensure that the results of North American cooperative efforts are measured, (b) highlight success stories in regulatory cooperation, and (c) make recommendations to regulators to improve cooperation.

III. Action Plan

This Action Plan outlines specific objectives and measures for each Framework Goal, which are to be moved forward and measured through the trilateral Regulatory Cooperation Coordinating Committee.

Goal 1: To strengthen regulatory cooperation, including at the outset of the regulatory process.	
Objectives	Measures
A. Increase the transparency of the rulemaking process.	• Develop intergovernmental "early alert" mechanisms to systematically and proactively share information throughout the rule development process to avoid incompatibility issues. • On a systematic basis seek and provide an opportunity to comment on each other's regulatory proposals that could have implications for the other Partners and consult throughout the process.

Goal 1: To strengthen regulatory cooperation, including at the outset of the regulatory process.

B. Promote good governance by sharing best practices.	• Increase contacts between and among central agencies and government regulators on regulatory policy issues and practices of mutual interest, e.g. regulatory reform and review, instrument choice, regulatory tools such as compliance strategies and regulatory analysis. • Develop and maintain an illustrative inventory of best practices from which regulators can draw upon as a resource. • Hold meetings/conference calls of regulatory analysts to share knowledge and best practices in regulatory analysis to better understand the differences among the three countries in regulation and to determine how to move towards greater consistency in regulatory approaches and analytical practices across the three jurisdictions. • Establish a voluntary exchange program in which officials from Partners' regulatory agencies work in the agency of a Partner country.
C. Increase information sharing among regulators.	• Facilitate and develop mechanisms to enable the sharing of information throughout the regulatory process. • Share regulatory agendas. • Develop annual work-plans that identify areas of mutual interest for regulatory cooperation. • Develop a mechanism to share information on the status of regulations that are subject to an expedited process.

Goal 2: To streamline regulations and regulatory processes.

Objectives	Measures
A. Increase the use of joint analysis or evaluation of regulatory issues of mutual interest, information exchange on implementation approaches, or work sharing to further improve the timeliness and efficiency of regulatory processes.	• Identify, develop and conduct pilot project(s) in joint regulatory impact analysis, including cost-benefit analysis and/or risk assessment.
B. Leverage existing mechanisms such as the SPP Prosperity Working Groups, NAFTA working groups and bilateral and/or trilateral undertakings, to anticipate regulatory issues.	• Identify, develop and conduct pilot project(s) for developing a compatible approach to rules and regulations in a particular sector.

Goal 3: To encourage compatibility of regulations, promote the use or adoption of relevant international standards, as well as domestic voluntary consensus standards, in regulations, and eliminate redundant testing and certification requirements, consistent with our WTO obligations.

Objectives	Measures
A. Work towards more compatible and coordinated regulatory approaches.	• Encourage the introduction of the Framework's Goals relating to regulatory compatibility into practices, policies, directives and orders. • Work cooperatively towards including assessment of trade impact in the regulatory impact analysis to reduce regulatory barriers to trade among the Partners. • The Coordinating Committee is to develop, for consideration, criteria for compatibility of regulations among the Partners in domestic regulatory review processes where feasible.
B. To promote the use or adoption of relevant international standards, as well as domestic voluntary consensus standards, in regulations.	• Promote the coordination of views related to the development of international standards and convey those views to the relevant parties that participate in international standards for as appropriate. • Work cooperatively to encourage the use or adoption of relevant international standards, as well as domestic voluntary consensus standards, in regulations.
C. Eliminate redundant testing and certification requirements.	• Work cooperatively to eliminate redundant testing and certification, by, for example, accepting the results of conformity assessment procedures. • Identify, develop and conduct pilot projects to eliminate redundant testing and certification requirements.



Executive Office of the President
Office of Management and Budget



Executive Office of the President
Office of Science and Technology Policy

September 19, 2007

M-07-24

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Susan E. Dudley 
Administrator, Office of Information and Regulatory Affairs,
Office of Management and Budget

Sharon L. Hays 
Associate Director and Deputy Director for Science,
Office of Science and Technology Policy

SUBJECT: Updated Principles for Risk Analysis

Federal agencies take a variety of actions to improve public health, safety, and the environment. Agency activities designed to reduce risks are influenced by numerous factors, including Congressional priorities, information on the degree of risk faced by different populations, entities, or individuals, resources available, and the ease of implementing chosen priorities. Development of these actions often begins with an assessment of the risks posed under certain conditions, as well as assessments of the potential changes in risk achievable due to different policy options.

In 1995, an interagency working group, co-chaired by the Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP), developed a set of principles to guide policymakers in assessing, managing, and communicating policies to address environmental, health, and safety risks (the 1995 Principles).¹ The 1995 Principles, shared with regulatory agencies in a memorandum from Sally Katzen, then Administrator of OMB's Office of Information and Regulatory Affairs (OIRA), remain valid today.

This Memorandum reinforces the 1995 Principles with reference to more recent guidance from the scientific community, the Congress, and the Executive Branch. This Memorandum also benefits from feedback received on OMB's Proposed Risk Assessment Bulletin issued in 2006 (Proposed Risk Assessment Bulletin).²

¹ U.S. Office of Mgmt. and Budget (OMB), Memorandum for the Regulatory Working Group, *Principles for Risk Analysis* (1995), available at http://www.whitehouse.gov/omb/infoereg/regpol/jan1995_risk_analysis_principles.pdf.

² OMB, *Proposed Risk Assessment Bulletin*, (2006) [hereinafter Proposed Risk Assessment Bulletin], available at http://www.whitehouse.gov/omb/infoereg/proposed_risk_assessment_bulletin_010906.pdf.

In January 2006, OIRA, in consultation with OSTP, released the Proposed Risk Assessment Bulletin for public comment and asked the National Academy of Sciences (NAS) to conduct an expert peer review.³ The NAS issued its report on the Proposed Risk Assessment Bulletin in 2007 (the 2007 NAS Report on the Proposed Risk Assessment Bulletin).⁴ While supportive of the goal of “increasing the quality and objectivity of risk assessment in the federal government,” the NAS recommended an approach that would “outline goals and general principles of risk assessment.”⁵ After carefully evaluating these constructive recommendations from the NAS, as well as feedback from a rigorous interagency review, and public comments,⁶ we have decided not to issue the bulletin in final form. Rather, we are issuing this Memorandum to reinforce generally-accepted principles for risk analysis upon which a wide consensus now exists.

Recognizing the diversity of documents that stem from risk analysis techniques, this Memorandum reinforces generally-accepted principles for risk analysis related to environmental, health, and safety risks.⁷ As a whole, the Memorandum endeavors to enhance the scientific quality, objectivity, and utility of Agency risk analyses and the complementary objectives of improving efficiency and consistency among the Federal family.⁸ The general principles presented here should continue to assist and guide agencies as they conduct risk analyses, and thereby should enhance the multiple decisions that are based upon these analyses.

The 1995 Principles were divided into five parts: general principles, principles for risk assessment, principles for risk management, principles for risk communication, and priority setting.⁹ This Memorandum reiterates each of these principles (in bold text) and, where appropriate, highlights and references more recent guidance (in plain text). OMB and OSTP will

³ See Press Release, OMB, OMB Requests Peer Review of Proposed Risk Assessment Bulletin (Jan. 9, 2006), available at <http://www.whitehouse.gov/omb/pubpress/2006/2006-01.pdf>.

⁴ National Research Council, National Academy of Sciences, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* (2007) [hereinafter 2007 NAS Report on the Proposed Risk Assessment Bulletin].

⁵ *Id.* at 6 - 7.

⁶ OMB received 79 public comments on the Proposed Risk Assessment Bulletin. These comments are posted on OMB's website, available at http://www.whitehouse.gov/omb/inforeg/comments_rab/list_rab2006.html.

⁷ While many of the principles presented in this Memorandum may be relevant to other fields, such as financial or information technology risk analyses, the focus of this Memorandum is on those risk analyses related to environmental, health, and safety risks.

⁸ The enhancement of information quality, objectivity, transparency, and reproducibility is addressed in other OMB guidance as well. See OMB, Circular A-4 for Regulatory Review (2003) [hereinafter Circular A-4] (includes requirements for regulatory analysis as it relates to risk management decisions, particularly those required under Executive Order 12866), available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>. In addition, pursuant to what is commonly referred to as the Information Quality Act (Sec. 515 of the Treasury and General Government Appropriations Act for FY 2001, Pub. L. No. 106-554), OMB issued government-wide Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter Information Quality Guidelines], available at <http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>; and its Final Information Quality Bulletin for Peer Review (2004), 70 Fed. Reg. 2664 (Jan. 14, 2005) [hereinafter Peer Review Bulletin], available at <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>. These documents were each issued first as a proposal for public comment. In addition, the Information Quality Guidelines were then implemented by agencies in their own agency-specific information quality guidelines. This Memorandum is intended to complement and support the Information Quality Guidelines.

⁹ This framework is consistent with the long-standing distinction between risk assessment, risk management, and risk communication. See National Research Council, National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process* (1983).

work with Federal agencies to ensure consistency with the principles in this memorandum. Agencies should review their current risk analysis practices and guidelines and incorporate these principles as they develop, update, and issue risk analyses and guidelines.

Should you have any questions regarding this Memorandum, or would like to discuss it, please do not hesitate to contact either of us or our staff at 202-395-4852 (OIRA) or 202-456-7116 (OSTP).

General Principles

- 1. These Principles are intended to be goals for agency activities with respect to the assessment, management, and communication of environmental, health, and safety risks. Agencies should recognize that risk analysis is a tool—one of many, but nonetheless an important tool—in the regulatory tool kit. These Principles are intended to provide a general policy framework for evaluating and reducing risk, while recognizing that risk analysis is an evolving process and agencies must retain sufficient flexibility to incorporate scientific advances.**

The 2007 NAS Report on the Proposed Risk Assessment Bulletin recommended that OMB “develop goals for risk assessment that emphasize the central objective of enhanced scientific quality and the complementary objectives of efficiency and consistency among agencies evaluating the same or similar risks.”¹⁰ Recognizing that “[r]isk assessment is not a monolithic process or a single method,” and that “[a]ll risk assessments share some common principles, but their application varies widely among domains,” the NAS recommended that “affected federal agencies develop their own technical risk assessment guidelines that are consistent with the OMB general principles.”¹¹

- 2. The Principles in this document are intended to be applied and interpreted in the context of statutory policies and requirements, and Administration priorities.**
- 3. As stated in Executive Order No. 12866, “In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction” [Section 1(b)(4)]. Further, in developing regulations, federal agencies should consider “...how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency” [Section 4(c)(1)(D)].¹²**

Agencies should refer to Circular A-4 for expanded and updated guidance regarding best practices for agency regulatory analysis.¹³

¹⁰ 2007 NAS Report on the Proposed Risk Assessment Bulletin, *supra* note 4, at 110.

¹¹ *Id.* at 106, 110-11.

¹² See Exec. Order No. 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), *available at* <http://www.whitehouse.gov/omb/inforeg/eo12866.pdf>. See also Exec. Order No. 13132, 72 Fed. Reg. 2763 (Jan. 23, 2007), *available at* http://www.whitehouse.gov/omb/inforeg/eo12866/index_eo12866.html.

¹³ See footnote 8. Circular A-4 refined OMB’s “Economic Analysis of Federal Regulations Under Executive Order 12866” (1996) (a “best practices” guide to preparing a regulatory analysis), *available at*

4. **In undertaking risk analyses, agencies should establish and maintain a clear distinction between the identification, quantification, and characterization of risks, and the selection of methods or mechanisms for managing risks. Such a distinction, however, does not mean separation. Risk management policies may induce changes in human behaviors that can alter risks (i.e., reduce, increase, or change their character), and these linkages must be incorporated into evaluations of the effectiveness of such policies.**
5. **The depth or extent of the analysis of the risks, benefits and costs associated with a decision should be commensurate with the nature and significance of the decision.**

Subsequent reports have re-affirmed this principal. The 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management (referred to as the Presidential Commission on Risk) issued a two-volume report that stated as follows:

The level of detail considered in a risk assessment and included in a risk characterization should be commensurate with the problem's importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.¹⁴

A 2007 NAS report on global change assessments evaluated lessons learned from relevant past global change assessments.¹⁵ The NAS, drawing on its analysis and the relevant literature, identified essential elements of effective assessments and included elements relating to the adequacy of funding and the balance between benefits of the assessment and the opportunity costs of producing it.¹⁶

<http://www.whitehouse.gov/omb/inforeg/riaguide.html>. The "best practices" guide was issued as guidance in 2000, OMB's Memorandum for the Heads of Departments and Agencies on Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements (2000), *available at* <http://www.whitehouse.gov/omb/memoranda/m00-08.pdf>; and reaffirmed in 2001, OMB's Memorandum for the President's Management Council on Presidential Review of Agency Rulemaking (2001), *available at* http://www.whitehouse.gov/omb/inforeg/oira_review-process.html. Before finalization, Circular A-4 went through public comment, interagency review, and peer review.

¹⁴ Presidential/Congressional Commission on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management*, 1 Final Report 25 (1997) [hereinafter Risk Commission Report I].

¹⁵ See National Research Council, National Academy of Sciences, *Analysis of Global Change Assessments: Lessons Learned* (2007) [hereinafter 2007 NAS Report on Global Change Assessments].

¹⁶ *Id.*, *supra* note 15, at 4 (two essential elements of effective assessments are "[a]dequate funding that is both commensurate with the mandate and effectively managed to ensure an efficient assessment process" and a "balance between the benefits of a particular assessment and the opportunity costs (e.g., commitments of time and effort) to the scientific community").

Principles for Risk Assessment

- 1. Agencies should employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment.**

Risk analyses should be based upon the best available scientific methodologies, information, data, and weight of the available scientific evidence.¹⁷ The Presidential Commission on Risk observed:

Because so many judgments must be based on limited information, it is critical that all reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.¹⁸

Congress emphasized using the best available scientific evidence for risk information in the 1996 amendments to the Safe Drinking Water Act (SDWA).¹⁹ Pursuant to the SDWA, an agency is directed “to the degree that an agency action is 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 the reliability of the method and the nature of the decision justifies use of the data).²⁰

Agencies have adopted or adapted this SDWA standard in their Information Quality Guidelines with regard to the analysis of risks to human health, safety, and the environment.²¹

- 2. Characterizations of risks and of changes in the nature or magnitude of risks should be both qualitative and quantitative, consistent with available data. The characterizations should be broad enough to inform the range of policies to reduce risks.**

In the 1996 SDWA amendments, Congress adopted a basic quality standard for the dissemination of public information about risks of adverse health effects. Under the 1996

¹⁷ In this Memorandum, “scientific” information includes information related to applied sciences (such as engineering) and technical information related to these fields.

¹⁸ Risk Commission Report I, *supra* note 14, at 38. The Risk Commission Report I provides examples of the kinds of considerations entailed in making judgments on the basis of the weight of the scientific evidence in a toxicity study: quality of the toxicity study, appropriateness of the toxicity study methods, consistency of results across studies, biological plausibility of statistical associations, and similarity of results to responses and effects in humans.

¹⁹ 42 U.S.C. § 300g-1(b)(3)(A,B).

²⁰ 42 U.S.C. § 300g-1(b)(3)(A).

²¹ Links to agency specific information quality guidelines can be found in the OMB Draft 2007 Report to Congress on the Costs and Benefits of Federal Regulations, Appendix C, *available at* http://www.whitehouse.gov/omb/inforeg/2007_cb/2007_draft_cb_report.pdf. For specific examples of agency guidelines, see <http://dms.dot.gov/submit/DataQualityGuidelines.pdf> (Department of Transportation guidelines), <http://aspe.hhs.gov/infoquality/Guidelines/index.shtml> (Department of Health and Human Services guidelines), <http://www.sti.nasa.gov/qualinfo.html> (National Aeronautics and Space Administration guidelines), <http://www.dol.gov/informationquality.htm> (Department of Labor guidelines).

SDWA amendments, the Environmental Protection Agency is directed “to ensure that the presentation of information on public health effects is comprehensive, informative, and understandable.”²² The Information Quality Guidelines adapt this language and further direct the agencies to:

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.²³

Agencies have adopted or adapted this standard in their Information Quality Guidelines with regard to analysis of risks to human health, safety, and the environment.²⁴

In addition, the Information Quality Guidelines state that agency disseminations should be objective; these guidelines, as well as individual agency information quality guidelines, provide further discussion of objectivity and its application in agency disseminations.²⁵ While risks should not be minimized nor exaggerated, the 2007 NAS Report on the Proposed Risk Assessment Bulletin stated that “[i]nformation on the variability of effects across potentially affected populations is essential to decision-making.”²⁶

When characterizing risk in its 1996 report on understanding risk and how it informs decisions, the NAS stated that “quantitative models to organize and interpret data are particularly important to risk characterization.”²⁷ When a risk analysis is influential,²⁸ increased efforts to provide useful quantitative estimates of risk are particularly important. Due to the inherent uncertainties associated with estimates of risk, presentation of a single estimate may be misleading and

²² 42 U.S.C. § 300g-1(b)(3)(B).

²³ See Information Quality Guidelines, *supra* note 8.

²⁴ See footnote 21.

²⁵ See Information Quality Guidelines, *supra* note 8. On a substantive level, objectivity ensures accurate, reliable and unbiased information.

²⁶ See 2007 NAS Report on the Proposed Risk Assessment Bulletin, *supra* note 4, at 63 (in referring to the Proposed Risk Assessment Bulletin’s statement that risk assessments should be presented such that they are “neither minimizing nor exaggerating the nature and magnitude of risks,” the NAS stated that this “could, however, degrade risk analysis if it were interpreted so as to deprive decision-makers of important information on sensitive subpopulations on the grounds that such information may generate risk estimates considerably higher than a central tendency or general population estimates.”).

²⁷ National Research Council, National Academy of Sciences, *Understanding Risk: Informing Decisions in a Democratic Society* 99-100 (1996) [hereinafter 1996 NAS Report on Understanding Risk and Informing Decisions].

²⁸ In this Memorandum, the term “influential” is defined in the same way as it is defined in the Information Quality Guidelines. Influential means that “the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.” In their information quality guidelines, agencies have defined “influential” in ways appropriate for them given the nature and multiplicity of issues for which the agencies are responsible.

provide a false sense of precision.²⁹ Expert panels agree that when a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided.³⁰ When something more than a superficial analysis can be conducted, quantitative uncertainty analysis, sensitivity analysis, and a discussion of model uncertainty can greatly inform risk management decisions.³¹

Experts have recognized that when presenting risk information qualitatively, or quantitatively, agencies' methodological approaches will likely vary and will depend upon the context for which the analysis is used.³² These methodologies are continuing to develop as the science associated with quantitative uncertainty analysis advances. As technical guidance continues to develop, so too should agencies' presentation of quantitative risk information.

²⁹ See National Research Council, National Academy of Sciences, *Models in Environmental Regulatory Decision Making* 136 (2007) [hereinafter 2007 NAS Report on Environmental Decision Making] ("there are substantial problems in reducing the results of a large-scale study with many sources of uncertainty to a single number or even a single probability distribution. We contend that such an approach draws the line between the role of analysts and the role of policy makers in decision making at the wrong place."); *Id.* at 7 ("Effective decision making will require providing policy makers with more than a single probability distribution for a model result (and certainly more than just a single number, such as the expected net benefit, with no indication of uncertainty). Such summaries obscure the sensitivities of the outcome to individual sources of uncertainty, thus undermining the ability of policy makers to make informed decisions and constraining the efforts of stakeholders to understand the basis for the decisions."). See also 1996 NAS Report on Understanding Risk and Informing Decisions, *supra* note 27, at 66 ("Risk characterizations often fail because they attribute meaning to scientific estimates in ways that mislead participants in the risk decision process or are incomprehensible to them.").

³⁰ See 2007 NAS Report on the Proposed Risk Assessment Bulletin, *supra* note 4, at 37 ("The committee agrees with OMB that in some cases 'presentation of single estimates of risk is misleading' and that ranges of 'plausible risk' should be presented; however, the challenge is in the operational definitions of such words as *central*, *expected*, and *plausible*.") (emphasis in original).

³¹ See 2007 NAS Report on Environmental Decision Making, *supra* note 29, at 6 ("A wide range of possibilities is available for performing model uncertainty analysis. At one extreme, all model uncertainties could be represented probabilistically, and the probability distribution of any model outcome of interest could be calculated. However, in assessing environmental regulatory issues, these analyses generally would be quite complicated to carry out convincingly, especially when some of the uncertainties in critical parameters have broad ranges or when the parameter uncertainties are difficult to quantify. Thus, although probabilistic uncertainty analysis is an important tool, requiring EPA to do complete probabilistic regulatory analyses on a routine basis would probably result in superficial treatments of many sources of uncertainty. The practical problems of performing a complete probabilistic analysis stem from models that have large numbers of parameters whose uncertainties must be estimated in a cursory fashion. Such problems are compounded when models are linked into a highly complex system, for example, when emissions and meteorological model results are used as inputs into an air quality model."); *Id.* at 7 ("It is not necessary to choose between purely probabilistic approaches and deterministic approaches. Hybrid analyses combining aspects of probabilistic and deterministic approaches might provide the best solution for quantifying uncertainties, given the finite resources available for any analysis. For example, a sensitivity analysis might be used to determine which model parameters are most likely to have the largest impacts on the conclusions, and then a probabilistic analysis could be used to quantify bounds on the conclusions due to uncertainties in those parameters.").

³² *Id.* at 7-8 ("In some cases, presenting results from a small number of model scenarios will provide an adequate uncertainty analysis (for example, cases in which the stakes are low, modeling resources are limited, or insufficient information is available). In many instances, however, probabilistic methods will be necessary to characterize properly at least some uncertainties and to communicate clearly the overall uncertainties.").

3. Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.

If important judgments are supported by, or conflict with, empirical data, that information should be discussed. The discussion should address the range of scientific and/or technical opinions regarding the likelihood of plausible alternate judgments and the direction and magnitude of any resulting changes that might arise in the analysis due to changes in key judgments.³³ Every effort should be made to perform a quantitative evaluation of reasonable alternative assumptions.³⁴ When an analysis combines multiple assumptions, the basis and rationale for combining the assumptions should be explicitly described.³⁵

Critical judgments are often made when choosing and presenting study results. Results based on different effects and/or different studies should be presented to convey how the choice of effect and/or study influences the analysis. The presentation of information regarding different scientifically plausible endpoints should allow for a robust discussion of the available data, associated uncertainties, and underlying science. In its 2007 report evaluating global change assessments, the NAS recommended that “[t]here should be a deliberate effort to clarify the importance of alternative assumptions and to illustrate the impacts of uncertainties.”³⁶ When relying on data from one study over others, the agency should provide a clear rationale and/or scientific basis for its choice.³⁷

4. Risk assessments should encompass all appropriate hazards (e.g., acute and chronic risks, including cancer and non-cancer risks, to human health and the environment). In addition to considering the full population at risk, attention should be directed to subpopulations that may be particularly susceptible to such risks and/or may be more highly exposed.

A good risk analysis should clearly summarize the scope of the assessment, including a description of: the agent, technology and/or activity that is the subject of the analysis; the hazard of concern; the affected entities (populations, subpopulations, individuals, natural resources, ecosystems, critical infrastructure, or other) that are the subject of the assessment; the exposure/event scenarios relevant to the objectives of the assessment; and the type of event-

³³ See 1996 NAS Report on Understanding Risk and Informing Decisions, *supra* note 27, at 53 (“Simplifying assumptions generate especially serious problems when some of the assumptions are unreasonable in the face of information available to people outside the analytical process.”).

³⁴ *Id.* at 99 (“Without good analysis, deliberative processes can arrive at agreements that are unwise or not feasible.”). See also National Research Council, National Academy of Sciences, *Health Risks from Dioxin and Related Compounds* 7 (2006) (“Although EPA [in its dioxin assessment] addressed many sources of variability and uncertainty qualitatively, the committee noted that the Reassessment would be substantially improved if its risk characterization included more quantitative approaches. Failure to characterize variability and uncertainty thoroughly can convey a false sense of precision in the conclusions of the risk assessment.”).

³⁵ See Circular A-4, *supra* note 8, at 39 (“Inferences and assumptions used in your analysis should be identified, and your analytical choices should be explicitly evaluated and adequately justified.”).

³⁶ See 2007 NAS Report on Global Change Assessments, *supra* note 15, at 126.

³⁷ See Circular A-4, *supra* note 8, at 39.

consequence or dose-response relationship for the hazard of concern.³⁸ In the 2007 NAS Report on the Proposed Risk Assessment Bulletin, the NAS reaffirmed that including this information would improve the clarity of a risk analysis and is consistent with the recommendations of previous expert reports.³⁹

More recent reports have reaffirmed that, in addition to considering the full population or entities at risk, the risk analysis should also consider subpopulations or sub-entities that may be particularly susceptible to such risks and/or may experience greater exposures.⁴⁰ If a risk analysis is to address only specific subpopulations, the scope should be very clear about this limitation.

Where there are known differences in risk for different individuals, subpopulations or ecosystems, analysts should characterize this variability. Risk managers will be better informed when an understanding of variability and the key contributors to the cause of this variability are presented in the risk analysis.⁴¹ As guidance on the presentation of risk information to the public continues to develop, so too will agencies' presentation and discussion of variability.

The President's Commission on Risk stated: "A good risk management decision is based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment."⁴² This may include consideration of both positive and negative studies, in light of each study's technical quality. Agencies and the risk assessment community are continuing to develop techniques for weight of evidence evaluations.

Agencies should consider confounding and/or synergistic factors. The scientific process of considering these elements may assist policy makers in developing a broader sense of how risk can be reduced significantly and the range of decision options that need to be considered in developing risk management approaches.⁴³

³⁸ See Risk Commission Report I, *supra* note 14, at 24 (a list of questions should be addressed in a risk characterization).

³⁹ See 2007 NAS Report on the Proposed Risk Assessment Bulletin, *supra* note 4, at 62.

⁴⁰ See Risk Commission Report I, *supra* note 14, at 24 (a list of questions that includes asking about individuals or groups that are at risk and if some people are more likely to be at risk than others).

⁴¹ See 2007 NAS Report on the Proposed Risk Assessment Bulletin, *supra* note 4, at 80 ("information on the variability of effects across potentially affected populations--due to differences in sensitivity, exposure, or both--is essential to decision-making.").

⁴² See Risk Commission Report I, *supra* note 14, at 23; *Id.* at 23-24 ("It is important that risk assessors respect the objective scientific basis of risks and procedures for making inferences in the absence of adequate data. Risk assessors should provide risk managers and other stakeholders with plausible conclusions about risk that can be made on the basis of the available information, along with evaluations of the scientific weight of evidence supporting those conclusions and descriptions of major sources of uncertainty and alternative views.").

⁴³ *Id.* at 24 (a list of questions that includes asking about "[w]hat other sources cause the same type of effects or risks.").

5. **Peer review of risk assessments can ensure that the highest professional standards are maintained. Therefore, agencies should develop policies to maximize its use.**

Agencies should refer to the Peer Review Bulletin for updated guidance regarding agency best practices for peer review.⁴⁴

6. **Agencies should strive to adopt consistent approaches to evaluating the risks posed by hazardous agents or events.**

Principles for Risk Management

1. **In making significant risk management decisions, agencies should analyze the distribution of the risks and the benefits and costs (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of risk management strategies. Reasonably feasible risk management strategies, including regulation, positive and negative economic incentives, and other ways to encourage behavioral changes to reduce risks (e.g., information dissemination), should be evaluated. Agencies should employ the best available scientific, economic and policy analysis, and such analyses should include explanations of significant assumptions, uncertainties, and methods of data development.**

Agencies should refer to Circular A-4 for updated guidance regarding agency best practices for regulatory analysis.⁴⁵

2. **In choosing among alternative approaches to reducing risk, agencies should seek to offer the greatest net improvement in total societal welfare, accounting for a broad range of relevant social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable).**

Agencies should refer to Circular A-4 for updated guidance regarding agency best practices for regulatory analysis.⁴⁶

Principles for Risk Communication

1. **Risk communication should involve the open, two-way exchange of information between professionals, including both policy makers and “experts” in relevant disciplines, and the public.**

In describing its approach to risk characterization in the 1996 NAS Report on Understanding Risk and Informing Decisions, NAS stated that “[t]he responsible organization’s staff should describe the stated and implicit purposes of the decision-making activity, the type of decision and general aims furthered by the activity, and the intended users of the risk characterization.”⁴⁷

⁴⁴ See Peer Review Bulletin, *supra* note 8.

⁴⁵ See Circular A-4, *supra* note 8.

⁴⁶ *Id.*

⁴⁷ See 1996 NAS Report on Understanding Risk and Informing Decisions, *supra* note 27, at 146; *Id.* (“Different types of decisions may require different types of knowledge and perspectives and hence require different participants in the analytic-deliberative process—both inside and outside the organization.”).

Agencies should provide this information as it will assist the readers and users in better understanding the questions that the analysis sought to answer and will help to ensure that the risk analyses are used for their intended purposes. This information is particularly important in cases where likely users of the risk analyses are not the original intended audience for the document.

2. Risk management goals should be stated clearly, and risk assessments and risk management decisions should be communicated accurately and objectively in a meaningful manner.

An executive summary that discloses the objectives and scope, the key findings of the analysis, and the key scientific limitations and uncertainties can be an important part of risk communication.⁴⁸ In the 2007 NAS Report on the Proposed Risk Bulletin, the NAS commented that the inclusion of an executive summary could improve the clarity of risk assessments.⁴⁹ Presentation of information in a helpful and concise introductory section of the report will not only foster improved communication of the findings, but will also help ensure that the risk analysis is appropriately interpreted by diverse end users.

To maximize public understanding and participation in risk-related decisions, agencies should:

a. explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;

A high degree of transparency with respect to data, assumptions, and methods will increase the credibility of the risk analysis, and will allow interested individuals, internal and external to the agency, to understand better the technical basis of the analysis.⁵⁰

b. describe the sources, extent and magnitude of significant uncertainties associated with the assessment or decision;

In the 1996 NAS Report on Understanding Risk and Informing Decisions, the NAS observed that “[t]here is strong agreement that risk analysts should explicitly summarize uncertainty, and

⁴⁸ Key limitations are those that are most likely to affect significantly the determinations and/or estimates of risk presented in the analysis.

⁴⁹ See 2007 NAS Report on the Proposed Risk Assessment Bulletin, *supra* note 4, at 64 (“These qualitative standards . . . [presented in an executive summary] could improve the clarity of risk assessment in the federal government if risk assessments do not implement them already (although the existence of such problems is not established by the bulletin.”)).

⁵⁰ See 1996 NAS Report on Understanding Risk and Informing Decisions, *supra* note 27, at 67; *Id.* at 100 (in a good quantitative analysis, “[a]ny assumptions used are clearly explained, used consistently, and tested for reasonableness,” “[c]alculations are presented in such a form that they can be checked by others interested in verifying the results,” and “[u]ncertainties are indicated, including those in data, models, parameters, and calculations.”). See 2007 NAS Report on Global Change Assessments, *supra* note 15, at 126 (NAS recommends that “[t]here should be a deliberate effort to clarify the importance of alternative assumptions and to illustrate the impacts of uncertainties.”). See also U.S. Environmental Protection Agency, *Science Policy Council Handbook, Risk Characterization* 15 (2000) [hereinafter EPA Risk Characterization Handbook] (“[Transparency] ensures that any reader understands all the steps, logic, key assumptions, limitations, and decisions in the risk assessment, and comprehends the supporting rationale that lead to the outcome.”). In the EPA Risk Characterization Handbook, EPA lists 10 elements of full disclosure. *Id.* at 15-16.

there are methods for doing so.”⁵¹ In the 2007 NAS Report on Global Change Assessments, when referring to critical elements of a credible, legitimate and salient assessment, the NAS included as one of four central elements:

Deliberative and consistent methods of treating and communicating uncertainties add credibility and salience. Regardless of method (statistics, sensitivity analysis, scenario development, or expert judgment), each measure must be defined and communicated in a consistent manner.⁵²

In the same report the NAS also stated:

An effective characterization of uncertainty in assessments requires determining what sorts of uncertainty information would be useful for decision makers as well as developing quantitative or qualitative measures of uncertainty The manner in which uncertainties are acknowledged and characterized will affect both the salience and credibility of the assessment.”⁵³

The agency also should identify the sources of the underlying information (consistent with sensitive information and confidentiality protections) and the supporting data and models, so that the public can evaluate whether there may be some reason to question objectivity.⁵⁴ Data should be accurately documented, and error sources affecting data quality should be identified and disclosed.⁵⁵

c. make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary versus involuntary risk; and,

When making risk comparisons, agencies should be careful to consider the perspectives, assumptions, attitudes and context that the public associates with each risk. Agencies may want to consult the risk communication literature when considering appropriate comparisons. Although the risk assessor has considerable latitude in making risk comparisons, the fundamental point is that risk should be placed in a context that is useful and relevant for the intended audience.⁵⁶ Furthermore, effective communication of risk information can assist the public in

⁵¹ See 1996 NAS Report on Understanding Risk and Informing Decisions, *supra* note 27, at 107 (“When uncertainty is recognizable and quantifiable, the language of probability can be used to describe it.”). See also EPA Risk Characterization Handbook, *supra* note 50, at 41 (“While it is generally preferred that quantitative uncertainty analyses are used in each risk characterization, there is no single recognized guidance that currently exists on how to conduct an uncertainty analysis. Nonetheless, risk assessors should perform an uncertainty analysis Uncertainty analysis should not be restricted to discussion of precision and accuracy, but should include such issues as data gaps and models.”).

⁵² See 2007 NAS Report on Global Change Assessments, *supra* note 15, at 60.

⁵³ *Id.* at 126.

⁵⁴ See Information Quality Guidelines, *supra* note 8.

⁵⁵ See OMB, Statistical Policy Working Paper No. 31, *Measuring and Reporting Sources of Error in Surveys*, 1-5 (2001) (“The measurement and reporting of error/sources is important for everyone who uses statistical data. For the analyst, this information helps data analyses through an awareness of the limitations of the data.”), available at http://www.fcsm.gov/01papers/SPWP31_final.pdf.

⁵⁶ See National Research Council, National Academy of Sciences, *Improving Risk Communication* 165-79 (1989). See also Risk Commission Report I, *supra* note 14, at 4 (the problems a regulation is intended to address should be placed in their “public health and ecological context.”).

balancing benefits and risks.⁵⁷ As our understanding regarding the presentation of risk information to policy makers and the public continues to develop, so too will agencies' presentation and discussion of risk comparison information.

d. provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.

Agencies should refer to OMB's Final Bulletin for Agency Good Guidance Practices, as well as the Peer Review Bulletin, for updated guidance regarding best practices for increasing public access and public comment concerning guidance documents and influential scientific information.⁵⁸ In addition, as noted in the OMB Information Quality Guidelines, influential risk analyses should be reproducible.⁵⁹ For guidance on how to provide the public with timely access to government information, Agencies should refer to OMB's Circular A-130, which addresses the management of Federal information resources, and OMB Memorandum 06-02, which addresses improving public access to Federal information.⁶⁰

Principles for Priority Setting Using Risk Analysis

1. To inform priority setting, agencies should seek to compare risks, grouping them in broad categories of concern (e.g., high, moderate, and low).
2. Agencies should set priorities for managing risks so that those actions resulting in the greatest net improvement in societal welfare are taken first, accounting for relevant management and social considerations such as different types of health or environmental impacts; individual preferences; the feasibility of reducing or avoiding risks; quality of life; environmental justice; and the magnitude and distribution of both short- and long-term benefits and costs.
3. The setting of priorities should be informed by internal agency experts and a broad range of individuals in state and local government, industry, academia, and nongovernmental organizations, as well as the public at large. Where possible, consensus views should be reflected in the setting of priorities.
4. Agencies should attempt to coordinate risk reduction efforts wherever feasible and appropriate.

⁵⁷ See Institute of Medicine, National Academy of Sciences, *Seafood Choices: Balancing Benefits and Risks* 207 (2006) ("In the committee's judgment, it is important to conduct substitution analyses of the potential impacts of changes in consumption despite the uncertainties about the underlying nutrient and contamination levels."). *Id.* at 231 (in referring to guidance and information that can simplify such tradeoffs, the NAS lists considerations for guidance development).

⁵⁸ See OMB, *Final Bulletin for Agency Good Guidance Practices* (2007), available at http://www.whitehouse.gov/omb/fedreg/2007/012507_good_guidance.pdf, and Peer Review Bulletin, *supra* note 8.

⁵⁹ See Information Quality Guidelines, *supra* note 8, 67 Fed. Reg. at 8460 (independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of precision).

⁶⁰ See OMB, Circular A-130, *Management of Federal Information Resources* (2000), available at <http://www.whitehouse.gov/omb/circulars/a130/a130trans4.pdf>; OMB Memorandum No. 06-02, *Improving Public Access to and Dissemination of Government Information and Using the Federal Enterprise Architecture Data Reference Model* (2005), available at <http://www.whitehouse.gov/omb/memoranda/fy2006/m06-02.pdf>.

Security and Prosperity Partnership of North America

Common Regulatory Principles

On August 21, 2007, Leaders of Canada, Mexico and the United States released the Regulatory Cooperation Framework (RCF), seeking to improve trilateral regulatory cooperation to (1) lower costs for North American businesses, producers, governments and consumers; (2) maximize trade in goods and services across our borders; and (3) protect health, safety, and the environment.

As one element of the Framework, governments agreed to develop and maintain an inventory of regulatory best practices from which regulators can draw upon as a resource. The establishment of this inventory will be an important milestone in advancing regulatory cooperation through the Framework.

The *OECD Guiding Principles for Regulatory Quality and Performance*

(<http://www.oecd.org/dataoecd/19/51/37318586.pdf>) represent a broad-based, international consensus on regulatory policy and form a good basis for common Framework principles. Canada, Mexico and the United States reaffirm their commitment to these Principles, and believe that they provide a useful point of reference in developing an inventory of regulatory best practices.

Accordingly, Canada, Mexico and the United States have approved the following common regulatory principles to guide their respective regulatory policies and practices.

RCF Common Regulatory Principles

1. Justify the need for regulation, including the consideration of market failures.
2. Identify alternatives to addressing a regulatory need, including non-regulatory options.
3. Assess the costs and benefits of regulatory and, where appropriate, non-regulatory alternatives so that options that maximize net benefits can be identified.
4. Minimize the adverse impact of regulation on a fair, competitive and innovative market economy.
5. Minimize unnecessarily divergent or duplicative requirements within North America.
6. Promote performance-based regulation where appropriate and to the extent practicable.
7. Ensure timeliness in regulatory decision-making.
8. Write regulations in plain language so they are easily understood.
9. Ensure transparent regulatory development and implementation, making regulations and regulatory impact analyses easily accessible.
10. Evaluate and review existing regulations routinely.

Security and Prosperity Partnership of North America

Illustrative Inventory of Best Practices

Below is a non-exhaustive inventory of best practices in North America that provides guidance on how to achieve the RCF Common Regulatory Principles.

CANADA

- Cabinet Directive on Streamlining Regulation
[<http://www.regulation.gc.ca/directive/directive01-eng.asp>]
- Assessing, Selecting, and Implementing Instruments for Government Action
[<http://www.regulation.gc.ca/documents/gl-ld/asses-eval/asses-evaltb-eng.asp>]
- Canadian Cost-Benefit Analysis Guide: Regulatory Proposals
[<http://www.regulation.gc.ca/documents/gl-ld/analys/analysb-eng.asp>]
- Guidelines on International Regulatory Obligations and Cooperation
[<http://www.regulation.gc.ca/documents/gl-ld/iroc-cori/iroc-coritb-eng.asp>]
- Guidelines for Effective Regulatory Consultations
[<http://www.regulation.gc.ca/documents/gl-ld/erc-cer/erc-certb-eng.asp>]
- Developing Regulations: The Basic Steps and the Plain Language Approach
[Link to French and English PDF versions of document]

MEXICO

- Regulatory Impact Assessment (Spanish only)
[<http://www.cofemermir.gob.mx>]
- Presidential Order for Regulatory Quality (Spanish only)
[<http://www.cofemer.gob.mx/documentos/marcojuridico/acuerdos/acr.pdf>]
- Federal Law of Administrative Procedures (Spanish only)
[<http://www.cofemer.gob.mx/documentos/marcojuridico/LEYES/lfpa.pdf>]
- Federal Law on Metrology and Standardization (Spanish only)
[<http://www.cofemer.gob.mx/documentos/marcojuridico/LEYES/lfmn.pdf>]
- COFEMER Website (Spanish only)
[<http://www.cofemer.gob.mx>]

UNITED STATES

- Executive Order 12866 (English only)
[http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf]
- Trade Agreements Act / Subchapter II – Technical Barriers to Trade (English only)
[http://www.access.gpo.gov/uscode/title19/chapter13_subchapterii.html]
- Office of Management and Budget's Guidance on Regulatory Analysis (English only)
[<http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>]

THE WHITE HOUSE

WASHINGTON

May 9, 2008

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND
AGENCIES
THE ADMINISTRATOR OF THE OFFICE OF
INFORMATION AND REGULATORY AFFAIRS

FROM: JOSHUA B. BOLTEN
CHIEF OF STAFF

SUBJECT: Issuance of Agency Regulations at the End of the
Administration

Over the last seven years, our Administration has worked to achieve through regulation important public benefits while minimizing regulatory costs on the American people. The President has emphasized that the American people deserve a regulatory system that protects and improves their health, safety and environment, secures their rights, and ensures a fair and competitive economic system, while respecting their prerogative to make their own decisions and not imposing unnecessary costs. We need to continue this principled approach to regulation as we sprint to the finish, and resist the historical tendency of administrations to increase regulatory activity in their final months. We must recognize that the burden imposed by new regulations is cumulative and has a significant effect on all Americans.

Every regulatory agency and department has a responsibility for continuing to ensure regulations issued in this final year are in the best interests of the American public. To the extent permitted by law, the heads of executive departments and agencies should continue to minimize costs and maximize benefits for each of their upcoming regulations, and should avoid issuing regulations that are unnecessary. Except in extraordinary circumstances, regulations to be finalized in this Administration should be proposed no later than June 1, 2008, and final regulations should be issued no later than November 1, 2008.

To ensure we continue to serve the American people through carefully-designed regulations, the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) will coordinate an effort to complete Administration priorities in this final year while providing for an appropriately open and transparent process and controlling regulatory costs. In this effort, OIRA will work closely with the heads of the President's policy councils, and rely on its centralized review authority under Executive Order 12866.

Pursuant to Executive Order 12866, agencies shall continue to assess the need for regulation, examine alternatives, design regulations in the most cost-effective manner to achieve regulatory objectives, and assess both the costs and benefits of intended regulations. Circular A-4 provides guidance to agencies for analyzing the effects of regulation. Agencies should view each regulation as part of a broader regulatory framework and, in cooperation with OIRA, make careful and coordinated policy choices that do not impose undue regulatory burdens on the American people.

Agencies should examine the regulations they intend to promulgate before the end of this Administration for compliance with this memorandum and provide all information and assistance requested by the Administrator of OIRA in this important endeavor. In identifying priorities and establishing schedules, agencies should provide adequate time for necessary analysis, interagency consultation, robust public comment, and a careful evaluation of and response to those comments. However, I also want to emphasize that nothing in this memorandum alters or impedes the ability of the executive departments and agencies to perform their responsibilities under existing law.

Finally, the OIRA Administrator will report on a regular basis regarding agency compliance with this memorandum.

cc:

Chairman of the Council on Environmental Quality
Chairman of the Council of Economic Advisors
Director, Office of Science and Technology Policy
Assistants to The President

THE WHITE HOUSE

WASHINGTON

MEMORANDUM

THROUGH: JIM NUSSLE

FROM: STEVE MCMILLIN

SUBJECT: EARMARKS

In the 1990s, congressional earmarking exploded – in both the number of earmarks and amount of funding involved. According to Citizens Against Government Waste, the FY 1991 appropriations bills contained 546 earmarks totaling \$3.1 billion. A decade later, the FY 2001 appropriations bills contained 6,333 earmarks totaling \$18.5 billion. At the start of his Administration, and each year thereafter, the President requested and vigorously pursued the enactment of the Legislative Line Item Veto legislation that would have allowed him to selectively veto earmarked projects. The President highlighted the problems with earmarks in Budget requests and Statements of Administration Policy on various appropriations bills, but focused most vigorously on defending the discretionary top line set by his Budget, while letting the Congress set many of the details. As he succeeded over the years in enforcing the top line, the President began to increase emphasis on the earmark problem. In 2007, he established a comprehensive public earmark database, and called on Congress to voluntarily cut the number and amount in half and to improve transparency by including any earmarks in bill text, rather than report language, and established a comprehensive public earmark database to track these efforts. In 2008, the President continued his push for earmark reform by promising to veto any appropriations bill that did not cut earmarks in half, and issuing an Executive Order directing Federal agencies to ignore any future earmarks that are not voted on by Congress, and to post on the internet all communications from Congress advocating for a specific earmark or project. As a result of these efforts, the number and amount of earmarks did decline slightly in 2008 to 11,524 and \$16.5 billion.

- ***Pursuing Legislative Line Item Veto.*** Each of the President's eight budget submissions proposed that the President should have the legislative line item veto authority. The *Blueprint for New Beginnings* in 2001 read:

A perennial criticism of the Federal Government is that the annual budget contains too many special interest or "pork-barrel" spending items. The persistence of these special interest items erodes citizen confidence in Government. With the arrival of huge budget surpluses, there has been an explosion in spending and special interest spending. ... It is the rare Member who will challenge questionable spending for fear that provisions important to him or her will be challenged in return.

The result of this logrolling is that the President is left with an all or nothing proposition. He must either sign the entire appropriations bill with special interest projects or veto the entire

bill and invite a potential Government shutdown. The President proposes that the Congress correct a constitutional flaw in the Line Item Veto Act enacted in 1996...

The President transmitted a legislative proposal on March 6, 2006, and succeeded in gaining House passage of a similar proposal and committee approval in the Senate. However, the proposal was never enacted into law.

- ***Highlighting Problems with Earmarking.*** Beginning with the Statements of Administration Position (SAPs) on the FY 2002 appropriations bills and continuing throughout the Bush Presidency, the Administration highlighted areas where extensive congressional earmarking severely limited the effectiveness of underlying programs. In the FY 2003 Budget, the President also presented several vignettes about particularly intrusive or ill-advised earmarks.
- ***Prohibiting Agencies from Following Earmarks in Report Language or By Other Non-Statutory Congressional Communication.*** After the FY 2007 Full-Year Continuing Resolution was signed into law with a clause stating that there were no earmarks funded through the bill, Director Portman issued a memo to agencies to help prevent further congressional earmarking by requiring full merit-based allocations of funds. The following year, the President issued an Executive Order, directing Federal agencies to ignore any future earmarks that are not voted on by Congress and to post communications from Congress to federal agencies advocating funding for particular projects. As a result, earmarks will be subject to the light of day and an up or down vote by lawmakers. Members of Congress will have the opportunity to advocate for projects they support, but their views will be posted on the internet and considered as part of an Agency's merit-based decision making process.
- ***Challenging Congress to Reduce Earmarks by Half.*** In a January 3, 2007 speech and again in the 2007 State of the Union address, the President called on the Congress to increase transparency by disclosing earmark sponsors and including earmarks in bill language and to reduce wasteful spending by cutting the number and dollar amount of earmarks in half. On April 13, 2007, the Administration published the 2005 earmark baseline in a public website from which the goal was to be measured, and in July began to publish tracking data as bills moved through the appropriations process. The new earmarks database (<http://earmarks.omb.gov>) provides more information on earmarks in one place than has ever been available through the Federal Government, and is an important part of a broader effort to bring greater accountability and transparency to Federal spending.

While the Congress did not meet the President's challenge, the final totals for the FY 2008 appropriations bills were less than the 2005 baseline: 11,524 earmarks, totaling \$16.5 billion, which represents a 15% reduction in number and 13% reduction in amount. Since the Congress did not succeed in voluntarily meeting the President's goal of reducing earmarks by half, in the 2008 State of the Union, the President promised to veto any bills that did not cut the number and dollar amount of earmarks in half. Congress responded to this challenge (and to the President's insistence on overall spending limits) by virtually abandoning their appropriations responsibilities for FY 2009. Congress

included three of the regular spending bills (with approximately 2,600 earmarks) in a 5-month continuing resolution that contained no earmarks for the other nine appropriations bills.

The President has established earmark reform as a top priority for the nation, and has put in place a strong set of tools for a continued reduction in wasteful earmarks. By upholding the President's Executive Order and continuing to publish the earmarks database, the next Administration is well positioned to continue the progress made by President Bush on this issue.

EARMARKS (2001-2008)

(TAB)

February 28, 2001

(1)

The President, in the *Blueprint for New Beginnings*, proposed the Legislative Line Item Veto, requested no funding for the continuation of earmarks in the FY 2002 Budget Request, and proposed the creation of a bipartisan commission to eliminate pork barrel spending. Every Budget thereafter proposed the Legislative Line Item Veto and zeroed out spending for earmarked items in the budget year.

February 4, 2002

The President submitted the FY 2003 Budget, which highlighted several specific wasteful earmarks.

March 6, 2006

(2)

The President transmitted a legislative proposal, the Legislative Line Item Veto Act of 2006, to give the President line-item veto authority to reduce wasteful spending. On June 22nd, the House approved H.R. 4890, the Legislative Line Item Veto Act of 2006, by the strong bipartisan margin of 247-172. The Senate Budget Committee also reported S. 3521, the Stop Over Spending Act of 2006, on June 20, 2006. Title I of the Senate bill contained the Legislative Line Item Veto, but the bill was never considered on the Senate floor.

January 3, 2007

(3)

The President called on the Congress to reform the earmark process by fully disclosing all earmarks, stop putting them in report language, and cutting the cost and number of earmarks by at least half. On January 5th, the House adopted a rule requiring disclosure of the sponsor, beneficiary, and purpose of the earmark, along with information on whether there is any conflict of interest. The Senate included similar reforms in S. 1, which passed the Senate on January 17th, and became law on September 14, 2007 (P.L. 110-81). On February 9th, Chairman Obey sent a dear colleague letter, informing members how and when they should submit their earmark requests and following the President's lead, he also announced that "the Committee plans to reduce the dollar amount of earmarks in appropriations bills by 50 percent relative to the amounts planned in FY 2006." Obey noted that the reduction would not apply to accounts that are "project-based, like the Corps of Engineers." (The Senate refused to adopt an earmark reduction target.)

January 25, 2007

(4)

Director Portman issued a memo to agencies asking them to collect information on earmarks for FY 2005 to enable OMB to publish a database that would serve as a benchmark for the President's cut in half goal.

February 15, 2007

(5)

The President signed the full-year CR, which includes a moratorium on earmarks for FY 2007 for the agencies covered under the CR. As a consequence, for FY 2007, there were no earmarks for any agency other than the Department of Defense and the Department of Homeland Security (for which bills had passed as stand-alone measures). On the same day, Director Portman issued a memo to agencies to help prevent earmarking in the implementation of FY 2007 appropriations.

April 13, 2007

(6)

OMB posted a FY 2005 database of earmarks, listing 13,497 earmarks at a cost of nearly \$19 billion. This database established the benchmark from which the President judged whether Congress cut earmarks by half for FY 2008.

July, 2007

The Administration began publishing tracking data on earmarks in the 2008 appropriations bills as they progressed through the various Congressional stages of action. In his Statements of Administration Policy, the President continued to call for cutting the number and dollar amount of earmarks in half.

December 26, 2007

(7)

The President -- when signing the final appropriations bill -- expressed disappointment in Congress' failure to achieve the President's goal of cutting the total number and dollar amount of appropriations bill earmarks in half from 2005 levels (see H.R. 2764 signing statement). Between the Defense Appropriations bill and the Consolidated Appropriations Act, the Congress had appropriated more than 11,700 earmarks, totaling approximately \$16.9 billion, representing only a 13% reduction in total number of earmarks, and an 11% reduction in total earmarks dollars.

January 28, 2008

(8)

The President, in his State of the Union address, stated his intention to veto appropriations bills that do not cut the number and cost of earmarks in half.

January 29, 2008

(9)

The President issued an Executive Order directing Federal agencies to ignore any future earmarks that are not voted on by Congress and to post certain communications from Congress.

July 7, 2008

OMB posted a FY 2008 database of earmarks, establishing the benchmark from which the President will judge whether Congress has cut earmarks by half in the FY 2009 appropriations bills. OMB subsequently (September 5, 2008) began posting data tracking earmarks in FY 2009 appropriations bills.

September 5, 2008

The Administration began publishing tracking data for earmarks in the 2009 appropriations bills as they progressed through the various Congressional stages of action. In his Statement of Administration Policy on the Military Construction and Veterans Affairs Appropriations bill, the President reiterated the veto threat concerning cutting the number and dollar amount of earmarks in half.

A



A BLUEPRINT FOR NEW BEGINNINGS

A RESPONSIBLE BUDGET
FOR AMERICA'S PRIORITIES

VIII. BUDGET PROCESS REFORM

In recent years, the Nation has turned to Washington in the Fall, wondering if the Government will shut down because Republicans and Democrats cannot agree on a budget. And following each year's chaos and brinkmanship there are cries for budget process reform to prevent repetition of the spectacle. Important changes can be made, but the heart of the problem lies not in the integrity of the budget process, but in the deterioration of Congress' adherence to existing rules.

This past year was typical. As Congress failed to meet its deadlines and legislation piled up at the end of the fiscal year, Washington made hasty decisions simply to keep the Government running under the imminent threat of a Government shutdown. Congress enacted 21 temporary funding laws to keep the Government open while President Clinton and Congress negotiated an agreement on a huge omnibus spending bill. That omnibus measure comprised nine separate bills, totaling 2,080 pages, and was finally signed into law on December 21st, nearly three months after the beginning of the fiscal year.

The end product exceeded Congress' budget by \$36 billion and the President's Budget by \$13 billion for 2001 alone. It contained over 6,000 earmarks, or unrequested projects, for a total cost of over \$15 billion.

To provide for a more orderly and responsible budget process and to wrest waste out of the Federal budget, the President proposes immediate and structural reform measures.

Immediate Action:

- Restore an atmosphere of order and respect for the legally established process. In addition to the reforms outlined here, the ultimate reform the President calls for is responsibility in the conduct of the people's business;
- Abide by the budget. Once Congress agrees to a budget, it should abide by the limits established therein. Ultimately, the President proposes that the resolution be a law, requiring his approval. Until that time, the President wants to work with the Congress to adopt and abide by a budget that contains total spending within a reasonable limit determined in advance;
- Establish a National Emergency Reserve fund to budget for true emergencies;
- Eliminate advance appropriations except where clearly justified;
- Complete action on appropriations bills in an orderly and timely fashion to avoid Government shutdowns; and
- Curtail congressional earmarking, especially for special interest spending.

Structural Reforms:

- Enforce and extend limits on spending and the "pay-as-you-go" (PAYGO) requirement.
- Convert the annual budget and appropriations process to a biennial cycle.
- Make the current non-binding budget resolution a binding law.
- Restore the President's line-item veto authority.

In addition to these initiatives, the President would support legislation to create a bipartisan commission to eliminate pork barrel spending and legislation to create a sunset review board to review agencies and programs periodically.

Spending Limits and Pay-As-You-Go

In 1990, Congress enacted the Budget Enforcement Act (BEA) with specific dollar limits on discretionary spending—amounts provided in annual appropriations acts—and a PAYGO requirement for all other legislation. The PAYGO requirement prohibits decreases in a surplus resulting from enactment of new laws that change mandatory spending—

Table S-4. Bridge to 2002 Proposed Discretionary Spending
(Budget authority, dollar amounts in billions)

2001 Enacted	635.0
Department of Defense:	
Additions:	
Campaign initiatives	4.4
Pay, inflation, health, and other	9.8
Non-Department of Defense:	
Additions:	
Campaign initiatives	10.4
Pay and programmatic increases	9.6
National Emergency Reserve	5.6
Technical adjustments (contract renewals, new advances, etc.)	6.3
Offsets: ¹	
Non-repetition of earmarked funding	-4.3
Non-repetition of one-time funding	-4.1
Program decreases	-12.1
2002 Total Discretionary	660.7
2002 Discretionary Baseline	660.7
Increase over 2001 Enacted	25.7
Percentage Increase	4.0%

¹ The final distribution of offsets has yet to be determined.

TO THE CONGRESS OF THE UNITED STATES:

In my State of the Union Address, I asked the Congress to give the President a line item veto. Today, I am sending the Congress a legislative proposal to give the President line item authority to reduce wasteful spending. This legislation will help to limit spending and ensure accountability and transparency in the expenditure of taxpayer funds.

Although the Congress achieved significant spending restraint this past year, appropriations and other bills that are sent to my desk still contain spending that is not fully justified, is a low priority, or is earmarked to avoid the discipline of competitive or merit-based reviews. When this legislation is presented to me, I now have no ability to line out unnecessary spending. In 1996, the Congress gave the President a line item veto -- an important tool to limit wasteful spending -- but the Supreme Court struck down that version of the law in 1998.

My proposed legislation, the "Legislative Line Item Veto Act of 2006," would provide a fast-track procedure to require the Congress to vote up-or-down on rescissions proposed by the President. There has been broad bipartisan support for similar proposals in the past. Under this proposal, the President could propose legislation to rescind wasteful spending, and the Congress would be obligated to vote quickly on that package of rescissions, without amendment. The same procedure would apply to new mandatory spending and to special interest tax breaks given to small numbers of individuals.

Forty-three Governors have a line item veto to reduce spending. The President needs similar authority to help control unjustified and wasteful spending in the Federal budget. I urge you to promptly consider and send me this legislation for enactment to reduce unnecessary spending and help achieve my goal of cutting the deficit in half by 2009.

GEORGE W. BUSH

THE WHITE HOUSE,
March 6, 2006.

LEGISLATIVE LINE ITEM VETO ACT OF 2006

Section-by-Section Summary

SECTION 1. SHORT TITLE

Section 1 gives the bill the short title, the “Legislative Line Item Veto Act of 2006”.

SECTION 2. LEGISLATIVE LINE ITEM VETO

Section 2 amends Title X of the Congressional Budget and Impoundment Control Act of 1974 by deleting Part C and inserting the following new Part:

PART C—LEGISLATIVE LINE ITEM VETO

Section 1021. (a) **PROPOSED RESCISSIONS.** This subsection provides the President with the authority to propose the rescission of any dollar amount of discretionary budget authority or any item, in whole or in part, of new direct spending.

(b) **TRANSMITTAL OF SPECIAL MESSAGE.** This subsection describes the transmittal of a special message by the President to the Congress proposing to rescind budget authority contained in an appropriations Act or any item of direct spending. The contents of the special message shall include: (1) the amount of budget authority or the specific item of direct spending proposed to be rescinded; (2) the account, department, or establishment of Government that is the subject of the rescission; (3) reasons for the rescission; (4) the estimated fiscal, economic, and budgetary effect of the proposed rescission; (5) other relevant information about the proposed rescission; and (6) a draft bill that would effectuate the President’s request. The subsection specifies that the amounts of budget authority or items of direct spending that are rescinded must be used for deficit reduction and cannot be used to offset other spending increases. In addition, the subsection specifies that not later than five days following the date of enactment of a rescission bill, the Chairmen of the Senate and House Budget Committees would be required to make the necessary adjustments to Committee allocations. Also, the Office of Management and Budget would be required to make the necessary adjustments to its spending caps.

(c) **PROCEDURES FOR EXPEDITED CONSIDERATION.** This subsection specifies that the House and Senate Leadership may introduce (by request) the President’s proposed bill to rescind budget authority or an item of direct spending within two days following receipt of the special message by the President. After that period has elapsed, any member of Congress may introduce the President’s proposal. Once introduced, the rescission bill would be referred to the appropriate committee and that committee would have five days to report the bill without substantive revision and with or without recommendation. Failure to meet the specified deadline would result in the bill being automatically discharged and placed on the appropriate calendar for action. A vote on

final passage must occur in the House and the Senate on or before the close of the 10th day of session following introduction of the bill. This subsection would also establish procedural rules for consideration of a rescission bill in the House of Representatives and the Senate. For example, motions to proceed to the consideration of the bill would not be subject to debate, motions to limit debate would not be subject to debate, and motions to recommit or reconsider would not be in order. Debate on the bill would be limited to four hours in the House and 10 hours in the Senate.

(d) **AMENDMENTS AND DIVISIONS PROHIBITED.** This subsection specifies that no amendment to a bill considered under this section would be in order in either House of Congress and that it would not be in order to demand a division of the question in the House.

(e) **TEMPORARY PRESIDENTIAL AUTHORITY TO WITHHOLD.** This subsection would allow the President to temporarily withhold any budget authority for up to 180 calendar days from the date the President transmits the special message to the Congress. The subsection also makes clear that the President has the authority to make funds available at an earlier time if he concludes Congress is unlikely to enact specific rescissions into law.

(f) **TEMPORARY PRESIDENTIAL AUTHORITY TO SUSPEND.** This subsection would allow the President to temporarily suspend the execution of any item of direct spending for up to 180 calendar days from the date the President transmits the special message to the Congress. The subsection would also make clear that the President has the authority to terminate a suspension at an earlier time if he concludes Congress is unlikely to enact specific rescissions into law.

(g) **DEFINITIONS.** This subsection defines the terms: (1) appropriation law; (2) deferral; (3) dollar amount of discretionary budget authority; (4) rescind or rescission; (5) direct spending; (6) item of direct spending; (7) suspend the execution and (8) targeted tax benefit.

(h) **APPLICATION TO TARGETED TAX BENEFITS.** This subsection authorizes the President to propose the repeal of any targeted tax benefit in any bill that includes such a benefit in the same way the President is allowed to rescind an item of direct spending.

The bill also provides that, for purposes of judicial review, the provisions of the Act are severable. If any provision of the Act or the amendments made by it are held to be unconstitutional, then the remainder of the Act shall not be affected by the Court's holding. The bill also provides that it would apply only to spending contained in bills passed subsequent to the passage of this proposed Act.

A BILL

To amend the Congressional Budget and Impoundment Control Act of 1974 to provide Line Item Rescission Authority.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Legislative Line Item Veto Act of 2006”.

SEC. 2. LEGISLATIVE LINE ITEM VETO.

(a) IN GENERAL—Title X of the Congressional Budget and Impoundment Control Act of 1974 (2 U.S.C. 621 et seq.) is amended by deleting Part C and inserting the following:

“PART C—LEGISLATIVE LINE ITEM VETO”

“SEC. 1021. (a) PROPOSED RESCISSIONS—The President may propose, at the time and in the manner provided in subsection (b), the rescission of any dollar amount of discretionary budget authority or the rescission, in whole or in part, of any item of direct spending.

“(b) TRANSMITTAL OF SPECIAL MESSAGE—

“(1) SPECIAL MESSAGE—

“(A) IN GENERAL—The President may transmit to Congress a special message proposing to rescind any dollar amount of discretionary budget authority or any item of direct spending.

“(B) CONTENTS OF SPECIAL MESSAGE—Each special message shall specify, with respect to the budget authority or item of direct spending proposed to be rescinded—

“(i) the amount of budget authority or the specific item of direct spending that the President proposes be rescinded;

“(ii) any account, department, or establishment of the Government to which such budget authority or item of direct spending is available for obligation, and the specific project or governmental functions involved;

“(iii) the reasons why such budget authority or item of direct spending should be rescinded;

“(iv) to the maximum extent practicable, the estimated fiscal, economic, and budgetary effect (including the effect on outlays and receipts in each fiscal year) of the proposed rescission;

“(v) to the maximum extent practicable, all facts, circumstances, and considerations relating to or bearing upon the proposed rescission and the decision to effect the proposed rescission, and the estimated effect of the proposed rescission upon the objects, purposes, and programs for which the budget authority or item of direct spending is provided; and

“(vi) a draft bill that, if enacted, would rescind the budget authority or item of direct spending proposed to be rescinded in that special message.

“(2) ENACTMENT OF RESCISSION BILL—

“(A) DEFICIT REDUCTION—Amounts of budget authority or items of direct spending which are rescinded pursuant to enactment of a bill as provided under this section shall be dedicated only to deficit reduction and shall not be used as an offset for other spending increases.

“(B) ADJUSTMENT OF COMMITTEE ALLOCATIONS—Not later than 5 days after the date of enactment of a rescission bill as provided under this section, the chairs of the Committees on the Budget of the Senate and the House of Representatives shall revise levels under section 311(a) and adjust the committee allocations under section 302(a) to reflect the rescission, and the appropriate committees shall report revised allocations pursuant to section 302(b), as appropriate.

“(C) ADJUSTMENTS TO CAPS—After enactment of a rescission bill as provided under this section, the Office of Management and Budget shall revise applicable limits under the Balanced Budget and Emergency Deficit Control Act, as appropriate.

“(c) PROCEDURES FOR EXPEDITED CONSIDERATION—

“(1) IN GENERAL—

“(A) INTRODUCTION—Before the close of the second day of session of the Senate and the House of Representatives, respectively, after the date of receipt of a special message transmitted to Congress under subsection (b), the majority leader or minority leader of each House shall introduce (by request) a bill to rescind the amounts of budget authority or items of direct spending, as specified in the special message and the President’s draft bill. If the bill is not introduced as provided in the preceding sentence in either House, then, on the third day of session of that House after the date of receipt of that special message, any Member of that House may introduce the bill.

“(B) REFERRAL AND REPORTING—The bill shall be referred to the appropriate committee. The committee shall report the bill without substantive revision and with or without recommendation. The committee shall report the bill not later than the fifth day of session of that House after the date of introduction of the bill in that House. If the committee fails to report the bill within that period, the committee shall be automatically discharged from consideration of the bill, and the bill shall be placed on the appropriate calendar.

“(C) FINAL PASSAGE—A vote on final passage of the bill shall be taken in the Senate and the House of Representatives on or before the close of the 10th day of session of that House after the date of the introduction of the bill in that House. If the bill is passed, the Secretary of the Senate or the Clerk of the House of Representatives, as the case may be, shall cause the bill to be transmitted to the other House before the close of the next day of session of that House.

“(2) CONSIDERATION IN THE HOUSE OF REPRESENTATIVES—

“(A) MOTION TO PROCEED TO CONSIDERATION—A motion in the House of Representatives to proceed to the consideration of a bill under this subsection shall be highly privileged and not debatable. An amendment to the motion shall not be in order, nor shall it be in order to move to reconsider the vote by which the motion is agreed to or disagreed to.

“(B) LIMITS ON DEBATE—Debate in the House of Representatives on a bill under this subsection shall not exceed 4 hours, which shall be divided equally between those favoring and those opposing the bill. A motion further to limit debate shall not be debatable. It shall not be in order to move to recommit a bill under this subsection or to move to reconsider the vote by which the bill is agreed to or disagreed to.

“(C) APPEALS—Appeals from decisions of the Chair relating to the application of the Rules of the House of Representatives to the procedure relating to a bill under this section shall be decided without debate.

“(D) APPLICATION OF HOUSE RULES—Except to the extent specifically provided in this section, consideration of a bill under this section shall be governed by the Rules of the House of Representatives. It shall not be in order in the House of Representatives to consider any bill introduced pursuant to the provisions of this section under a suspension of the rules or under a special rule.

“(3) CONSIDERATION IN THE SENATE—

“(A) MOTION TO PROCEED TO CONSIDERATION—A motion to proceed to the consideration of a bill under this subsection in the Senate shall not be debatable. It shall not be in order to move to reconsider the vote by which the motion to proceed is agreed to or disagreed to.

“(B) LIMITS ON DEBATE—Debate in the Senate on a bill under this subsection, and all debatable motions and appeals in connection therewith (including debate pursuant to subparagraph (D)), shall not exceed 10 hours, equally divided and controlled in the usual form.

“(C) APPEALS—Debate in the Senate on any debatable motion or appeal in connection with a bill under this subsection shall be limited to not more than 1 hour, to be equally divided and controlled in the usual form.

“(D) MOTION TO LIMIT DEBATE—A motion in the Senate to further limit debate on a bill under this subsection is not debatable.

“(E) MOTION TO RECOMMIT—A motion to recommit a bill under this subsection is not in order.

“(F) CONSIDERATION OF THE HOUSE BILL—

“(i) IN GENERAL—If the Senate has received the House companion bill to the bill introduced in the Senate prior to the vote required under paragraph (1)(C), then the Senate may consider, and the vote under paragraph (1)(C) may occur on, the House companion bill.

“(ii) PROCEDURE AFTER VOTE ON SENATE BILL—If the Senate votes, pursuant to paragraph (1)(C), on the bill introduced in the Senate, then immediately following that vote, or upon receipt of the House companion bill, the House bill shall be deemed to be considered, read the third time, and the vote on passage of the Senate bill shall be considered to be the vote on the bill received from the House.

“(d) AMENDMENTS AND DIVISIONS PROHIBITED—No amendment to a bill considered under this section shall be in order in either the Senate or the House of Representatives. It shall not be in order to demand a division of the question in the House of Representatives (or in a Committee of the Whole). No motion to suspend the application of this subsection shall be in order in the House of Representatives, nor shall it be in order in the House of Representatives to suspend the application of this subsection by unanimous consent.

“(e) TEMPORARY PRESIDENTIAL AUTHORITY TO WITHHOLD.—

“(1) IN GENERAL.—At the same time as the President transmits to Congress a special message pursuant to subsection (b), the President may direct that any dollar amount of discretionary budget authority proposed to be rescinded in that special message shall not be made available for obligation for a period not to exceed 180 calendar days from the date the President transmits the special message to Congress.

“(2) EARLY AVAILABILITY.—The President may make any dollar amount of discretionary budget authority deferred pursuant to paragraph (1) available at a time earlier than the time specified by the President if the President determines that continuation of the deferral would not further the purposes of this Act.”

“(f) TEMPORARY PRESIDENTIAL AUTHORITY TO SUSPEND.—

“(1) IN GENERAL.—At the same time as the President transmits to Congress a special message pursuant to subsection (b), the President may suspend the execution of any item of direct spending proposed to be rescinded in that special message for a period not to exceed 180 calendar days from the date the President transmits the special message to Congress.

“(2) EARLY AVAILABILITY.—The President may terminate the suspension of any item of direct spending at a time earlier than the time specified by the President if the President determines that continuation of the suspension would not further the purposes of this Act.”

“(g) DEFINITIONS—For purposes of this section—

“(1) the term “appropriation law” means any general or special appropriation Act, and any Act or joint resolution making supplemental, deficiency, or continuing appropriations;

“(2) the term “deferral” has, with respect to any dollar amount of discretionary budget authority, the same meaning as the phrase “deferral of budget authority” defined in section 1011(1) in Part B (2 U.S.C. § 682(1));

“(3) the term “dollar amount of discretionary budget authority” means the entire dollar amount of budget authority and obligation limitations—

“(A) specified in an appropriation law, or the entire dollar amount of budget authority required to be allocated by a specific proviso in an appropriation law for which a specific dollar figure was not included;

“(B) represented separately in any table, chart, or explanatory text included in the statement of managers or the governing committee report accompanying such law;

“(C) required to be allocated for a specific program, project, or activity in a law (other than an appropriation law) that mandates the expenditure of budget authority from accounts, programs, projects, or activities for which budget authority is provided in an appropriation law;

“(D) represented by the product of the estimated procurement cost and the total quantity of items specified in an appropriation law or included in the statement of managers or the governing committee report accompanying such law; or

“(E) represented by the product of the estimated procurement cost and the total quantity of items required to be provided in a law (other than an appropriation law) that mandates the expenditure of budget authority from accounts, programs, projects, or activities for which dollar amount of discretionary budget authority is provided in an appropriation law;

“(4) the terms “rescind” or “rescission” mean to modify or repeal a provision of law to prevent:

“(A) budget authority from having legal force or effect;

“(B) in the case of entitlement authority, to prevent the specific legal obligation of the United States from having legal force or effect; and

“(C) in the case of the food stamp program, to prevent the specific provision of law that provides such benefit from having legal force or effect.

“(5) the term “direct spending” means budget authority provided by law (other than an appropriation law); entitlement authority; and the food stamp program;

“(6) the term “item of direct spending” means any specific provision of law enacted after the effective date of the Legislative Line Item Veto Act of 2006 that is estimated to result in a change in budget authority or outlays for direct spending relative to the most recent levels calculated pursuant to section 257 of the Balanced Budget and Emergency Deficit Control Act of 1985 and included with a budget submission under section 1105(a) of title 31, United States Code, and with respect to estimates made after that budget submission that are not included with it, estimates consistent with the economic and technical assumptions underlying the most recently submitted President’s budget; and

“(7) the term “suspend the execution” means, with respect to an item of direct spending or a targeted tax benefit, to stop for a specified period, in whole or in part, the carrying into effect of the specific provision of law that provides such benefit.

“(8) (A) The term “targeted tax benefit” means—

“(i) any revenue-losing provision that provides a Federal tax deduction, credit, exclusion, or preference to 100 or fewer beneficiaries under the Internal Revenue Code of 1986 in any fiscal year for which the provision is in effect; and

“(ii) any Federal tax provision that provides temporary or permanent transitional relief for 10 or fewer beneficiaries in any fiscal year from a change to the Internal Revenue Code of 1986.

“(B) A provision shall not be treated as described in subparagraph (A)(i) if the effect of that provision is that—

“(i) all persons in the same industry or engaged in the same type of activity receive the same treatment;

“(ii) all persons owning the same type of property, or issuing the same type of investment, receive the same treatment; or

“(iii) any difference in the treatment of persons is based solely on—

“(I) in the case of businesses and associations, the size or form of the business or association involved;

“(II) in the case of individuals, general demographic conditions, such as income, marital status, number of dependents, or tax-return-filing status;

“(III) the amount involved; or

“(IV) a generally-available election under the Internal Revenue Code of 1986.

“(C) A provision shall not be treated as described in subparagraph (A)(ii) if—

“(i) it provides for the retention of prior law with respect to all binding contracts or other legally enforceable obligations in existence on a date contemporaneous with congressional action specifying such date; or

“(ii) it is a technical correction to previously enacted legislation that is estimated to have no revenue effect.

“(D) For purposes of subparagraph (A)—

“(i) all businesses and associations that are members of the same controlled group of corporations (as defined in section 1563(a) of the Internal Revenue Code of 1986) shall be treated as a single beneficiary;

“(ii) all qualified plans of an employer shall be treated as a single beneficiary;

“(iii) all holders of the same bond issue shall be treated as a single beneficiary; and

“(iv) if a corporation, partnership, association, trust or estate is the beneficiary of a provision, the shareholders of the corporation, the partners of the partnership, the members of the association, or the beneficiaries of the trust or estate shall not also be treated as beneficiaries of such provision.

“(E) For the purpose of this paragraph, the term “revenue-losing provision” means any provision that results in a reduction in Federal tax revenues for any one of the two following periods—

“(i) the first fiscal year for which the provision is effective; or

“(ii) the period of the 5 fiscal years beginning with the first fiscal year for which the provision is effective.

“(F) The terms used in this paragraph shall have the same meaning as those terms have generally in the Internal Revenue Code of 1986, unless otherwise expressly provided.

“(h) APPLICATION TO TARGETED TAX BENEFITS—The President may propose the repeal of any targeted tax benefit in any bill that includes such a benefit, under the same conditions, and subject to the same Congressional consideration, as a proposal under this section to rescind an item of direct spending .”.

(b) EXERCISE OF RULEMAKING POWERS—Section 904 of the Congressional Budget Act of 1974 (2 U.S.C. 621 note) is amended—

(1) in subsection (a), by striking “and 1017” and inserting “1017, and 1021”; and

(2) in subsection (d), by striking “section 1017” and inserting “sections 1017 and 1021”.

(c) CLERICAL AMENDMENTS—(1) Section 1(a) of the Congressional Budget and Impoundment Control Act of 1974 is amended by—

(i) striking “Parts A and B” before “title X” and inserting “Parts A, B, and C”; and

(ii) striking the last sentence and inserting at the end the following new sentence: “Part C of title X also may be cited as the ‘Legislative Line Item Veto Act of 2006.’”

(2) TABLE OF CONTENTS.—The table of contents set forth in section 1(b) of the Congressional Budget and Impoundment Control Act of 1974 is amended by deleting the contents for part C of title X and inserting the following:

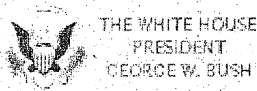
“PART C—LEGISLATIVE LINE ITEM VETO

Sec. 1021. Expedited consideration of certain proposed rescissions.”.

(d) SEVERABILITY.—If any provision of this Act or the amendments made by it is held to be unconstitutional, the remainder of this Act and the amendments made by it shall not be affected by the holding.

(e) EFFECTIVE DATE. —The amendments made by this Act shall—

- (1) take effect on the date of enactment of this Act; and
- (2) apply only to any dollar amount of discretionary budget authority, item of direct spending, or targeted tax benefit provided in an Act enacted on or after the date of enactment of this Act.

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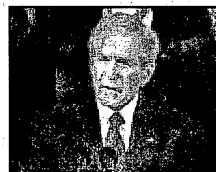
For Immediate Release
Office of the Press Secretary
January 3, 2007

President Bush Meets with Cabinet, Proposes Balanced Budget and Earmark Reform

Rose Garden

- Fact Sheet: A Balanced Budget by 2012 & Earmark Reform
- In Focus: Budget Management
- President Bush's Cabinet

10:19 A.M. EST



VIDEO Multimedia

President's Remarks

[view](#)

THE PRESIDENT: Thank you all. We just finished our first Cabinet meeting of 2007. I want to thank my Cabinet officers for joining me here. We discussed our priorities for the next two years, and how we plan to achieve them. The Congress has changed; our obligations to the country haven't changed.

Tomorrow, members of the 110th Congress will take their oaths of office, and I congratulate them. I welcome their arrival into town. I'm looking forward to working with them, and so are members of my Cabinet. We've all been entrusted with public office at a momentous time in our nation's history. And together we have important things to do. It's time to set aside politics and focus on the future.



I've been encouraged by the productive meetings that I've had with many of the new leaders of Congress, people from both parties. I want to thank them for coming down to the White House and talking to me about their ambitions and their goals for our country. I'm hopeful that Republicans and Democrats can find common ground to serve our folks, to do our jobs, to be constructive for our country.

One area where we must work together is that we've got to make sure we spend the people's money wisely. Over the past few years, pro-growth economic policies have generated higher revenues. Together with spending restraint, these policies allowed us to meet our goal of cutting the budget deficit in half three years ahead of schedule. We did so without taxing the working people. We kept taxes low.

It's now time to take the next step. Next month I will submit a five-year budget proposal that will balance the federal budget by 2012. This budget will restrain spending while setting priorities. It will address the most urgent needs of our nation, in particular the need to protect ourselves from radicals and terrorists; the need to win the war on terror; the need to maintain a strong national defense; and the need to keep this economy growing by making tax relief permanent.

By balancing the budget through pro-growth economic policies and spending restraint, we are better positioned to tackle longer-term fiscal challenges facing our country, namely the entitlement programs. These programs need to be reformed for the sake of younger Americans. We need to reform Social Security and Medicare and Medicaid so future generations of Americans can benefit from these vital programs without bankrupting our country.

Another area where we can work together is to reform the earmark process. One important message we all should take from the elections is that people want to end the secretive process by which Washington insiders are able to get billions of dollars directed to projects, many of them pork barrel projects that have never been reviewed or voted on by the Congress.

Some of the earmarks are not even included in legislation. They are stuffed into committee reports that have never been passed, and are never signed into law. Earmarks often divert precious funds from vital priorities like

national defense. And each year they cost the taxpayers billions of dollars.

I appreciate the fact that Senator Byrd and Congressman Obey, the Democrats who will lead the appropriations process in the new Congress, heard the same message. For this year's budget, they pledged to maintain current levels of spending without additional earmarks. They agreed to a temporary moratorium on all earmarks. And this is a good start, and I appreciate their position. I also appreciate the fact that House Republicans last fall passed strong earmark reform idea -- put forth earmark reform ideas. And I appreciate their hard work.



But we need to do more. Here's my own view to end the "dead of the night" process: Congress needs to adopt real reform that requires full disclosure of the sponsors, the costs, the recipients, and the justifications for every earmark. Congress needs to stop the practice of concealing earmarks in so-called report language. And Congress needs to cut the number and cost of earmarks next year by at least half.

To help rein in wasteful spending and restore fiscal discipline in Washington, I call on Congress to give the President the tool that 43 governors have, a line-item veto.

There are just a few of the issues that we're going to need to work on in the year ahead. This new year brings new opportunities for progress, and I'm looking forward to working with the new Congress.

Thank you for your time.

END 10:25 A.M. EST

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THE WHITE HOUSE
PRESIDENT
GEORGE W. BUSH

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Reforms To Spend Tax Dollars Wisely

2007 State of the Union Policy Initiatives
In Focus: Budget Management

Tonight, President Bush Will Discuss Three Major Reforms To Spend Tax Dollars Wisely And Keep America's Economy Strong. Next week, the President will deliver a full report on the state of our economy, which has added more than 7.2 million jobs since August 2003. Americans are finding jobs and taking home more pay.

To Spend Tax Dollars Wisely, We Must:

- **Balance The Budget Through Pro-Growth Policies And Spending Restraint.**
- **Enact Common-Sense Reforms To Help Prevent Billions Of Taxpayer Dollars From Being Spent On Unnecessary Earmarks.**
- **Reform Entitlement Programs To Address The Longer-Term Fiscal Challenge Facing Our Country.**

Balancing The Budget Through Pro-Growth Policies And Spending Restraint

Earlier This Month, The President Announced He Will Propose A Balanced Budget. On February 5, the Administration will present its five-year budget proposal. The President's budget will reduce the deficit over the next five years and produce a balanced budget by 2012. The Budget will achieve balance while addressing the Nation's most critical needs, including support for the Global War on Terror and sustaining the strength of our economy through permanent tax relief.

- **The President's Tax Relief Has Spurred Robust Economic Growth, Millions Of Jobs, And Rising Wages.**
- **A Strong U.S. Economy Is Fueling Higher Tax Revenues.** Tax revenues rose 11.8 percent in 2006 following a 14.6 percent increase in 2005. Receipts have increased nearly 35 percent since the tax relief was fully implemented in 2003, and 70 percent of the reduction in the deficit last year was attributable to increased tax revenues.
- **The Deficit Has Been Cut In Half Three Years Ahead Of The President's 2009 Goal.** Historic revenue growth and a continued commitment to spending restraint contributed to this reduction.
- **Better Spending Restraint Is Necessary To Help Achieve A Balanced Budget.** While funding the Nation's priorities, we must keep spending under control. That means restraining spending growth, doing more with less, and eliminating programs that are not getting the job done.

Enacting Common-Sense Reforms To Help Prevent Billions Of Taxpayer Dollars From Being Spent On Unnecessary Earmarks

Earmark Reform Will Help Eliminate Wasteful Spending. Earmarks are provisions included in legislation that are often not subject to legislative or public scrutiny and that often lead to wasteful Federal spending. Earmarks have tripled in number over the last decade and have increased spending by billions of dollars. The President applauds Congress' progress in requiring the disclosure of the sponsors, costs, recipients, and justification for each earmark, and calls on Congress to go further by enacting comprehensive earmark reform that brings greater

transparency and accountability to the Congressional budget process, including:

- Stopping the practice of concealing earmarks in so-called report language instead of placing them in the actual language of the bill,
- Cutting the number and cost of all earmarks at least in half by the end of this session.

Reforming Entitlement Programs To Address The Longer-Term Fiscal Challenge Facing Our Country

The President Believes Balancing The Budget Through Pro-Growth Economic Policies And Spending Restraint Better Positions Us To Tackle The Longer-Term Fiscal Challenge Facing Our Country:
Reforming Entitlements. Reforming Social Security, Medicare, and Medicaid will enable future generations to benefit from these vital programs without bankrupting our country. The President has led the way in focusing attention on this problem and in promoting real solutions, and passing legislation to enact such reforms will require bipartisan cooperation.

Return to this article at:

<http://www.whitehouse.gov/stateoftheunion/2007/initiatives/budget.html>

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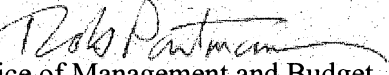
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

January 25, 2007

M-07-09

MEMORANDUM FOR THE HEADS OF DEPARTMENTS AND AGENCIES

FROM: Rob Portman 
Director, Office of Management and Budget

PURPOSE: Collection of information on earmarks

On January 3, 2007, the President called on the Congress to enact earmark reform, including reducing the number and cost of earmarks by at least half. To provide a transparent baseline from which the cut-in-half goal will be measured, agencies will be required to:

- 1) identify and catalogue earmarks in all appropriations bills and certain authorization bills, including report language;
- 2) submit that data to OMB; and
- 3) provide rapid analysis of the earmarks in each bill as they move through the legislative process in order to facilitate the development of an Administration position on the bill.

Definition

For the purposes of this data collection the definition of an earmark is as follows:

Earmarks are funds provided by the Congress for projects or programs where the congressional direction (in bill or report language) circumvents the merit-based or competitive allocation process, or specifies the location or recipient, or otherwise curtails the ability of the Administration to control critical aspects of the funds allocation process.

Laws and Years Covered by Baseline Earmark Data Collection

Appropriations Acts. Agencies should plan to provide earmark information for all enacted appropriations bills in FY 2005. All earmarks should be reported that were encompassed by those bills including those in any congressional report. Agencies should prioritize their data collection to focus first on the appropriations bills, since legislative

action on those bills is likely to commence this spring. (As has been reported, Congress has indicated they do not intend to include additional earmarks in the Continuing Resolution expected for the Appropriations bills that were not enacted for the remainder of FY 2007.)

Authorization and Other Legislation. Agencies should also plan on providing information on earmarks in authorizing and other bills that are identified based on consultation with OMB. These bills will likely include the Department of Defense FY 2007 Authorization Act and the Farm Security and Rural Investment Act of 2002.

Timeline

- **January-February** – Agencies collect relevant data.
- **Early February** – OMB distributes final guidance on developing the baseline data and makes the data application available for updating.
- **February 28** – Agencies complete data entry.
- **March 7** – OMB completes review of data.
- **March 12** – OMB posts information to the public Internet.

Attachment A: Expected data elements

Attachment B: Additional guidance on the definition of an earmark

Expected Data Elements

Agencies should begin assembling the following information for each earmark:

- Recipient, including –
 - Name,
 - Address, and
 - Type of entity (e.g., Federal, State government, locality, for-profit, non-profit, private educational institution, public educational institution, etc.).
- Cost, including whether the amount provided is sufficient to complete the project, if applicable;
- Brief description of project;
- Whether this is a first-time or continuing item;
- Budget information such as account name and Treasury account, and whether the earmark is funded through discretionary or mandatory funding;
- Whether the earmark is in statutory language, report language, or other; and
- The citation for the earmark, including a transcript, PDF or scanned copy of the relevant statutory language, report language, or other communication of congressional intent.

Earmark Data Collection Workgroup

The E-gov Budget Formulation and Execution Line of Business (BFE LoB) Task Force is forming a workgroup to help guide this effort. All agencies with significant earmarks, especially those with some form of internal earmark tracking system of their own, are encouraged to participate. Contact your agency's Task Force representative, or the BFE LoB Program Management Office at the Department of Education (Sandi McCabe, 202-401-1847, BUDGETLOB@Ed.gov).

Additional Guidance on the Definition of an Earmark

As discussed in the main body of the memo, for the purposes of this data collection the definition of an earmark is as follows¹ :

Earmarks are funds provided by the Congress for projects or programs where the congressional direction (in bill or report language) circumvents the merit-based or competitive allocation process, or specifies the location or recipient, or otherwise curtails the ability of the Administration to control critical aspects of the funds allocation process.

- Earmarks vs. Unrequested Funding. At the broadest level, unrequested funding is any additional funding provided by the Congress -- in either bill or report language -- for activities/projects/programs not requested by the Administration. Earmarks are a subset of unrequested funding. The distinction between earmarks and unrequested funding is programmatic control or lack thereof of in the allocation process.
- Earmarks and Programmatic "Control." If the congressional direction accompanying a project/program/funding in an appropriations bill or report or other communication purports to affect the ability of the Administration to control critical aspects of the awards process for the project/program/funding, this IS an earmark. Note: The definition of "control critical aspects" includes specification of the location or recipient or otherwise circumventing the merit-based or competitive allocation process and may be program specific. However, if the Congress adds funding and the Administration retains control over the awards process for the project/program/funding, it is NOT an earmark; it is unrequested funding.
- Earmarks Include:
 - A) Add-ons. If the Administration asks for \$100 million for formula grants, for example, and Congress provides \$110 million and places restrictions (such as site-specific locations) on the additional \$10 million, the additional \$10 million is counted as an earmark.
 - B) Carve-outs. If the Administration asks for \$100 million and Congress provides \$100 million but places restrictions on some portion of the funding, the restricted portion is counted as an earmark.
 - C) Funding provisions that do not name grantee, but are so specific that only one grantee can qualify for funding.

¹ OMB has used this definition to gather data on earmarks in appropriations bills in previous Budget Data Requests. This definition is equivalent to the definition that the Congress recently developed for disclosing earmarks in spending legislation (H. Res. 6 and the Senate-passed version of S. 1).



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR
M-07-10

February 15, 2007

MEMORANDUM FOR THE HEADS OF DEPARTMENTS AND AGENCIES

FROM: Rob Portman

PURPOSE: To provide guidance to Departments and Agencies about obligating FY 2007 funds under a full-year Continuing Resolution (CR) with no Congressional earmarks.

BACKGROUND

On February 15, 2007, the President signed H.J.Res. 20, a joint resolution passed by the Congress, that provides appropriations for FY 2007, with a moratorium on earmarks. Section 112 of this joint resolution states that any "language specifying an earmark in a committee report or statement of managers accompanying an appropriations Act for FY 2006 shall have no legal effect with respect to funds appropriated" under the joint resolution. The joint resolution provides appropriations as a full-year CR, replacing the three CRs that have been enacted thus far during the current fiscal year.

GUIDANCE

Agencies whose funding is provided by the CRs should adhere to the following:

I. The "Authority and Conditions Provided" and "Projects and Activities" referenced in H.J.Res. 20 refer to prior statutory language only, and not to committee reports or other non-statutory earmarks. In implementing this Memorandum, agencies shall adhere to all applicable laws. With regard to the CR's own statutory language, OMB's General Counsel has determined that the phrase "under the authority and conditions provided," which appears in Section 101(a) of the CR, only refers to items provided in prior *statutes* that were enacted into law. To the extent that the language in Section 101(a) of the CR provides funding for "projects or activities," this phrase likewise applies only to prior statutory language that was enacted into law. Section 112 of H.J.Res. 20 explicitly affirms this, noting that any "language specifying an earmark in a committee report or statement of managers accompanying an appropriations Act for fiscal year 2006 shall have no legal effect with respect to funds appropriated" under the joint resolution. For agencies funded by the CR, this means that unless a project or activity is specifically identified in statutory text, agencies should not obligate funds on the basis of earmarks contained in Congressional reports or documents, or other written or oral communications regarding earmarks. While the Administration welcomes input to help make informed decisions, no oral or written communication concerning earmarks shall supersede statutory criteria, competitive awards, or merit-based decision-making, as set forth in Section II below.

II. Agencies shall fund activities based on authorized, transparent, statutory criteria and merit-based decision-making (including competitive awards). Federal funds shall be expended only for purposes where the CR grants authority in law for this spending or where there are other authorities in statutes to provide this funding. In particular, agencies subject to the CR are advised to fund activities within each account in accordance with authorizing law, using statutory criteria, such as funding formulas, eligibility standards, and merit-based decision-making. In the application of authorized discretion, each agency shall use transparent and merit-based determinations to achieve program objectives, consistent with the purpose of the statute and Administration policy (including the President's Budget). Government-wide and agency regulations and policy governing the selection of grant recipients or contractors will be in effect.

Agencies shall pay particular heed to existing statutes, regulations, and Administration policy with respect to promoting and providing for competition in soliciting offers and awarding contracts and competitive grants. Note, in particular, that 10 U.S.C. 2304, 41 U.S.C. 253, and the Federal Acquisition Regulation require, with certain limited exceptions, that contracting officers promote and provide for full and open competition in soliciting offers and awarding Government contracts. OMB circular A-110 further affirms this requirement: "All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition." With respect to grants, agencies should take note of language from the Federal Grant and Cooperative Agreement Act of 1977 (31 U.S.C. §§ 6301-6308) and its implementing regulations 43 FR 36860, which were enacted and issued to "promote increased discipline in selecting and using procurement contracts, grant agreements, and cooperative agreements, maximize competition in making procurement contracts, and encourage competition in making grants and cooperative agreements." In short, funding decisions should be based on the merits, in accordance with the law.

This memorandum applies to budgetary resources provided under continuing resolutions for FY 2007, including: Public Laws 109-289 (division B), 109-369, 109-383, and H.J. Res. 20; unless and until modified or superseded by a subsequent memorandum.

Questions about this memorandum may be directed to OMB's Associate Directors or to OMB's General Counsel.

[OMB Home](#)[White House Website](#)

Earmarks

What is an Earmark?

Earmarks are funds provided by the Congress for projects or programs where the congressional direction (in bill or report language) circumvents the merit-based or competitive allocation process, or specifies the location or recipient, or otherwise curtails the ability of the Executive Branch to properly manage funds. Congress includes earmarks in appropriation bills - the annual spending bills that Congress enacts to allocate discretionary spending - and also in authorization bills.

What Does the Earmarks Database Show?

This database provides more information on earmarks in one place than has ever been available through the Federal Government. It is part of an effort to bring greater accountability and transparency to Federal spending. This step is also consistent with changes in the House Rules and Senate legislation during the 110th Congress, which requires more disclosure for earmarks.

Browse:

- [Estimates of FY 2009 Appropriations Earmarks](#)
- [FY 2008 Appropriations Earmarks](#)
- [Totals for FY 2008 Appropriations Earmarks/Benchmark for "Cut in Half" Goal](#)
- [FY 2005 Appropriations Earmarks](#)
- [FY 2005 Authorization Earmarks](#)
- Search Earmarks full text:

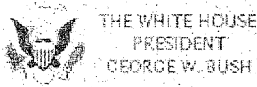
☒ 2009 Appropriations Tracking ☐ 2008 Appropriations
☐ 2005 Appropriations ☐ 2005 Authorizations

Limitations of the Earmarks Database:

Many earmarks in the 2008 database do not list recipients/beneficiaries. This information will be available after the fiscal year ends on September 30, 2008. In addition, the recipient/beneficiary listed in the database may not represent the final recipient/beneficiary of a particular earmark. For example, if the Federal Government provides funds to a specific recipient (e.g., a City), the recipient may forward the funds or benefits to another entity.

The 2005 database was not designed, and cannot accurately be used, to identify individual congressional sponsors of earmarks. Congressional sponsors are included in the 2008 database as identified by Congress. When earmarks do not have sponsors explanations are noted.

Last Updated: September 12, 2008 (Changes from last update)

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For Immediate Release
Office of the Press Secretary
December 26, 2007

President Bush Signs H.R. 2764 into Law

Today, I signed into law H.R. 2764, legislation that will fund the Federal Government within the reasonable and responsible spending levels I proposed -- without raising taxes and without the most objectionable policy changes considered by the Congress. This law provides a down payment for the resources our troops need, without arbitrary timelines for withdrawal. The Congress should quickly take action next year to provide the remainder of the funding needed by our troops.

[White House News](#)

I am disappointed in the way the Congress compiled this legislation, including abandoning the goal I set early this year to reduce the number and cost of earmarks by half. Instead, the Congress dropped into the bill nearly 9,800 earmarks that total more than \$10 billion. These projects are not funded through a merit-based process and provide a vehicle for wasteful Government spending.

There is still more to be done to rein in Government spending. In February I will submit my budget proposal for fiscal year 2009, which will once again restrain spending, keep taxes low, and continue us on a path towards a balanced budget. I look forward to working with the Congress in the coming year to ensure taxpayer dollars are spent wisely.



Finally, this legislation contains certain provisions similar to those found in prior appropriations bills passed by the Congress that might be construed to be inconsistent with my Constitutional responsibilities. To avoid such potential infirmities, the executive branch will interpret and construe such provisions in the same manner as I have previously stated in regard to similar provisions.

GEORGE W. BUSH

THE WHITE HOUSE,

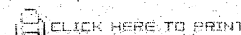
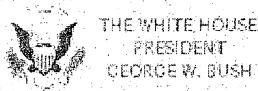
December 26, 2007.

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For Immediate Release
Office of the Press Secretary
January 28, 2008

Fact Sheet: President Bush Takes Action to Prevent Wasteful Earmarks

Announces Executive Order, Pledges Veto

Too many earmarks, too little accountability. Earmarks are provisions often snuck into legislation not subject to legislative or public scrutiny and that often lead to wasteful Federal spending. Earmarks have tripled in number over the last decade and have increased spending by billions of dollars. Most earmarks are not even included in legislative text and are not subject to an up or down vote of Congress.

White House News

Earmark reform will help eliminate wasteful spending. Taxpayer dollars should be spent wisely or not at all. That's why it's necessary for the number and cost of earmarks be reduced, that their origin and purposes be transparent, and that they be included in the text of the bills voted upon by the Congress and presented to the President.

On Tuesday, President Bush will issue an Executive Order directing Federal agencies to ignore any future earmark that is not voted on and included in a law approved by Congress. This will effectively end the common practice of concealing earmarks in so-called report language instead of placing them in the actual text of the bill. This means earmarks will be subject to votes, which will better expose them to the light of day and help constrain excessive and unjustified spending.

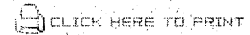
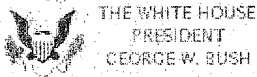
- **The Executive Order will provide that with regard to all future appropriations laws and other legislation enacted into law, executive agencies will not commit, obligate, or expend funds on the basis of earmarks from any non-statutory source, including requests included in congressional committee reports or other congressional documents, or communications from or on behalf of Members of Congress, or any other non-statutory source, except when required by law, or when an agency itself decides that a project or other transaction has merit under statutory criteria or other merit-based decision-making.**
- **The Supreme Court says report language is not legally binding.** The U.S. Supreme Court has made clear that committee reports and other legislative history materials do not bind executive agencies.
 - In 1993 the Supreme Court stated that, "... a fundamental principle of appropriations law is that where 'Congress merely appropriates lump-sum amounts without statutorily restricting what can be done with those funds, a clear inference arises that it does not intend to impose legally binding restrictions, and indicia in committee reports and other legislative history as to how the funds should or are expected to be spent do not establish any legal requirements on' the agency." *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993)
 - The Supreme Court reiterated in 2005 that "language contained in Committee Reports is not legally binding". *Cherokee Nation v. Leavitt*, 543 U.S. 631 "646" (2005).

The President in the State of the Union will pledge to veto any appropriations bill Congress sends him that does not cut the number and cost of earmarks in half. Last year, President Bush asked Congress to voluntarily cut the number and cost of earmarks in half and to refrain from slipping earmarks into committee reports that never come to a vote in Congress. Unfortunately, neither goal was met – the FY08 appropriations bills passed by Congress contained more than 11,700 earmarks totaling almost \$17 billion. If the Executive Order does not induce Congress to be accountable and get excessive earmarks under control, this veto warning will help ensure real discipline against excess and waste.

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<http://www.whitehouse.gov/news/releases/2008/01/20080128-2.html>



For Immediate Release
Office of the Press Secretary
January 29, 2008

Executive Order: Protecting American Taxpayers From Government Spending on Wasteful Earmarks

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

White House News

Section 1. Policy. It is the policy of the Federal Government to be judicious in the expenditure of taxpayer dollars. To ensure the proper use of taxpayer funds that are appropriated for Government programs and purposes, it is necessary that the number and cost of earmarks be reduced, that their origin and purposes be transparent, and that they be included in the text of the bills voted upon by the Congress and presented to the President. For appropriations laws and other legislation enacted after the date of this order, executive agencies should not commit, obligate, or expend funds on the basis of earmarks included in any non-statutory source, including requests in reports of committees of the Congress or other congressional documents, or communications from or on behalf of Members of Congress, or any other non-statutory source, except when required by law or when an agency has itself determined a project, program, activity, grant, or other transaction to have merit under statutory criteria or other merit-based decisionmaking.

Sec. 2. Duties of Agency Heads. (a) With respect to all appropriations laws and other legislation enacted after the date of this order, the head of each agency shall take all necessary steps to ensure that:

- (i) agency decisions to commit, obligate, or expend funds for any earmark are based on the text of laws, and in particular, are not based on language in any report of a committee of Congress, joint explanatory statement of a committee of conference of the Congress, statement of managers concerning a bill in the Congress, or any other non-statutory statement or indication of views of the Congress, or a House, committee, Member, officer, or staff thereof;
- (ii) agency decisions to commit, obligate, or expend funds for any earmark are based on authorized, transparent, statutory criteria and merit-based decision making, in the manner set forth in section II of OMB Memorandum M-07-10, dated February 15, 2007, to the extent consistent with applicable law; and
- (iii) no oral or written communications concerning earmarks shall supersede statutory criteria, competitive awards, or merit-based decisionmaking.

(b) An agency shall not consider the views of a House, committee, Member, officer, or staff of the Congress with respect to commitments, obligations, or expenditures to carry out any earmark unless such views are in writing, to facilitate consideration in accordance with section 2(a)(ii) above. All written communications from the Congress, or a House, committee, Member, officer, or staff thereof, recommending that funds be committed, obligated, or expended on any earmark shall be made publicly available on the Internet by the receiving agency, not later than 30 days after receipt of such communication, unless otherwise specifically directed by the head of the agency, without delegation, after consultation with the Director of the Office of Management and Budget, to preserve appropriate confidentiality between the executive and legislative branches.

(c) Heads of agencies shall otherwise implement within their respective agencies the policy set forth in section 1 of this order, consistent with such instructions as the Director of the Office of Management and Budget may prescribe.

(d) The head of each agency shall upon request provide to the Director of the Office of Management and Budget information about earmarks and compliance with this order.

Sec. 3. Definitions. For purposes of this order:

(a) The term "agency" means an executive agency as defined in section 105 of title 5, United States Code, and the United States Postal Service and the Postal Regulatory Commission, but shall exclude the Government Accountability Office; and

(b) the term "earmark" means funds provided by the Congress for projects, programs, or grants where the purported congressional direction (whether in statutory text, report language, or other communication) circumvents otherwise applicable merit-based or competitive allocation processes, or specifies the location or recipient, or otherwise curtails the ability of the executive branch to manage its statutory and constitutional responsibilities pertaining to the funds allocation process.

Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) authority granted by law to an agency or the head thereof; or
- (ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

(b) This order shall be implemented in a manner consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its agencies, instrumentalities, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

THE WHITE HOUSE,

January 29, 2008.

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<http://www.whitehouse.gov/news/releases/2008/01/20080129-5.html>

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THE WHITE HOUSE

WASHINGTON

November 4, 2008

MEMORANDUM

THROUGH: JIM NUSSLE
FROM: CLAY JOHNSON
SUBJECT: MANAGEMENT

The Bush Administration has made it the official policy of the Federal government to spend taxpayers' money effectively, and more effectively every year; it has improved Federal agencies' ability to spend their funds effectively; and it has established mechanisms to hold agencies accountable for how they spend tax dollars.

The President's vision for reform called for the Government to be:

- Results-oriented,
- Citizen-centered, not bureaucracy-centered, and
- Market-based, actively promoting competition and innovation

Government likes to begin new things, to declare grand new programs and causes, but not to ensure the taxpayers get what they think they are paying for. The President sought to change this, to focus on what we finish, not what we begin.

In 2001, President Bush launched the President's Management Agenda (PMA). He also directed each Cabinet Secretary and Agency head to designate a "chief operating officer," most often at the deputy secretary level, to support and implement the PMA.

The PMA focused on the most significant opportunities to improve performance, namely:

- Human Capital Management
- Financial Performance
- Competitive Sourcing (currently "Commercial Services Management")
- Expanding Electronic Government
- Budget and Performance Integration (currently "Performance Improvement")

Additionally the PMA focused on nine more targeted opportunities for improvement, including: faith-based and community initiatives, management and performance at the Department of Housing and Urban Development, and privatization of military housing. In subsequent years the PMA's focus expanded to include Improper Payments (2004), Real Property (2004), and Credit Management (2007).

OMB worked with agencies to establish clear, objective definitions of success and near-success, and OMB and each agency then agreed on what the agency would do each quarter to move toward the desired management capabilities. OMB developed a scorecard to rate each agency's status, the level of success they had accomplished, and their progress each quarter. By setting clear goals, and making each agency's performance transparent, the Administration increased the accountability for, and hence the effectiveness of, how the agencies spent the taxpayers' money.

In 2001, 85% of the government's management practices were deemed unacceptable, and the National Science Foundation was the only one of the 26 major agencies that had a satisfactory management practice in place, specifically, in Financial Performance. Today, 45% of the government's management practices are as desired and only 15% are deemed unacceptable. Agencies are clearly committed to becoming more effective: 80% of the time, agencies made the improvements they said they would make, when they said they would make them.

Today all Federal executives have specific management and program performance goals: they are now held formally accountable for their performance.

Human Capital Management

The Federal government is only as effective as its people. President Bush sought to ensure Federal agencies had employees who were well trained and managed, when they needed them.

In 2002, President Bush signed the Chief Human Capital Officers (CHCO) Act, which required each agency to designate an individual who could help ensure its agency selected, developed, trained, and effectively managed a high-quality, productive workforce. These CHCOs also work with the Office of Personnel Management to implement government-wide standards for excellence, and have established the CHCO Council to share best practices and development.

President Bush also instituted a program to rate employees against mission-aligned, results-oriented goals. In 2001, Federal employees were appraised on competency rather than actual performance.

The Administration also implemented pay-for-performance systems to increase government performance, incentivize and reward high-performers, recruit talented employees, and encourage accountability to the public. Nearly 350,000 Federal employees (about 19 percent of the total Federal workforce) work under pay-for-performance systems today. Since 2004, the Administration has converted approximately 180,000 civilian employees of the Department of Defense to a new pay-for-performance system called the National Security Personnel System. Additionally, since 2004, the Administration has implemented pay-for-performance among members of the Federal government's Senior Executive Service (SES), its highest level managers.

Financial Performance

When President Bush took office, Federal agencies were not accounting for their expenditures throughout the year. As a result they published their annual financial reports five months after the end of the fiscal year. As a part of the PMA, the Administration required all agencies to file their financial reports within 45 days of year-end, which made agencies account for their expenditures on a monthly basis. All agencies have met this reporting standard since FY2005.

Under President Bush, agency financial information is also more reliable, as demonstrated by improved results on financial statement audits. Of the 24 major Federal agencies, 19 received a clean opinion on their financial statement audit in 2007. Thirteen of these agencies, up from seven in 2001, achieved both a clean audit and had no material weaknesses in financial reporting identified by their auditor. Across government, auditor-identified material weaknesses are on the decline with a drop of more than a 35 percent since 2001.

In addition, Federal agencies are actively managing their improper payments. In 2001, Federal managers, Congress, and the taxpayers did not know the extent of improper payments and the cause of those errors. Today, 80 percent of all Federal outlays are actively measured and/or reviewed for improper payments. Once agencies identify program errors, they begin implementing corrective actions to eliminate similar errors in the future. Over the past four years, agencies have recovered \$850 million in improper contract payments. Of the errors originally measured in Fiscal Year 2004, the government has reduced improper spending by \$7.9 billion.

Also Federal agencies are actively managing their real property. In 2001, the Federal government did not have an accurate inventory of its real property or know how these assets were being managed. Today the government is managing its \$1.5 trillion in real property, knows exactly what it owns and what it needs, and is being held accountable for disposing of the difference. Agencies have disposed of more than \$7 billion in unneeded assets since 2004.

Commercial Services Management (Originally “Competitive Sourcing”)

Nearly one quarter of all Federal employees perform tasks that are not inherently governmental and can clearly be performed by commercial entities – tasks like information technology support, administrative services, and building maintenance. Historically, the government realizes cost savings between 20 and 50 percent when Federal and private sector providers compete to perform these commercial functions, regardless of who “wins” the competition. The Administration called for each agency to develop the capability to professionally review these competitive opportunities, as only the Department of Defense had been previously challenged to do.

Through the PMA, agencies have conducted approximately 1,400 public-private competitions of their commercial activities involving more than 51,000 full time employees that are projected to save taxpayers more than \$7 billion over 5 to 10 years, or a little more than \$1 billion per year. Before proceeding with these competitions, agencies performed a series of analyses to evaluate:

- 1) Efficiency of current operations
- 2) Private sector capability and availability to perform the function

- 3) Potential risk to the agency's ability to accomplish its mission if the function were performed by the private sector

In many cases, agency management has pursued internal business process reengineering (BPR) as an alternative to public-private competition to close identified performance gaps in their commercial support services.

In 2008, the "Competitive Sourcing" initiative was renamed "Commercial Services Management" to recognize the broader range of activities that agencies use to improve the operation of their commercial functions. The broader initiative will use both BPR efforts and public-private competitions to most effectively perform work that is commercial in nature.

Expanded Electronic Government

The Federal government spends more on information technology (IT), \$71 billion in FY2008, than any other organization in the world. Through the PMA, the Administration has established clear investment and management guidelines for all IT spending, identified the opportunities to consolidate or eliminate duplicative Federal IT systems, and defined the standards that must be met to secure all its systems and data.

With its large IT expenditures, the Federal government also directly serves the citizenry, sending and receiving vast amount of information and money. This "citizen interface" used to be organized by Federal agency, not by citizen need. Through the PMA, the Administration established a focus on citizens. Today, Americans can access a wide range of services online, through consolidated government sites including:

- GovBenefits.gov, where citizens can locate and determine potential eligibility for government benefits and services.
- Business.gov, where businesses have easy access to regulatory compliance information, forms, contacts, and related information.
- Regulations.gov, where citizens can easily access and participate in the rulemaking process.
- Grants.gov, where all competitive, discretionary Federal grant opportunities are accessible by Federal grant seekers through a single website.
- Recreation.gov, where citizens can plan a vacation or make reservations for campsites and cabins, and tours at Federal recreation sites.
- USAJobs.gov, where Federal job-seekers can find and apply for job opportunities across the federal government.
- USA.gov, where citizens can find official government information available through a single Internet gateway. The Administration also created GobiernoUSA.gov, which is the first website to offer comprehensive government information in Spanish.
- fbo.gov, where commercial vendors and government buyers can post, search, monitor, and retrieve opportunities solicited by the entire Federal contracting community.
- IRS Free-File, where taxpayers have access to free on-line preparation and electronic tax filing services.

Performance Improvement (Originally “Budget and Performance Integration”)

New Federal programs are frequently created with minimal review or assessment of existing programs that address the same perceived problem, and there is little attention to how programs, new or old, really perform. In 2001, half of all Federal programs could not demonstrate they were achieving results, only half had clear, outcome-oriented goals, and program performance was assessed on an as-needed and inconsistent basis.

President Bush’s management agenda requires that each Federal program has clear outcome goals showing a formal commitment to continuous improvement, quantifiable measures of success, and plans for accomplishing the goals. The Program Assessment Ratings Tool was developed to ensure a consistent approach to these assessments. The goals, performance, program ratings, and plans to improve are made transparent and available to the public on the ExpectMore.gov website. By 2007, 89 percent of programs established or clarified their long-term and annual performance goals, and 82 percent of these programs were achieving their goals.

In November 2007, President Bush signed an Executive Order entitled “Improving Government Program Performance.” For the first time in American history, this document made it the official policy of the Federal government that each program would spend taxpayer dollars effectively and more effectively every year. The Executive Order established a Performance Improvement Officer at every department to help the head of the department manage and ensure performance, and a Performance Improvement Council to facilitate the sharing of best performance management practices and the creation of the performance management community.

Future Challenges

During the Bush Administration, Federal employees have made significant progress in making their agencies more effective and efficient, but challenges remain. The Federal government needs to define and establish successful procurement practices and disciplines. We need to improve our ability effectively manage employees and contracts. In addition, we need to establish truly results-oriented cultures, practices, and other key elements to continuous performance improvement. If Federal employees remain committed to effective management, the Federal government will continue to perform more effectively every year.

Federal Financial Management Timeline

December 2001

(TAB 1)

President Bush signs the Defense Authorization Act for Fiscal Year 2002, which includes provisions on Recovery Audits. This legislation requires agencies to identify errors made in paying contractors and collect any overpayments.

November 2002

(TAB 2)

President Bush signs the Improper Payments Information Act of 2002 (IPIA), which requires all Federal agencies to identify programs and activities susceptible to improper payments and to annually report to Congress the amount of all improper payments.

November 2003

Major Federal departments and agencies accelerate their financial reporting from a baseline average of 147 days after fiscal year end to an average of 80 days.

February 2004

(TAB 3)

President Bush signs Executive Order 13327, Federal Real Property Asset Management, requiring Federal agencies to manage their real property portfolios at the right size, cost, and condition to most effectively serve program missions and goals.

September 2004

President Bush adds the Real Property Management Initiative to the President's Management Agenda (PMA) to hold agencies accountable for meeting key milestones and performance outcomes highlighted in the February Executive Order.

November 2004

Twenty-three of the 24 agencies affected by the Chief Financial Officers Act (CFO Act) submit their audited financial statements by November 15, just 45 days after the fiscal year-end. By comparison, private sector year-end reporting deadlines are set 60 days after the fiscal year ends.

November 2004

Federal departments and agencies first reported the extent of their improper payments and recovery audit efforts in their annual Performance Accountability Reports.

December 2004

President Bush adds the Eliminating Improper Payments Initiative to the President's Management Agenda to hold agencies accountable for meeting the provisions of the IPIA.

November 2005

All 24 Federal departments and agencies affected by the CFO Act submit their audited financial statements by November 15, and continue to do so every subsequent year of the Bush Administration.

December 2005

All Federal agencies submit their real property inventory to the Federal Real Property Portfolio database. Specifically, agencies reported key inventory and performance data on each individual asset. For the first time in recent history, the Federal government has comprehensive inventory of its real property holdings, more than one billion assets including land, buildings, and holdings. Having this database means that the Federal government can make smarter management decisions.

November 2007

For the third consecutive year, Federal departments and agencies reduced the overall error rate in programs reported from previous years.

September 2007

Federal agencies exceed more than \$7 billion in eliminations of unneeded real property since the 2004 Executive Order took effect.

Competitive Sourcing Timeline

May 2003

(TAB 4)

Government-wide rules for conducting public-private competitions to increase efficiency, fairness, transparency, and accountability for results are revised and published in the Federal Register as OMB Circular A-76, Performance of Commercial Activities.

February 2004

Agencies are given formal requirements to ensure consistent and clear reporting to Congress of competition results.

April 2007

Federal agencies are directed to independently validate a reasonable sample of their competitions to substantiate savings and reinforce public trust and confidence in the competitive sourcing initiative.

July 2008

The "Competitive Sourcing" initiative was renamed as "Commercial Services Management" to recognize the broader range of activities that agencies use to improve the operation of their commercial functions. The broader initiative will track both public-private competition and business process reengineering efforts.

Performance Improvement Timeline

February 2002

(TAB 5)

Performance Assessment Rating Tool (PART) is developed. This set of questions designed to assess the strengths and weaknesses of Federal programs is first applied to 243 programs and published online and in the President's Budget.

Spring 2005

PART receives the Innovations in American Government Award from the Kennedy School of Government at Harvard University, recognizing these assessments for their ability to motivate Federal programs to establish clearly defined, outcome-focused goals; to collect data to show progress and problems; and to articulate next steps to Congress and the public.

February 2006

Program performance ratings and plans to improve are made more accessible and transparent on ExpectMore.gov to increase accountability for improved effectiveness.

September 2006

(TAB 6)

President Bush signed the Federal Funding Accountability and Transparency Act into law, mandating the creation of a single, searchable website containing information on all Federal grants, contracts, and loans greater than \$25,000.

November 2007

(TAB 7)

President Bush signs Executive Order (EO) 13450: Improving Government Program Performance. The EO establishes official Federal government policy to spend taxpayer dollars effectively and more effectively each year. The EO requires agencies and programs to have:

- Clear annual and long-term goals and specific plans to achieve them.
- A designated Performance Improvement Officer at each Federal agency who reports directly to the Secretary or agency head.

December 2007

USASpending.gov launches, ahead of the deadline mandated by the Federal Funding Accountability and Transparency Act. This website posts data on all Federal contracts, grants, and loans over \$25,000, making it the most comprehensive database of Federal spending and an important step in building public confidence in the government's spending of taxpayer money.

February 2008

Agencies appoint Performance Improvement Officers required by the EO, develop their plans for implementing the EO, and launch the Performance Improvement Council.

Expanded Electronic Government Timeline

December 2002

(TAB 8)

President Bush signs the E-Government Act of 2002 which authorizes and establishes the Office of E-Government and Information Technology to address citizen services and strengthen information technology oversight.

May 2002

GovBenefits.gov launches, providing citizens a single location to determine their eligibility for Federal benefit programs.

January 2003

E-Rulemaking and partner agencies launch Regulations.gov. For the first time, citizens can access and comment on proposed Federal regulations from a single website.

January 2003

IRS's Free File Initiative launches, allowing citizens to file their taxes online for free. Through five filing seasons, approximately 19.3 million returns have been filed through the Free File program.

August 2003

Enhanced re-launch of USAJobs.gov, where job-seekers can search openings and apply for jobs across the Federal government. Since 2003, USAJobs has hosted over 167 million visits, and job seekers have created almost 1.7 million online resumes.

October 2003

Grants.gov launches, making all competitive, discretionary Federal grant opportunities available to grant-seekers through a single website.

May 2004

The Business Gateway initiative launches websites (business.gov and forms.gov) to help businesses locate compliance information at a consolidated online location.

August 2004

(TAB 9)

President Bush issues Homeland Security Presidential Directive/HSPD-12 to enhance security, increase Government efficiency, reduce identity fraud, and protect personal privacy by

establishing a mandatory, Government-wide standard for secure and reliable forms of identification issued by the Federal Government to its employees and contractors.

May 2006

(TAB 10)

President Bush issues Executive Order 13402, Strengthening Federal Efforts To Protect Against Identity Theft, to deter, prevent, detect, investigate, proceed against, and prosecute unlawful use by persons of the identifying information of other persons.

August 2006

(TAB 11)

President Bush issues Executive Order 13411, Improving Assistance for Disaster Victims, to ensure individuals who are victims of a terrorist attack, natural disaster, or other incident that is the subject of an emergency or major disaster declaration have prompt and efficient access to Federal disaster assistance, as well as information regarding assistance available from State and local government and private sector sources.

September 2006

Relaunched Business Gateway websites (business.gov and forms.gov) with a new focus on providing easy access to regulatory compliance information, forms, contacts, and related information.

July 2007

Time Magazine names USA.gov one of its "Twenty-Five Sites We Can't Live Without". Over 35 million USA Services inquiries were handled by visits to USA.gov and other websites as of December 2007.

July 2007

(TAB 12)

The President issues Executive Order 13439 to review and assess current import safety procedures and methods, survey the authorities and practices of Federal agencies, and outline preliminary steps necessary to enhance the safety of imported products.

December 2007

One hundred percent of agencies post their discretionary grant opportunities on Grants.gov.

Business.gov expanded to include information from more than 9,000 state, territory, county, and city government websites providing information on starting and managing a business while complying with regulations from all levels of government.

Redesigned Regulations.gov features a streamlined, simplified homepage, full-text search capability, a fast indexed-based commercial search engine, and an RSS feed. Within a month, 90 percent of active rulemakings with additional supplemental materials are available for citizens to review when looking at or commenting on Federal regulations. Within two months, citizens and

other interested parties have downloaded 57 million regulatory actions or supplemental material from the site.

February 2008

Sixty-five percent of major agencies have converted from using paper-based personnel folders to electronic versions. This increases cost savings, improves agency Continuity of Operations and disaster recovery coverage for electronic files, and streamlines human resources support processes and portability of personnel records as employees move between agencies.

A

Tab 1

Recovery Auditing Act

As included in the Defense Authorization Act for Fiscal Year 2002

SUBCHAPTER VI: RECOVERY AUDITS

'Sec. 3561. Identification of errors made by executive agencies in payments to contractors and recovery of amounts erroneously paid

(a) **PROGRAM REQUIRED-** The head of each executive agency that enters into contracts with a total value in excess of \$500,000,000 in a fiscal year shall carry out a cost-effective program for identifying any errors made in paying the contractors and for recovering any amounts erroneously paid to the contractors.

(b) **RECOVERY AUDITS AND ACTIVITIES-** A program of an executive agency under subsection (a) shall include recovery audits and recovery activities. The head of the executive agency shall determine, in accordance with guidance provided under subsection (c), the classes of contracts to which recovery audits and recovery activities are appropriately applied.

(c) **OMB GUIDANCE-** The Director of the Office of Management and Budget shall issue guidance for the conduct of programs under subsection (a). The guidance shall include the following:

(1) Definitions of the terms 'recovery audit' and 'recovery activity' for the purposes of the programs.

(2) The classes of contracts to which recovery audits and recovery activities are appropriately applied under the programs.

(3) Protections for the confidentiality of--

(A) sensitive financial information that has not been released for use by the general public; and

(B) information that could be used to identify a person.

(4) Policies and procedures for ensuring that the implementation of the programs does not result in duplicative audits of contractor records.

(5) Policies regarding the types of contracts executive agencies may use for the procurement of recovery services, including guidance for use, in appropriate circumstances, of a contingency contract pursuant to which the head of an executive agency may pay a contractor an amount equal to a percentage of the total amount collected for the United States pursuant to that contract.

(6) Protections for a contractor's records and facilities through restrictions on the authority of a contractor under a contract for the procurement of recovery services for an executive agency--

(A) to require the production of any record or information by any person other than an officer, employee, or agent of the executive agency;

(B) to establish, or otherwise have, a physical presence on the property or premises of any private sector entity for the purposes of performing the contract; or

(C) to act as agents for the Government in the recovery of funds erroneously paid to contractors.

(7) Policies for the appropriate types of management improvement programs authorized by section 3564 of this title that executive agencies may carry out to address overpayment problems and the recovery of overpayments.

Sec. 3562. Disposition of recovered funds

(a) **AVAILABILITY OF FUNDS FOR RECOVERY AUDITS AND ACTIVITIES PROGRAM-** Funds collected under a program carried out by an executive agency under section 3561 of this title shall be available to the executive agency for the following purposes:

(1) To reimburse the actual expenses incurred by the executive agency in the administration of the program.

(2) To pay contractors for services under the program in accordance with the guidance issued under section 3561(c)(5) of this title.

(b) **FUNDS NOT USED FOR PROGRAM-** Any amounts erroneously paid by an executive agency that are recovered under such a program of an executive agency and are not used to reimburse expenses or pay contractors under subsection (a)--

(1) shall be credited to the appropriations from which the erroneous payments were made, shall be merged with other amounts in those appropriations, and shall be available for the purposes and period for which such appropriations are available; or

(2) if no such appropriation remains available, shall be deposited in the Treasury as miscellaneous receipts.

(c) **PRIORITY OF OTHER AUTHORIZED DISPOSITIONS-** Notwithstanding subsection (b), the authority under such subsection may not be exercised to use, credit, or deposit funds collected under such a program as provided in that subsection to the extent that any other provision of law requires or authorizes the crediting of such funds to a nonappropriated fund instrumentality, revolving fund, working-capital fund, trust fund, or other fund or account.

Sec. 3563. Sources of recovery services

(a) **CONSIDERATION OF AVAILABLE RECOVERY RESOURCES-** (1) In carrying out a program under section 3561 of this title, the head of an executive agency shall consider all resources available to that official to carry out the program.

(2) The resources considered by the head of an executive agency for carrying out the program shall include the resources available to the executive agency for such purpose from the following sources:

(A) The executive agency.

(B) Other departments and agencies of the United States.

(C) Private sector sources.

(b) **COMPLIANCE WITH APPLICABLE LAW AND REGULATIONS-** Before entering into a contract with a private sector source for the performance of services under a program of the executive agency carried out under section 3561 of this title, the head of an executive agency shall comply with--

- (1) any otherwise applicable provisions of Office of Management and Budget Circular A-76; and
- (2) any other applicable provision of law or regulation with respect to the selection between employees of the United States and private sector sources for the performance of services.

Sec. 3564. Management improvement programs

In accordance with guidance provided by the Director of the Office of Management and Budget under section 3561 of this title, the head of an executive agency required to carry out a program under such section 3561 may carry out a program for improving management processes within the executive agency--

- (1) to address problems that contribute directly to the occurrence of errors in the paying of contractors of the executive agency; or
- (2) to improve the recovery of overpayments due to the agency.

Sec. 3565. Relationship to authority of inspectors general

Nothing in this subchapter shall be construed as impairing the authority of an Inspector General under the Inspector General Act of 1978 or any other provision of law.

Sec. 3566. Privacy protections

Any nongovernmental entity that, in the course of recovery auditing or recovery activity under this subchapter, obtains information that identifies an individual or with respect to which there is a reasonable basis to believe that the information can be used to identify an individual, may not disclose the information for any purpose other than such recovery auditing or recovery activity and governmental oversight of such activity, unless disclosure for that other purpose is authorized by the individual to the executive agency that contracted for the performance of the recovery auditing or recovery activity.

Sec. 3567. Definition of executive agency

Notwithstanding section 102 of this title, in this subchapter, the term 'executive agency' has the meaning given that term in section 4(1) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(1)).'

- (2) The table of sections at the beginning of chapter 35 of such title is amended by adding at the end the following:

SUBCHAPTER VI--RECOVERY AUDITS

3561. Identification of errors made by executive agencies in payments to contractors and recovery of amounts erroneously paid.

3562. Disposition of recovered funds.

3563. Sources of recovery services.

3564. Management improvement programs.

3565. Relationship to authority of inspectors general.

3566. Privacy protections.

3567. Definition of executive agency.

(b) REPORTS- (1) Not later than 30 months after the date of the enactment of this Act, and annually for each of the first two years following the year of the first report, the Director of the Office of Management and Budget shall submit to the Committee on Government Reform of the House of Representatives and the Committee on Governmental Affairs of the Senate, a report on the implementation of subchapter VI of chapter 35 of title 31, United States Code (as added by subsection (a)).

- (2) Each report shall include--

(A) a general description and evaluation of the steps taken by the heads of executive agencies to carry out the programs under such subchapter, including any management improvement programs carried out under section 3564 of such title 31;

(B) the costs incurred by executive agencies to carry out the programs under such subchapter; and

(C) the amounts recovered under the programs under such subchapter.

(c) CONFORMING AMENDMENT- Section 3501 of such title is amended by inserting and subchapter VI' after 'section 3513'.

Tab 2

Improper Payments Information Act of 2002

Public Law 107-300
107th Congress

An Act

To provide for estimates and reports of improper payments by Federal agencies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Improper Payments Information Act of 2002".

SEC. 2. ESTIMATES OF IMPROPER PAYMENTS AND REPORTS ON ACTIONS TO REDUCE THEM.

- (a) Identification of Susceptible Programs and Activities.--The head of each agency shall, in accordance with guidance prescribed by the Director of the Office of Management and Budget, annually review all programs and activities that it administers and identify all such programs and activities that may be susceptible to significant improper payments.
- (b) Estimation of Improper Payment.--With respect to each program and activity identified under subsection (a), the head of the agency concerned shall--
 - (1) estimate the annual amount of improper payments; and
 - (2) submit those estimates to Congress before March 31 of the following applicable year, with all agencies using the same method of reporting, as determined by the Director of the Office of Management and Budget.
- (c) Reports on Actions To Reduce Improper Payments.--With respect to any program or activity of an agency with estimated improper payments under subsection (b) that exceed \$10,000,000, the head of the agency shall provide with the estimate under subsection (b) a report on what actions the agency is taking to reduce the improper payments, including--
 - (1) a discussion of the causes of the improper payments identified, actions taken to correct those causes, and results of the actions taken to address those causes;
 - (2) a statement of whether the agency has the information systems and other infrastructure it needs in order to reduce improper payments to minimal cost-effective levels;
 - (3) if the agency does not have such systems and infrastructure, a description of the resources the agency has requested in its budget submission to obtain the necessary information systems and infrastructure; and

(4) a description of the steps the agency has taken to ensure that agency managers (including the agency head) are held accountable for reducing improper payments.

(d) Definitions.--For the purposes of this section:

(1) Agency.--The term ``agency" means an executive agency, as that term is defined in section 102 of title 31, United States Code.

(2) Improper payment.--The term ``improper payment"--

(A) means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and

(B) includes any payment to an ineligible recipient, any payment for an ineligible service, any duplicate payment, payments for services not received, and any payment that does not account for credit for applicable discounts.

(3) Payment.--The term ``payment" means any payment (including a commitment for future payment, such as a loan guarantee) that is--

(A) made by a Federal agency, a Federal contractor, or a governmental or other organization administering a Federal program or activity; and

(B) derived from Federal funds or other Federal resources or that will be reimbursed from Federal funds or other Federal resources.

(e) Application.--This section--

(1) applies with respect to the administration of programs, and improper payments under programs, in fiscal years after fiscal year 2002; and

(2) requires the inclusion of estimates under subsection (b)(2) only in annual budget submissions for fiscal years after fiscal year 2003.

(f) Guidance by the Office of Management and Budget.--Not later than 6 months after the date of enactment of this Act, the Director of the Office of Management and Budget shall prescribe guidance to implement the requirements of this section.

Approved November 26, 2002.

LEGISLATIVE HISTORY--H.R. 4878:

SENATE REPORTS: No. 107-333 (Comm. on Governmental Affairs).

CONGRESSIONAL RECORD, Vol. 148 (2002):

July 9, considered and passed House.

Oct. 17, considered and passed Senate, amended.

Nov. 12, House concurred in Senate amendment.

Tab 3

Executive Order 13327

Federal Real Property Asset Management

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 121(a) of title 40, United States Code, and in order to promote the efficient and economical use of Federal real property resources in accordance with their value as national assets and in the best interests of the Nation, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the United States to promote the efficient and economical use of America's real property assets and to assure management accountability for implementing Federal real property management reforms. Based on this policy, executive branch departments and agencies shall recognize the importance of real property resources through increased management attention, the establishment of clear goals and objectives, improved policies and levels of accountability, and other appropriate action.

Sec. 2. Definition and Scope. (a) For the purpose of this executive order, Federal real property is defined as any real property owned, leased, or otherwise managed by the Federal Government, both within and outside the United States, and improvements on Federal lands. For the purpose of this order, Federal real property shall exclude: interests in real property assets that have been disposed of for public benefit purposes pursuant to section 484 of title 40, United States Code, and are now held in private ownership; land easements or rights-of-way held by the Federal Government; public domain land (including lands withdrawn for military purposes) or land reserved or dedicated for national forest, national park, or national wildlife refuge purposes except for improvements on those lands; land held in trust or restricted fee status for individual Indians or Indian tribes; and land and interests in land that are withheld from the scope of this order by agency heads for reasons of national security, foreign policy, or public safety.

(b) This order shall not be interpreted to supersede any existing authority under law or by executive order for real property asset management, with the exception of the revocation of Executive Order 12512 of April 29, 1985, in section 8 of this order.

Sec. 3. Establishment and Responsibilities of Agency Senior Real Property Officer. (a) The heads of all executive branch departments and agencies cited in sections 901(b)(1) and (b)(2) of title 31, United States Code, and the Secretary of Homeland Security, shall designate among their senior management officials, a Senior Real Property Officer. Such officer shall have the education, training, and experience required to administer the necessary functions of the position for the particular agency.

(b) The Senior Real Property Officer shall develop and implement an agency asset management planning process that meets the form, content, and other requirements established by the Federal Real Property Council established in section 4 of this order. The initial agency asset management

plan will be submitted to the Office of Management and Budget on a date determined by the Director of the Office of Management and Budget. In developing this plan, the Senior Real Property Officer shall:

(i) identify and categorize all real property owned, leased, or otherwise managed by the agency, including, where applicable, those properties outside the United States in which the lease agreements and arrangements reflect the host country currency or involve alternative lease plans or rental agreements;

(ii) prioritize actions to be taken to improve the operational and financial management of the agency's real property inventory;

(iii) make life-cycle cost estimations associated with the prioritized actions;

(iv) identify legislative authorities that are required to address these priorities;

(v) identify and pursue goals, with appropriate deadlines, consistent with and supportive of the agency's asset management plan and measure progress against such goals;

(vi) incorporate planning and management requirements for historic property under Executive Order 13287 of March 3, 2003, and for environmental management under Executive Order 13148 of April 21, 2000; and

(vii) identify any other information and pursue any other actions necessary to the appropriate development and implementation of the agency asset management plan.

(c) The Senior Real Property Officer shall be responsible, on an ongoing basis, for monitoring the real property assets of the agency so that agency assets are managed in a manner that is:

(i) consistent with, and supportive of, the goals and objectives set forth in the agency's overall strategic plan under section 306 of title 5, United States Code;

(ii) consistent with the real property asset management principles developed by the Federal Real Property Council established in section 4 of this order; and

(iii) reflected in the agency asset management plan.

(d) The Senior Real Property Officer shall, on an annual basis, provide to the Director of the Office of Management and Budget and the Administrator of General Services:

(i) information that lists and describes real property assets under the jurisdiction, custody, or control of that agency, except for classified information; and

(ii) any other relevant information the Director of the Office of Management and Budget or the Administrator of General Services may request for inclusion in the Government-wide listing of all Federal real property assets and leased property.

(e) The designation of the Senior Real Property Officer shall be made by agencies within 30 days after the date of this order.

Sec. 4. Establishment of a Federal Real Property Council. (a) A Federal Real Property Council (Council) is established, within the Office of Management and Budget for administrative purposes, to develop guidance for, and facilitate the success of, each agency's asset management plan. The Council shall be composed exclusively of all agency Senior Real Property Officers, the Controller of the Office of Management and Budget, the Administrator of General Services, and any other full-time or permanent part-time Federal officials or employees as deemed necessary by the Chairman of the Council. The Deputy Director for Management of the Office of Management and Budget shall also be a member and shall chair the Council. The Office of Management and Budget shall provide funding and administrative support for the Council, as appropriate.

(b) The Council shall provide a venue for assisting the Senior Real Property Officers in the development and implementation of the agency asset management plans. The Council shall work with the Administrator of General Services to establish appropriate performance measures to determine the effectiveness of Federal real property management. Such performance measures shall include, but are not limited to, evaluating the costs and benefits involved with acquiring, repairing, maintaining, operating, managing, and disposing of Federal real properties at particular agencies. Specifically, the Council shall consider, as appropriate, the following performance measures:

- (i) life-cycle cost estimations associated with the agency's prioritized actions;
- (ii) the costs relating to the acquisition of real property assets by purchase, condemnation, exchange, lease, or otherwise;
- (iii) the cost and time required to dispose of Federal real property assets and the financial recovery of the Federal investment resulting from the disposal;
- (iv) the operating, maintenance, and security costs at Federal properties, including but not limited to the costs of utility services at unoccupied properties;
- (v) the environmental costs associated with ownership of property, including the costs of environmental restoration and compliance activities;
- (vi) changes in the amounts of vacant Federal space;
- (vii) the realization of equity value in Federal real property assets;
- (viii) opportunities for cooperative arrangements with the commercial real estate community; and
- (ix) the enhancement of Federal agency productivity through an improved working environment.

The performance measures shall be designed to enable the heads of executive branch agencies to track progress in the achievement of Government-wide property management objectives, as well as allow for comparing the performance of executive branch agencies against industry and other public sector agencies.

(c) The Council shall serve as a clearinghouse for executive agencies for best practices in evaluating actual progress in the implementation of real property enhancements. The Council

shall also work in conjunction with the President's Management Council to assist the efforts of the Senior Real Property Officials and the implementation of agency asset management plans.

(d) The Council shall be organized and hold its first meeting within 60 days of the date of this order. The Council shall hold meetings not less often than once a quarter each fiscal year.

Sec. 5. Role of the General Services Administration. (a) The Administrator of General Services shall, to the extent permitted by law and in consultation with the Federal Real Property Council, provide policy oversight and guidance for executive agencies for Federal real property management; manage selected properties for an agency at the request of that agency and with the consent of the Administrator; delegate operational responsibilities to an agency where the Administrator determines it will promote efficiency and economy, and where the receiving agency has demonstrated the ability and willingness to assume such responsibilities; and provide necessary leadership in the development and maintenance of needed property management information systems.

(b) The Administrator of General Services shall publish common performance measures and standards adopted by the Council.

(c) The Administrator of General Services, in consultation with the Federal Real Property Council, shall establish and maintain a single, comprehensive, and descriptive database of all real property under the custody and control of all executive branch agencies, except when otherwise required for reasons of national security. The Administrator shall collect from each executive branch agency such descriptive information, except for classified information, as the Administrator considers will best describe the nature, use, and extent of the real property holdings of the Federal Government.

(d) The Administrator of General Services, in consultation with the Federal Real Property Council, may establish data and other information technology (IT) standards for use by Federal agencies in developing or upgrading Federal agency real property information systems in order to facilitate reporting on a uniform basis. Those agencies with particular IT standards and systems in place and in use shall be allowed to continue with such use to the extent that they are compatible with the standards issued by the Administrator.

Sec. 6. General Provisions. (a) The Director of the Office of Management and Budget shall review, through the management and budget review processes, the efforts of departments and agencies in implementing their asset management plans and achieving the Government-wide property management policies established pursuant to this order.

(b) The Office of Management and Budget and the General Services Administration shall, in consultation with the landholding agencies, develop legislative initiatives that seek to improve Federal real property management through the adoption of appropriate industry management techniques and the establishment of managerial accountability for implementing effective and efficient real property management practices.

(c) Nothing in this order shall be construed to impair or otherwise affect the authority of the Director of the Office of Management and Budget with respect to budget, administrative, or legislative proposals.

(d) Nothing in this order shall be construed to affect real property for the use of the President, Vice President, or, for protective purposes, the United States Secret Service.

Sec. 7. Public Lands. In order to ensure that Federally owned lands, other than the real property covered by this order, are managed in the most effective and economic manner, the Departments of Agriculture and the Interior shall take such steps as are appropriate to improve their management of public lands and National Forest System lands and shall develop appropriate legislative proposals necessary to facilitate that result.

Sec. 8. Executive Order 12512 of April 29, 1985, is hereby revoked.

Sec. 9. Judicial Review. This order is intended only to improve the internal management of the executive branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.

GEORGE W. BUSH

THE WHITE HOUSE,

February 4, 2004.

Tab 4

Circular A-76

Performance of Commercial Activities

TO THE HEADS OF EXECUTIVE DEPARTMENTS AND ESTABLISHMENTS

SUBJECT: Performance of Commercial Activities

1. **Purpose.** This circular establishes federal policy for the competition of commercial activities.
2. **Supersession.** This circular supersedes Office of Management and Budget (OMB) Circular No. A-76 (Revised 1999), August 4, 1983; Circular No. A-76 Revised Supplemental Handbook (Revised 2000), March 1996; Office of Federal Procurement Policy Letter 92-1, "Inherently Governmental Functions," September 23, 1992; and OMB Transmittal Memoranda 1 through 25, Performance of Commercial Activities.
3. **Authority.** Reorganization Plan No. 2 of 1970 (31 U.S.C. § 1111); Executive Order 11541; the Office of Federal Procurement Policy Act (41 U.S.C. § 405); and the Federal Activities Inventory Reform (FAIR) Act of 1998 (31 U.S.C. § 501 note).
4. **Policy.** The longstanding policy of the federal government has been to rely on the private sector for needed commercial services. To ensure that the American people receive maximum value for their tax dollars, commercial activities should be subject to the forces of competition. In accordance with this circular, including Attachments A-D, agencies shall:
 - a. Identify all activities performed by government personnel as either commercial or inherently governmental.
 - b. Perform inherently governmental activities with government personnel.
 - c. Use a streamlined or standard competition to determine if government personnel should perform a commercial activity. [See OMB Memorandum M-08-11 (February 20, 2008), number 4, when applying this provision]
 - d. Apply the Federal Acquisition Regulation (FAR), 48 C.F.R. Chapter 1, in conjunction with this circular, for streamlined and standard competitions.
 - e. Comply with procurement integrity, ethics, and standards of conduct rules, including the restrictions of 18 U.S.C. § 208, when performing streamlined and standard competitions.
 - f. Designate, in writing, an assistant secretary or equivalent level official with responsibility for implementing this circular, hereafter referred to as the competitive sourcing official (CSO). Except as otherwise provided by this circular, the CSO may delegate, in writing, specified responsibilities to senior-level officials in the agency or agency components.

- g. Require full accountability of agency officials designated to implement and comply with this circular by establishing performance standards in annual performance evaluations.
- h. Centralize oversight responsibility to facilitate fairness in streamlined and standard competitions and promote trust in the process. Agencies shall allocate resources to effectively apply a clear, transparent, and consistent competition process based on lessons learned and best practices. Lessons learned and best practices resulting from a streamlined or standard competition process shall be posted on SHARE A-76!
- i. Develop government cost estimates for standard and streamlined competitions in accordance with Attachment C using the COMPARE costing software. Agencies shall not use agency budgetary estimates to develop government cost estimates in a streamlined or standard competition.
- j. Track execution of streamlined and standard competitions in accordance with Attachment B.
- k. Assist adversely affected federal employees in accordance with 5 C.F.R. Parts 330 and 351. The statutory veterans' preference for appointment and retention (5 U.S.C. §§ 1302, 3301, 3302, 3502) applies to actions taken pursuant to this circular.
- l. Not perform work as a contractor or subcontractor to the private sector, unless specific statutory authority exists or the CSO receives prior written OMB approval.

5. Scope.

- a. Except as otherwise provided by law, this circular shall apply to executive departments named in 5 U.S.C. § 101 and independent establishments as defined in 5 U.S.C. § 104. These departments and independent establishments are referred to in this circular as "agencies". Except as otherwise provided by law, this circular shall apply to military departments named in 5 U.S.C. § 102.
- b. As provided by Attachment A, the CSO may exempt a commercial activity performed by government personnel from performance by the private sector.
- c. The CSO (without delegation) shall receive prior written OMB approval to deviate from this circular (e.g., time limit extensions, procedural deviations, or costing variations for a specific streamlined or standard competition, or inventory process deviations). Agencies shall include any OMB approved deviations in the public announcement and solicitation for a streamlined or standard competition. Agencies are encouraged to use this deviation procedure to explore innovative alternatives to standard or streamlined competitions, including public-private partnerships, public-public partnerships, and high performing organizations.
- d. A streamlined or standard competition is not required for private sector performance of a new requirement, private sector performance of a segregable expansion to an existing commercial activity performed by government personnel, or continued private sector performance of a commercial activity. Before government personnel may perform a new requirement, an expansion to an existing commercial activity, or an activity performed by the private sector, a streamlined or standard competition shall be used to determine whether government personnel should perform the

commercial activity. [See OMB Memorandum M-08-11 (February 20, 2008), number 4, when applying this provision]

- e. The CSO shall identify savings resulting from completed streamlined and standard competitions in accordance with OMB Circular No. A-11, *Preparation, Submission, and Execution of the Budget*.
 - f. This circular shall not be construed to alter any law, executive order, rule, regulation, treaty, or international agreement.
 - g. Noncompliance with this circular shall not be interpreted to create a substantive or procedural basis to challenge agency action or inaction, except as stated in Attachments A and B.
 - h. The Department of Defense CSO (without delegation) shall determine if this circular applies to the Department of Defense during times of a declared war or military mobilization.
6. **Effective Date.** This circular is effective upon publication in the *Federal Register* and shall apply to inventories required, and streamlined and standard competitions initiated, after the effective date.
7. **Transition.** Agencies shall apply the following transition procedures to direct conversions and cost comparisons, including streamlined cost comparisons, initiated but not completed by the effective date of this circular.
- a. Agencies shall convert initiated streamlined cost comparisons and direct conversions to streamlined or standard competitions under this revised circular.
 - b. Agencies shall convert initiated cost comparisons for which solicitations have not been issued prior to the effective date to standard competitions under this revised circular or, at the agency's discretion if permitted by this revised circular, to streamlined competitions.
 - c. The circular in effect prior to this revision shall govern cost comparisons for which solicitations have been issued, unless agencies, at their discretion, convert such cost comparisons to standard competitions under this revised circular, or, if permitted by this revised circular, to streamlined competitions.
 - d. In applying transition procedures, agencies shall not combine the requirements of this revised circular with those in the prior circular.
 - e. When complying with the transition procedures required by this paragraph, agencies shall make a public announcement within 30 days after the effective date of this revised circular pursuant to this transition paragraph. For conversions made at an agency's discretion, agencies shall make public announcement on the date the agency's decision takes effect.

8. **Attachments.**

Attachment A -- **Inventory Process**
Attachment B -- **Public-Private Competition**
Attachment C -- **Calculating Public-Private Competition Costs**
Attachment D -- **Acronyms and Definitions**

Mitchell E. Daniels, Jr.
Director

Tab 5

Sample Questions from the Performance Assessment Rating Tool (PART)

- Does the program address a specific and existing problem, interest, or need?
- Is the program designed so that it is not redundant or duplicative of any other Federal, State, local, or private effort?
- Does the program have a limited number of specific long-term performance measures that focus on outcomes and meaningfully reflect the purpose of the program?
- Does the program have ambitious targets and timeframes for its long-term measures?
- Does the program (including program partners) achieve its annual performance goals?
- Are independent evaluations of sufficient scope and quality conducted on a regular basis or as needed to support program improvements and evaluate effectiveness and relevance to the problem, interest, or need?
- Are budget requests explicitly tied to accomplishment of the annual and long-term performance goals, and are the resource needs presented in a complete and transparent manner in the program's budget?
- Does the program use strong financial management practices?
- Has the program demonstrated adequate progress in achieving its long-term performance goals?
- Does the program demonstrate improved efficiencies or cost-effectiveness in achieving program goals each year?

Tab 6

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282
109th Congress

An Act

To require full disclosure of all entities and organizations receiving
Federal funds.

Be it enacted by the Senate and House of Representatives of the
United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ``Federal Funding Accountability and
Transparency Act of 2006".

SEC. 2. FULL DISCLOSURE OF ENTITIES RECEIVING FEDERAL FUNDING.

(a) Definitions.--In this section:

(1) Entity.--The term "entity"--

(A) includes, whether for profit or nonprofit--

- (i) a corporation;
- (ii) an association;
- (iii) a partnership;
- (iv) a limited liability company;
- (v) a limited liability partnership;
- (vi) a sole proprietorship;
- (vii) any other legal business entity;
- (viii) any other grantee or contractor that is not excluded by subparagraph (B) or (C); and
- (ix) any State or locality;

(B) on and after January 1, 2009, includes any subcontractor or subgrantee; and

(C) does not include--

- (i) an individual recipient of Federal assistance; or
- (ii) a Federal employee.

(2) Federal award.--The term "Federal award"--

(A) means Federal financial assistance and expenditures that--

- (i) include grants, subgrants, loans, awards, cooperative agreements, and other

- forms of financial assistance;
 - (ii) include contracts, subcontracts, purchase orders, task orders, and delivery orders;
 - (B) does not include individual transactions below \$25,000; and
 - (C) before October 1, 2008, does not include credit card transactions.
- (3) Searchable website.--The term "searchable website" means a website that allows the public to--
- (A) search and aggregate Federal funding by any element required by subsection (b)(1);
 - (B) ascertain through a single search the total amount of Federal funding awarded to an entity by a Federal award described in paragraph (2)(A)(i), by fiscal year;
 - (C) ascertain through a single search the total amount of Federal funding awarded to an entity by a Federal award described in paragraph (2)(A)(ii), by fiscal year; and
 - (D) download data included in subparagraph (A) included in the outcome from searches.

(b) In General.--

- (1) Website.--Not later than January 1, 2008, the Office of Management and Budget shall, in accordance with this section, section 204 of the E-Government Act of 2002 (Public Law 107-347; 44 U.S.C. 3501 note), and the Office of Federal Procurement Policy Act (41 U.S.C. 403 et seq.), ensure the existence and operation of a single searchable website, accessible by the public at no cost to access, that includes for each Federal award--
- (A) the name of the entity receiving the award;
 - (B) the amount of the award;
 - (C) information on the award including transaction type, funding agency, the North American Industry Classification System code or Catalog of Federal Domestic Assistance number (where applicable), program source, and an award title descriptive of the purpose of each funding action;
 - (D) the location of the entity receiving the award and the primary location of performance under the award, including the city, State, congressional district, and country;
 - (E) a unique identifier of the entity receiving the award and of the parent entity of the recipient, should the entity be owned by another entity; and
 - (F) any other relevant information specified by the Office of Management and Budget.
- (2) Scope of data.--The website shall include data for fiscal year 2007, and each fiscal year thereafter.
- (3) Designation of agencies.--The Director of the Office of Management and Budget is authorized to designate one or more Federal agencies to participate in the development, establishment, operation, and support of the single website. In the initial designation, or in subsequent instructions and guidance, the Director may specify the scope of the responsibilities of each such agency.
- (4) Agency responsibilities.--Federal agencies shall comply with the instructions and

guidance issued by the Director of the Office of Management and Budget under paragraph (3), and shall provide appropriate assistance to the Director upon request, so as to assist the Director in ensuring the existence and operation of the single website.

(c) Website.--The website established under this section--

- (1) may use as the source of its data the Federal Procurement Data System, Federal Assistance Award Data System, and Grants.gov, if all of these data sources are searchable through the website and can be accessed in a search on the website required by this Act, provided that the user may--
 - (A) specify such search shall be confined to Federal contracts and subcontracts;
 - (B) specify such search shall be confined to include grants, subgrants, loans, awards, cooperative agreements, and other forms of financial assistance;
- (2) shall not be considered in compliance if it hyperlinks to the Federal Procurement Data System website, Federal Assistance Award Data System website, Grants.gov website, or other existing websites, so that the information elements required by subsection (b)(1) cannot be searched electronically by field in a single search;
- (3) shall provide an opportunity for the public to provide input about the utility of the site and recommendations for improvements;
- (4) shall be updated not later than 30 days after the award of any Federal award requiring a posting; and
- (5) shall provide for separate searches for Federal awards described in subsection (a) to distinguish between the Federal awards described in subsection (a)(2)(A)(i) and those described in subsection (a)(2)(A)(ii).

(d) Subaward Data.--

(1) Pilot program.--

- (A) In general.--Not later than July 1, 2007, the Director of the Office of Management and Budget shall commence a pilot program to--
 - (i) test the collection and accession of data about subgrants and subcontracts; and
 - (ii) determine how to implement a subaward reporting program across the Federal Government, including--
 - (I) a reporting system under which the entity issuing a subgrant or subcontract is responsible for fulfilling the subaward reporting requirement; and
 - (II) a mechanism for collecting and incorporating agency and public feedback on the design and utility of the website.
- (B) Termination.--The pilot program under subparagraph (A) shall terminate not later than January 1, 2009.

(2) Reporting of subawards.--

- (A) In general.--Based on the pilot program conducted under paragraph (1), and, except as provided in subparagraph (B), not later than January 1, 2009, the Director of the Office of Management and Budget--
 - (i) shall ensure that data regarding subawards are disclosed in the same manner as data regarding other Federal awards, as required by this Act; and
 - (ii) shall ensure that the method for collecting and distributing data about

subawards under clause (i)--

- (I) minimizes burdens imposed on Federal award recipients and subaward recipients;
- (II) allows Federal award recipients and subaward recipients to allocate reasonable costs for the collection and reporting of subaward data as indirect costs; and
- (III) establishes cost-effective requirements for collecting subaward data under block grants, formula grants, and other types of assistance to State and local governments.

(B) Extension of deadline.--For subaward recipients that receive Federal funds through State, local, or tribal governments, the Director of the Office of Management and Budget may extend the deadline for ensuring that data regarding such subawards are disclosed in the same manner as data regarding other Federal awards for a period not to exceed 18 months, if the Director determines that compliance would impose an undue burden on the subaward recipient.

(e) Exception.--Any entity that demonstrates to the Director of the Office of Management and Budget that the gross income, from all sources, for such entity did not exceed \$300,000 in the previous tax year of such entity shall be exempt from the requirement to report subawards under subsection (d), until the Director determines that the imposition of such reporting requirements will not cause an undue burden on such entities.

(f) Construction.--Nothing in this Act shall prohibit the Office of Management and Budget from including through the website established under this section access to data that is publicly available in any other Federal database.

(g) Report.--

(1) In general.--The Director of the Office of Management and Budget shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Government Reform of the House of Representatives an annual report regarding the implementation of the website established under this section.

(2) Contents.--Each report submitted under paragraph (1) shall include--

- (A) data regarding the usage and public feedback on the utility of the site (including recommendations for improving data quality and collection);
- (B) an assessment of the reporting burden placed on Federal award and subaward recipients; and
- (C) an explanation of any extension of the subaward reporting deadline under subsection (d)(2)(B), if applicable.

(3) Publication.--The Director of the Office of Management and Budget shall make each report submitted under paragraph (1) publicly available on the website established under this section.

SEC. 3. CLASSIFIED INFORMATION.

Nothing in this Act shall require the disclosure of classified information.

SEC. 4. GOVERNMENT ACCOUNTABILITY OFFICE REPORTING REQUIREMENT.

Not later than January 1, 2010, the Comptroller General shall submit to Congress a report on compliance with this Act.

Approved September 26, 2006.

LEGISLATIVE HISTORY--S. 2590:

SENATE REPORTS: No. 109-329 (Comm. on Homeland Security and Governmental Affairs).

CONGRESSIONAL RECORD, Vol. 152 (2006):

Sept. 7, considered and passed Senate.

Sept. 13, considered and passed House.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 42 (2006):

Sept. 26, Presidential remarks.

Tab 7

Executive Order: 13450 **Improving Government Program Performance**

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 305 and 306 of title 5, sections 1115, 1116, and 9703 of title 31, and chapter 28 of title 39, United States Code, and to improve the effectiveness and efficiency of the Federal Government and promote greater accountability of that Government to the American people, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the Federal Government to spend taxpayer dollars effectively, and more effectively each year. Agencies shall apply taxpayer resources efficiently in a manner that maximizes the effectiveness of Government programs in serving the American people.

Sec. 2. Definitions. As used in this order:

(a) "agency" means:

(i) an executive agency as defined in section 105 of title 5, United States Code, other than the Government Accountability Office; and

(ii) the United States Postal Service and the Postal Regulatory Commission;

(b) "agency Performance Improvement Officer" means an employee of an agency who is a member of the Senior Executive Service or equivalent service, and who is designated by the head of the agency to carry out the duties set forth in section 5 of this order.

Sec. 3. Duties of Heads of Agencies. To assist in implementing the policy set forth in section 1 of this order, the head of each agency shall, with respect to each program administered in whole or in part by the agency:

(a) approve for implementation:

(i) clear annual and long-term goals defined by objectively measurable outcomes; and

(ii) specific plans for achieving the goals, including:

(A) assignments to specified agency personnel of:

(1) the duties necessary to achieve the goals; and

(2) the authority and resources necessary to fulfill such duties;

(B) means to measure:

(1) progress toward achievement of the goals; and

(2) efficiency in use of resources in making that progress; and

(C) mechanisms for ensuring continuous accountability of the specified agency personnel to the head of the agency for achievement of the goals and efficiency in use of resources in achievement of the goals;

(b) assist the President, through the Director of the Office of Management and Budget (Director), in making recommendations to the Congress, including budget and appropriations recommendations, that are justified based on objective performance information and accurate estimates of the full costs of achieving the annual and long-term goals approved under subsection (a)(i) of this section; and

(c) ensure that agency Internet websites available to the public include regularly updated and accurate information on the performance of the agency and its programs, in a readily useable and searchable form, that sets forth the successes, shortfalls, and challenges of each program and describes the agency's efforts to improve the performance of the program.

Sec. 4. Additional Duties of the Director of the Office of Management and Budget. (a) To assist in implementing the policy set forth in section 1 of this order, the Director shall issue instructions to the heads of agencies concerning:

(i) the contents, and schedule for approval, of the goals and plans required by section 3 of this order; and

(ii) the availability to the public in readily accessible and comprehensible form on the agency's Internet website (or in the Federal Register for any agency that does not have such a website), of the information approved by the head of each agency under section 3 of this order and other information relating to agency performance.

(b) Instructions issued under subsection (a) of this section shall facilitate compliance with applicable law, presidential guidance, and Office of Management and Budget circulars and shall be designed to minimize duplication of effort and to assist in maximizing the efficiency and effectiveness of agencies and their programs.

Sec. 5. Duties of Agency Performance Improvement Officers. Subject to the direction of the head of the agency, each agency Performance Improvement Officer shall:

(a) supervise the performance management activities of the agency, including:

(i) development of the goals, specific plans, and estimates for which section 3 of this order provides; and

(ii) development of the agency's strategic plans, annual performance plans, and annual performance reports as required by law;

(b) advise the head of the agency, with respect to a program administered in whole or in part by the agency, whether:

(i) goals proposed for the approval of the head of the agency under section 3(a)(i) of this order are:

(A) sufficiently aggressive toward full achievement of the purposes of the program; and

(B) realistic in light of authority and resources assigned to the specified agency personnel referred to in section 3(a)(ii)(A) of this order with respect to that program; and

(ii) means for measurement of progress toward achievement of the goals are sufficiently rigorous and accurate;

(c) convene the specified agency personnel referred to in section 3(a)(ii)(A) of this order, or appropriate subgroups thereof, regularly throughout each year to:

(i) assess performance of each program administered in whole or in part by the agency; and

(ii) consider means to improve the performance and efficiency of such program;

(d) assist the head of the agency in the development and use within the agency of performance measures in personnel performance appraisals, and, as appropriate, other agency personnel and planning processes; and

(e) report to the head of the agency on the implementation within the agency of the policy set forth in section 1 of this order.

Sec. 6. Establishment and Operation of Performance Improvement Council. (a) The Director shall establish, within the Office of Management and Budget for administrative purposes only, a Performance Improvement Council (Council), consistent with this order.

(b) The Council shall consist exclusively of:

(i) the Deputy Director for Management of the Office of Management and Budget, who shall serve as Chair;

(ii) such agency Performance Improvement Officers, as determined by the Chair; and

(iii) such other full-time or permanent part-time employees of an agency, as determined by the Chair with the concurrence of the head of the agency concerned.

(c) The Chair or the Chair's designee, in implementing subsection (d) of this section, shall convene and preside at the meetings of the Council, determine its agenda, direct its work, and establish and direct subgroups of the Council, as appropriate to deal with particular subject matters, that shall consist exclusively of members of the Council.

(d) To assist in implementing the policy set forth in section 1 of this order, the Council shall:

(i) develop and submit to the Director, or when appropriate to the President through the Director, at times and in such formats as the Chair may specify, recommendations concerning:

(A) performance management policies and requirements; and

(B) criteria for evaluation of program performance;

(ii) facilitate the exchange among agencies of information on performance management, including strategic and annual planning and reporting, to accelerate improvements in program performance;

(iii) coordinate and monitor a continuous review by heads of agencies of the performance and management of all Federal programs that assesses the clarity of purpose, quality of strategic and performance planning and goals, management excellence, and results achieved for each agency's programs, with the results of these assessments and the evidence on which they are based made available to the public on or through the Internet website referred to in subsection (d)(iv);

(iv) to facilitate keeping the public informed, and with such assistance of heads of agencies as the Director may require, develop an Internet website that provides the public with information on how well each agency performs and that serves as a comprehensive source of information on:

(A) current program performance; and

(B) the status of program performance plans and agency Performance and Accountability Reports; and

(C) consistent with the direction of the head of the agency concerned after consultation with the Director, any publicly available reports by the agency's Inspector General concerning agency program performance;

(v) monitor implementation by agencies of the policy set forth in section 1 of this order and report thereon from time to time as appropriate to the Director, or when appropriate to the President through the Director, at such times and in such formats as the Chair may specify, together with any recommendations of the Council for more effective implementation of such policy;

(vi) at the request of the head of an agency, unless the Chair declines the request, promptly review and provide advice on a proposed action by that agency to implement the policy set forth in section 1 of this order; and

(vii) obtain information and advice, as appropriate, in a manner that seeks individual advice and does not involve collective judgment or consensus advice or deliberation, from:

(A) State, local, territorial, and tribal officials; and

(B) representatives of entities or other individuals.

(e)(i) To the extent permitted by law, the Office of Management and Budget shall provide the funding and administrative support the Council needs, as determined by the Director, to implement this section; and

(ii) the heads of agencies shall provide, as appropriate and to the extent permitted by law, such information and assistance as the Chair may request to implement this section.

Sec. 7. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an agency or the head thereof; or

(ii) functions of the Director relating to budget, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law (including laws and executive orders relating to the protection of information from disclosure) and subject to the availability of appropriations.

(c) In implementing this order, the Director of National Intelligence shall perform the functions assigned to the Director of National Intelligence by the National Security Act of 1947, as amended (50 U.S.C. 401 et seq.), consistent with section 1018 of the Intelligence Reform and Terrorism Prevention Act (Public Law 108-458), and other applicable laws.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

THE WHITE HOUSE,

November 13, 2007

*Available at <http://www.whitehouse.gov/news/releases/2007/11/print/20071113-9.html>

E-Government Act of 2002

Title II - Federal Management and Promotion of Electronic Government Services

§ 207. Accessibility, usability, and preservation of government information.

(a)PURPOSE- The purpose of this section is to improve the methods by which Government information, including information on the Internet, is organized, preserved, and made accessible to the public.

(b) DEFINITIONS- In this section, the term--

(1)"Committee" means the Interagency Committee on Government Information established under subsection (c); and

* * *

(c) INTERAGENCY COMMITTEE-

(1) ESTABLISHMENT- Not later than 180 days after the date of enactment of this title, the Director shall establish the Interagency Committee on Government Information.

(2) MEMBERSHIP- The Committee shall be chaired by the Director or the designee of the Director and--

(C) share effective practices for access to, dissemination of, and retention of Federal information.

(A) shall include representatives from--

(i) the National Archives and Records Administration;

* * *

(3) FUNCTIONS- The Committee shall--

(A) engage in public consultation to the maximum extent feasible, including consultation with interested communities such as public advocacy organizations;

(B) conduct studies and submit recommendations, as provided under this section, to the Director and Congress; and

(C) share effective practices for access to, dissemination of, and retention of Federal information.

(4) TERMINATION- The Committee may be terminated on a date determined by the Director, except the Committee may not terminate before the Committee submits all recommendations required under this section.

(d) CATEGORIZING OF INFORMATION-

(1) COMMITTEE FUNCTIONS- Not later than 2 years after the date of enactment of this Act, the Committee shall submit recommendations to the Director on--

(A) the adoption of standards, which are open to the maximum extent feasible, to enable the organization and categorization of Government information--

(i) in a way that is searchable electronically, including by searchable identifiers; and

(ii) in ways that are interoperable across agencies;

(B) the definition of categories of Government information which should be classified under the standards; and

(C) determining priorities and developing schedules for the initial implementation of the standards by agencies.

* * *

(e) PUBLIC ACCESS TO ELECTRONIC INFORMATION-

(1) COMMITTEE FUNCTIONS- Not later than 2 years after the date of enactment of this Act, the Committee shall submit recommendations to the Director and the Archivist of the United States on--

(A) the adoption by agencies of policies and procedures to ensure that chapters 21, 25, 27, 29, and 31 of title 44, United States Code, are applied effectively and comprehensively to Government information on the Internet and to other electronic records; and

(B) the imposition of timetables for the implementation of the policies and procedures by agencies.

(2) FUNCTIONS OF THE ARCHIVIST- Not later than 1 year after the submission of recommendations by the Committee under paragraph (1), the Archivist of the United States shall issue policies--

(A) requiring the adoption by agencies of policies and procedures to ensure that chapters 21, 25, 27, 29, and 31 of title 44, United States Code, are applied effectively and comprehensively to Government information on the Internet and to other electronic records; and

(B) imposing timetables for the implementation of the policies, procedures, and technologies by agencies.

(3) MODIFICATION OF POLICIES- After the submission of agency reports under paragraph (4), the Archivist of the United States shall modify the policies, as needed, in consultation with the Committee and interested parties.

(4) AGENCY FUNCTIONS- Each agency shall report annually to the Director, in the report established under section 202(g), on compliance of that agency with the policies issued under paragraph (2)(A).

* * *

(f) AGENCY WEBSITES-

(1) STANDARDS FOR AGENCY WEBSITES- Not later than 2 years after the effective date of this title, the Director shall promulgate guidance for agency websites that includes--

(A) requirements that websites include direct links to--

(i) descriptions of the mission and statutory authority of the agency;

(ii) information made available to the public under subsections (a)(1) and (b) of section 552 of title 5, United States Code (commonly referred to as the 'Freedom of Information Act');

(iii) information about the organizational structure of the agency; and

(iv) the strategic plan of the agency developed under section 306 of title 5, United States Code; and

(B) minimum agency goals to assist public users to navigate agency websites,
including--

- (i) speed of retrieval of search results;
- (ii) the relevance of the results;
- (iii) tools to aggregate and disaggregate data; and
- (iv) security protocols to protect information.

(2) AGENCY REQUIREMENTS-

(A) Not later than 2 years after the date of enactment of this Act, each agency shall--

- (i) consult with the Committee and solicit public comment;
- (ii) establish a process for determining which Government information the agency intends to make available and accessible to the public on the Internet and by other means;
- (iii) develop priorities and schedules for making Government information available and accessible;
- (iv) make such final determinations, priorities, and schedules available for public comment;
- (v) post such final determinations, priorities, and schedules on the Internet; and
- (vi) submit such final determinations, priorities, and schedules to the Director, in the report established under section 202(g).

(B) Each agency shall update determinations, priorities, and schedules of the agency, as needed, after consulting with the Committee and soliciting public comment, if appropriate.

(3) PUBLIC DOMAIN DIRECTORY OF PUBLIC FEDERAL GOVERNMENT WEBSITES-

(A) ESTABLISHMENT- Not later than 2 years after the effective date of this title, the Director and each agency shall--

(i) develop and establish a public domain directory of public Federal Government websites; and

(ii) post the directory on the Internet with a link to the integrated Internet-based system established under section 204.

(B) DEVELOPMENT- With the assistance of each agency, the Director shall--

(i) direct the development of the directory through a collaborative effort, including input from--

(I) agency librarians;

(II) information technology managers;

(III) program managers;

(IV) records managers;

(V) Federal depository librarians; and

(VI) other interested parties; and

(ii) develop a public domain taxonomy of subjects used to review and categorize public Federal Government websites.

(C) UPDATE- With the assistance of each agency, the Administrator of the Office of Electronic Government shall--

(i) update the directory as necessary, but not less than every 6 months; and

(ii) solicit interested persons for improvements to the directory.

(g) ACCESS TO FEDERALLY FUNDED RESEARCH AND DEVELOPMENT-

(1) DEVELOPMENT AND MAINTENANCE OF GOVERNMENTWIDE REPOSITORY AND WEBSITE-

(A) REPOSITORY AND WEBSITE- The Director of the Office of Management and Budget (or the Director's delegate), in consultation with the Director of the Office of Science and Technology Policy and other relevant agencies, shall ensure the development and maintenance of--

(i) a repository that fully integrates, to the maximum extent feasible, information about research and development funded by the Federal Government, and the repository shall--

(I) include information about research and development funded by the Federal Government, consistent with any relevant protections for the information under section 552 of title 5, United States Code, and performed by--

(aa) institutions not a part of the Federal Government, including State, local, and foreign governments; industrial firms; educational institutions; not-for-profit organizations; federally funded research and development centers; and private individuals; and

(bb) entities of the Federal Government, including research and development laboratories, centers, and offices; and

(II) integrate information about each separate research and development task or award, including--

(aa) the dates upon which the task or award is expected to start and end;

(bb) a brief summary describing the objective and the scientific and technical focus of the task or award;

(cc) the entity or institution performing the task or award and its contact information;

(dd) the total amount of Federal funds expected to be provided to the task or award over its lifetime and the amount of funds expected to be provided in each fiscal year in which the work of the task or award is ongoing;

(ee) any restrictions attached to the task or award that would prevent the sharing with the general public of any or all of the information required by this subsection, and the reasons for such restrictions; and

(ff) such other information as may be determined to be appropriate; and

(ii) 1 or more websites upon which all or part of the repository of Federal research and development shall be made available to and searchable by Federal agencies and non-Federal entities, including the general public, to facilitate--

(I) the coordination of Federal research and development activities;

(II) collaboration among those conducting Federal research and development;

(III) the transfer of technology among Federal agencies and between Federal agencies and non-Federal entities; and

(IV) access by policymakers and the public to information concerning Federal research and development activities.

(B) OVERSIGHT- The Director of the Office of Management and Budget shall issue any guidance determined necessary to ensure that agencies provide all information requested under this subsection.

(2) AGENCY FUNCTIONS- Any agency that funds Federal research and development under this subsection shall provide the information required to populate the repository in the manner prescribed by the Director of the Office of Management and Budget.

(3) COMMITTEE FUNCTIONS- Not later than 18 months after the date of enactment of this Act, working with the Director of the Office of Science and Technology Policy, and after consultation with interested parties, the Committee shall submit recommendations to the Director on--

(A) policies to improve agency reporting of information for the repository established under this subsection; and

(B) policies to improve dissemination of the results of research performed by Federal agencies and federally funded research and development centers.

(4) FUNCTIONS OF THE DIRECTOR- After submission of recommendations by the Committee under paragraph (3), the Director shall report on the recommendations of the Committee and Director to Congress, in the E-Government report under section 3606 of title 44 (as added by this Act).

(5) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated for the development, maintenance, and operation of the Governmentwide repository and website under this subsection--

(A) \$2,000,000 in each of the fiscal years 2003 through 2005; and

(B) such sums as are necessary in each of the fiscal years 2006 and 2007.

Tab 9

Homeland Security Presidential Directive/HSPD-12

Subject: Policy for a Common Identification Standard for Federal Employees and Contractors

(1) Wide variations in the quality and security of forms of identification used to gain access to secure Federal and other facilities where there is potential for terrorist attacks need to be eliminated. Therefore, it is the policy of the United States to enhance security, increase Government efficiency, reduce identity fraud, and protect personal privacy by establishing a mandatory, Government-wide standard for secure and reliable forms of identification issued by the Federal Government to its employees and contractors (including contractor employees).

(2) To implement the policy set forth in paragraph (1), the Secretary of Commerce shall promulgate in accordance with applicable law a Federal standard for secure and reliable forms of identification (the "Standard") not later than 6 months after the date of this directive in consultation with the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Homeland Security, the Director of the Office of Management and Budget (OMB), and the Director of the Office of Science and Technology Policy. The Secretary of Commerce shall periodically review the Standard and update the Standard as appropriate in consultation with the affected agencies.

(3) "Secure and reliable forms of identification" for purposes of this directive means identification that (a) is issued based on sound criteria for verifying an individual employee's identity; (b) is strongly resistant to identity fraud, tampering, counterfeiting, and terrorist exploitation; (c) can be rapidly authenticated electronically; and (d) is issued only by providers whose reliability has been established by an official accreditation process. The Standard will include graduated criteria, from least secure to most secure, to ensure flexibility in selecting the appropriate level of security for each application. The Standard shall not apply to identification associated with national security systems as defined by 44 U.S.C. 3542(b)(2).

(4) Not later than 4 months following promulgation of the Standard, the heads of executive departments and agencies shall have a program in place to ensure that identification issued by their departments and agencies to Federal employees and contractors meets the Standard. As promptly as possible, but in no case later than 8 months after the date of promulgation of the Standard, the heads of executive departments and agencies shall, to the maximum extent practicable, require the use of identification by Federal employees and contractors that meets the Standard in gaining physical access to Federally controlled facilities and logical access to Federally controlled information systems. Departments and agencies shall implement this directive in a manner consistent with ongoing Government-wide activities, policies and guidance issued by OMB, which shall ensure compliance.

(5) Not later than 6 months following promulgation of the Standard, the heads of executive departments and agencies shall identify to the Assistant to the President for Homeland Security and the Director of OMB those Federally controlled facilities, Federally controlled information

systems, and other Federal applications that are important for security and for which use of the Standard in circumstances not covered by this directive should be considered. Not later than 7 months following the promulgation of the Standard, the Assistant to the President for Homeland Security and the Director of OMB shall make recommendations to the President concerning possible use of the Standard for such additional Federal applications.

(6) This directive shall be implemented in a manner consistent with the Constitution and applicable laws, including the Privacy Act (5 U.S.C. 552a) and other statutes protecting the rights of Americans.

(7) Nothing in this directive alters, or impedes the ability to carry out, the authorities of the Federal departments and agencies to perform their responsibilities under law and consistent with applicable legal authorities and presidential guidance. This directive is intended only to improve the internal management of the executive branch of the Federal Government, and it is not intended to, and does not, create any right or benefit enforceable at law or in equity by any party against the United States, its departments, agencies, entities, officers, employees or agents, or any other person.

(8) The Assistant to the President for Homeland Security shall report to me not later than 7 months after the promulgation of the Standard on progress made to implement this directive, and shall thereafter report to me on such progress or any recommended changes from time to time as appropriate.

GEORGE W. BUSH

*Available at <http://www.whitehouse.gov/news/releases/2004/08/20040827-8.html>

Tab 10

Executive Order 13402 Strengthening Federal Efforts To Protect Against Identity Theft

By the authority vested in me as President by the Constitution and the laws of the United States of America, in order to strengthen efforts to protect against identity theft, it is hereby ordered as follows:

Section 1. *Policy.* It is the policy of the United States to use Federal resources effectively to deter, prevent, detect, investigate, proceed against, and prosecute unlawful use by persons of the identifying information of other persons, including through:

- (a) increased aggressive law enforcement actions designed to prevent, investigate, and prosecute identity theft crimes, recover the proceeds of such crimes, and ensure just and effective punishment of those who perpetrate identity theft;
- (b) improved public outreach by the Federal Government to better (i) educate the public about identity theft and protective measures against identity theft, and (ii) address how the private sector can take appropriate steps to protect personal data and educate the public about identity theft; and
- (c) increased safeguards that Federal departments, agencies, and instrumentalities can implement to better secure government-held personal data.

Sec. 2. *Establishment of the Identity Theft Task Force.*

- (a) There is hereby established the Identity Theft Task Force.
- (b) The Task Force shall consist exclusively of:
 - (i) the Attorney General, who shall serve as Chairman of the Task Force;
 - (ii) the Chairman of the Federal Trade Commission, who shall serve as Co-Chairman of the Task Force;
 - (iii) the Secretary of the Treasury;
 - (iv) the Secretary of Commerce;
 - (v) the Secretary of Health and Human Services;

- (vi) the Secretary of Veterans Affairs;
- (vii) the Secretary of Homeland Security;
- (viii) the Director of the Office of Management and Budget;
- (ix) the Commissioner of Social Security;
- (x) the following officers of the United States:
 - (A) the Chairman of the Board of Governors of the Federal Reserve System;
 - (B) the Chairperson of the Board of Directors of the Federal Deposit Insurance Corporation;
 - (C) the Comptroller of the Currency;
 - (D) the Director of the Office of Thrift Supervision;
 - (E) the Chairman of the National Credit Union Administration Board; and
 - (F) the Postmaster General; and
- (xi) such other officers of the United States as the Attorney General may designate from time to time, with the concurrence of the respective heads of departments and agencies concerned.
- (c) The Chairman and Co-Chairman shall convene and preside at the meetings of the Task Force, determine its agenda, direct its work and, as appropriate, establish and direct subgroups of the Task Force that shall consist exclusively of members of the Task Force. Such subgroups may address particular subject matters, such as criminal law enforcement or private sector education and outreach. The Chairman and Co-Chairman may also designate, with the concurrence of the head of department, agency, or instrumentality of which the official is part, such other Federal officials as they deem appropriate for participation in the Task Force subgroups.
- (d) A member of the Task Force, including the Chairman and Co-Chairman, may designate, to perform the Task Force or Task Force subgroup functions of the member, any person who is a part of the member's department, agency, or instrumentality and who has high-level policy or operational duties or responsibilities related to the mission of the Task Force.

Sec. 3. *Functions of the Task Force.* The Task Force, in implementing the policy set forth in section 1 of this order, shall:

- (a) review the activities of executive branch departments, agencies, and instrumentalities relating to the policy set forth in section 1, and building upon these prior activities, prepare and submit in writing to the President within 180 days after the date of this order a coordinated strategic plan to further improve the effectiveness and efficiency of the Federal Government's activities in the areas of identity theft awareness, prevention, detection, and prosecution;

(b) coordinate, as appropriate and subject to section 5(a) of this order, Federal Government efforts related to implementation of the policy set forth in section 1 of this order;

(c) obtain information and advice relating to the policy set forth in section 1 from representatives of State, local, and tribal governments, private sector entities, and individuals, in a manner that seeks their individual advice and does not involve collective judgment or consensus advice and deliberation and without giving any such person a vote or a veto over the activities or advice of the Task Force;

(d) promote enhanced cooperation by Federal departments and agencies with State and local authorities responsible for the prevention, investigation, and prosecution of significant identity theft crimes, including through avoiding unnecessary duplication of effort and expenditure of resources; and

(e) provide advice on the establishment, execution, and efficiency of policies and activities to implement the policy set forth in section 1:

(i) to the President in written reports from time to time, including recommendations for administrative action or proposals for legislation; and

(ii) to the heads of departments, agencies, and instrumentalities as appropriate from time to time within the discretion of the Chairman and the o-Chairman.

Sec. 4. Cooperation. (a) To the extent permitted by law and applicable presidential guidance, executive departments, agencies, and instrumentalities shall provide to the Task Force such information, support, and assistance as the Task Force, through its Chairman and Co-Chairman, may request to implement this order.

(b) The Task Force shall be located in the Department of Justice for administrative purposes, and to the extent permitted by law, the Department of Justice shall provide the funding and administrative support the Task Force needs to implement this order, as determined by the Attorney General.

Sec. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or instrumentality or the head thereof; and

(ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is intended only to improve the internal management of the Federal Government and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its departments, agencies, instrumentalities, or entities, its officers or employees, or any other person.

Sec. 6. Termination. Unless the Task Force is sooner terminated by the President, the Attorney General may terminate the Task Force by a written notice of its termination published in the **Federal Register**.

GEORGE W. BUSH
THE WHITE HOUSE,
May 10, 2006.

Tab 11

Executive Order 13411 **Improving Assistance for Disaster Victims**

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (42 U.S.C. 5121 *et seq.*) (the “Stafford Act”), and to take further actions to improve the delivery of Federal disaster assistance, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the Federal Government to ensure that individuals who are victims of a terrorist attack, natural disaster, or other incident that is the subject of an emergency or major disaster declaration under the Stafford Act, and who are thereby eligible for financial or other assistance delivered by any department or agency of the executive branch (Federal disaster assistance), have prompt and efficient access to Federal disaster assistance, as well as information regarding assistance available from State and local government and private sector sources.

Sec. 2. Task Force on Disaster Assistance Coordination. (a) Plan to Improve Delivery of Federal Disaster Assistance. To further the policy in section 1 of this order, there is established the interagency “Task Force on Disaster Assistance Coordination” (Task Force). The Task Force shall develop a plan to streamline and otherwise improve the delivery of Federal disaster assistance (Plan). The Plan shall:

- (i) include an inventory of Federal disaster assistance programs and assess the effectiveness of their respective delivery mechanisms;
- (ii) recommend specific actions to improve the delivery of Federal disaster assistance, which shall include actions to provide a centralized application process for Federal disaster assistance, provide a centralized and continuously updated clearinghouse from which disaster victims may obtain information regarding Federal disaster assistance and State and local government and private sector sources of disaster assistance, reduce unnecessarily duplicative application forms and processes for Federal disaster assistance, and strengthen controls designed to prevent improper payments and other forms of fraud, waste, and abuse; and
- (iii) include an implementation schedule for the Plan’s recommendations that provides for the phased implementation of the Plan by December 31, 2008, including quarterly milestones and metrics to be used to measure and evaluate implementation.

(b) Membership of the Task Force. (i) The Task Force shall consist exclusively of the following members, or their designees who shall be at the Assistant Secretary level (or its equivalent) or higher:

- (A) the Secretary of Homeland Security, who shall serve as Chair;
- (B) the Secretary of the Treasury;
- (C) the Secretary of Defense;
- (D) the Attorney General;
- (E) the Secretary of Agriculture;
- (F) the Secretary of Commerce;
- (G) the Secretary of Labor;
- (H) the Secretary of Health and Human Services;
- (I) the Secretary of Housing and Urban Development;
- (J) the Secretary of Education;
- (K) the Secretary of Veterans Affairs;
- (L) the Director of the Office of Personnel Management;
- (M) the Commissioner of Social Security;
- (N) the Administrator of the Small Business Administration;
- (O) the Director of the Office of Management and Budget; and
- (P) such other officers of the United States as the Secretary of Homeland Security may designate from time to time.

(ii) The Secretary of Homeland Security, or the Secretary's designee, shall convene and preside at meetings of the Task Force, determine its agenda, direct its work, and, as appropriate to address specific subject matters, establish and direct subgroups of the Task Force. A member of the Task Force may designate, to perform Task Force subgroup functions of the member, any person who is part of such member's department or agency and who is either an officer of the United States appointed by the President or a member of the Senior Executive Service.

(c) Plan Approval and Implementation. Not later than March 1, 2007, the Secretary of Homeland Security shall submit the Plan to the President for approval through the Assistant to the President for Homeland Security and Counterterrorism and the Director of the Office of Management and Budget. Upon approval of the Plan by the President, the Secretary of Homeland Security, assisted by the Task Force, shall coordinate the implementation of the Plan. Until the completion of such implementation, the Secretary of Homeland Security shall submit a quarterly progress

report to the Assistant to the President for Homeland Security and Counterterrorism and the Director of the Office of Management and Budget.

Sec. 3. *Assistance and Support.* To the extent permitted by law, the heads of all executive departments and agencies shall provide such assistance and information as the Secretary of Homeland Security may request in carrying out the Secretary's responsibilities under this order. Consistent with applicable law and subject to the availability of appropriations, the Department of Homeland Security shall provide necessary funding and administrative support for the Task Force.

Sec. 4. *Administration.* This order shall: (a) be implemented in a manner consistent with applicable laws, including Federal laws protecting the information privacy rights and other legal rights of Americans, and subject to the availability of appropriations;

(b) be implemented in a manner consistent with the statutory authority of the principal officers of executive departments and agencies as heads of their respective departments or agencies; and

(c) not be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, regulatory, and legislative responsibilities.

Sec. 5. *Judicial Review.* This order is intended only to improve the internal management of the Federal Government and is not intended to, and does not, create any rights or benefits, substantive or procedural, enforceable at law or in equity by a party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

THE WHITE HOUSE,
August 29, 2006.

*Available at: <http://www.whitehouse.gov/news/releases/2006/08/20060829-9.html>

Tab 12

Executive Order: 13439

Establishing An Interagency Working Group on Import Safety

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to ensure that the executive branch takes all appropriate steps to promote the safety of imported products, it is hereby ordered as follows:

Section 1. Establishment of Interagency Working Group on Import Safety. The Secretary of Health and Human Services shall establish within the Department of Health and Human Services for administrative purposes only an Interagency Working Group on Import Safety (Working Group).

Sec. 2. Membership and Operation of Working Group.

(a) The Working Group shall consist exclusively of the following members, or their designees who shall be officers of the United States appointed by the President or members of the Senior Executive Service:

- (i) the Secretary of Health and Human Services, who shall serve as Chair;
- (ii) the Secretary of State;
- (iii) the Secretary of the Treasury;
- (iv) the Attorney General;
- (v) the Secretary of Agriculture;
- (vi) the Secretary of Commerce;
- (vii) the Secretary of Transportation;
- (viii) the Secretary of Homeland Security;
- (ix) the Director of the Office of Management and Budget;
- (x) the United States Trade Representative;
- (xi) the Administrator of the Environmental Protection Agency;
- (xii) the Chairman of the Consumer Product Safety Commission; and

(xiii) other officers or full-time or permanent part-time employees of the United States, as determined by the Chair, with the concurrence of the head of the department or agency concerned.

(b) The Chair shall convene and preside at meetings of the Working Group, determine its agenda, and direct its work. The Chair may establish and direct subgroups of the Working Group, as appropriate to deal with particular subject matters, that shall consist exclusively of members of the Working Group. The Chair shall designate an officer or employee of the Department of Health and Human Services to serve as the Executive Secretary of the Working Group. The Executive Secretary shall head any staff assigned to the Working Group and any subgroups thereof, and such staff shall consist exclusively of full-time or permanent part-time Federal employees.

Sec. 3. Mission of Working Group. The mission of the Working Group shall be to identify actions and appropriate steps that can be pursued, within existing resources, to promote the safety of imported products, including the following:

(a) reviewing or assessing current procedures and methods aimed at ensuring the safety of products exported to the United States, including reviewing existing cooperation with foreign governments, foreign manufacturers, and others in the exporting country's private sector regarding their inspection and certification of exported goods and factories producing exported goods and considering whether additional initiatives should be undertaken with respect to exporting countries or companies;

(b) identifying potential means to promote all appropriate steps by U.S. importers to enhance the safety of imported products, including identifying best practices by U.S. importers in selection of foreign manufacturers, inspecting manufacturing facilities, inspecting goods produced on their behalf either before export or before distribution in the United States, identifying origin of products, and safeguarding the supply chain; and

(c) surveying authorities and practices of Federal, State, and local government agencies regarding the safety of imports to identify best practices and enhance coordination among agencies.

Sec. 4. Administration of Working Group. The Chair shall, to the extent permitted by law, provide administrative support and funding for the Working Group.

Sec. 5. Recommendations of Working Group. The Working Group shall provide recommendations to the President, through the Assistant to the President for Economic Policy, on the matters set forth in section 3 within 60 days of the date of this order, unless the Chair determines that an extension is necessary. The Working Group may take other actions it considers appropriate to promote the safety of imported products.

Sec. 6. Termination of Working Group. Following consultation with the Assistant to the President for Economic Policy, the Chair shall terminate the Working Group upon the completion of its duties.

Sec. 7. General Provisions.

(a) Nothing in this order shall be construed to impair or otherwise affect (i) authority granted by law to a department, agency, or the head thereof, or (ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

THE WHITE HOUSE,

July 18, 2007.