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The President

Executive Order 12866—Regulatory
Planning and Review

Presidential Documents

Title 3—

Executive Order 12866 of September 30, 1993

The President

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them; a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, 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:

Section 1. Statement of Regulatory Philosophy and Principles. (a) *The Regulatory Philosophy.* Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public 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. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) *The Principles of Regulation.* To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) 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.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation

is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) 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.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) 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.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations 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 the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people.

(a) *The Agencies.* Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) *The Office of Management and Budget.* Coordinated review of agency rulemaking is necessary to ensure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function: Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President, the Vice President, and other regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations, as provided by this Executive order.

(c) *The Vice President.* The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order. In fulfilling their responsibilities under this Executive order, the President and the Vice President shall be assisted by the regulatory policy advisors within the Executive Office of the President and by such agency officials and personnel as the President and the Vice President may, from time to time, consult.

Sec. 3. Definitions. For purposes of this Executive order: (a) "Advisors" refers to such regulatory policy advisors to the President as the President and Vice President may from time to time consult, including, among others: (1) the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Assistant to the President for Science and Technology; (7) the Assistant to the President for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Deputy Assistant to the President and Director of the White House Office on Environmental Policy; and (12) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" or "rule" 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. It does not, however, include:

(1) Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations or rules that are limited to agency organization, management, or personnel matters; or

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "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 rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

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

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and 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.

Sec. 4. Planning Mechanism. In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law: (a) *Agencies' Policy Meeting.* Early in each year's planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.

(b) *Unified Regulatory Agenda.* For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) *The Regulatory Plan.* For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;

(D) A statement of the need for each such action and, if applicable, 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;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies, the Advisors, and the Vice President.

(4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency, the Advisors, and the Vice President.

(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies, the Advisors, and the Vice President.

(6) The Vice President, with the Advisors' assistance, may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) *Regulatory Working Group.* Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, the Advisors, and the Vice President. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Vice President on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) *Conferences.* The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regula-

tions promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Vice President, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

Sec. 6. Centralized Review of Regulations. The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) *Agency Responsibilities.* (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory

actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) 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 subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) *OIRA Responsibilities.* The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did

not attend, and telephone conversations between OIRA personnel and any such persons); and .

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

During the Vice Presidential and Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Vice President shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

At the end of this review process, the President, or the Vice President acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

Sec. 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without

any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Vice President, as provided under section 7 of this order. Upon receipt of this request, the Vice President shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

Sec. 9. Agency Authority. Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law.

Sec. 10. Judicial Review. Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.



THE WHITE HOUSE,
September 30, 1993.

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Editorial note: For the President's remarks on signing this Executive order, see issue 39 of the *Weekly Compilation of Presidential Documents*.

THE FIRST YEAR OF EXECUTIVE ORDER NO. 12866

I. INTRODUCTION AND SUMMARY

Just over one year ago, on September 30, 1993, President Clinton issued Executive Order No. 12866, "Regulatory Planning and Review." The Order was designed to restore integrity and accountability to centralized regulatory review, qualities notably absent during the previous administration. The Order also articulated this Administration's philosophy and principles regarding regulation. These are best summarized in the Order's opening lines:

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable.

The President directed the OIRA Administrator to report on the implementation of the Executive Order after its first six months. A written report covering the period October 1, 1993, through March 31, 1994, was delivered to the President and Vice President on May 1, 1994, as requested, and was published in the Federal Register on May 10, 1994.

In the Report, we described in some detail the progress we have made, including improved coordination both between OMB and the agencies and among agencies themselves; more timely OMB review of significant rules; more openness and early

participation by the public in rulemaking; and extensive outreach to State, local, and tribal governments and to small businesses. We also noted that the startup time had been longer than we had anticipated, and that to some extent it was simply too early to judge the success of the Order. In particular, while we had extensive information on the process, we had little information on the substantive compliance with the Order.

We now have data on the period April 1 through September 30, 1994, giving us an opportunity to evaluate the full first year of implementation. Overall, we continue to be pleased with the progress that has been made in achieving the objectives of the Executive Order, but at the same time we are acutely conscious of the work that remains to be done to realize the full benefits that we had hoped to achieve.

As will be discussed below, the processes established by the Order are now for the most part in place, and in general they are operating well. We also have more experience with, and a better feel for, the implementation of the philosophy and principles set out in the Order, particularly as they are reflected in the rules that OIRA reviews. While insufficient time and/or data have resulted in some regulations that may not be the most cost-effective means of achieving their objectives, there are many examples where agencies, by adhering to the philosophy and principles of the Order, have in fact produced "smarter" regulations. In these cases -- whether through increased outreach to the public, greater inter-agency cooperation, improved analysis, or all of the above -- agencies have been better able to balance the complex variety of factors that make up regulatory benefits and costs.

It is important to keep in mind the constraints under which the agencies are operating. The regulatory pipeline is a long one, and it is not uncommon for rules to be issued years after

the authorizing statute or the regulatory initiative first began; indeed, many of the rules promulgated by the agencies this past year were conceived and to a large extent developed before this Administration took office, and thus before the Executive Order was signed. More importantly, some of the rules that have been issued were required by statutes that contain highly prescriptive regulatory requirements, complete with time lines that drive much of the rulemaking process, particularly in the areas of health, safety, and the environment. In addition, rulemaking is often driven by other factors beyond the direct control of the Executive Branch, such as court decisions and dramatic public events that require immediate action.

Moreover, agencies today face unusual pressures to regulate. With budgetary constraints so tight, and with the difficulty of enacting new legislation in the highly partisan atmosphere that characterized the last Congress, the only means left for the agencies to implement their initiatives is through regulation. This puts inordinate pressure on any attempt to hold steady or reduce the amount of regulation in which they are engaged.

Measuring the success of the Order is complicated by other factors as well. While some of its processes can be measured with precision (for example, the number of rules reviewed by OIRA), it is not so easy to judge the success of the philosophy and principles of the Order in producing "smarter" regulations. It is tempting to argue that if all the affected stakeholders are equally irritated, then the correct balance has been struck. Whatever the truth in this, it is a uniquely gloomy definition of success to which we do not subscribe. We believe it is possible for parties to be satisfied, if not jubilant, with the outcome of a rulemaking, recognizing it for what it is, or should be -- a good faith effort in an imperfect world to further the public good.

One of the reasons it is difficult to easily measure the success of the Order is that neither the philosophy nor any of the basic principles -- development of alternatives, setting regulatory priorities, obtaining the best reasonably available information, assessing benefits and costs, considering Federal, State, local, and tribal needs, coordinating with other agencies -- lends itself to facile, mechanical application. Stated another way, the principles of the Order are not a simple check list of tasks. Instead, they are a complex and interactive body of standards that require reasoned judgment, difficult decisions, and balances of competing priorities.

Moreover, though the principles appear simple and straightforward, they are not always easy to apply in particular situations, and the agencies are often faced with imperfect information and limited personnel and financial resources to devote to analysis. And they ultimately face what must be acknowledged as a daunting task: In a society composed of complex and changing webs of institutional and individual behavior, they must predict the future, attempting to control behavior harmful to the common good, without impeding or unwittingly restraining acceptable and beneficial activities.

Finally, under the Executive Order, OIRA reviews only "significant" rules, less than half the rules formerly reviewed by OIRA and an even smaller percentage of the rulemaking documents that are published in the Federal Register. Accordingly, we neither track nor evaluate the extent to which the more routine but numerous regulations that are being issued by the agencies meet the principles of the Order.

For all of these reasons, we cannot assert that the philosophy and principles espoused in the Order either have or have not always been met by the agencies in their regulatory programs. We can, however, provide information that clearly

indicates that agencies are applying the principles in many and diverse rulemakings. We urge those who wish to rush to judgement to remember that even modest changes take enormous effort and much time to accomplish. Based on our experiences this past year that are described below, we believe that the Executive Order sets in place the means to make those changes, and that we are moving in the right direction.

The May 1st Report on Executive Order No. 12866 contained both a short history of regulatory programs of the U.S. Government and a detailed description of the Order and its objectives. These will not be repeated here. Instead, we update the data about the various processes established in the Order, followed by descriptions of some of the substantive changes we are seeing.

II. IMPLEMENTATION OF THE PROCESSES SET FORTH IN THE ORDER

Regulatory Planning

In the May 1st Report, we noted that the regulatory planning process set forth in Section 4 of the Executive Order had just begun. On April 5, 1994, the Vice President convened the Agencies' Policy Meeting. Guidance to the agencies was issued by the OIRA Administrator at this meeting, with additional guidance provided on May 12, 1994.

Draft Regulatory Plans were due to OIRA on June 1st. We asked for Regulatory Plan submissions from over 30 agencies -- all Cabinet agencies except the Department of State; major non-Cabinet agencies, including the Environmental Protection Agency (EPA); and several independent agencies. Some of the agencies, including the Departments of Defense (DOD) and Housing and Urban Development (HUD), as well as the Consumer Product Safety Commission (CPSC), Equal Employment Opportunity Commission (EEOC), the National Archives and Records Administration (NARA), and the Nuclear Regulatory Commission (NRC), submitted Plans on June 1st. Most of the Plans were submitted within the first two weeks of June. However, it took longer than expected to receive Plans from all the major regulatory agencies; in fact, several were not submitted until the end of June and the last was not submitted until late July.

As required by the Order (Section 4(c)(3)), the draft Regulatory Plans were circulated by OIRA to other affected agencies, the regulatory Advisors, and the Vice President within 10 days of receipt. Agencies were reminded to comment to the OIRA Administrator on any planned regulatory action of another agency that might conflict with its own policies (Section 4(c)(5)). Very few substantive comments were received by OIRA.

OIRA and OVP staff reviewed the Plans for conformance to Section 4. In general, the draft Plans, though a good start, were uneven. Several were serious, thoughtful efforts; several others were perfunctory. The better efforts were those of the Departments of Commerce (DOC), Labor (DOL), and Transportation (DOT), and EPA. In several of these cases, agency overviews were well-written descriptions of departmental objectives and their relationship to Presidential priorities.

After consultations with the Vice President's Office (Section 4(c)(6)), many agencies reviewed their draft Plans and improved them. These were submitted to OIRA during late August and September. At present the task of preparing the Regulatory Plans for publication in the Federal Register with the Unified Regulatory Agenda (as required by Section 4(c)(7)) is proceeding on schedule. The Plans and Agenda are to be published on or about October 31, 1994.

The draft Regulatory Plans alerted us to areas where more than one agency was engaged in regulation, and they helped raise these issues to agencies' upper level managers. However, the Plans did not provide very many common themes, and, taken as a whole, they did not produce a consistent or coherent statement of the regulatory priorities of this Administration. While this is disappointing, it is not surprising given the different statutory mandates and missions of the agencies.

Cooperation and Coordination

OIRA and the Agencies: The improved relationships between OIRA and among the agencies that were noted in the May 1st Report have continued, grown, and generally become the norm. There remain differences of view, which can be quite sharp. But for the most part, the differences are healthy, leading to better rules, rather than sources of friction that are unproductive and detract from joint efforts.

Staffs of both OIRA and the regulatory agencies are now quite familiar with what at the turn of the year was a new and untried review process. The procedures by which agencies and OIRA select rulemakings as "significant," and thus subject to OMB review, has matured -- conforming to the requirements of Section 6(a)(3)(a) of the Order, yet retaining a necessary flexibility. While a monthly or bi-monthly list remains a common norm, many variations have developed. Moreover, agencies and OIRA staff have worked out an arrangement to designate informally, often over the phone, non-significant rules that must be published quickly. Even the most orderly regulatory planning and tracking systems must be able to accommodate unexpected events.

Some of the agencies have developed the practice of consulting OIRA staff on whether particular rules are significant even before putting them on a monthly list. Some agencies voluntarily submit advanced drafts so that OIRA staff can make a more informed judgement regarding significance. Also, in some cases, agencies exempted from the centralized review requirements of the Order have voluntarily submitted rules for review. For example, the Advisory Council on Historic Preservation (ACHP), which is formally exempted from the Order, submitted a draft proposal for review, knowing that it needed further interagency coordination. Thus, though the Order formally requires agencies to provide OIRA with a list "indicating those [rules] which the agency believes are significant regulatory actions" (Section 6(a)(3(A))), and specifically states that "OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3(A))" (Section 6(b)(1)), a flexibility built on trust and collegiality has developed with many of the agencies that permits the system to work smoothly and efficiently. This was unheard of a short time ago. We hope the pattern that is developing will ultimately spread to the agencies where historically there has been the greatest resistance to such a cooperative relationship.

Another specific manifestation of the improved relationship between OIRA and the agencies, which is a very constructive development, is the practice of early briefings by agencies on the content of significant rules. For example, early in the process of developing its rules for drug and alcohol testing for various transportation officials and workers, DOT consulted with the OIRA Administrator and staff on the major issues on which it would have to decide in the rulemaking. It then held subsequent briefings to update OIRA on the decisions being made at DOT and to continue to search for feedback. By the time the rules were submitted for OIRA review, there had been sufficient discussion of the important provisions that the review was promptly concluded.

In another instance, HUD was developing rules related to public housing policy regarding the elderly and the disabled. HUD officials provided information to OIRA and to other OMB staff even as decisions were being presented to HUD officials. This enabled the issues of concern to be addressed on a real time basis, and resulted in review being completed much more quickly than would otherwise have occurred.

As a final example, in March 1994, the Department of Education (ED) identified seven final regulations pertaining to student financial assistance programs that had to be published by a May 1, 1994, statutory deadline. OIRA worked with the Department's teams, discussing issues and reviewing early drafts as they were developed. As a result of this cooperative effort, a thorough review under the Executive Order took place, while, at the same time, the formal time period for review averaged only one day and the statutory deadline was met.

Lastly in the area of improved relationships between the agencies and OIRA, the Regulatory Training and Exchange Program has grown and developed. As mentioned in the May 1st Report, the

program, which implements a recommendation of the National Performance Review, brings agency career staff to OIRA on training details, so that they can learn how regulatory review is conducted and to work on Regulatory Working Group (RWG) matters. The objective of the program is to provide expertise to agency career staff regarding regulatory review that can be incorporated into the working practices of the agency.

OIRA has now hosted seven detailees, from the Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and DOT. Two trainees are currently at OIRA. In addition, an OIRA analyst has undertaken a training detail at HHS. All of these details have been extremely successful and well received, both by the trainees and by OIRA. The agency detailees have been fully engaged in substantive regulatory review, and we understand they have gained a new appreciation for the perspective of the central reviewer. They have all been senior career officials, highly motivated and knowledgeable, and have not only fit in well at OIRA, but have offered valuable insights to OIRA staff regarding agency points of view. As the good news about the program travels, we hope that more agencies will take advantage of this excellent opportunity.

Interagency Coordination: Just as important as improved relationships between OIRA and the agencies are better working relationships among the agencies themselves and the consequent heightened awareness of the need for interagency coordination and cooperation in complex rulemaking endeavors. The Executive Branch is an extensive enterprise, and its programs are dispersed among hundreds of different agencies, subagencies, and offices. We obviously cannot claim that there are no glitches, but we believe agencies are making strong efforts to engage in much more extensive interagency coordination.

For example, in the ACHP example noted above, the agency met at length with the Department of Interior (DOI), DOT, USDA, HUD, and EPA in developing its proposed rule. Not all these agencies were satisfied with the proposal that was eventually drafted, but all agreed that they had been fully consulted. This process is not over, and will continue during and subsequent to the public comment period, as ACHP develops its final rule.

In another instance, DOC, DOI, and the Council of Economic Advisors (CEA) worked closely together on DOC and DOI rulemakings that seek, through a survey methodology called "contingent valuation," to quantify the non-use value of damages to natural resources. After substantial consultation among the primary participants, as well as with EPA and the Department of Energy (DOE), DOI and DOC issued coordinated proposed rules whose comment periods only recently closed. It is expected that there will be even more extensive interagency coordination before the final rules are issued.

It is worth noting that interagency coordination is often quite time- and resource-consuming and not without its frustrations. Agencies do after all have different perspectives on their overlapping jurisdictions and mandates, and the process of working out an accommodation is not necessarily a trivial task. In such instances, however, OIRA can often serve as a facilitator of debate, leading to resolution of issues.

For example, a USDA final rule on farmland protection was drafted to implement a statutory requirement that Federal agencies measure the adverse effects of their programs on the conversion of farmland to nonagricultural uses. During its review at OIRA, the draft rule was the subject of extensive coordination among USDA, DOT, HUD, the Department of Justice (DOJ), and Treasury. Although the 90-day review period had to be extended, eventually the agencies reached understandings and

resolved their disagreements. All agreed that the result was a rule that met the intent of the statute without unduly burdening or restricting other Federal programs.

Similarly, coordination among agencies was essential to the issuance of EPA's rule on General Conformity. The Clean Air Act Amendments of 1990 (CAA) require that Federal agencies insure that any actions they undertake or support are consistent with State air quality planning under the Clean Air Act -- i.e., Federal actions must be shown to be in "conformity" with State implementation plans and must not cause or contribute to air quality problems.

Through its rulemaking, EPA sought to delineate the steps Federal agencies were to take and when they were to take them. EPA had initially chosen to interpret the statutory language to require the complex conformity determinations and mitigation/offsetting measures for a vast range of Federal actions -- even those where the Federal agency might exert no continuing control, such as the sale of DOD property or the granting of a Corps of Engineers wetlands modification permit. Because other Federal agencies' activities were clearly affected by this rulemaking, there were a series of multi-lateral and bi-lateral discussions organized by OIRA. As a result of those discussions, certain definitions were refined and certain proposed procedures simplified -- again producing a rule that met the intent of the statute without unduly burdening or restricting other Federal programs.

An example involving HHS and the National Science Foundation (NSF) illustrates the importance of interagency coordination in resolving difficulties with stakeholders and developing a consistent Federal policy. In September 1989, HHS's Public Health Service (PHS) proposed guidelines to prevent financial conflicts of interest by federally funded scientists. The

proposal was severely criticized by the research community as being unreasonably harsh and burdensome, and it was soon withdrawn. NSF then began its own efforts to address this issue, publishing a proposed policy for comment. Over the past year, OIRA and the Office of Science and Technology Policy (OSTP) worked with NSF and HHS to develop a coordinated policy regarding how agencies should regulate financial holdings of scientists who receive Federal grants. After several interagency meetings and extensive discussions, NSF and HHS agreed to develop a common approach. Moreover, the rules are designed to provide maximum flexibility to universities in implementing policies on how to address potential conflicts of interest.

The success of this effort is shown in an article published in Science Magazine describing the rules as "being roundly applauded for their reasonableness." (Science, Vol 265, July 8, 1994, p. 179-80). Whereas the original proposals were considered prescriptive and would have required institutions to turn over researchers' financial disclosures to the government, the final NSF rule states general aims leaving implementation to the universities. The article quotes the associate vice chancellor for research at the University of Illinois as viewing the rule as "a positive example of the process working for both sides. Institutions made comments [on the 1989 proposal], and the agency responded in a thoughtful way."

The coordination and cooperation described above is the result of strong support by the President and Vice President and of trust and cooperation among agency regulatory policy officials. The mechanisms established by the Executive Order to stimulate and encourage such coordination are working well. The Regulatory Working Group (RWG) has continued its role of keeping high level agency regulatory policy officials in touch with each other and with the White House regulatory policy advisors.

The RWG followed up its initial meetings in November, January, and March, with meetings in April, May, June, and August. Implementation of the Executive Order was a frequent agenda item for these meetings, along with discussions of the Regulatory Plans, centralized review and the process by which rules are determined to be significant, public involvement and outreach in rulemaking, and the Section 5 review of existing regulations. Important legislative issues related to regulatory affairs were also discussed, including unfunded mandates, risk analysis, regulatory flexibility analysis, and takings. In addition, the RWG heard periodic reports by the four subgroups on cost-benefit analysis, risk analysis, streamlining, and the use of information technology in rulemaking. Finally, small business issues and issues related to the Paperwork Reduction Act were often subjects of discussion among the RWG members.

The Federal Partnership - Intergovernmental Cooperation:
Executive Order No. 12866 places particular emphasis on improving the Federal Government's relationship with State, local, and tribal governments. (See Sections 1(b)(9), Section 4(e), Section 6(a)(1), and Section 6(a)(3)(B)(ii).) Executive Order No. 12875, "Enhancing the Intergovernmental Partnership," further addresses this issue, focusing on reduction of nonstatutory unfunded mandates largely through a process of formal consultation and coordination.

OIRA has continued its outreach to State, local, and tribal governments (Section 4(e)). In the May 1st Report, we noted that OIRA had held two conferences with representatives of these entities. We sponsored a third forum in July, at which representatives from the National Governors' Association, the League of Cities, the Conference of State Legislatures, the National Association of Counties, and the Advisory Commission on Intergovernmental Relations spoke about their regulatory concerns.

While we have no standard of measurement to gauge improvements, our sense is that agencies are generally taking seriously their obligations to work together with other governmental entities. For example, HHS Secretary Shalala writes to the governors on occasion summarizing major Departmental initiatives of interest to the States. This is part of an HHS effort to "strengthen the federal-state partnership that is crucial to the successful operation of so many of our Department's programs." It is our understanding that this effort to inform the States has been much appreciated.

Another example from HHS involves PHS. Over the next year, the agency has committed to extensive consultation with the States in developing guidelines for state mental health services planning. Such guidelines will assist States in establishing useful goals and objectives for monitoring the management of, and investments in, State mental health services.

EPA recently issued a proposal that would limit toxic air emissions from municipal waste combustors, many of which are either owned or operated by local governmental entities. In preparing its proposal, EPA consulted extensively with a wide variety of stakeholders, including the Conference of Mayors, the National League of Cities, the National Association of Counties, the Municipal Waste Management Association, and the Solid Waste Association of North America. In drafting its proposal, EPA considered the concerns expressed by these groups, and discussion with them will continue following the proposal.

A recent rulemaking by the Architectural and Transportation Barriers Compliance Board (ATBCB) concerning Americans with Disabilities Act (ADA) rules is another illustration of consultation with State and local officials, as well as of interagency coordination. ATBCB's rules set standards for State and local government implementation of the ADA through technical

specifications for the design of buildings, parks, roads, and the like to make them accessible to people with disabilities. (The ATBCB standards will ultimately be implemented through rules issued by DOJ and DOT.) In the course of Executive Order review, the ATBCB requested comment about the scope of State and local accommodations in order to develop a better cost estimate to accompany the final rule; summarized prior consultations with States and localities, consistent with the provisions of Executive Order No. 12875; and, after meeting with DOJ, DOT, and OMB, developed a list of State and local organizations to receive copies of the rulemaking documents for comment.

ED also engaged in an extensive process of consultation with State and local entities during development of a regulatory proposal that would have required States to provide supplementary services, in excess of Federal funds for these services, to certain disadvantaged students receiving vocational education. ED held two public meetings with State and local education officials and student representatives, solicited written public comment on the issue, and worked with States to obtain additional information on the costs that the rule would impose on them. Unfortunately, this process did not result in agreement on certain issues, leading Congress to intervene to prevent the Notice of Proposed Rulemaking (NPRM) from being published. This highlights the fact that while consultation is essential to effective rulemaking, it may not be sufficient -- for all the consultation may not change the different participants' perspectives and does not necessarily ensure agreement.

It is also worth noting that some agencies are not only consulting with States, but actively seeking to enhance State flexibility and eliminate unnecessarily burdensome regulatory barriers. For example, HHS's Health Care Financing Agency (HCFA) is developing a Medicaid final rule which will simplify the process of obtaining Medicaid home and community-based services

waivers, thereby enabling States to offer a wide variety of cost-effective alternatives to institutional care. The rule will simplify the cost effectiveness test by eliminating the "bed capacity test," which had become burdensome and unproductive to maintain; it will also give States increased flexibility to assess their programs. Also in HHS, the Administration for Children and Families modified its Adoption and Foster Care Analysis and Reporting System to reduce burdens on States. Rather than require the submission of all reporting data, the agency allowed States to submit a sample of the data associated with the management and reporting of foster care and adoption cases.

Two final examples illustrate efforts by agencies to include tribal governments as partners. HUD consulted with tribal representatives in developing amendments to the Indian Housing Consolidated Program to simplify program processes, reduce the number of regulatory requirements, and provide more flexibility to local tribal and Indian housing authority officials. HUD held a session with the National American Indian Housing Council, regional Indian Housing Authority (IHA) associations, and tribal leaders. While HUD was fashioning the proposed rule, comments were solicited from the Native American housing community, and after publication of the proposed rule, the program offices continued to consult with the IHAs and tribes on the proposed changes.

The second example is the rulemaking on Indian Self-Determination, where DOI and HHS worked with tribal representatives to break a four-year logjam which had delayed publication of a proposed rule. The purpose of the rule is to implement a system whereby Indian programs currently administered by the Federal government may be contracted to, and administered by, American Indian tribes. There were extensive consultations with tribes, including three regional meetings and one national

meeting, to discuss their concerns with the proposed rule, which was published in January 1994. The Department is pursuing other ways to increase tribal participation in the development of the final rule, including forming a tribal committee under the Federal Advisory Committee Act.

Openness: Public Involvement

The trend toward increased public involvement in the rulemaking process has continued since the spring, and we believe it has become a common feature of rulemaking in the Clinton/Gore Administration. Although we have no statistics to measure increased public involvement, it is our sense that agencies increasingly are seeking ways to involve those affected by rulemaking, not only through formal means -- such as regulatory negotiations and longer comment periods after publication of proposed rules -- but also through more informal means earlier in the rulemaking process.

For example, HUD wanted to amend its existing regulations to simplify and expedite the Comprehensive Grant Program planning and funding process for certain housing agencies. In developing its proposal, the Department held a series of working sessions with various interest groups, housing authorities, and residents, soliciting their ideas and suggestions. HUD then published its proposed rule which incorporated many of their recommendations.

Agencies are also using electronic means to obtain early and more extensive public input. For example, last winter ED began developing a proposal to amend existing regulations governing the independent living programs. The Department sent out more than 400 letters inviting comments, along with computer diskettes that contained a draft of the proposed regulations, to State vocational rehabilitation agencies, statewide independent living councils, centers for independent living, constituent organizations, and other interested parties. The draft of the

proposed rules was also made available on the "DIMENET" AND "RSA BBS" electronic bulletin boards. A series of public meetings and teleconferences enabled a cross-section of individuals representing a wide variety of organizations and viewpoints to contribute their thoughts during the developmental process.

When the NPRM was published in the Federal Register, the Department made it available through these electronic bulletin boards, and a "CompareRite" copy of the proposal was provided that showed changes that were made as a result of the earlier public involvement. The public was also invited to submit comments on the NPRM electronically via the bulletin boards. This is an outstanding example of how outreach and technology can help the government to solicit the views of those most knowledgeable about a rulemaking. It also serves to increase the sense of partnership between the government and the public by making the rulemaking a joint enterprise rather than the imposition of commands by Federal authority.

Regulatory Negotiation: Another way this Administration has encouraged communication between the regulators and regulatory stakeholders beyond the barebones of the Administrative Procedure Act (APA) notice and comment procedures has been its encouragement of negotiated rulemaking or "reg neg."

A reg neg brings together the stakeholders in a potential regulatory situation to negotiate a proposed document that then goes through APA procedures. By involving interested parties directly in the drafting of the rule, and by having them negotiate out at least some areas of disagreement, it is expected that the rule will be more intelligently drafted and less contentious when it is proposed, and it will be more readily accepted and less likely to be litigated when it becomes final.

The Executive Order (Section 6(a)(1)) directed agencies to explore and use -- where appropriate -- regulatory negotiation as a consensual mechanism for developing rules. In addition, implementing a recommendation of the National Performance Review, the President by separate memorandum issued the same day as the Executive Order, directed each agency to identify to OIRA at least one rulemaking that it would develop through the use of reg neg during the upcoming year, or explain why the use of negotiated rulemaking would not be feasible.

The May 1st Report noted that agencies had provided reg neg candidates to OIRA by December 31, 1993, as the President had directed. Since then, many agencies have continued the substantial planning that is necessary for a successful reg neg, or have begun (or in some cases, concluded) reg negs.

DOT, which was the first agency to use reg neg over a decade ago and has much experience with this technique, has recently identified over a half-dozen possible candidates for negotiation during the next year; the Federal Railroad Administration (FRA) has already published a notice seeking public comment on its proposal to use reg neg for one of these -- a rulemaking addressing the hazards railroad workers face along rights-of-way from moving equipment. EPA is actively engaged in reg negs for disinfectant byproducts, enhanced surface water treatment, and small nonroad engines. DOI has formed a committee under the Federal Advisory Committee Act to deal with a Federal gas valuation rulemaking. OSHA has established a reg neg committee to examine its steel erection standard. And reg neg committees have also been approved for Federal Communications Commission (FCC) and Interstate Commerce Commission (ICC) projects.

Reg negs do not always work, though the experience so far with the technique is generally favorable. ED has been required by statute to use regulatory negotiation in many of its

rulemakings. One recent reg neg involving direct loans was a very prominent but not entirely successful negotiation. Although consensus was reached on a majority of the provisions in this rule, the negotiators did not agree on certain key provisions, including the mechanism by which borrowers would repay their loans. Nonetheless, a trade publication wrote that certain interests "who might otherwise have been the first to pounce on the proposed regulations said they were intimately familiar with -- and generally happy with -- the rules after spending the first half of this year negotiating with ED."

Another ED reg neg, involving guarantee agency reserves was less publicized but more successful in reaching agreement. The rule involved how to handle funds held in reserve by the agencies that "guarantee," or reinsure, student loans under the bank-based loan program. The negotiations took place two days a month from January to July 1994 and involved the Department, guarantee agency representatives, student representative, school associations, and State higher education officials. OMB observed the negotiations and concurred with the consensus NPRM that emerged, reviewing the formal submission from ED in one day. ED expects to publish the final rule by December of this year, with little or no problem in the process.

Small Business: Regulations often create a disproportionate burden on small businesses, since, for example, the same recordkeeping or reporting requirement may consume a much greater percentage of the managerial or administrative resources of a small business than of a large business. As a result, OIRA and the Small Business Administration (SBA) have taken steps to improve the participation of the small business community in the rulemaking process. We noted in our May 1st Report that OIRA and SBA sponsored a Small Business Forum in March 1994 for this purpose. This Forum brought together representatives of small business and six of the Federal agencies who most regulate them -

- the Internal Revenue Service (IRS), the Food and Drug Administration (FDA), DOT, EPA, DOL, and DOJ.

This Forum was followed by work sessions, which took place over a three-month period, that developed findings and recommendations centered around five industry sectors -- chemicals and metals; food processing; transportation and trucking; restaurants; and the environment, recycling, and waste disposal. These sessions were capped with a town-meeting-style forum held at the Chamber of Commerce in Washington and chaired by the Administrators of OIRA and SBA. An audience of about 75 small business owners, who had come to Washington to participate in SBA's Small Business Week and many of whom were winners of SBA small business awards, directed questions and comments to a panel of agency officials representing the six regulatory agencies listed above.

A second Small Business Forum was held on July 27, 1994, in which the recommendations and findings of these work groups were presented. The concerns expressed by small businesses and the recommendations drafted by agency staff to help alleviate these concerns parallel to a remarkable degree principal provisions of the Executive Order. These include:

- o the need for better coordination among Federal agencies;
- o the need for more small business involvement in the regulatory development process;
- o the inability of small business owners to comprehend overly complex regulations and those that are overlapping, inconsistent and redundant;
- o the burdens caused by cumulative, overlapping, and/or inconsistent Federal, State, and local regulatory and recordkeeping requirements;

- o the need for tangible evidence of paperwork reduction; and,
- o the perceived existence of an adversarial relationship between small business owners and federal agencies.

Officials from the participating agencies pledged to move ahead with various activities responsive to some of the recommendations and to examine ways to respond to the remaining recommendations. In addition, pilot projects with the governors' offices of New York and North Carolina were announced. These States will work with SBA and the regulatory agencies on means of improving Federal-State coordination regarding burdens on small businesses and State projects to improve their own ability to communicate better with, and involve small businesses in, State regulatory decisionmaking.

As a general matter, however, it is our experience that regulatory agencies still tend to draft one-size-fits-all rules, rather than tailoring them to particular regulated communities, including small businesses. It appears that it will take further effort before such tailoring becomes commonplace. We believe that more extensive early involvement by SBA in the rulemaking process could help move this process forward. Accordingly, we are currently developing with SBA a process to assure that SBA's Chief Counsel for Advocacy has full opportunity to review significant agency rulemakings where such tailoring would be most appropriate and to have agencies implement the Regulatory Flexibility Act more effectively and completely.

Integrity of OIRA Review

Prior to this Administration, the regulatory review process had been severely criticized for delay, uncertainty, favoritism, and secrecy. Restoring the integrity of centralized review was one of the primary tasks facing this Administration as it drafted Executive Order No. 12866.

Disclosure: Section 6(b)(4) of the Executive Order sets forth certain disclosure procedures "to ensure greater openness, accessibility, and accountability in the regulatory review process." OIRA's practices regarding these procedures were described in detail in our May 1st Report. It is a telling measure of the almost complete success of these procedures that there is little additional to say about them and, as far as we know, little interest in them anymore. OIRA adheres to these procedures, and they have long become routine.

We continue to make available a daily list of draft agency regulations under review. Starting in August 1994, this list was made available electronically as well on the Internet. Monthly statistics and data on rules for which review has been completed are also made public. Meetings and telephone calls with persons outside the Executive Branch on regulations under review continue to be logged, and an agency representative invited to such meetings. As of March 31st this log had 36 entries. It now contains an additional 35 entries for meetings that occurred between April 1st and September 30th. In all but 6 instances, these meetings were chaired by the OIRA Administrator; in these 6, the meetings were chaired by other OMB officials. An agency representative was invited to all meetings and attended in all but 5 instances. Materials sent to OIRA on pending regulations from anyone outside the Executive Branch are kept in a public file and a copy is forwarded to the appropriate agency. After a regulatory action that has undergone review is published, documents exchanged between OIRA and the agency during the review, including the draft rule submitted for review, are made available to anyone requesting them. As far as we know, this aspect of the Order is working as it was envisioned.

Regulatory Review Statistics: Executive Order No. 12866 changed the scope of centralized regulatory review by having OIRA review only "significant" rules. This was designed to return

responsibility for routine rulemaking to the agencies, to reduce delay, and to focus OIRA's limited resources on the most important rules. In the May 1st Report, we described in detail how this process was working. We noted that establishing the process for determining whether rules were "significant" or "not significant" had taken longer than anticipated to set up, but that after the first three months, the process of limiting the rules reviewed by OIRA seemed to be working. Based on another six months of experience, we can say that there continue to be some disagreements about whether or not a particular rule is significant, and not infrequently reaching a final decision can take longer than we would like. However, the significant problems we described in the May 1st Report that characterized the process during its first three months have for all practical purposes been resolved.

OIRA's regulatory review statistics show that in other respects as well, what was intended by the Executive Order has, in fact, taken place. Between April 1 and September 30, 1994, OIRA reviewed 388 rules (Table 1). By way of comparison, during the first six months of the Order, OIRA reviewed 755 rules (Table 2) [Note: see Tables 1 and 2 in the May 1 Report; the 755 figure includes rules submitted for review prior to Executive Order No. 12866.] Even though the first six months of the Order included review of rules received before the signing of the Executive Order and the continued submission of some non-significant rules, the total for the first year of the Order is 1143 reviews. This is half of the average reviews per year for the previous 10 years, slightly over 2,200. Between January 1 and September 30, 1994, when for the most part only significant rules were submitted to OIRA for review, OIRA reviewed 661 rules. At this rate, OIRA will review fewer than 900 rules in 1994, a 60% reduction from the annual average of the previous decade. Thus, the number of rules OIRA reviews has been reduced substantially.

The agencies with the greatest number of rules submitted for OIRA review between April 1 and September 30th were HHS 82, USDA 65, EPA 47, ED 35, HUD 34, and DOT 31. These six agencies account for 76% of the rules reviewed by OIRA. Table 1 also shows that of the 388 rules reviewed during the second six months of the Order, 66 (17%) were "economically significant," while 322 (83%) were significant for other reasons (Section 3(f)(2,3, and 4)). USDA and EPA had by far the most economically significant rules, 21 and 16, respectively.

Of the total of 388 rules, 149 or 38% were proposed rules; 179 or 46% were final rules; and the remaining 60 or 15% were notices (such as HHS, HUD, or ED funding notices, notices of selection criteria, or notices of procedures). OIRA concluded review without any changes being made on 58% of the rules reviewed; it concluded review with changes on 35%. The remaining 7% were withdrawn by the agency, were returned because they were sent improperly (5 USDA rules), or were cleared in order for an agency to meet a court or statutory deadline (8 of 9 were EPA rules). The percentage of rules cleared with changes varied widely by agency -- 18% for USDA, 26% for HHS, 26% for DOT, 47% for HUD, 60% for EPA, and 69% for ED.

The average review time for all rules reviewed was 30 days, compared to 38 days for those reviewed during the first six months of the Order. Reviews of economically significant rules were on average slightly longer (31 days) than those of other significant rules. Average review times for all rules varied by agency -- from below mean for USDA (22 days) and DOT (22 days); to about mean for HHS (29 days) and ED (30 days); to above the mean for HUD (37 days) and EPA (48 days).

In our May 1st Report, we indicated that once the review process was fully implemented and agencies submitted only significant rules to OIRA, the total number of rules reviewed was

likely to decrease. As noted above, this has certainly proven to be the case. We also predicted that the percentage of rules cleared with changes would increase. This has occurred to some degree; the average percentage of rules cleared with changes over the past decade averaged about 22% compared to 35% for the rules reviewed between April and September 1994.

We also predicted that average review time was likely to increase, particularly for economically significant rules. This has not proven to be the case. In fact, average review time is about what it has been over the past decade. More specifically, the review time for economically significant rules is only marginally greater than review time for other significant rules. There are several factors that may explain, in part, this phenomenon. We note, for example, that USDA had the greatest number of economically significant rules (21) and a very short average review time (14 days). This is because most of USDA's economically significant rules are crop price supports, regulations that essentially codify decisions already made through the appropriations process. It may also be that the average review time for economically significant rules is relatively low because agencies are consulting with OIRA earlier in the process, thereby obviating the need for lengthy reviews when the rule is formally submitted. Regarding the review time for significant rules in general, it appears that the Order's limitation of 90 days for review, as well as the OIRA Administrator's practice of having all rules under review longer than 60 days raised for her consideration, has resulted in an expedited review process.

OIRA's review is limited to 90 days except that extensions may be granted by the Director or requested by an agency head (Section 6(b)(2)(B and C)). Such extensions have been needed infrequently; for example, of the 388 rules reviewed between April and September, only 11 or 3% were extended beyond the 90-

day period. All of these extensions were made at the request of the agency.

The 90-day review period has generally proven adequate, and as has been noted, we are able to complete most reviews within that time period. However, in some instances 90 days is simply not enough to conduct an adequate review. Where interagency coordination is needed (such as USDA's Farmland Protection rule or EPA's General Conformity rule), issues may take more time to resolve, if only because of the logistics of getting all of the interested agencies together. In some other instances, we are rushed at the end of the review period, or rules must be extended beyond that period, because agencies are slow in responding to OMB questions or requests for analysis. Some of these may be the result of limited resources or otherwise beyond the control of the agency, but in some cases it may reflect a conscious decision by the agency that this rulemaking is of lesser importance than other pressing matters. We understand, and indeed sympathize, but it remains a concern for us because the agency's delay is on our clock and it is Executive Order review that is ultimately curtailed.

III. APPLICATION OF THE PHILOSOPHY AND PRINCIPLES SET FORTH IN THE EXECUTIVE ORDER

The processes described above -- regulatory planning, interagency and intergovernmental coordination, openness and encouraged public participation, restoring integrity to centralized review -- were all designed to lead to better, more focused, more effective, less burdensome -- i.e., smarter-- regulation. The many examples cited above demonstrate that the regulatory process has been improved. The question remains, are the philosophy and principles of the Order being applied to the fullest extent? Are we really getting smarter regulation? This is difficult to answer because, as noted in the Introduction, there is no direct measure of performance that we can use. We do have anecdotes, however, suggesting that the Administration is producing smarter regulations, as we now discuss.

One of the more important features of the Executive Order is its emphasis on good data and good analysis to inform (and not just justify) decisionmaking. One example of the application of this principle is DOT's National Highway Traffic Safety Administration (NHTSA) rulemaking on side-impact protection for light trucks. In the spring of 1994, NHTSA submitted to OIRA for review a proposed rule that would extend to light trucks many of the same side-impact protection requirements now applicable to passenger cars. The proposal was accompanied by a first-rate regulatory analysis prepared by NHTSA staff. The analysis revealed that while the added requirements were cost-effective when applied to the protection of front seat passengers, they were not cost-effective for protecting rear seat passengers. For this reason, NHTSA decided to delete the language proposing to prescribe requirements affecting rear seat passengers, instead seeking comment on the issue.

Another example is HUD's rulemaking on mobile home wind requirements. In the wake of Hurricane Andrew, HUD moved to upgrade the safety of mobile homes. However, increased safety standards means increased costs. The Wall Street Journal quotes HUD's Assistant Secretary for Housing as remarking that the issue requires "the classic balancing act. We could make these homes completely safe and solid - so much so that they'd be out of reach for lower-income consumers." To inform its policy choices and to stimulate discussion among the various stakeholders, HUD's draft regulatory impact analysis set forth the tradeoffs, and the data they are based on, for public scrutiny. Both the data and the analysis have been criticized, but this rulemaking demonstrates the value of analysis, even if it is flawed, in engaging stakeholders in the debate that leads to reasonable balances, as suggested by HUD's Assistant Secretary.

Another feature of the Executive Order is its preference for focused (or tailored) requirements and for performance-based (or flexible) provisions rather than across-the-board, mechanically applied, command-and-control approaches. An example of the application of these principles is the EPA proceeding on lead abatement. Congress directed EPA to create model inspection, worker training, and cleanup regulations for lead abatement of housing, commercial buildings, and various industrial structures. EPA plans to issue these regulations in phases throughout 1994. The first phase included primarily administrative matters, -- e.g., worker training, certification, and State program administration regulations. Initially, the proposal was heavily prescriptive (e.g., detailed diagrams for soil sampling), included extensive paperwork requirements (e.g., detailed documentation of each, identical sampling effort), and did not distinguish between potentially high-risk and low-risk lead hazards. EPA and OIRA staff, working together, substantially revised the draft proposal to reduce the prescriptive character of the rule, adopt more of a performance standard approach, and

re-focus the requirements on the more important sources of health risk (e.g., spending less resources on testing and studies, leaving more for cleanup itself). This revised proposal should also provide States and local governments with greater flexibility in establishing lead abatement programs than had originally been contemplated.

Also relevant here is the EPA combined sewer overflow policy. EPA developed a policy for controlling combined sewer overflows (CSOs) -- i.e., instances when, as a result of heavy rains, sewage and other waste overflow normal channels, bypassing treatment plants. The new policy ensures that an extensive planning effort is undertaken, so that cost-effective CSO controls can be developed that meet appropriate health and environmental objectives. It establishes clear control targets, but provides sufficient flexibility to municipalities so that they can tailor programs to their specific circumstances.

The DOT alcohol and drug testing rules were mentioned above as an example of improved agency/OIRA relations. They are also illustrative of a rulemaking where the Department approached a complex issue analytically and made significant improvements to its rule, reducing burden without reducing safety, by applying the principles of the Executive Order. For example, in its final rule, DOT adopted a performance-based approach for determining the rate of random drug and alcohol testing. Thus, based on already existing performance-based data, the random drug testing rate was reduced from 50% to 25% for the airline and rail industries; for alcohol testing, the testing rate will be 25% if the industry violation rate in any year is less than 1%, and it may decrease to 10% if the industry violation rate is less than 0.5% for two consecutive years. DOT also simplified and streamlined its requirements for reporting drug testing data, introducing sampling techniques and otherwise reducing the burden

and complexity of the information collection requirements from employers.

Another example from DOT involves the Coast Guard's rulemaking involving overfill devices. The Coast Guard was required by statute to promulgate rules involving the installation of signalling (overfill) devices to alert crew about the likelihood of a unanticipated spill. In its proposal, the Coast Guard added material concerning the use of lower cost signalling devices (i.e., stick gauges) rather than more costly and sophisticated alarm devices. The final rule, which will be published soon, will allow the lower cost devices on certain vessels (i.e., tank barges) thus significantly reducing the cost of the rule from about \$90 million to about \$40 million (npv) over 15 years. The Coast Guard does not believe that the use of the less costly signalling devices on these vessels will significantly increase the risk of small unanticipated spills.

An example from DOL's Occupational Safety and Health Administration (OSHA) is that agency's rulemaking on asbestos. In preparing its final rule governing asbestos in the workplace, OSHA made substantial changes to its proposal to improve the clarity of the regulation and ensure that as much flexibility as possible was retained in process-specific standards. Thus, for example, while the proposal could be read to require extensive controls (e.g., glove bags, mini-enclosure, and respirators) for any maintenance work conducted around asbestos-containing materials, even if exposure was negligible (e.g., pulling wires above suspended ceilings), OSHA's final rule required such controls only when there is a physical disturbance of the materials. In addition, the final rule avoided inconsistencies with existing EPA standards by eliminating the use of terms to classify asbestos that differed from those used by EPA. Finally, OSHA raised in the preamble of the final rule the possibility of its adopting an action level to serve as a clear regulatory

threshold below which fewer protective measures would be needed if practical sampling devices become available.

HHS also has been attentive to the principles of the Order. For example, the Mammography Quality Standards Act of 1992 required FDA to establish Federal certification and inspection programs for mammography facilities; regulations for accrediting bodies for mammography facilities; and standards for mammography equipment, personnel, and practices. In designing these rules, FDA made the standards less burdensome on mammography facilities, which are nearly all small businesses, by incorporating existing standards to the maximum extent possible. It also provided for the issuance of Federal certificates to facilities already accredited by the American College of Radiology; required facilities to submit certification information only to an accrediting body and not to FDA; and permitted flexibility in meeting certain other standards.

As noted above, HHS has also been sensitive to minimizing the burden of Federal regulations on State, local, and tribal governments. For example, this past year, the Maternal and Child Health Bureau developed a streamlined, block grant application and annual report. The revisions resulted from an impressive consultation effort with State maternal and child health groups and the National Governor's Association. The burden imposed by the requirements has been cut in half, while the materials are easier to understand and will be more useful in local, State, and Federal planning.

HHS has also taken steps to streamline the burden on the private sector as well. In March 1994, HCFA published a rule that replaced the annual requirement for physicians to provide hospitals with a signed acknowledgement concerning penalties for misrepresenting certain information with a one-time signing requirement, fulfilled at the time a physician is initially

granted hospital admitting privileges. One major medical association characterized this change as one that will alleviate the "hassle factor" for physicians and one that is an important step toward restoring mutual trust between the Federal government and the medical profession.

Another example of burden reduction comes from DOT. The Federal Aviation Administration (FAA) realized that not all regulatory modifications are dramatic, but incremental efforts to reduce burden and unnecessary provisions can add up to significant improvements. Recently, in a broader rule that made other changes to the medical certification standards, FAA responded to an American Medical Association report suggesting that the burdens of the medical certification process for pilots could be significantly reduced by extending the two-year certification to a three-year duration for younger pilots. This simple change will cut the overall paperwork associated with the certification process by about 15% in total, and over 30% for those pilots under age 40.

In the same vein is a recent SBA action that eliminated a longstanding regulatory prohibition on making financial assistance available to businesses engaged in media-oriented activity. The so-called opinion molder rule had been based on a concern about Federal agency involvement in potential prior restraint of free speech; the result was a ban on SBA assistance to businesses involved in media activities. After first considering modest revisions to the rule, SBA concluded that the concern was no longer a valid one, and that the demand for assistance from small businesses in the media field far outweighed the need for caution in this area.

Several of the latter examples involve rethinking or redesigning existing regulation. Focusing on existing regulations has been an important feature of the Executive Order,

and, as we now discuss, we are beginning to see real progress in this area.

IV. IMPLEMENTATION OF THE LOOKBACK PROVISIONS OF THE EXECUTIVE ORDER

Individuals who must comply with Federal rules frequently comment, often with great frustration and anger, that it is the accumulated burden of rules in effect -- many of which appear unnecessary, redundant, outdated, or downright stupid -- that is so exasperating to them. In response to these concerns, the Executive Order provides that agencies are to review existing regulations to ensure that their rules are still timely, compatible, effective, and do not impose unnecessary burdens (Section 5).

In the May 1st Report we noted that this review of existing regulation, a "lookback" process, had begun, although it had proven more difficult to institute than we had anticipated. We observed that, understandably, agencies are focused on meeting obligations for new rules, often under statutory or court deadlines, at a time when staff and budgets are being reduced; under these circumstances, it is hard to muster resources for the generally thankless task of rethinking and rewriting current regulatory programs. Six months later, we are somewhat further along, although we continue to believe that any real progress will depend on the extent to which senior policy officials recognize and attend to this effort.

It is important to emphasize what the lookback effort is and is not. It is not directed at a simple elimination or expunging of specific regulations from the Code of Federal Regulations. Nor does it envision tinkering with regulatory provisions to consolidate or update provisions. Most of this type of change has already been accomplished, and the additional dividends to be realized are unlikely to be significant. Rather, the lookback provided for in the Executive Order speaks to a fundamental re-engineering of entire regulatory systems, many of which have

remained fundamentally unchanged for 30 to 50 years. To do this successfully requires a dedicated team in an agency with broad understanding of the program's objectives, expertise in the intricacies of the regulatory program, an intimate knowledge of the stakeholders, and resourcefulness, tenacity, resolve, and support.

Probably the best example of such a re-engineering of a regulatory system is the work currently being done by the DOC's Bureau of Export Administration (BXA) to rewrite the Export Administration Regulations (EAR). This comprehensive review is intended to simplify and clarify this lengthy and complex body of regulations that establishes licensing regimes for dual-use products -- i.e., those that may have both commercial and military applications -- and to make the regulations more user-friendly, which they currently are not. The rules were first promulgated in 1949 to implement the Export Control Act of 1949. There has not been a complete overhaul of the EAR since that time. This effort is important enough that DOC has chosen it as one of its four entries for the Regulatory Plan.

In its re-engineering of the EAR, BXA is following the recommendations of the Trade Promotion Coordinating Committee (TPCC), a Presidential committee mandated by the Export Enhancement Act of 1992. BXA has already published a notice in the Federal Register requesting comment on a simplification of the program. Meanwhile, a task force within the agency has been working on a complete overhaul and restructuring of the rules. In particular, the rules are being fundamentally redirected from the current negative presumption that all exports subject to the Act are prohibited unless authorized, to a positive approach that all exports are permitted unless a license is specifically required. The agency tentatively plans to have an NPRM published by the end of this year.

A good example of an institutionalized 'lookback' program is the continual review of selected regulations by DOT's National Highway Traffic Safety Administration (NHTSA). NHTSA has been conducting these safety standard evaluations for over 15 years, and to our knowledge, it is the only program of its kind in the Executive Branch. NHTSA rules deal primarily with automobile and light truck safety. On a regular basis, the agency selects rules from its current programs to review, evaluating not only the effectiveness of the rule and whether there are any provisions that are unnecessary, unduly burdensome, or in need of change for other reasons, but also reviewing the initial analysis itself -- whether the predicted costs and benefits have been realized, and, if not, why not. This approach not only enables the agency to modify its current rules based on analysis, but also helps the staff continually improve the analytic techniques used in assessing the costs and benefits of new rules. Indeed, its recent standards for side-impact protection resulted directly from a review of its previous standard, which revealed that the rule was not providing benefits in multi-vehicle accidents. More recently, the agency completed reviews of front seat protection in passenger cars and its glass-plastic windshield standard No. 205. NHTSA also recently published a Federal Register notice describing its future evaluation plans and soliciting public comment on which additional assessments it should pursue.

DOT's Federal Highway Administration (FHWA), like BXA, has initiated a major, "zero-based" review of its Federal Motor Carrier Safety Regulations. These are the primary body of regulations that are designed to ensure the safety of commercial trucks and drivers. The regulations have not been extensively revised since the early 1970's. The goals and objectives of the zero-base review are (1) to focus on those areas of enforcement and compliance that are most effective in reducing motor carrier accidents; (2) to reduce compliance costs; (3) to encourage innovation; and (4) to clearly and succinctly describe what is

required by the regulations. Through the zero-base review, FHWA intends to develop a unified, performance-based regulatory system that will enhance safety on the nation's highways while minimizing the burdens placed on the motor carrier industry.

Other DOT lookback efforts include FRA's revision of its power brake regulations to reduce the frequency with which railroads must inspect their brake systems. Recently, the FRA proposed performance-based rules that would reduce inspection frequencies, as long as brake systems, when inspected, meet certain brake defect ratios. Also, FAA is reviewing its regulations to identify those rules that are inconsistent with state-of-the-art technology or current industry practice. To enhance its ability to perform its statutory role without undue economic burden on the aviation industry, FAA announced a comprehensive review in January of this year, asking interested parties to identify those regulations that are believed to be unwarranted or inappropriate. The comments provided in response to this notice are assisting the agency in establishing its priorities for future regulatory changes.

USDA is also conducting several lookbacks. The Food and Nutrition Service (FNS) has proposed to revise its school meal nutrition standards, the first major modification to these standards in nearly 50 years. To ensure that children have access to healthy meals at school, USDA has updated nutrition standards to meet the Dietary Guidelines for Americans and, at the same time, USDA has streamlined the administration of the rule so that local school food service staffs may concentrate on providing healthful food for their students rather than on bureaucratic red tape.

This effort was the result of extensive outreach and substantial analysis by USDA. Although commenters on the rule

have raised concerns, the initial press reaction to the proposal was overwhelmingly positive. The New York Times concluded:

The Agriculture Department recognizes that these ironclad rules (current meal patterns) are irrelevant in a nation where most children get not only too much protein but too much fat, saturated fat, cholesterol and sodium School meals might finally catch up with late-20th-century nutrition science.

USDA and HHS are also working to re-engineer their food safety and inspection regulatory programs. Building upon their generally successful efforts to coordinate the nutrition labeling of foods, USDA and HHS are moving forward with ambitious plans to modernize the system of food safety regulation in the United States. Both Departments took steps in 1993 and 1994 to require Hazard Analysis Critical Control Point systems (HACCP) in the production of food.

The Food Safety and Inspection Service (FSIS) at the USDA has initiated a comprehensive review of the regulations that ensure the safety of all meat and poultry. The meat and poultry regulations are based upon the Federal Meat Inspection Act first passed in 1907. Although the meat and poultry statutes and regulations have been amended a number of times over the last 85 years, USDA has never undertaken a top-to-bottom review of the inspection system.

FSIS' review is intended to move the meat and poultry inspection system -- currently based upon "organoleptic" inspection, whereby an inspector uses the senses of touch, sight and smell to test the safety of the product -- towards more science-based procedures that address microbial contamination. For example, under a HACCP system, plants would identify the points along their processing line that are vulnerable to the

greatest hazards (risk of contamination), and devise plans to mitigate those hazards.

FDA, which has jurisdiction over all foods not regulated by FSIS, such as fish, fruits, and vegetables, has announced plans to greatly expand its use of HACCP systems. FDA sees HACCP as a revolutionary way to ensure that proper production processes and controls are being maintained, even when an inspector is not present. In January 1994, FDA issued a proposed rule that would require HACCP analysis and recordkeeping by all firms that process seafood in the United States. Also, after consultation with USDA, FDA published an Advance Notice of Proposed Rulemaking in August 1994 exploring the possibility of extending HACCP systems beyond the seafood industry to other food production within the next ten years.

Other agencies are also conducting lookbacks. In HHS, HCFA is looking at Medicare regulations that govern conditions of participation for home health agencies and hospitals, and conditions of coverage for the payment of end stage renal disease. HCFA believes that the existing rules are unnecessarily burdensome, outdated, and process oriented, and should be replaced with more universally applicable provisions that are patient/outcome oriented and driven by meaningful data to better ensure healthy outcomes for aged patients and those with disabilities. In redesigning these regulations, HCFA has met, and is continuing to meet, with a variety of provider and consumer representatives.

HUD has planned a review of its public housing development program rules. The current rules are outdated and contain unnecessary restrictions on the flexibility of public housing authorities (PHAs). HUD expects to revise the regulations to provide more flexibility for all participants, with even greater flexibility for the best performers. "High performer" PHAs will

have maximum latitude to develop public housing within very broad parameters, and with minimal HUD oversight; remaining PHAs will be given broadened responsibility commensurate with their abilities and areas of expertise. Streamlining the program will help to reduce a substantial pre-construction pipeline and expedite the provision of replacement housing for developments that should be fully or partially replaced.

The Office of the Comptroller of the Currency (OCC) has started a review of existing regulations on national bank lending limits to modernize, simplify, clarify, and eliminate unnecessary regulatory burden. In developing this review project, OCC designed a more efficient internal review process that involved senior agency officials earlier in the project to provide policy guidance. OCC published an NPRM in February 1994.

DOL's Pension and Welfare Benefit Administration (PWBA) has initiated a review of its rule concerning disclosure of plan information to participants. Since enactment of the Employee Retirement Income Security Act (ERISA) in 1974, there have been few modifications either to the law's reporting and disclosure provisions or to the underlying regulations. PWBA issued a Request for Information last December to solicit comments from the public concerning the adequacy and timeliness of the information provided pursuant to these rules. The agency is currently reviewing the many comments to assess the need for regulatory and/or statutory changes. Also at DOL, OSHA has started a review of its outdated walking and working surfaces standards with an eye to replacing them with performance-oriented standards to permit more flexibility in compliance.

Several Departments have used the Federal Register to gather information on those regulations that might be candidates for elimination, modification, or other improvement. DOE published a notice of inquiry in the Federal Register and has solicited

recommendations from over 200 stakeholder organizations and DOE field offices. Based on this input, DOE prepared a second notice of inquiry targeting particular areas of its regulations for review. Similarly, DOI published a notice in the Federal Register announcing its intent to review its significant existing regulations and requesting public comment on which regulations should be reviewed. After a 60-day comment period, DOI published a second notice, announcing which regulations will be reviewed, and requesting specific comments on how those regulations should be revised.

These examples of lookbacks vary from major projects well underway to initial, in some cases tentative and not fully formed, efforts. They are indicative of a serious effort by this Administration to look not only at rules that are being developed, but at the accumulation of regulatory programs that are already on the books. There is no apparent reason why every Department and agency cannot initiate at least one such project. We expect that lookbacks will become more prevalent and more productive over the coming months.

CONCLUSION

In our May 1st Report, we concluded that while it was too early to arrive at a final judgment regarding the success of the new system, the early indications were that there had been substantial improvement in the rulemaking process. With six months more experience and data, we are more confident that the Executive Order is making a difference, that the Administration is moving in the right direction, and that there is much to be proud of. As before, however, our optimism is guarded; we know full well that there is much to be done to obtain the benefits we are seeking to realize.

EXECUTIVE ORDER REV CODE
 APRIL 1, 1994 - SEPTEMBER 30, 1994

TABLE 1

AGENCY	NUMBER OF REVIEWS				A C T I O N S T A K E N							AVERAGE REVIEW TIME		
	OTHER THAN ECON SIG	ECON SIG	TOTAL		WITHOUT CHANGE	WITH CHANGE	WITHDRAWN BY AGENCY	IMPROPERLY SENT	RETURNED SUSPENDED	EMERGENCY	STAT/JUD DEADLINE	ECON SIG	OTHER THAN ECON SIG	ALL
USDA	21	44	65		46	12	1	5	0	0	1	14	25	22
DOC	2	5	7		5	2	0	0	0	0	0	14	4	7
DOO	1	4	5		5	0	0	0	0	0	0	60	38	40
ED	1	34	35		9	24	2	0	0	0	0	68	29	30
DOE	1	1	2		0	2	0	0	0	0	0	37	73	55
HR'S	5	77	82		60	21	0	1	0	0	0	20	29	29
HUD	0	34	34		14	16	4	0	0	0	0	NA	37	37
DOI	2	8	10		4	4	0	0	0	0	0	12	40	31
DOJ	1	5	6		5	0	0	0	0	1	0	2	8	7
DOL	2	2	4		1	3	0	0	0	0	0	47	61	54
STATE	0	5	5		5	0	0	0	0	0	0	NA	12	12
DOY	5	26	31		21	8	1	1	0	0	0	50	16	22
TREAS	0	1	1		1	0	0	0	0	0	0	NA	2	2
VA	0	9	9		5	4	0	0	0	0	0	NA	25	25
EPA	16	31	47		9	28	2	0	0	0	0	NA	49	48
ACHP	0	1	1		1	0	0	0	0	0	0	NA	39	39
ACTION	0	1	1		1	0	0	0	0	0	0	NA	55	55
AID	0	1	1		1	0	0	0	0	0	0	NA	15	15
AT&CB	2	0	2		1	1	0	0	0	0	0	47	NA	47
CNCS	1	0	1		1	0	0	0	0	0	0	27	NA	27
FAR	4	3	7		5	1	1	0	0	0	0	60	NA	60
FENA	0	1	1		1	0	0	0	0	0	0	NA	14	14
GSA	0	5	5		5	0	0	0	0	0	0	NA	43	43
IHS	0	1	1		1	0	0	0	0	0	0	NA	47	47
JMWFF	0	1	1		1	0	0	0	0	0	0	NA	30	30
NASA	0	4	4		3	1	0	0	0	0	0	NA	18	18
NSF	0	1	1		0	1	0	0	0	0	0	NA	6	6
OGE	0	1	1		0	1	0	0	0	0	0	NA	71	71
OPM	0	12	12		7	3	2	0	0	0	0	NA	42	42
OTRIMDAG	0	1	1		1	0	0	0	0	0	0	NA	14	14
SBA	2	4	6		4	2	0	0	0	0	0	13	7	9
USIA	0	1	1		1	0	0	0	0	0	0	NA	NA	NA

TOTALS: 66 322 388 224 134 15 7 1.8% 0.0% 0.0% 0.3% 9 31 30
 % TOTAL: 17.0% 83.0% 100.0% 57.7% 34.5% 3.4% 1.8% 0.0% 0.0% 0.3% 2.3%

TABLE 2

EXECUTIVE ORDER P. BY CODE
OCTOBER 1, 1993 - MARCH 31, 1994

AGENCY	NUMBER OF REVIEWS			A C T I O N S							AVERAGE REVIEW TIME			
	ECON SIG	OTHER THAN ECON SIG	TOTAL	WITHOUT CHANGE	WITH CHANGE	WITHDRAWN BY AGENCY	INPROPERLY SENT	RETURNED	SUSPENDED	EMERGENCY	STAT/JUD DEADLINE	ECON SIG	OTHER THAN ECON SIG	ALL
USDA	13	199	122	85	26	7	2	0	0	0	2	37	23	29
DOC	1	55	56	38	15	3	0	0	0	0	0	128	23	25
DOJ	0	10	10	1	5	4	0	0	0	0	0	NA	55	55
ED	2	33	35	3	26	6	0	0	0	0	0	NA	46	44
DOE	1	9	10	5	5	0	0	0	0	0	0	78	82	82
MHS	8	198	166	118	30	11	5	2	0	0	0	46	38	59
HUD	4	31	35	19	12	4	0	0	0	0	0	52	45	46
DOJ	1	40	41	29	11	1	0	0	0	0	0	4	33	33
DOJ	0	15	15	15	0	0	0	0	0	0	0	NA	17	17
DOJ	1	1	2	0	2	0	0	0	0	0	0	NA	20	15
STATE	0	6	6	5	1	0	0	0	0	0	0	NA	17	17
DOT	15	36	51	22	27	2	0	0	0	0	0	16	48	37
TREAS	2	4	6	2	4	4	0	0	0	0	0	1	70	47
VA	0	29	29	21	4	4	0	0	0	0	0	NA	62	62
EPA	16	53	69	15	38	0	0	0	0	0	16	40	53	50
AID	0	1	1	0	1	0	0	0	0	0	0	NA	36	36
CMS	1	3	4	0	4	0	0	0	0	0	0	NA	23	23
EEOC	0	2	2	1	0	1	0	0	0	0	0	NA	116	116
FAR	3	3	6	3	3	1	0	0	0	0	0	39	23	31
FEMA	0	4	4	0	4	0	0	0	0	0	0	NA	38	38
FFIEC	0	1	1	0	1	0	0	0	0	0	0	NA	70	70
GSA	0	18	18	11	7	0	0	0	0	0	0	NA	36	36
INS	0	1	1	1	0	0	0	0	0	0	0	NA	10	10
MARA	0	2	2	1	1	0	0	0	0	0	0	NA	116	116
NASA	0	8	8	6	1	1	0	0	0	0	0	NA	31	31
NSF	0	5	5	3	1	1	0	0	0	0	0	NA	73	73
OGE	0	1	1	1	0	0	0	0	0	0	0	NA	2	2
OMB	0	1	1	0	1	0	0	0	0	0	0	NA	108	108
OPM	0	23	23	17	3	3	0	0	0	0	0	NA	22	22
OTH/INDAG	0	1	1	0	1	0	0	0	0	0	0	NA	74	74
RRB	0	5	5	0	0	0	5	0	0	0	0	NA	39	39
SBA	3	13	16	9	6	1	0	0	0	0	0	15	42	36
USIA	0	3	3	3	0	0	0	0	0	0	0	NA	6	6

TOTALS:	71	684	755	434	238	51	12	2	0	0	18	33	38	38
% TOTAL:	9.4%	90.6%	100.0%	57.5%	31.5%	6.8%	1.6%	0.3%	0.0%	0.0%	2.4%			



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

Economic Analysis of Federal Regulations Under Executive Order 12866

After President Clinton signed Executive Order 12866, "Regulatory Planning and Review," the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget convened an interagency group to review the state of the art for economic analyses of regulatory actions required by the Executive Order. The group was co-chaired by a Member of the Council of Economic Advisers and included representatives of all the major regulatory agencies. This document represents the results of an exhaustive two-year effort by the group to describe "best practices" for preparing the economic analysis of a significant regulatory action called for by the Executive Order.

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ECONOMIC ANALYSIS OF FEDERAL REGULATIONS UNDER EXECUTIVE ORDER 12866

INTRODUCTION

In accordance with the regulatory philosophy and principles provided in Sections 1(a) and (b) and Section 6(a)(3)(C) of Executive Order 12866, an Economic Analysis (EA) of proposed or existing regulations should inform decisionmakers of the consequences of alternative actions. In particular, the EA should provide information allowing decisionmakers to determine that:

- There is adequate information indicating the need for and consequences of the proposed action;
- The potential benefits to society justify the potential costs, recognizing that not all benefits and costs can be described in monetary or even in quantitative terms, unless a statute requires another regulatory approach;
- The proposed action will maximize net benefits to society (including potential economic, environmental, public health and safety, and other advantages; distributional impacts; and equity), unless a statute requires another regulatory approach;
- Where a statute requires a specific regulatory approach, the proposed action will be the most cost-effective, including reliance on performance objectives to the extent feasible;
- Agency decisions are based on the best reasonably obtainable scientific, technical, economic, and other information.

While most EAs should include these elements, variations consistent with the spirit and intent of the Executive Order may be warranted for some regulatory actions. In particular, regulations establishing terms or conditions of Federal grants, contracts, or financial assistance may call for a different form of regulatory analysis, although a full-blown benefit-cost analysis of the entire program may be appropriate to inform Congress and the President more fully about its desirability.

The EA that the agency prepares should also satisfy the requirements of the "Unfunded Mandates Reform Act of 1995" (P.L. 104-4). Title II of this statute (Section 201) directs agencies "unless otherwise prohibited by law [to] assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector..." Section 202(a) directs agencies to provide a qualitative and quantitative assessment of the anticipated costs and benefits of a Federal mandate resulting in annual expenditures of \$100 million or more, including the costs and benefits to State, local, and tribal

analysis because of the importance and complexity of the issue, the need for expedition, the nature of the statutory language and the extent of statutory discretion, and the sensitivity of net benefits to the choice of regulatory alternatives. In particular, a less detailed or intensive analysis of the entire range of regulatory options is needed when regulatory options are limited by statute. Even in these cases, however, agencies should provide some analysis of other regulatory options that satisfy the philosophy and principles of the Executive Order, in order to provide decisionmakers with information for judging the consequences of the statutory constraints. Whenever an agency has questions about such issues as the appropriate analytical techniques to use or the alternatives that should be considered in developing an EA under the Executive Order, it should consult with the Office of Management and Budget as early in the analysis stage as possible.

Preliminary and final Economic Analyses of economically "significant" rules (as defined in Section 3(f)(1) of the Executive Order) should contain three elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an analysis of benefits and costs. These elements are described in Sections I-III below. The same basic analytical principles apply to the review of existing regulations, as called for under Section 5 of the Executive Order. In this case, the regulation under review should be compared to a baseline case of not taking the regulatory action and to reasonable alternatives.

I. STATEMENT OF NEED FOR THE PROPOSED ACTION

In order to establish the need for the proposed action, the analysis should discuss whether the problem constitutes a significant market failure. If the problem does not constitute a market failure, the analysis should provide an alternative demonstration of compelling public need, such as improving governmental processes or addressing distributional concerns. If the proposed action is a result of a statutory or judicial directive, that should be so stated.

A. Market Failure

The analysis should determine whether there exists a market failure that is likely to be significant. In particular, the analysis should distinguish actual market failures from potential market failures that can be resolved at relatively low cost by market participants. Examples of the latter include spillover effects that affected parties can effectively internalize by negotiation, and problems resulting from information

ways in which "reputation effects" may serve to provide adequate information. Buyers may obtain reasonably adequate information about product characteristics even when the seller does not provide that information, for example, if buyer search costs are low (as when the quality of a good can be determined by inspection at point of sale), if buyers have previously used the product, if sellers offer warranties, or if adequate information is provided by third parties. In addition, insurance markets are important sources of information about risks.

Government action may have unintentional harmful effects on the efficiency of market outcomes. For this reason there should be a presumption against the need for regulatory actions that, on conceptual grounds, are not expected to generate net benefits, except in special circumstances. In light of 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, unless they have hidden safety hazards or other defects or involve externalities and the problem cannot be adequately dealt with by voluntary standards or information disclosing the hazard to potential 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).

B. Appropriateness of Alternatives to Federal Regulation

Even where a market failure exists, there may be no need for Federal regulatory intervention if other means of dealing with the market failure would resolve the problem adequately or better than the proposed Federal regulation would. These alternatives may include the judicial system, antitrust enforcement, and workers' compensation systems. Other nonregulatory alternatives could include, for example, subsidizing actions to achieve a desired outcome; such subsidies may be more efficient than rigid mandates. Similarly, a fee or charge, such as an effluent discharge fee, may be a preferable alternative to banning or restricting a product or action. Legislative

therefore misleading and inappropriate to characterize a standard as a performance standard if it is set so that there is only one feasible way to meet it; as a practical matter, such a standard is a design standard. In general, a performance standard should be preferred wherever that performance can be measured or reasonably imputed. Performance standards should be applied with a scope appropriate to the problem the regulation seeks to address. For example, to create the greatest opportunities for the regulated parties to achieve cost savings while meeting the regulatory objective, compliance with air emission standards can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable air quality outcomes (such as "hot spots" from local pollution concentration).

2. Different Requirements for Different Segments of the Regulated Population. There might be different requirements established for large and small firms, for example. If such a differentiation is made, it should be based on perceptible differences in the costs of compliance or in the benefits to be expected from compliance. It is not efficient to place a heavier burden on one segment of the regulated population solely on the grounds that it is better able to afford the higher cost; this has the potential to load on the most productive sectors of the economy costs that are disproportionate to the damages they create.

3. Alternative Levels 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 decrease). It is important to consider alternative levels of stringency to better understand the relationship between stringency and the size and distribution of benefits and costs among different groups.

4. Alternative Effective Dates of Compliance. The timing of a regulation may also have an important effect on its net benefits. For example, costs of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs efficiently. 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, although the benefits also could be lower.

5. Alternative Methods of Ensuring Compliance. Compliance alternatives for Federal, state, or local enforcement include on-site inspection, periodic reporting, and compliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their costs and benefits, promising alternatives should be considered in identifying the regulatory alternative that maximizes net benefits. For example, in some circumstances random monitoring will

7. **More Market-Oriented Approaches.** In general, alternatives that provide for more market-oriented approaches, with the use of economic incentives replacing command-and-control requirements, are more cost-effective and should be explored. Market-oriented alternatives that may be considered include fees, subsidies, penalties, marketable permits or offsets, changes in liabilities or property rights (including policies that alter the incentive of insurers and insured parties), and required bonds, insurance or warranties. (In many instances, implementing these alternatives will require legislation.)

8. **Considering Specific Statutory Requirements.** When a statute establishes a specific regulatory requirement and the agency has discretion to adopt a more stringent standard, the agency should examine the benefits and costs of the specific statutory requirement as well as the more stringent alternative and present information that justifies the more stringent alternative if that is what the agency proposes.

III. ANALYSIS OF BENEFITS AND COSTS

A. General Principles

The preliminary analysis described in Sections I and II will lead to the identification of a workable number of alternatives for consideration.

1. **Baseline.** The benefits and costs of each alternative must be measured against a baseline. The baseline should be the best assessment of the way the world would look absent the proposed regulation. That assessment may consider a wide range of factors, including the likely evolution of the market, likely changes in exogenous factors affecting benefits and costs, likely changes in regulations promulgated by the agency or other government entities, and the likely degree of compliance by regulated entities with other regulations. Often it may be reasonable for the agency to forecast that the world absent the regulation will resemble the present. For the review of an existing regulation, the baseline should be no change in existing regulation; this baseline can then be compared against reasonable alternatives.

When more than one baseline appears reasonable or the baseline is very uncertain, and when the estimated benefits and costs of proposed rules are likely to vary significantly with the baseline selected, the agency may choose to measure benefits and costs against multiple alternative baselines as a form of sensitivity analysis. For example, the agency may choose to conduct a sensitivity analysis involving the consequences for

cost-effectiveness analysis will generally not yield an unambiguous choice; nevertheless, such an analysis is helpful for calculating a "breakeven" value for the unmonetized benefits (i.e., a value that would result in the action having positive net benefits). Such a value can be evaluated for its reasonableness in the discussion of the justification of the proposed action. Cost-effectiveness analysis should also be used to compare regulatory alternatives in cases where the level of benefits is specified by statute.

If the proposed regulation is composed of a number of distinct provisions, it is important to evaluate the benefits and costs of the different provisions separately. The interaction effects between separate provisions (such that the existence of one provision affects the benefits or costs arising from another provision) may complicate the analysis but does not eliminate the need to examine provisions separately. In such a case, the desirability of a specific provision may be appraised by determining the net benefits of the proposed regulation with and without the provision in question. Where the number of provisions is large and interaction effects are pervasive, it is obviously impractical to analyze all possible combinations of provisions in this way. Some judgment must be used to select the most significant or suspect provisions for such analysis.

3. Discounting. One of the problems that arises in developing a benefit-cost analysis is that the benefits and costs often occur in different time periods. When this occurs, it is not appropriate, when comparing benefits and costs, to simply add up the benefits and costs accruing over time. Discounting takes account of the fact that resources (goods or services) that are available in a given year are worth more than the identical resources available in a later year. One reason for this is that resources can be invested so as to return more resources later. In addition, people tend to be impatient and to prefer earlier consumption over later consumption.

(a) Basic considerations. Constant-dollar benefits and costs must be discounted to present values before benefits and costs in different years can be added together to determine overall net benefits. To obtain constant dollar estimates, benefit and cost streams in nominal dollars should be adjusted to correct for inflation. The basic guidance on discount rates for regulatory and other analyses is provided in OMB Circular A-94. The discount rate specified in that guidance is intended to be an approximation of the opportunity cost of capital, which is the before-tax rate of return to incremental private investment. The Circular A-94 rate, which was revised in 1992 based on an extensive review and public comment, reflects the rates of return on low yielding forms of capital, such as housing, as well as the higher rates of returns yielded by corporate capital. This average rate currently is estimated to be 7 percent in real

into account changes over time in relative values may have an effect similar to discounting environmental impacts at a lower rate, it is important to separate the effects of discounting from the effects of relative price changes in the economic analysis. In particular, the discount rate should not be adjusted for expected changes in the relative prices of goods over time. Instead, any changes in relative prices that are anticipated should be incorporated directly in the calculations of benefit and cost streams.

(b) Additional considerations. Modern research in economic theory has established a preferred model for discounting, sometimes referred to as the shadow price approach. The basic concept is that economic welfare is ultimately determined by consumption; investment affects welfare only to the extent that it affects current and future consumption. Thus, any effect that a government program has on public or private investment must be converted to an associated stream of effects on consumption before being discounted.

Converting investment-related benefits and costs to their consumption-equivalents as required by this approach involves calculating the "shadow price of capital." This shadow price reflects the present value of the future changes in consumption arising from a marginal change in investment, using the consumption rate of interest (also termed the rate of time preference) as the discount rate. The calculation of the shadow price of capital requires assumptions about the extent to which government actions -- including regulations -- crowd out private investment, the social (i.e., before-tax) returns to this investment, and the rate of reinvestment of future yields from current investment.

Estimates of the shadow price are quite sensitive to these assumptions. For example, in some applications it may be appropriate to assume that access to global capital markets implies no crowding out of private investment by government actions or that monetary and fiscal authorities determine aggregate levels of investment so that the impact of the contemplated regulation on total private investment can be ignored. Alternatively, there is evidence that domestic saving affects domestic investment and that regulatory costs may also reduce investment. In these cases, more substantial crowding out would be an appropriate assumption.

The rate of time preference is also a complex issue. Generally, it is viewed as being approximated by the real return to a safe asset, such as Government debt. However, a substantial fraction of the population does little or no saving and may borrow at relatively high interest rates.

contracting cancer) and the lack of complete knowledge about parameter values that define risk relationships (for example, the relationship between presence of a carcinogen in the food supply and the rate of absorption of the carcinogen) should be considered.

The term "uncertainty" often is used in economic assessments as a synonym for risk. However, in this document uncertainty refers more specifically to the fact that knowledge of the probabilities and sets of possible outcomes that characterize a probability distribution of risks, based on experimentation, statistical sampling, and other scientific tools, is itself incomplete. Thus, for example, a cancer risk might be described as a one-in-one-thousand chance of contracting cancer after 70 years of exposure. However, this estimate may be uncertain because individuals vary in their levels of exposure and their sensitivity to such exposures; the science underlying the quantification of the hazard is uncertain; or there are plausible competitors to the model for converting scientific knowledge and empirical measures of exposures into risk units. Estimates of regulatory benefits entail additional uncertainties, such as the appropriate measures for converting from units of risk to units of value. Cost estimates also will be uncertain when there are uncertainties in opportunity costs or the compliance strategies of regulated entities.

Estimating the benefits and costs of risk-reducing regulations includes two components: a *risk assessment* that, in part, characterizes the probabilities of occurrence of outcomes of interest; and a *valuation* of the levels and changes in risk experienced by affected populations as a result of the regulation. It is essential that both parts of such evaluations be conceptually consistent. In particular, risk assessments should be conducted in a way that permits their use in a more general benefit-cost framework, just as the benefit-cost analysis should attempt to capture the results of the risk assessment and not oversimplify the results (e.g., the analysis should address the benefit and cost implications of probability distributions).

Risk management is an activity conceptually distinct from risk assessment or valuation, involving a policy of whether and how to respond to risks to health, safety, and the environment. The appropriate level of protection is a policy choice rather than a scientific one. The risk assessment should generate a credible, objective, realistic, and scientifically balanced analysis; present information on hazard, dose-response, and exposure (or analogous material for non-health assessments); and explain the confidence in each assessment by clearly delineating strengths, uncertainties, and assumptions, along with the impacts of these factors on the overall assessment. The data, assumptions, models, and inferences used in the risk assessment to construct

results representing a range of plausible scenarios, together with any information that can help in providing a qualitative judgment of which scenarios are more scientifically plausible.

In the absence of adequate valid data, properly identified assumptions are necessary for conducting an assessment. The existence of plausible alternative models and their implications should be carried through as part of each risk characterization product. Alternative models and assumptions should be used in the risk assessment as needed to provide decisionmakers with information on the robustness of risk estimates and estimates of regulatory impacts. As with other elements of an EA, there should be balance between thoroughness of analysis in the treatment of risk and uncertainty and practical limits on the capacity to carry out analysis. The range of models, assumptions, or scenarios presented in the risk assessment need not be exhaustive, nor is it necessary that each alternative be evaluated at every step of the assessment. The assessment should provide sufficient information for decisionmakers to understand the degree of scientific uncertainty and the robustness of estimated risks, benefits, and costs. The choice of models or scenarios used in the risk assessment should be explained.

Where feasible, data and assumptions should be presented in a manner that permits quantitative evaluation of their incremental effects. The cumulative effects of assumptions and inferences should also be evaluated. A full characterization of risks should include findings for the entire affected population and relevant subpopulations. Assumptions should be consistent with reasonably obtainable scientific information. Thus, for example, low-dose toxicity extrapolations should be consistent with physiological knowledge; assumptions about environmental fate and transport of contaminants should be consistent with principles of environmental chemistry.

The material provided should permit the reader to replicate the analysis and quantify the effects of key assumptions. Such analyses are becoming increasingly easy to perform because of advances in computing power and new methodological developments. Thus, the level and scope of disclosure and transparency should increase over time.

In order for the EA to evaluate outcomes involving risks, risk assessments must provide some estimates of the probability distribution of risks with and without the regulation. Whenever it is possible to quantitatively characterize the probability distributions, some estimates of central tendency (e.g., mean and median) must be provided in addition to

robustness of conclusions about net benefits with respect to changes in model parameters. Sensitivity analysis should convey as much information as possible about the likely plausibility or frequency of occurrence of different scenarios (sets of parameter values) considered.

- *Delphi methods* involve derivation of estimates by groups of experts and can be used to identify attributes of subjective probability distributions. This method can be especially useful when there is diffuse or divergent prior knowledge. Care must be taken, however, to preserve any scientific controversy arising in a delphi analysis.
- *Meta-analysis* involves combining data or results from a number of different studies. For example, one could re-estimate key model parameters using combined data from a number of different sources, thereby improving confidence in the parameter estimates. Alternatively, one could use parameter estimates (elasticities of supply and demand, implicit values of mortality risk reduction) from a number of different studies as data points, and analyze variations in those results as functions of potential causal factors. Care must be taken to ensure that the data used are comparable, that appropriate statistical methods are used, and that spurious correlation problems are considered. One significant pitfall in the use of meta-analysis arises from combining results from several studies that do not measure comparable independent or dependent variables.

New methods may become available in the future as well. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

Uncertainty may arise from a variety of fundamentally different sources, including lack of data, variability in populations or natural conditions, limitations in fundamental scientific knowledge (both social and natural) resulting in lack of knowledge about key relationships, or fundamental unpredictability of various phenomena. The nature of these different sources may suggest different approaches. For example, when uncertainty is due to lack of information, one policy alternative may be to defer action pending further study. One factor that may help determine whether further study is justifiable as a policy alternative is an evaluation of the potential benefits of the information relative to the resources needed to acquire it and the potential costs of delaying action. When uncertainty is due largely to observable variability in populations or natural conditions, one policy alternative may be to refine targeting, that is, to differentiate policies across key subgroups. Analysis of such policies should

information on the incidence of regulatory effects in calculating total net benefits estimates.

The importance of including estimates of individuals' willingness to pay for risk reduction varies. Willingness to pay for reduced risks is likely to be more significant if risks are difficult to diversify because of incomplete risk and insurance markets, or if the net benefits of the regulation are correlated with overall market returns to investment. When the effects of regulation fall primarily on private parties, it is sufficient to incorporate measures of individual risk aversion. For regulatory benefits or costs that accrue to the Federal government (for example, income from oil production), the Federal government should be treated as risk neutral because of its high degree of diversification.

As noted in the previous section, the discount rate generally should not be adjusted as a device to account for the uncertainty of future benefits or costs. Any allowance for uncertainty should be made by adjusting the monetary values of changes in benefits or costs (for the year in which they occur) so that they are expressed in terms of their certainty equivalents. The adjustment for uncertainty may well vary over time because the degree of uncertainty may change. For example, price forecasts are typically characterized by increasing uncertainty (forecast error) over time, because of an increasing likelihood of unforeseen (and unforeseeable) changes in market conditions as time passes. In such cases, the certainty equivalents of net benefits will tend to change systematically over time; these changes should be taken into account in analyzing regulations that have substantial effects over a long time period. Uncertainty that increases systematically over time will result in certainty equivalents that fall systematically over time; however, these decreases in certainty equivalents will mimic the effects of an increase in the discount rate only under special circumstances.

5. Assumptions. Where benefit or cost estimates are heavily dependent on certain assumptions, it is essential to make those assumptions explicit and, where alternative assumptions are plausible, to carry out sensitivity analyses based on the alternative assumptions. If the value of net benefits changes sign with alternative plausible assumptions, further analysis may be necessary to develop more evidence on which of the alternative assumptions is more appropriate. Because the adoption of a particular estimation methodology sometimes implies major hidden assumptions, it is important to analyze estimation methodologies carefully to make hidden assumptions explicit.

Special challenges arise in evaluating the results of an EA that relies strongly upon proprietary data or analyses whose disclosure is limited by confidentiality agreements.

measure the potential U.S. loss from the threat of future retaliation by foreign governments. This threat should then be treated as a qualitative cost (see section 7).

7. Nonmonetized Benefits and Costs. Presentation of monetized benefits and costs is preferred where acceptable estimates are possible. However, monetization of some of the effects of regulations is often difficult if not impossible, and even the quantification of some effects may not be easy. Effects that cannot be fully monetized or otherwise quantified should be described. Those effects that can be quantified should be presented along with qualitative information to characterize effects that are not quantified.

Irrespective of the presentation of monetized benefits and costs, the EA should present available physical or other quantitative measures of the effects of the alternative actions to help decisionmakers understand the full effects of alternative actions. These include the magnitude, timing, and likelihood of impacts, plus other relevant dimensions (e.g., irreversibility and uniqueness). For instance, assume the effects of a water quality regulation include increases in fish populations and habitat over the affected stream segments and that it is not possible to monetize such effects. It would then be appropriate to describe the benefits in terms of stream miles of habitat improvement and increases in fish population by species (as well as to describe the timing and likelihood of such effects, etc.). Care should be taken, however, when estimates of monetized and physical effects are mixed in the same analysis so as to avoid double-counting of benefits. Finally, the EA should distinguish between effects unquantified because they were judged to be relatively unimportant, and effects that could not be quantified for other reasons.

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

Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including their magnitude, likelihood, and incidence of effects on particular groups. Agencies should

result of a proposed regulation. To the extent possible, the probability distributions of benefits should be presented. Extreme estimates should be presented as complements to central tendency and other estimates. If fundamental scientific disagreement or lack of knowledge precludes construction of a scientifically defensible probability distribution, benefits should be described under plausible alternative assumptions, along with a characterization of the evidence underlying each alternative view. This will allow for a reasoned determination by decisionmakers of the appropriate level of regulatory action.

It is important to guard against double-counting of benefits. For example, if a regulation improves the quality of the environment in a community, the value of real estate in the community might rise, reflecting the greater attractiveness of living in the improved environment. Inferring benefits from changes in property values is complex. On the one hand, the rise in property values may reflect the capitalized value of these improvements. On the other hand, benefit estimates that do not incorporate the consequences of land use changes will not capture the full effects of regulation. For regulations with significant effects on land uses, these effects must be separated from the capitalization of direct regulatory impacts into property values.

1. General Considerations. The concept of "opportunity cost" is the appropriate construct for valuing both benefits and costs. The principle of "willingness-to-pay" captures the notion of opportunity cost by providing an aggregate measure of what individuals are willing to forgo to enjoy a particular benefit. Market transactions provide the richest data base for estimating benefits based on willingness-to-pay, as long as the goods and services affected by a potential regulation are traded in markets. It is more difficult to estimate benefits where market transactions are difficult to monitor or markets do not exist. Regulatory analysts in these cases need to develop appropriate proxies that simulate market exchange. Indeed, the analytical process of deriving benefit estimates by simulating markets may suggest alternative regulatory strategies that create such markets.

Either willingness-to-pay (WTP) or willingness-to-accept (WTA) can provide an appropriate measure of benefits, depending on the allocation of property rights. The common preference for WTP over WTA measures is based on the empirical difficulties in estimating the latter.

Estimates of willingness-to-pay based on observable and replicable behavior deserve the greatest level of confidence. Greater uncertainty attends benefit estimates that are neither derived from market transactions nor based on behavior that is observable or

A variety of methods have been developed for estimating indirectly traded benefits. Generally, these methods apply statistical techniques to distill from observable market transactions the portion of willingness-to-pay that can be attributed to the benefit in question. Examples include estimates of the value of environmental amenities derived from travel-cost studies, hedonic price models that measure differences or changes in the value of land, and statistical studies of occupational-risk premiums in wage rates. For all these methods, care is needed in designing protocols for reliably estimating benefits or in adapting the results of previous studies to new applications. The use of occupational-risk premiums can be a source of bias because the risks, when recognized, may be voluntarily rather than involuntarily assumed, and the sample of individuals upon which premium estimates are based may be skewed toward more risk-tolerant people.

Contingent-valuation methods have become increasingly common for estimating indirectly traded benefits, but the reliance of these methods on hypothetical scenarios and the complexities of the goods being valued by this technique raise issues about its accuracy in estimating willingness to pay compared to methods based on (indirect) revealed preferences. Accordingly, value estimates derived from contingent-valuation studies require greater analytical care than studies based on observable behavior. For example, the contingent valuation instrument must portray a realistic choice situation for respondents -- where the hypothetical choice situation corresponds closely with the policy context to which the estimates will be applied. The practice of contingent valuation is rapidly evolving, and agencies relying upon this tool for valuation should judge the reliability of their benefit estimates using this technique in light of advances in the state of the art.

4. Principles and Methods for Valuing Goods That Are Not Traded Directly or Indirectly in Markets. Some types of goods, such as preserving environmental or cultural amenities apart from their use and direct enjoyment by people, are not traded directly or indirectly in markets. The practical obstacles to accurate measurement are similar to (but generally more severe than) those arising with respect to indirect benefits, principally because there are few or no related market transactions to provide data for willingness-to-pay estimates.

For many of these goods, particularly goods providing "nonuse" values, contingent-valuation methods may provide the only analytical approaches currently available for estimating values. The absence of observable and replicable behavior with respect to the good in question, combined with the complex and often unfamiliar nature of the goods being valued, argues for great care in the design and execution of surveys,

Valuing lost production and other time-related costs gives rise to a number of methodological concerns. For occupational illness or injury, lost production can be measured by losses in workers' value of marginal product. In valuing the effects of broader environmental hazards, however, attention must be given to the composition of the exposed population. For example, some portion of the working-age population may be unemployed, while others will be retired. Still others may have chosen to be homemakers or home caregivers. Valuation of nonfatal illness or injury to these parts of the population presents a greater challenge than valuing the loss of employee services using wage rates. Finally, the valuation of health impacts on children or retirees through the direct-cost approach is especially problematic since their zero opportunity cost in the labor market is not a good proxy for the social cost of illness. The agency should use whatever approach it can justify but should provide a clear explanation of the assumptions and reasoning used in the valuation.

(b) Fatality risks. Values of fatality risk reduction often figure prominently in assessments of government action. Estimates of these values that are as accurate as possible, given the circumstances being assessed and the state of knowledge, will reduce the prospects for inadequate or excessive action.

Reductions in fatality risks as a result of government action are best monetized according to the willingness-to-pay approach. The value of changes in fatality risk is sometimes expressed in terms of the "value of statistical life" (VSL) or the "value of a life". These terms are confusing at best and should be carefully described when used. It should be made clear that these terms refer to the willingness to pay for reductions in risks of premature death (scaled by the reduction in risk being valued). That is, such estimates refer only to the value of relatively small changes in the risk of death. They have no application to an identifiable individual.

There is also confusion about the term "statistical life." This term refers to the sum of risk reductions expected in a population. For example, if the annual risk of death is reduced by one in a million for each of two million people, that represents two "statistical lives" saved per year (two million x one millionth = two). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives saved.

Another way of expressing reductions in fatality risks is in terms of the "value of statistical life-years extended" (VSLY). For example, if a regulation protected individuals whose average remaining life expectancy was 40 years, then a risk reduction of one fatality would be expressed as 40 life-years extended. This approach

which the net benefits of the two alternatives are equal). This method will frequently be infeasible because of its computational demands but, where feasible, it may be a useful addition to the sensitivity analysis.

An implicit valuation approach that could be used entails calculations of the net incremental cost per unit of reduction in fatality risk (cost per "statistical life saved") of alternative measures, with net incremental costs defined as costs minus monetized benefits. Alternatives can be arrayed in order of increasing reductions in expected fatalities. Generally this will also correspond to increasing incremental cost. (It is possible that there will be some initial economies of scale, with declining incremental costs. If incremental costs are declining over a broad range of alternative measures, it is likely that there are flaws in the definition of the measures or the estimation of their effects.) The incremental cost per life saved then can be calculated for each adjacent pair of alternatives. With this construction, the choice to undertake a certain set of measures while eschewing others implies a lower and upper bound for the value per life saved; it would be at least as large as the incremental cost of the most expensive measure undertaken, but not as large as the cheapest measure not undertaken. In contrast to explicit valuation approaches, this avoids the necessity of specifying in advance a value for reductions in fatality risks. However, the range of values should be consistent with estimated values of reductions in fatality risks calculated according to the willingness-to-pay methodology, and the method should be consistently applied across regulatory decisions (within statutory limitations), in order to assure that regulation achieves the greatest risk reduction possible from the level of resources committed to risk reduction.

While there are theoretical advantages to using a value of statistical life-year-extended approach, current research does not provide a definitive way of developing estimates of VSLY that are sensitive to such factors as current age, latency of effect, life years remaining, and social valuation of different risk reductions. In lieu of such information, there are several options for deriving the value of a life-year saved from an estimate of the value of life, but each of these methods has drawbacks. One approach is to use results from the wage compensation literature (which focus on the effect of age on WTP to avoid risk of occupational fatality). However, these results may not be appropriate for other types of risks. Another approach is to annualize the VSL using an appropriate rate of discount and the average life years remaining. This approach does not provide an independent estimate of VSLY; it simply rescales the VSL estimate. Agencies should consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area.

(Producers' surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit. Consumers' surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the distance between the price and the demand curve for that unit.)

The opportunity cost of an alternative also incorporates the value of the benefits forgone as a consequence of that alternative. For example, the opportunity cost of banning a product (e.g., a drug, food additive, or hazardous chemical) is the forgone net benefit of that product, taking into account the mitigating effects of potential substitutes. As another example, even if a resource required by regulation does not have to be paid for because it is already owned by the regulated firm, the use of that resource to meet the regulatory requirement has an opportunity cost equal to the net benefit it would have provided in the absence of the requirement. Any such forgone benefits should be monetized wherever possible and either added to the costs or subtracted from the benefits of that alternative. Any costs that are averted as a result of an alternative should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

All costs calculated should be incremental, that is, they should represent changes in costs that would occur if the regulatory option is chosen compared to costs in the base case (ordinarily no regulation or the existing regulation) or under a less stringent alternative. Future costs that would be incurred even if the regulation is not promulgated, as well as costs that have already been incurred (sunk costs), are not part of incremental costs. If marginal cost is not constant for any component of costs, incremental costs should be calculated as the area under the marginal cost curve over the relevant range. A schedule of monetized costs should be included that would show the type of cost and when it would occur; the numbers in this table should be expressed in constant, undiscounted dollars.

The EA should identify and explain the data or studies on which cost estimates are based with enough detail to permit independent assessment and verification of the results. Where cost estimates are derived from a statistical study, the EA should provide sufficient information so that an independent observer can determine the representativeness of the sample, the reliability of extrapolations used to develop aggregate estimates, and the statistical significance of the results.

(a) Scarcity rents and monopoly profits. If, for example, sales of a competitively produced product were restricted by a government regulation so as to raise prices to consumers, the resulting profit increases for sellers are not a net social benefit of the rule, nor is their payment by consumers generally a net social cost, though there may be important distributional consequences. The social benefit-cost effects of the regulation would be represented by changes in producers' and consumers' surpluses, including the net surplus reduction from reduced availability of the product. The same conclusion applies if the government restriction provides an opportunity for the exercise of market power by sellers, in which case the net cost of the regulation would include the cost of reduced product provision due both to the government mandate and the induced change in market structure.

(b) Insurance payments. Potential pitfalls in benefit-cost analysis may also arise in the case of insurance payments, which are transfers. Suppose, for example, a worker safety regulation, by decreasing employee injuries, led to reductions in firms' insurance premium payments. It would be incorrect to count the amount of the reduction in insurance premiums as a benefit of the rule. The proper measure of benefits for the EA is the value of the reduction in worker injuries, monetized as described previously, plus any reduction in real costs of administering insurance (such as the time insurance company employees needed to process claims) due to the reduction in worker insurance claims. Reductions in insurance premiums that are matched by reductions in insurance claim payments are changes in transfer payments, not benefits.

(c) Indirect taxes and subsidies. A third instance where special treatment may be needed to deal with transfer payments is the case of indirect taxes (tariffs or excise taxes) or subsidies on specific goods or services. Suppose a regulation requires firms to purchase a \$10,000 piece of imported equipment, on which there is a \$1,000 customs duty. For purposes of benefit-cost analysis, the cost of the regulation for each firm ordinarily would be \$10,000, not \$11,000, since the \$1,000 customs duty is a transfer payment from the firm to the Treasury, not a real resource cost. This approach, which implicitly assumes that the equipment is supplied at constant costs, should be used except in special circumstances. Where the taxed equipment is not supplied at constant cost, the technically correct treatment is to calculate how many of the units purchased as a result of the regulation are supplied from increased production and how many from decreased purchases by other buyers. The former units would be valued at the price without the tax and the latter units would be valued at the price including tax. This calculation is usually difficult and imprecise because it requires estimates of supply and demand elasticities, which are often difficult to obtain and inexact. Therefore, this treatment should only be used where the benefit-cost

SELECTED FURTHER READINGS

Judith D. Bentkover, Vincent T. Covello, and Jeryl Mumpower, Eds., *Benefits Assessment: The State of the Art*.

Jack Hirshliefer and John G. Riley, *The Analytics of Uncertainty and Information*. An advanced treatment of many issues related to risk and uncertainty.

Myrick Freeman, *The Measurement of Environmental and Resource Values: Theory and Methods*. A comprehensive high-level treatment of environmental valuation issues.

Robert C. Lind, Ed., *Discounting for Time and Risk in Energy Policy*. An advanced treatment of issues related to public and private sector discounting.

E. J. Mishan, *Economics for Social Decisions: Elements of Cost-Benefit Analysis*. Assumes some knowledge of economics. Chapters 5-8 should be helpful on the important subjects of producers' and consumers' surpluses (not discussed extensively in this guidance document).

Robert Cameron Mitchell and Richard C. Carson, *Using Surveys to Value Public Goods: The Contingent Valuation Method*. Provides a valuable discussion on the potential strengths and pitfalls associated with the use of contingent-valuation methods.

V. Kerry Smith, Ed., *Advances in Applied Micro-economics: Risk, Uncertainty, and the Valuation of Benefits and Costs*.

Edith Stokey and Richard Zeckhauser, *A Primer for Policy Analysis*. Chapters 9 and 10 provide a good introduction to basic concepts.

George Tolley, Donald Kenkel, and Robert Fabian, Eds., *Valuing Health for Policy: An Economic Approach*. An excellent summary of methods to value reduction in morbidity and extensions to life expectancy.

W. Kip Viscusi, *Risk By Choice*. Chapter 6 is a good starting point for the topic of valuing health and safety benefits. Other more technical sources are given in the bibliography.



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

JAN 12 1995

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

MEMORANDUM FOR REGULATORY WORKING GROUP

FROM: Sally Katzen *SJK*
SUBJECT: Principles for Risk Analysis

Attached is a statement of policy on risk assessment, management and communication. The principles are designed to define risk analysis and its purposes, and to generally guide agencies as they use risk analysis in the regulatory context. They are intended to provide a general framework -- a structure stating basic principles upon which a wide consensus now exists.

The principles are aspirational rather than prescriptive. Their application requires flexibility and practical judgment. The science of risk assessment is rapidly changing and its use is a function of a number of factors -- including legal mandates and available resources -- that vary from one regulatory program to another. We therefore do not offer these principles as conclusive, complete or irrevocable; they are intended to be used as a point of departure for future efforts within individual agencies and the Executive Branch broadly.

The principles should be interpreted and applied as a whole. Particular sections should not be quoted or extracted in isolation. The principles are not intended to provide the basis for judicial review or legislation.

Principles for Risk Assessment, Management, and Communication

Regulatory Working Group
January 12, 1995

A. 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.
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)].
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.

B. Principles for Risk Assessment

1. Agencies should employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment.
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.
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.
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.
5. Peer review of risk assessments can ensure that the highest professional standards are maintained. Therefore, agencies should develop policies to maximize its use.
6. Agencies should strive to adopt consistent approaches to evaluating the risks posed by hazardous agents or events.

C. 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.

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).

D. 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.
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. 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;
 - b. describe the sources, extent and magnitude of significant uncertainties associated with the assessment or decision;
 - c. make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary versus involuntary risks; and,

- d. provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.

E. Principles for Priority Setting Using Risk Analysis

1. To inform priority setting, agencies should seek to compare risks, grouping them into 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.



THE DIRECTOR

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

WASHINGTON, D.C. 20503

October 12, 1993

M-94-3

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

FROM: Leon E. Panetta
Director

A handwritten signature in black ink, appearing to be "LEON PANETTA", written over a horizontal line.

SUBJECT: Guidance for Implementing E.O. 12866

The President issued Executive Order No. 12866, "Regulatory Planning and Review," on September 30, 1993. This Order directs the Office of Management and Budget (OMB) to carry out the centralized review of significant regulatory actions under development at regulatory agencies.

Within OMB, the Office of Information and Regulatory Affairs (OIRA) has the primary responsibility under the Executive Order for a number of the specific regulatory review and planning functions. Sally Katzen, the OIRA Administrator, has prepared a memorandum setting forth initial steps to implement the Order. Among other things, each agency must promptly designate a Regulatory Policy Officer and begin discussions with OIRA concerning those regulations that warrant centralized review.

I urge you to send Administrator Katzen's memorandum (attached) to the appropriate officials for their immediate attention.

Attachment



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

October 12, 1993

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

FROM: Sally Katzen *S.Katzen*
Administrator, Office of
Information and Regulatory Affairs

SUBJECT: Guidance for Implementing E.O. 12866

The President issued Executive Order No. 12866, "Regulatory Planning and Review," on September 30, 1993 (58 Fed. Reg. 51735 (October 4, 1993)).¹ It calls upon Federal agencies and the Office of Information and Regulatory Affairs (OIRA) to carry out specific actions designed to streamline and make more efficient the regulatory process. This memorandum provides guidance on a number of the provisions of the new Order. Undoubtedly, with experience, additional questions will be raised, and we will attempt to respond promptly as they arise.

1. Coverage

The Order as a whole applies to all Federal agencies, with the exception of the independent regulatory agencies (Sec. 3(b)). The independent regulatory agencies are included in provisions concerning the "Unified Regulatory Agenda" (Sec. 4(b)) and "The Regulatory Plan" (Sec. 4(c)). However, while the President's "Statement of Regulatory Philosophy and Principles" (Sec. 1) applies by its terms only to those agencies that are not independent, the independent regulatory agencies are requested on a voluntary basis to adhere to the provisions that may be pertinent to their activities.

In addition, the Order states that the OIRA Administrator may exempt agencies otherwise covered by the Order. Appendix A is a first cut of those agencies that have few, if any, significant rulemaking proceedings each year; effective immediately, these agencies are exempt from the scope of the

¹ This Order replaces E.O. 12291 and E.O. 12498.

Order.² Like the independent agencies, those agencies listed in Appendix A are requested to adhere voluntarily to the relevant provisions of the Order, particularly the President's "Statement of Regulatory Philosophy and Principles" (Sec. 1).

2. Designation of Regulatory Policy Officer.

The Order directs each agency head to designate a Regulatory Policy Officer "who shall report to the agency head" (Sec. 6(a)(2)). This Regulatory Policy Officer is to be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations. Because the Regulatory Policy Officer will in most circumstances serve as the agency representative to the Regulatory Working Group (see below), please provide us with the name, mailing address, and telephone and fax numbers of your designee as soon as possible.

3. Regulatory Working Group.

The Order directs the OIRA Administrator to convene a Regulatory Working Group consisting, in part, of the representatives of the heads of each agency having significant domestic regulatory responsibility (Sec. 4(d)).

Again, we have made a first cut of a list of those agencies which should be members of the Regulatory Working Group, which is attached as Appendix B. Some of the Departments that have separate regulatory components may qualify for multiple representatives. Please notify us if you believe that your Department should have more than one representative. In suggesting additional representatives, please identify these persons and provide us with their mailing addresses, and telephone and fax numbers.

The Administrator is to convene the first meeting of the Regulatory Working Group within 30 days. It is therefore essential that we have your response as soon as possible.

4. Regulatory Planning Mechanism.

The Order emphasizes planning as a way of identifying significant issues early in the process so that whatever coordination or collaboration is appropriate can be achieved at

² To assure that the purposes of the Executive Order are carried out, we may ask these agencies to review particular significant regulatory actions of which we become aware. These Agencies should advise OIRA if they believe that a particular rule warrants centralized review.

the beginning of the regulatory development process rather than at the end (Sec. 4).

There are two specific planning documents discussed in the Order. The first, the semiannual Unified Regulatory Agenda (Sec. 4(b)), is on schedule and will be published before the end of October. Traditionally, all agencies participate, describing briefly the regulations under development. The Order does not call for any change in either the scope or format of this document.

The second planning document is the annual Regulatory Plan (Sec. 4(c)), which is to be published in October as part of the Unified Regulatory Agenda. The Regulatory Plan seeks to capture the most important significant regulations. In advance of agencies drafting their Regulatory Plans, the Vice President will meet with agency heads to seek a common understanding of regulatory priorities and to coordinate regulatory efforts to be accomplished in the upcoming year (Sec. 4(a)). The Vice President will convene the first meeting in early 1994. Following that meeting, we will provide appropriate guidance on the scope and structure of the submissions for the 1994 Regulatory Plan.

As you may recall, OMB had asked in OMB Bulletin No. 93-13 (May 13, 1993) that certain agencies prepare a draft 1993 Regulatory Program under the then applicable Executive Order No. 12498. Many agencies sent in some or all of their proposed programs. Other agencies informed us that they wanted to wait for the confirmation of political appointees or the issuance of the new Executive Order. While there is now insufficient time for all of the steps necessary to prepare a formal regulatory plan for this year, the materials we have received will be useful in preparing for the meeting with the Vice President and our other coordination efforts. Those agencies that have already drafted but not submitted materials, as well as those who wish to augment what we have already received, are encouraged to send these materials to OIRA.

5. Review of Existing Regulations.

The Order directs each agency to create a program under which it will periodically review its existing significant regulations to determine whether any should be modified or eliminated to make the agency's regulatory program more effective, less burdensome, and in greater alignment with the President's priorities and regulatory principles (Sec. 5). Specifically, within 90 days, agencies are to submit to the OIRA Administrator a program establishing, consistent with the agency's resources and regulatory priorities, the procedures for carrying out a periodic review of existing significant

regulations and identifying any legislative mandates that may merit enactment, amendment, or rescission (Sec. 5(a)).

We are aware that past Administrations have required agencies to undertake similar review efforts. Some of these have been so broad in scope that necessary analytic focus has been diffused, or needed follow-up has not occurred. This current effort should be more productive because it focuses only on significant regulations and the legislation that mandates them, and because we will be looking at groups of regulations across agencies with the help of the Vice President and the White House Regulatory Advisers, as well as the public.

Pursuant to the Order, we are asking each agency to send to the OIRA Administrator within 90 days a work-plan which identifies who and which office within the agency will be responsible for assuring that periodic reviews take place; the criteria to be used for selecting targets of review; the kinds of public involvement, data collection, economic and other analysis, and follow-up evaluation that are planned; the timetables to be applied; and, to the extent then known, the targets selected. As the program is implemented and an agency selects specific targets for review, please identify the specific programs, regulations, and legislation involved. To the extent they are relevant, we will share with you the review efforts of other agencies.

6. Centralized Review of Regulations.

One of the themes in the Order is greater selectivity in the regulations reviewed by OIRA, so that we can free up our resources to focus on the important regulatory actions and expedite the issuance of those that are less important. Another theme is that we are to determine early in the process which regulations are important (the term in the Order is - "significant"). Among other things, this will permit agencies to conduct the needed analyses for these regulations as part of the development process, not as an after-the-fact exercise (Sec. 6(a)(3)(B)).

The Order defines "significant" regulatory actions as those likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impact of entitlements, grants, user fees, or loan programs; or

(4) raising novel legal or policy issues (Sec. 3(f)).³ This definition is not wholly susceptible to mechanical application; rather, in many instances, it will require the exercise of judgment. We will work with the agencies to come to a consensus on the meaning of this term in the context of the specific programs and characteristics of each agency.

To begin, we ask the appropriate personnel at each agency to work with the OIRA desk officer(s) to develop an appropriate list of rulemakings that are under development for submission to OIRA. For each rulemaking, please use the format below:

DEPARTMENT/REGULATORY COMPONENT. Title ([Indicate significance⁴]; Upcoming Action: [Identify]⁵) Planned Submission/Publication: [date]; RIN: [number⁶]. Statutory/Judicial Deadline: [date, if any].

[Describe briefly what the agency is intending to do and why, including whether the program is new or

³ The Order is intended to cover any policy document of general applicability and future effect, which the agency intends to have the force and effect of law, such as guidances, funding notices, manuals, implementation strategies, or other public announcements, designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. Such documents are normally published in the Federal Register, but can also be made available to the affected public directly.

⁴ State one of the following: "Not Significant", "Significant", or "Economically Significant". A designation as "Economically Significant" means that the regulatory action is likely to result in the effects listed in the first subsection -- namely, i.e., "have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." A regulatory action that is considered "Economically Significant" must ultimately be supported by the analyses set forth in Section 6(a)(3)(C).

⁵ Indicate whether the upcoming regulatory action is a "Notice of Inquiry", "Funding Notice", "ANPRM", "NPRM", "Interim Final Rule", "Final Rule", or what other action it may be.

⁶ "RIN" is the Regulation Identifier Number published in the Unified Regulatory Agenda. If a RIN has not been assigned, the agency should obtain one through the normal process by contacting the Regulatory Information Service Center.

continuing and, if continuing, the significant changes in program operations or award criteria. Briefly describe issues associated with the rulemaking, as appropriate, e.g., impacts (both benefits and costs), interagency and intergovernmental (State and local) effects, budgetary effects (e.g., outlays, number of years and awards, administrative overhead), time pressures, and why the regulatory action is important, sensitive, controversial or precedential. For final regulatory actions, 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 comments.] ([Name and telephone number of program official who can answer detailed questions])

We are not looking for a lengthy or detailed description of the issues listed above. All we need is information sufficient to confirm the characterization of "significant" or "not significant". Similarly, for final regulatory actions, the description of the public comments and changes is simply to enable us to decide whether we can expedite or waive our review of the final rule where, for example, there are few or no public comments and little or no substantive change from the previously reviewed NPRM.

Under the Executive Order, within 10 working days after OIRA receives this list, we will meet with or call your office to discuss whether or not listed regulatory actions should be submitted for centralized review (Sec. 6(a)(3)(A)). The purpose of this meeting is to confirm the characterization of the proposal as "significant" or "not significant", the characterization is important because, absent a material change in the development of the rule, those characterized as "not significant" need not be submitted for OIRA review before publication.

OIRA will also want to discuss the timing for updates that would identify any new regulatory actions under development. OIRA implemented this procedure with several agencies on a pilot basis while the Order was being drafted. We are most pleased by the results. It has in some instances taken one or two tries to develop a process that works for a particular agency. In most instances, submission of a list once a month has proven sufficient for our purposes.

Once it is clear that a rulemaking warrants review by OIRA, the process will be facilitated by your advising the OIRA staff as soon as possible on the basic concept, direction, and scope of the rulemaking. This will enable us to identify early the issues that we are concerned about and to inform agency personnel of the type of analyses that OIRA will look for when it reviews the

regulatory action. All of this is designed to make the review process more efficient and avoid last minute problems.

When an agency submits a significant regulatory action for review, the Order sets forth certain information that each agency should provide a description of the need for the regulatory action, how the regulation will meet that need, and an assessment of the potential costs and benefits of the regulatory action, together with an explanation of how it is consistent with a statutory mandate, promotes the President's priorities, and avoids undue interference with State, local, and tribal governments. This should not impose additional burden on the agency. All of the information should have been prepared as part of the agency's deliberative process; and much, if not all, of this information should already be set forth in the preamble of the proposal so as to allow more informed public comment.

If the regulatory action is economically significant (as defined in Sec. 3(f)(1)),⁷ the Order sets forth additional information that an agency must provide -- an assessment of benefits, costs, and of potentially effective and reasonably feasible alternatives to the planned regulatory action (Sec. 6(a)(3)(C)). We recognize that this material may take different forms for different agencies. We are reviewing our current guidance to see what changes, if any, are appropriate. Pending the conclusion of this review, agencies should continue to adhere to the existing OMB guidance on how to estimate benefits and costs.

In order to assure that the public is aware of our review under the Order and the possible effects that this review may have had, agencies should indicate in the preamble to the regulatory action whether or not the regulatory action was subject to review under E.O. 12866. On the other hand, there is no requirement that an agency document (in the preamble or in its submissions to OIRA) compliance with each principle of regulation set forth in the beginning of the Executive Order (Sec. 1(b)); we do, however, expect agencies to adhere to these principles and to respond to any questions that may be raised about how a regulatory action is consistent with these provisions of the Order.

The OIRA Administrator was given the authority to exempt any category of agency regulations from centralized review (Sec. 3(d)(4)). To begin with, we have decided that the previously granted exemptions should be kept in effect, except as the Order

⁷ See footnote 4.

specifically includes them.⁴ Several additional exemptions have been added as a result of our ongoing discussions with agencies. A list of current exemptions is set forth in Appendix C. We will add to this list as experience warrants. We urge you to contact the Administrator, or have your staff contact your OIRA desk officer, to discuss those categories you believe may be suitable for exemption.

7. Openness and Public Accountability.

To assure greater openness and accountability in the regulatory review process, the Order sets forth certain responsibilities for OIRA (Sec. 6(b)(4)). Among other things, OIRA is placing in its public reading room a list of all agency regulatory actions currently undergoing review. This list is updated daily, and identifies each regulatory action by agency, title, date received, and date review is completed.

The reading room also contains a list of all meetings and telephone conversations with the public and Congress to discuss the substance of draft regulations that OIRA is reviewing. Within OIRA, only the Administrator (or an individual specifically designated by the Administrator -- generally the Deputy Administrator) may receive such oral communications.

When these meetings are scheduled, we are asking those outside the Executive branch to have communicated their concerns and supporting facts to the issuing agency before the meeting with OIRA. To assure that the matters discussed are known to the agency, we are inviting policy-level officials from the issuing agency to each such meeting.

In addition, written materials received from those outside the Executive branch will be logged in the reading room and forwarded to the issuing agency within 10 working days. It will be up to each agency to put these in its rulemaking docket.

After the regulation is published, OIRA is making available to the public the documents exchanged between OIRA and the issuing agency. These materials will also be made public even if the agency decides not to publish the regulatory action in the Federal Register. In addition, the Order directs that, after a

⁴ Section 3(d)(2) includes within the definition of "regulation" or "rule" those pertaining to "procurement" and the "import or export of non-defense articles and services." The OIRA Administrator interprets the latter to include within the scope of the Order the regulations of the Bureau of Export Administration, and to exclude State Department regulations involving the Munitions List.

regulatory action has been published in the Federal Register or otherwise released, each agency is to make available to the public the text submitted for review, and the required assessments and analyses (Sec. 6(a)(3)(E)). In addition, after the regulatory action has been published in the Federal Register or otherwise issued to the public, each agency is to identify for the public, in a complete, clear, and simple manner, the substantive changes that it made to the regulatory action between the time the draft was submitted to OIRA for review and the action was subsequently publicly announced, indicating those changes that were made at the suggestion or recommendation of OIRA (Sec. 6(a)(3)(E)(ii) & (iii)). Should you have any questions about these matters, please call the Administrator or one of your OIRA Desk Officers.

8. Time Limits for OIRA Review.

The Order sets forth strict time limits for OIRA review of regulatory actions. For any notices of inquiry, advance notice of proposed rulemaking, or other preliminary regulatory action, OIRA is to complete review within 10 working days (Sec. 6(b)(2)(A)). For all other regulatory actions, OIRA has 90 calendar days, unless OIRA has previously reviewed it and there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case there is a limit of 45 days (Sec. 6(b)(2)(B)). Because of these tight time limits, we must work closely together to ensure that requests for clarification or information are responded to promptly. Upon receipt of a regulatory action, we plan to take a quick look and make certain that whatever analyses should be included are included, and to get back promptly to the agency to ask for whatever is missing.

In some instances, a reason for OIRA review will be the potential effect of a regulation on other agencies. In these circumstances, OIRA will attempt to provide the affected agencies with copies of the draft regulatory action as soon as possible. If you are aware that another agency has an interest in the draft regulatory action, please let us know quickly.

We also want to stress the provision in the Order that calls upon each agency, in emergency situations or when the agency is obligated by law to act more quickly than normal review procedures allow, to notify OIRA as soon as possible and to schedule the rulemaking proceedings so as to permit sufficient time for OIRA to conduct an adequate review (Sec. 6(a)(3)(D)).

9. Regulation Identifier Number (RIN).

We ask that each agency include a Regulation Identifier Number in the heading of each regulatory action published in the

Federal Register.⁹ This will make it easier for the public and agency officials to track the publication history of regulatory actions throughout their life cycles and to link documents in the Federal Register with corresponding entries in the Unified Agenda of Federal Regulations (Sec. 4(b)) and the Regulatory Plan (Sec. 4(c)).

* * * * *

We look forward to working with you to implement this Executive Order. If you have any questions, please let us know. We will, of course, provide additional guidance as experience and need dictate.

⁹ The Office of the Federal Register has issued guidance to agencies on the placement of the RIN number in their documents. See Document Drafting Handbook, 1991 ed., p. 9.

APPENDIX A

AGENCIES EXEMPT FROM E.O. 12866

Advisory Council on Historic Preservation
African Development Foundation
Alaska Natural Gas Transportation System,
Office of the Federal Inspector
American Battle Monuments Commission
Arms Control and Disarmament Agency
Board for International Broadcasting
Central Intelligence Agency
Commission of Fine Arts
Committee for Purchase from the Blind
and Severely Handicapped
Export-Import Bank of the United States
Farm Credit System Assistance Board
Federal Financial Institutions Examination Council
Federal Mediation and Conciliation Service
Harry S. Truman Scholarship Foundation
Institute of Museum Services
Inter-American Foundation
International Development Corporation Agency
James Madison Memorial Fellowship Foundation
Merit Systems Protection Board
Navajo Hopi Indian Relocation Commission
National Capital Planning Commission
Office of Special Counsel
Overseas Private Investment Corporation
Panama Canal Commission
Pennsylvania Avenue Development Corporation
Peace Corps
Selective Service System
Tennessee Valley Authority
United States Metric Board
United States Information Agency
United States International Development Cooperation Agency

APPENDIX B

MEMBERS OF THE REGULATORY WORKING GROUP

Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of the Interior
Department of Justice
Department of Labor
Department of Transportation
Department of the Treasury
Department of Veterans Affairs
Environmental Protection Agency
Small Business Administration
General Services Administration
Equal Employment Opportunity Commission

APPENDIX C

REGULATORY ACTIONS EXEMPTED FROM CENTRALIZED REGULATORY REVIEW

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service--Special Nutrition program notices that revise reimbursement rates and eligibility criteria for the School Lunch, Child Care Food, and other nutrition programs.

Food and Nutrition Service--Food Stamp program notices that set eligibility criteria and deduction policies.

Agricultural Marketing Service--Regulations that establish voluntary standards for grading the quality of food.

Animal and Plant Health Inspection Service--Rules and notices concerning quarantine actions and related measures to prevent the spread of animal and plant pests and diseases.

Animal and Plant Health Inspection Service--Rules affirming actions taken on an emergency basis if no adverse comments were received.

Rural Electrification Administration--Rules concerning standards and specifications for construction and materials.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration--Certain time-sensitive pre-season and in-season Fishery Management Plan regulatory actions that set restrictions on fishing seasons, catch size, and fishing gear.

DEPARTMENT OF EDUCATION

Certain Final Rules Based on Proposed Rules--Final regulations based on proposed regulations that OMB previously reviewed where: (1) OMB had not previously identified issues for review in at final regulation stage; (2) Education received no substantive public comment; and (3) the proposed regulation is not substantively revised in the final regulation.

Rules Directly Implementing Statute--Final regulations that only incorporate statutory language with no interpretation.

Notices of Final Funding Priorities--Notices of final funding priorities for which OMB has previously reviewed the proposed priority.

DEPARTMENT OF ENERGY

Power Marketing Administrations--Regulations issued by various power administrations relating to the sale of electrical power that they produce or market.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration--Agency notices of funds availability.

Food and Drug Administration--Medical device reclassifications to less stringent categories.

Food and Drug Administration--OTC monographs, unless they may be precedent-setting or have large adverse impacts on consumers.

Food and Drug Administration--Final rules for which no comments were received and which do not differ from the NPRM.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining--Actions to approve, or conditionally approve, State regulatory mining actions or amendments to such actions.

Office of Surface Mining--Approval of State mining reclamation plans or amendments.

Office of Surface Mining--Cooperative agreements between OSM and States.

United States Fish and Wildlife Service--Certain parts of the annual migratory bird hunting regulations.

DEPARTMENT OF TRANSPORTATION

All Office of DOT--Amendments that postpone the compliance dates of regulations already in effect.

Coast Guard--Regatta regulations, safety zone regulations, and security zone regulations.

Coast Guard--Anchorage, drawbridge operations, and inland waterways navigation regulations.

Coast Guard--Regulations specifying amount of separation required between cargoes containing incompatible chemicals.

Federal Aviation Administration--Standard instrument approach procedure regulations, en route altitude regulations, routine air space actions, and airworthiness directives.

National Highway Traffic Safety Administration--Federal Motor Vehicle Safety Standard 109 table of tire sizes.

DEPARTMENT OF THE TREASURY

Internal Revenue Service, Bureau of Alcohol, Tobacco, and Firearms, and Customs Service--Revenue rulings and procedures, Customs decisions, legal determinations, and other similar ruling documents. Major legislative regulations are covered fully.

ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticides and Toxic Substances--Actions regarding pesticide tolerances, temporary tolerances, tolerance exemptions, and food additives regulations, except those that make an existing tolerance more stringent.

Office of Pesticides and Toxic Substances--Unconditional approvals of TSCA section 5 test marketing exemptions, and of experimental use permits under FIFRA.

Office of Pesticides and Toxic Substances--Decision documents defining and establishing registration standards; decision documents and termination decisions for the RPAR process; and data call-in requests made under section 3(c)(2)(B) of FIFRA.

Office of Air, Noise, and Radiation--Rules that unconditionally approve revisions to State Implementation Plans.

Office of Air, Noise, and Radiation--Unconditional approvals of equivalent methods for ambient air quality monitoring and of NSPS, NESHAPS, and PSD delegations to States; approvals of carbon monoxide and nitrogen oxide waivers; area designations of air quality planning purposes; and deletions from the NSPS source categories list.

Office of Water--Unconditional approvals of State Water Standards.

Office of Water--Unconditional approval of State underground injection control programs, delegations of NPDES authority to States; deletions from the 307(a) list of toxic pollutants; and suspension of Toxic Testing Requirements under NPDES.

Office of Solid Waste and Emergency Response--Unconditional approvals of State authorization under RCRA of State solid waste management plans and of hazardous waste delisting petitions under RCRA.

PENSION BENEFIT GUARANTY CORPORATION

Interest Rates--Changes in interest rates on later premium payments and delinquent employer liability payments under sections 6601 and 6621 of the Internal Revenue Code as amended by the Tax Equity and Fiscal Responsibility Act of 1982.