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September 20, 2001

MEMORANDUM FOR THE PRESIDENT'S MANAGEMENT COUNCIL

FROM: John D. Graham /s/
Administrator

SUBJECT: Presidential Review of Agency Rulemaking by OIRA

Federal regulations can provide cost-effective solutions to many problems. If not properly developed, regulations can lead to an enormous burden on the economy.

In this context, I call your attention to Executive Order No. 12866, "Regulatory Planning and Review." Under this Executive Order, the Administrator of the Office of Information and Regulatory Affairs (OIRA) carries out a regulatory review process on behalf of the President. The President's Chief of Staff, Andrew H. Card, Jr., has directed me to work with the agencies to implement vigorously the principles and procedures in E.O. 12866 until a modified or new Executive order is issued.

I want to stress that it is my goal to work with you to carry out OIRA's regulatory reviews thoroughly and cooperatively. To help us work together more effectively, I have attached a detailed description of how OIRA carries out this regulatory review, summarizing the principles we follow and the procedures we use. I request that you send this attachment to the appropriate officials in your agency that are responsible for regulatory development.

Working together to apply the regulatory principles in E.O. 12866, I believe we will strengthen the country's regulatory structure. I look forward to working with all of you and your staff.

Attachment

September 20, 2001

OMB REGULATORY REVIEW: PRINCIPLES AND PROCEDURES

This attachment describes the general principles and procedures that will be applied by OMB in the implementation of E.O. 12866 and related statutory and executive authority.

OIRA Review of Significant Regulations

E.O. 12866, "Regulatory Planning and Review,"⁽¹⁾ governs OIRA's oversight of agency rulemaking, requiring OIRA review of "significant" agency regulatory actions before they are proposed for public comment, and again before they are issued in final form. The Order defines "regulatory action" broadly to include all substantive action by an agency that is expected to lead to the issuance of a final rule. Over the past several years, OIRA staff have worked with agencies to develop a common understanding of what is meant by a "significant" regulatory action (see section 3(f)). While OIRA does not formally review non-significant regulatory actions, agencies are expected to ensure that they are consistent with the Order's regulatory principles (section 1).

Following agency transmittal to OIRA of a draft rule, OIRA reviews the draft rule for consistency with the regulatory principles stated in the Order, and with the President's policies and priorities. The review determines whether the

agency has, in deciding whether and how to regulate, assessed the costs and benefits of available regulatory alternatives (including the alternative of not regulating). Specifically, E.O. 12866 states that, "in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits... ." E.O. 12866 further states that, "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."

Regulatory Impact Analysis

Agencies must prepare a Regulatory Impact Analysis (RIA) for each regulation that OIRA or the agency designates as "economically significant." Section 3(f)(1) of the Order defines an "economically significant" rule as one likely to "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." This definition is functionally equivalent to the definition of a "major" rule as that term is used in the Congressional Review Act.⁽²⁾

The RIA must provide an assessment of benefits, costs, and potentially effective and reasonably feasible alternatives to the planned regulatory action (see section 6(a)(3)(C)). This is submitted to OIRA along with the applicable draft regulatory action. Preparing RIAs helps agencies evaluate the need for and consequences of possible Federal action. By analyzing alternate ways to structure a rule, agencies can select the best option while providing OIRA and the public a broader understanding of the ranges of issues that may be involved. Accordingly, it is important that a draft RIA be reviewed by agency economists, engineers, and scientists, as well as by agency attorneys, prior to submission to OIRA.

OIRA also relies on RIAs to meet its obligations (1) under the Congressional Review Act, which directs the OIRA Administrator to determine if final rules are "major"⁽³⁾ and (2) under another law,⁽⁴⁾ which requires the OMB Director to submit an annual report to Congress on the costs and benefits of Federal regulation.⁽⁵⁾ As a result, agency submissions to OIRA of economically significant rules shall include RIAs, regardless of the extent to which an agency is permitted by law to consider risks, costs, or benefits in issuing a regulation. RIAs should be prepared in a way consistent with OMB Memorandum M-00-08.⁽⁶⁾

Risk Assessments

OIRA's review also evaluates, on occasion in consultation with the Office of Science and Technology Policy, whether the agency has, in assessing exposure to a risk or environmental hazard, conducted an adequate risk assessment. The risk assessment should be an objective, realistic, and scientifically balanced analysis.

We note that in 1996 the Congress, for health decisions under the Safe Drinking Water Act, adopted a basic standard of quality for the use of science in agency decisionmaking. Congress directed an agency, "to the degree that an [a]gency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."⁽⁷⁾ We further note that, in 1996 the Congress adopted a basic quality standard for the dissemination of public information involving risk effects. Congress directed the agency, "to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable." Congress further directed the agency, "in a document made available to the public in support of a regulation [to] specify, to the extent practicable - (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data."⁽⁸⁾ OMB recommends that each agency consider adopting or adapting these basic Congressional standards for judging the quality of scientific information about risk it uses and disseminates.

Peer Review

For economically significant and major rulemakings, OMB recommends that agencies subject RIAs and supporting technical documents to independent, external peer review by qualified specialists. Given the growing public interest in peer review at agencies, OMB recommends that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner. OIRA will be giving a measure of deference to agency analysis that has been developed in conjunction with such peer review procedures.

Impact on State and Local Governments and Indian Tribal Governments

As part of OIRA's regulatory review, OIRA staff will ensure that regulatory clearance packages include, if applicable, the agency certification required by two Executive orders, E.O. 13132, "Federalism,"⁽⁹⁾ and E.O. 13175, "Consultation and Coordination with Indian Tribal Governments."⁽¹⁰⁾ As OMB Director Daniels has pledged to Congress, rulemaking proposals that were not subjected to adequate State and local consultation will be returned to agencies for reconsideration.

Impact on Energy Supply, Production, and Consumption

OIRA will also be reviewing agency "Statements of Energy Effects" and determining whether the agency should have submitted one with its regulatory clearance package. In order to ensure that agencies appropriately weigh and consider the effects of the Federal Government's regulations on the supply, distribution, and use of energy, E.O. 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,"⁽¹¹⁾ requires agencies to prepare and submit to OIRA a "Statement of Energy Effects" whenever they submit a significant energy action for OIRA review under E.O. 12866.

Impacts on Other Federal Agencies

An important aspect of OIRA's review of a draft rule is an evaluation of its possible impact on the programs of other Federal agencies. This evaluation often involves an interagency review by specialists from affected agencies and the coordination of agency positions, as necessary.

Impacts on Small Business

In particular, as in the past, OIRA often seeks the views of the Small Business Administration and the SBA Chief Counsel for Advocacy. We do this for two reasons. First, E.O. 12866 directs each agency to "tailor its regulations to impose the least burden on ... businesses of different sizes ..." (section 1(11)). Second, the Regulatory Flexibility Act⁽¹²⁾ sets forth the regulatory principle that Federal agencies endeavor, consistent with applicable statutes, to fit regulatory requirements to the scale of entities subject to the regulation, and designates the SBA Chief Counsel for Advocacy as the official responsible for overseeing agency compliance with that Act.

Clearance of Significant Regulatory Actions

In the course of OIRA's review of a draft regulatory action (and accompanying RIA and risk assessment, where applicable), the OIRA Desk Officer will work closely with agency staff. When OIRA has completed its review of a regulatory action, OIRA notifies the agency by telephone that it has concluded review. After receiving notification from OIRA that it has concluded review, the agency may issue the regulatory action.

In the case of a proposed rule, we encourage each agency to provide the public with at least 60 days to comment on proposals (section 6(a)(1)). In the case of a rule subject to statutory or judicial deadlines, OMB will not unilaterally delay publication beyond the deadline. In such cases, the agency must submit the rule to OIRA in a timely fashion, so as to provide a meaningful opportunity for Executive Office review. In cases where time frames are particularly tight due to a statutory or judicial deadline, agencies should consider submitting the draft rule to OIRA for preliminary review at the same time that it is being reviewed by senior agency policymakers.

Public Disclosure of OIRA Communications with Outside Parties

On occasion, parties outside the Executive branch will meet with the OIRA Administrator or his or her designee regarding a rule under review. OIRA will invite representatives of relevant agencies to such meetings and OIRA appreciates having agencies make senior regulatory policy officials available to attend such meetings. In addition, written materials received from those outside the Executive branch are retained for public inspection in OIRA's public docket room and forwarded to the rulemaking agency. It is the responsibility of each agency to place these in the rulemaking docket. These communications are disclosed to the public as described in E.O. 12866, section 6(b)(4).

The "Return" Letter

During the course of OIRA's review of a draft regulation, the Administrator may decide to send a letter to the agency that returns the rule for reconsideration. Such a return may occur if the quality of the agency's analyses is inadequate, if the regulatory standards adopted are not justified by the analyses, if the rule is not consistent with the regulatory principles stated in the Order or with the President's policies and priorities, or if the rule is not compatible with other Executive orders or statutes. As Director Daniels stated in an earlier memorandum, "if OMB determines that more substantial work is needed, OMB will return the draft rule to the agency for improved analysis."⁽¹³⁾ Since that memo was issued, OIRA has returned two agency draft rules, in both cases due to analytical problems.

It is important to understand that such a return does not necessarily imply that either OIRA or OMB is opposed to the draft rule. Rather, the return letter will explain why OIRA believes that the rulemaking would benefit from further consideration by the agency.

The "Prompt" Letter

The agencies prepare semi-annual regulatory agendas under E.O. 12866, section 4(b), outlining the agencies foreseeable regulatory priorities. OIRA plans to send, as occasion arises, what will be referred to as "prompt" letters. The purpose of a prompt letter is to suggest an issue that OMB believes is worthy of agency priority. Rather than being sent in response to the agency's submission of a draft rule for OIRA review, a "prompt" letter will be sent on OMB's initiative and will contain a suggestion for how the agency could improve its regulations. For example, the suggestion might be that an agency explore a promising regulatory issue for agency action, accelerate its efforts on an ongoing regulatory matter, or consider rescinding or modifying an existing rule. We will request prompt agency response to "prompt" letters, normally within 30 days.

OMB's Related Statutory and Executive Obligations

OIRA has related statutory and executive obligations that directly affect OIRA's responsibility to review agency regulatory actions under E.O. 12866.

- Under the Congressional Review Act,⁽¹⁴⁾ the OIRA Administrator determines if an agency final rule is "major" (in general, having an annual economic effect of over \$100,000,000), and thus subject to special provisions of that Act.⁽¹⁵⁾
- Under another law,⁽¹⁶⁾ the OMB Director must submit an annual report to Congress on the costs and benefits of Federal regulation; OIRA prepares that report, based largely on the regulatory impact analyses that agencies prepare in compliance with E.O. 12866.
- Under the Unfunded Mandates Reform Act,⁽¹⁷⁾ each agency must prepare a specific kind of benefit-cost analysis for any proposed and final rule "that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." When preparing such an analysis, the agency must also "identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule ...". OMB reports annually to Congress on agency compliance with these requirements.
- Under an appropriations rider,⁽¹⁸⁾ OMB is to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies. Under these OMB guidelines, agencies are to issue their own implementing guidelines that include administrative mechanisms allowing affected persons to seek and obtain correction of the information. This law affects the regulatory development process because Federal regulations may be based on the findings of scientific or other research studies disseminated by a Federal agency in the course of the rulemaking.
- Under the Paperwork Reduction Act,⁽¹⁹⁾ OIRA reviews and approves (or disapproves) each collection of information by a Federal agency. This includes information collections contained in agency regulations.

We are looking forward to working cooperatively with you and your staff to meet our respective statutory obligations and to move the President's programs forward.

If there are any questions concerning OIRA's regulatory review process, agency staff should contact the appropriate OIRA Desk Officer, the OIRA Deputy Administrator, Donald R. Arbuckle (395-5897), or the OIRA Administrator, John D. Graham (395-4852).

1. 58 Fed. Reg. 51735 (October 4, 1993).

2. 5 U.S.C. 804(2).

3. 5 U.S.C. 804(2).

4. Consolidated Appropriations Act of 2001 (H.R. 5658, section 624, P.L. 106-554).

5. See, OMB Memorandum M-00-08, "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements" (March 22, 2000).

6. See, OMB Memorandum M-01-23, "Improving Regulatory Impact Analyses" (June 19, 2001).
7. 42 U.S.C. 300g-1(b)(3)(A).
8. 42 U.S.C. 300g-1(b)(3)(B).
9. 64 Fed. Reg. 43255 (August 10, 1999). See, OMB Memorandum M-00-02, "Guidance for Implementing E.O. 13132, 'Federalism.' "
10. 65 Fed. Reg. 67249 (November 9, 2000). See, OMB Memorandum M-01-07, "Guidance for Implementing E.O. 13175, 'Consultation and Coordination with Indian Tribal Governments.' "
11. E.O. 13211 of May 18, 2001 (66 Fed. Reg. 28355 (May 22, 2001)). See, OMB Memorandum M-01-27, "Guidance for Implementing E.O. 13211" (July 13, 2001).
12. 5 U.S.C. chapter 6.
13. OMB Memorandum M-01-23, "Improving Regulatory Impact Analyses" (June 19, 2001).
14. 5 U.S.C. chapter 8.
15. See, OMB Memorandum M-99-13, "Guidance for Implementing the Congressional Review Act" (March 30, 1999).
16. The Consolidated Appropriations Act of 2001, H.R. 5658, section 624, P.L. 106-554.
17. P.L. 104-4, section 202 (March 22, 1995).
18. Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554).
19. 44 U.S.C. chapter 35.

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