OIRA Q&A's

OIRA's Review of Agency Regulations

1. What is OIRA?

Answer: "OIRA" is the Office of Information and Regulatory Affairs, which is a Federal office that Congress established in the 1980 Paperwork Reduction Act. OIRA is an office within the Office of Management and Budget, which is an agency within the Executive Office of the President. It is staffed by career civil servants, who have been carrying out the same kinds of economic analysis and related analyses for the past 20 years. In addition to reviewing draft regulations under Executive Order 12866, OIRA reviews collections of information under the Paperwork Reduction Act, and also develops and oversees the implementation of government-wide policies in the areas of information technology, information policy, privacy, and statistical policy.

2. What is the OIRA's role in the rulemaking process?

Answer: Executive Order 12866 describes OIRA's role in the rulemaking process. In it, the President directs agencies, to the extent permitted by law, to follow certain principles in rulemaking, such as consideration of alternatives and analysis of impacts, both benefits and costs. As the Executive Order directs, OIRA reviews agency draft regulations before publication to ensure agency compliance with this Executive Order.

3. How has the process of regulatory review changed under the Bush Administration?

Answer: It has not changed. Since 1993, OMB's Office of Information and Regulatory Affairs (OIRA) has operated under Presidential Executive Order 12866.

4. Who is the OIRA Administrator?

Answer: The OIRA Administrator is Dr. John Graham. Prior to joining OMB as OIRA Administrator, Dr. Graham was a tenured professor of policy and decision sciences at the Harvard School of Public Health. In addition, Dr. Graham founded the Harvard Center for Risk Analysis which he ran for over ten years. The Harvard Center for Risk Analysis received significant financial support from both the public and private sectors, disclosed this support publicly, operated with an independent scientific advisory committee, and published the majority of its studies in peer-reviewed journals.

5. Why is OIRA review needed?

Answer: The issuance of Presidential regulatory principles, and the centralized review of draft regulations, has been an accepted part of regulatory development for 30 years in one form or another. This began with President's's Nixon's "Quality of Life" program, and continued in the 1970s with President Ford's requirement in Executive Orders 11821 and 11949 for agencies to

prepare inflation/economic impact statements and with President Carter's Executive Order 12044 on "Improving Government Regulations." The OMB review process became more formalized in 1981 with President Reagan's Executive Order 12291, which was in effect from 1981 to September 1993 (the Reagan and Bush Administrations and the first nine months of the Clinton Administration). In September 1993, President Clinton issued Executive Order 12866, which retained the OMB review process in essentially the same form, and the Executive Order 12866 process remains in effect today. The review process ensures that agencies, to the extent permitted by law, comply with the regulatory principles stated in Executive Order 12866 and that the President's policies are reflected in agency rules. It also serves to ensure adequate interagency review of draft rules, so that agencies coordinate their rules with other agencies to avoid inconsistent, incompatible, or duplicative policies.

6. How long can OIRA take to review a draft regulation?

Answer: The period for OIRA review is limited by the Executive Order to 90 days. Under the Executive Order, the review period may be extended by the head of the rulemaking agency, and the OMB Director may extend the review period on a one-time basis for no more than 30 days. The average review time for the 700 rules submitted to OMB during 2001 was 58 days.

7. What does it mean when OIRA "returns" an agency rule?

Answer: In some cases, when OMB believes that an agency rule is not consistent with the principles set forth in Executive Order 12866, OIRA "returns" the rule to the agency for further review. "Returning" a rule means that OIRA has concluded that the draft is not consistent with the principles of Executive Order 12866 and that further agency effort is needed before the agency may publish the rule. For example, the agency may have provided inadequate analysis regarding alternatives. In such cases, agencies may, and frequently do, conduct further work on the draft and resubmit it for OMB consideration.

8. What is a "prompt" letter?

Answer: "Prompt" letters are a new mechanism designed to put OIRA in the pro-active role of suggesting issues that agencies might address. So far, OIRA has issued 4 prompt letters: to the Department of Health and Human Services concerning Trans Fatty Acid (TFA); to the Department of Labor concerning Automatic External Defibrillators (AEDs); to the National Highway Traffic Safety Administration (NHTSA) concerning frontal crash protection; and to the Environmental Protection Agency concerning Particulate Matter research. Prompt letters may suggest areas where further regulation may be needed to fill gaps in current environmental, health or safety protections; or they could be used to suggest areas where a current regulation is no longer needed and should be modified or rescinded.

OIRA and its Relationship with Outside Parties

9. Does OIRA talk to or meet with particular interest groups?

Answer: OIRA's policy is to meet with any party interested in discussing regulatory issues, whether they are from State or local governments, small business or other business or industry interests, or from the environmental, health or safety communities. Under OIRA procedures, as set forth in Executive Order 12866, all such meetings concerning regulations under review must be conducted by the OIRA Administrator or a specific designee, and a log, available on OIRA's website, is kept of such meetings.

10. What are OIRA's disclosure procedures?

Answer: In OIRA's public docket room and on its website [www.whitehouse.gov/omb/inforeg/regpol] OIRA provides extensive information about its work. This includes reports, "return" and "prompt" letters, speeches and testimony by the OIRA Administrator, and lists and statistics regarding regulatory review. For example, OIRA makes publicly available all substantive communications with any party outside the Executive Branch concerning regulations under review. If the OIRA Administrator or his designee meets with outside parties regarding a rule under review, the subject, date, and participants of the meeting are disclosed on the OIRA website. Any material received from outside parties on rules under review is placed in the public docket and noted on the OIRA website. Finally, after a rule is published, OIRA will make publicly available documents exchanged between OIRA and the rulemaking agency regarding rules that had been submitted for review.

11. How can outside parties best make their ideas known to OIRA?

Answer: Outside parties can, and are encouraged to, provide written comments to the OIRA Administrator on a rule that is under review or may soon be under review. Those parties may also request a meeting with the Administrator.

12. What is the best way to communicate with OIRA?

Answer: The best way to communicate with OIRA is by fax at (202) 395-3047. We are still experiencing delays in the regular mail due to the events of September 11th. Any thoughts you may wish to convey to us regarding regulatory affairs would be appreciated, as well as any comments on our web site.

Peer Review and Science in Regulation

13. What is the role of "peer review" in agency rulemaking?

Answer: OMB has recommended that agencies sponsor scientific peer reviews of their work using objective independent experts. The purpose of peer review is to provide an expert review

of the use of science that is free from the biases of the regulators and the interested parties. OMB has suggested that agencies use the following criteria in conducting peer review: (1) select peer reviewers primarily on the basis of necessary technical expertise, (2) ask peer reviewers to disclose to agencies, before a panel is formed, any prior technical/policy positions on relevant issues; (3) ask peer reviewers to disclose to agencies, before a panel is formed, their personal and institutional sources of revenue (private and public sector) that may create a real or perceived conflict of interest; and (4) require that the work of peer review panels be conducted in an open and rigorous manner. These criteria should ensure that peer reviewers are unbiased, objective, and do not reflect any particular ideological position.

Although agencies are not required to conduct peer review, OMB has offered to review draft agency rules under a more deferential standard if agencies have subjected their technical analyses

to independent peer review prior to submission to OIRA. The peer review process will assist the agency in ensuring that the information relied on is accurate, reliable, and unbiased in substance and presentation. The peer review process will assist OMB in conducting reviews more quickly.

Regulation and Benefit-Cost Analysis

14. Why does OIRA place so much emphasis on benefit-cost analysis, and what is its purpose in rulemaking?

Answer: As one of its regulatory principles, Executive Order 12866 states that agencies in developing a regulation "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." In addition, statutes such as the Regulatory Flexibility Act and the Unfunded Mandates Reform Act require agencies to evaluate the costs and benefits of covered rulemakings. Benefit-cost analysis is a widely used tool to help inform government decisions. It was first used during the 1930s to guide flood control efforts, the 1960s for defense planning and budgeting, and the 1970s for regulatory review. Benefit cost analysis is a framework to help decision makers keep their thinking straight and transparent. It systematically organizes the impacts of policy proposals, forces explicit assignment of values to the impacts, and forces judgements into the open.

OIRA List of 23 Regulations to be Reformed

15. OIRA's 2001 Benefit/Cost Report identifies 23 regulations for review. What does the list mean?

Answer: In its annual benefit cost report, OIRA is required by statute to make "recommendations for reform" of regulations. In response to this requirement, OIRA requested in its draft Benefit/Cost Report published in the spring of 2001, suggestions from the public on rules that

agencies should review

to assess the need for reform. 33 comments were received containing 71 specific suggestions for reform. 23 were rated by OIRA as Tier I, meaning that they were worthy of further review by the agencies. Agencies are now well along in the process of this review.

16. Who were the commentors on OIRA's 2001 Benefit/Cost Report?

Answer: We received 33 comments from our notice in the Federal Register asking for comments on this draft report and suggestions for reform. Those who commented represented a wide variety of groups, including individuals, a Member of Congress, universities, think tanks, corporations, Federal agencies, local governments, trade associations, and public interest groups. OMB is required by statute to include in the report suggestions for reform of regulations. A summary of the 71 specific suggestions for reform and who made the suggestion is in the report. All 33 comments are available for public inspection and copying in OIRA's docket library.

OMB's Data Quality Guidelines

17. What are OMB's new Data Quality Guidelines?

Answer: In the fall of 2000, Congress by statute directed OMB to issue government-wide Data Quality Guidelines by September 30, 2001. [PL. 106-554; H.R. 5658, Section 515.] After OMB issued proposed guidelines for public comment, OMB's Data Quality Guidelines were published in the Federal Register on September 28, 2001. After seeking another round of public comment on one issue, OMB's slightly-revised Guidelines were published on January 3, 2002. The purpose of the Guidelines is to improve the "quality, objectivity, utility and integrity of information . . . disseminated by Federal agencies." Based on OMB's guidelines, agencies are now developing their own implementing guidelines. Under the statute, such agency guidelines are to be issued by October 1, 2002.

In accordance with the statute, OMB's new data-quality guidelines require an administrative appeal process that is available to all members of the affected public, so that affected parties may seek and obtain correction of information disseminated by an agency that does not comply with the OMB or agency guidelines. Review of the appeal rests with the agency, not OMB. OMB anticipates that under the guidelines the quality of Federal information will improve and that the guidelines will not lead to undue or unnecessary delays.

Information Clearance Process:

18. What is OIRA's role in the review and approval of agency information collections?

Answer: The Paperwork Reduction Act (PRA) requires OMB to review and assign a control number to all agency collections of information. Agencies submit clearance requests to OIRA; OIRA then evaluates them under the standards of the Paperwork Reduction Act, clearing them if they comply and assigning a control number. OIRA conducts about 3000 of these reviews each

year.

19. What is the role of the agency's Chief Information Officer?

Answer: The position of Chief Information Officer (CIO) was established in the 1996 Clinger-Cohen Act to create a single agency official responsible for a variety of information related activities. In addition to overseeing the agency's compliance with the Paperwork Reduction Act's information collection requirements, the CIO's duties include information technology and its associated capital planning, enterprise architecture, computer security, and IT workforce issues.

20. What categories of information collection does OIRA review under the Paperwork Reduction Act?

Answer: The definition of "information" in the PRA is very broad. Thus, OIRA reviews forms (e.g., the IRS 1040), surveys (e.g., the Census), reporting and recordkeeping requirements (e.g., requirements on business to report workplace safety information to OSHA or air quality monitoring data to EPA) and third party disclosures (e.g., the nutrition labeling requirements of food).

21. What criteria does OIRA use to decide whether or not to approve an agency's collection of information?

Answer: The PRA requires that agency information collections minimize burden and duplication, have practical utility, and support the proper performance of the agency's mission. OIRA is obligated by law to use the paperwork clearance process and the criteria established by the Paperwork Reduction Act to review and approve or disapprove of an agency's collection of information.

22. What is the effect of OIRA disapproving an agency's collection of information?

Answer: If OIRA disapproves an information collection, the Paperwork Reduction Act states that the agency may not engage in the collection and that "no person shall be subject to any penalty for failing to comply" with the information collection.

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