Office of Information and Regulatory Affairs (OIRA) Q&A's

1. What is the Office of Information and Regulatory Affairs?

Answer: The Office of Information and Regulatory Affairs (OIRA) is a Federal office that Congress established in the 1980 Paperwork Reduction Act. It is part of the Office of Management and Budget, which is an agency within the Executive Office of the President. In addition to reviewing collections of information under the Paperwork Reduction Act, OIRA reviews draft regulations under Executive Order 12866 and develops and oversees the implementation of government-wide policies in the areas of information technology, information policy, privacy, and statistical policy. OIRA also oversees agency implementation of the Information Quality Law, including the peer review practices of agencies.

2. Who is the OIRA Administrator?

Answer: OIRA's Administrator is Susan E. Dudley

OIRA's Review of Agency Regulations

3. 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. These principles include consideration of alternatives to the rulemaking and analysis of the rule's effects on society, both its benefits and costs. As the Executive Order directs, OIRA reviews agency draft regulations before publication to ensure agency compliance with this Executive Order. OIRA's review process is described in much greater detail in the GAO report titled "OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews." You can find this report at: http://www.gao.gov. OIRA completes about 500 regulatory reviews each year.

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

Answer: The formal process by which OIRA reviews agencies' rules has been unchanged since Presidential Executive Order 12866 was issued in 1993. However, there have been several changes in OIRA's policies under the Bush Administration, including increased use of public letters explaining why rules were returned to agencies, new use of public letters prompting the development of rules, increased emphasis on economic analysis, stricter adherence to the 90-day time limit for OIRA review, and improvements in the transparency of the OIRA review process.

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 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. 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. There is no minimum period for review. 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 712 rules submitted to OMB during 2003 was 53 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 consideration. "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 mechanism created in 2001 that OIRA uses to pro-actively suggest issues that agencies might address. 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. To date, OIRA has issued 12 prompt letters on subjects ranging from the transfat content of foods to pollution from diesel engines. You can find the various prompt letters issued from OIRA at: http://www.reginfo.gov/public/jsp/EO/promptLetters.jsp.

9. Does OIRA provide summary information on the costs and benefits of major Federal rules?

Answer: Yes. You can find OIRA's annual report to Congress on the costs and benefits of Federal rules at: http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

OIRA and its Relationship with Parties outside the Executive Branch

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

Answer: OIRA's policy is to meet with any party interested in discussing 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, if such meetings concern regulations under review, they must be conducted by the OIRA Administrator or a specific designee, and a log, available on OIRA's website, is kept of such meetings.

11. What are OIRA's disclosure procedures?

Answer: Consistent with E.O. 12866, OIRA provides extensive information about its work related to regulatory review in OIRA's public docket room and on its website [www.whitehouse.gov/omb/inforeg/regpol]. The information 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 certain documents exchanged between OIRA and the rulemaking agency during the review period.

12. How can outside parties best make their ideas about rules under review known to OIRA?

Answer: Outside parties may 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.

13. 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 serious delays in the regular and overnight mail due to the procedures instituted to strengthen security. Any thoughts you may wish to convey to us would be appreciated.

Regulation and Benefit-Cost Analysis

14. Why does OIRA place so much emphasis on regulatory 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.

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects - good and bad - of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

15. Does OIRA provide technical guidance to agencies on how to do good regulatory analysis?

Answer: Yes. OMB has long provided guidance on regulatory analysis. The latest such guidance is OMB's Circular No. A-4, Guidelines for the Conduct of Regulatory Analysis, which we released in September 2003. These guidelines became fully effective for economically significant rules - generally, rules that have an annual effect on the economy of $100 million of more - on January 1, 2005. OMB developed the guidelines in collaboration with the President's Council of Economic Advisors, and revised the proposed guidelines based on public comments, peer review, and interagency review.

OIRA's Solicitations of Regulatory Reform Nominations

16. Why has OIRA solicited reform nominations for current regulations?

Answer: The Regulatory Right to Know Act requires OIRA to make "recommendations for reform" of regulations in its annual Benefit/Cost Report. 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. To date, OIRA has requested reforms in 3 of the previous 4 years; our latest effort in the 2004 draft Report to Congress was a solicitation of regulatory reform relevant to the manufacturing sector.

17. What is the status of OIRA's reform solicitations?

Answer: We reported on the status of the 2001, 2002, and 2004 nominations in detail in our 2004 Final Report to Congress.

In 2001, OMB received 71 suggestions for regulatory reform from 33 commenters. Of these, 23 agency actions were rated as "high priority" reviews. We estimate that action has been taken on about 75% of these high priority items.

In 2002, OMB received 316 suggestions for reform of regulations, guidance documents, and paperwork requirements from approximately 1,700 commenters. Many of these reforms are the subject of current rulemakings.

In 2004, OMB received 189 suggestions for reform of regulations, guidance documents, and paperwork requirements relevant to the manufacturing sector from 41 commenters. Federal agencies and OMB have determined that 76 of these 189 nominations have potential merit and justify further action. Future actions on these reform nominations range from performing a priority investigation and reporting to OMB in order to determine appropriate next steps, to issuing modernized regulations.

18. How does OIRA evaluate reform nominations?

Answer: OIRA and OMB work closely with the various agencies when deciding to go forward with particular regulatory reforms. We also work closely with the Office of Advocacy in the Small Business Administration and, in the case of the 2004 manufacturing reform nominations, the Department of Commerce's Office of the Assistant Secretary for Manufacturing and Services. The criteria by which the agencies reviewed the nominations were similar to the case we asked the commenters to make; for example, did the agency believe that a benefit-cost case could be made for the regulatory reform. Of course, OMB and the agencies also had to take into consideration agency resources and competing priorities. Most reforms must be adopted through a process that entails opportunity for public participation, such as notice and comment rulemaking, and thus will be subject to the same regulatory analysis requirements under Executive Order 12866 that apply to any new regulatory program.

Information Quality Guidelines and Peer Review Bulletin

19. What are Information Quality Guidelines?

Answer: The "Information Quality Act" is the informal name given to PL. 106-554; H.R. 5658, Section 515, through which Congress directed OMB to issue government-wide information quality guidelines by September 30, 2001. OMB's guidelines, published in the Federal Register on February 22, 2002, after extensive public comment, can be found at http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf.

On October 1, 2002, agency specific information quality guidelines became effective to ensure the "quality, objectivity, utility, and integrity" of all information disseminated by Federal agencies. Under both the agency and government-wide OMB guidelines, Federal agencies are taking appropriate steps to incorporate the information quality performance standards into agency information dissemination practices, and developing pre-dissemination review procedures to substantiate the quality of information before it is disseminated. Under the agency information quality guidelines, "affected persons" can request that the agencies correct information if they believe that scientific, technical, economic, statistical or other information disseminated does not meet the agency and OMB standards. If the requestor is dissatisfied with the initial agency response to a correction request, an appeal opportunity is provided by the agencies.

20. If a person wants to seek a correction in agency information, what should they do?

Answer: Each agency has their own information quality guidelines that lay out the procedures that should be followed for submitting an information quality correction request to that particular agency. This includes information on where to send the request and what types of information to include in the request. For more information, a person should look at the guidelines for the agency responsible for disseminating the information. Links to agencies' information quality guidelines can be found at: http://www.whitehouse.gov/omb/inforeg/agency_info_quality_links.html.

21. What is the role of peer review?

Answer: Peer review is an important procedure used by the scientific community to ensure the quality of information prior to publication. It involves critical review of a draft report by qualified scientists not involved in developing the report. Peer review includes an exchange of judgments about the appropriateness of methods and the strength of the author's inferences. The "Information Quality Bulletin for Peer Review," issued on December 16, 2004, establishes government-wide guidance aimed at enhancing the practice of peer review of government science. OMB believes that pre-dissemination peer review can strengthen the quality and credibility of government produced information. Influential scientific information that forms the basis of agency regulations (including the data and model used in regulatory impact assessments) is subject to the Information Quality Bulletin for Peer Review. OMB's Bulletin for Peer Review is one

aspect of a larger OMB effort to improve the quality of information upon which public policies are based.

Information Clearance Process

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

Answer: The Paperwork Reduction Act (PRA) requires agencies to submit approval requests for information collections to OIRA; OIRA then evaluates them under the standards of the Paperwork Reduction Act, approving them if they comply and assigning a control number. OIRA conducts about 3000 of these reviews each year.

23. 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.

24. What kinds of information 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).

25. 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, provide useful information, 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.

26. 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.

27. Does OIRA evaluate agency performance in minimizing paperwork burdens?

Answer: The Paperwork Reduction Act requires the Director of the Office of Management and Budget to report to Congress on Federal activities under the Act, based upon the performance results reported by agencies. The Information Collection Budget (ICB) is OMB's annual report in compliance with our responsibilities under the Act. The report covers government progress in making information collection more efficient and effective and reducing information collection burden on the public. You can find this annual report at: http://www.whitehouse.gov/omb/inforeg/infocoll.html.

OIRA Staffing

28. How large is OIRA's staff?

Answer: OIRA has more than 50 full-time professionals who work with agency professionals on specific issues and decisions.

29. Since OIRA-OMB is part of the Executive Office of the President, does that mean that OIRA employees are political appointees of the President?

Answer: No. The vast majority of OIRA employees are career public servants.

30. What types of training do OIRA staff typically possess?

Answer: Historically, OIRA staff have had graduate training in economics, policy analysis, statistics and information technology. Due to the growth of science-based regulation and information-quality concerns, OIRA has recently added new staffing with expertise in public health, toxicology, epidemiology, engineering, and other technical fields.

31. If a person is interested in working at OIRA, either as an intern or as a full-time employee, who should they contact?

Answer: Persons interested in employment at OIRA should send a resume and cover letter to Lisa Jones, Room 10201, 725 17th Street NW, Washington, DC 20503.