



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

THE DIRECTOR

April 25, 2007

M-07-13

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

FROM:

Rob Portman

A handwritten signature in blue ink that reads "Rob Portman".

SUBJECT:

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

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

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

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

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

Attachment



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

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

April 25, 2007

MEMORANDUM FOR REGULATORY POLICY OFFICERS

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

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

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

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

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

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

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

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

Attachment

A. General Information	1
1. When do Executive Order 13422 and the Agency Good Guidance Practices Bulletin take effect?	1
2. What agencies are covered by the Executive Order and the Bulletin?	1
B. Guidance Questions -- Applicable to <u>Both the Bulletin and the Executive Order</u>	1
3. What types of guidance documents are covered by the Bulletin and by the Executive Order?	1
4. What types of guidance documents are not covered by the Bulletin and by the Executive Order?	2
5. What is a “significant” guidance document?	2
6. What is an “economically significant” guidance document and how is it related to a “significant” guidance document?	2
7. Does either the Executive Order or the Bulletin require agencies to prepare a benefit-cost analysis for guidance documents as agencies are required to do for regulations?	3
C. Guidance Questions -- Applicable to Requirements specific <u>to the Bulletin</u>	3
8. Under the Bulletin, what are the requirements for the content of “significant” guidance documents?	3
9. Under the Bulletin, what information are agencies required to post on their Web sites?.....	4
10. Can a subcomponent of an agency establish a separate Web site listing guidance documents and/or designate more than one office to receive and address complaints from the public on the guidance documents?	4
11. What requirements does the Bulletin establish -- for public comments and for Agency responses to those comments -- for “economically significant” guidance documents?	5
12. What requirements does the Bulletin establish -- for public comments and for Agency responses to those comments -- for “significant” guidance documents? ..	5
13. Should agencies use Regulations.gov to process public comments for guidance documents?	6
14. Under the Bulletin, what should an agency do if it believes that it would not be feasible or appropriate for the agency to provide the public with advance notice of, and an opportunity to comment on, an economically significant guidance document before the agency issues the guidance in final form?	6
15. Under the Bulletin, what should an agency do if it needs to issue a significant guidance document to address an emergency situation?	6
16. What are the timelines for meeting the requirements of the Bulletin?	6

D. Guidance Questions – Applicable to Requirements specific to the Executive Order...	7
17. Under the Executive Order, what is an agency required to do when it wants to issue a “significant” guidance document?	7
18. Under the Executive Order, how should an agency provide advance notification to OIRA of a significant guidance document?.....	8
19. What is the next step when the OIRA Administrator determines that additional consultation under the Executive Order is warranted?	8
20. How will the OIRA Administrator determine which significant guidance documents are exempt from review under the Executive Order?.....	9
21. What is the time period for consultation with OIRA on significant guidance documents under the Executive Order?	9
22. What should an agency do, under the Executive Order, if the agency needs to issue a significant guidance document to address an emergency situation?.....	9
23. How were the Regulatory Principles of Executive Order 12866 amended to apply to guidance documents?.....	9
E. Non-Guidance provisions in Executive Order 13422	10
24. When does an agency head need to designate its Regulatory Policy Officer?	10
25. What changes does the Executive Order make to the appointment of the Regulatory Policy Officer?	10
26. Can the agency head designate as the Regulatory Policy Officer an agency employee who serves in a position for which the agency head (not the President) is the appointing official?.....	10
27. If there is a vacancy in the Presidentially-appointed position that the agency head has designated as the Regulatory Policy Officer, may the person who is serving in an “acting” capacity in that position be the Regulatory Policy Officer?	11
28. Are independent regulatory agencies required to designate a Presidential appointee as a Regulatory Policy Officer?.....	11
29. Will the Regulatory Policy Officers continue to report to their agency heads, as they did under Executive Order 12866 prior to its recent amendment?	11
30. Does the agency need to establish a Regulatory Policy Office, in addition to the agency head designating a Regulatory Policy Officer?	11
31. What changes does the Executive Order make to the responsibilities of the Regulatory Policy Officer?	11
32. When does a rulemaking “commence” for the purpose of meeting the new requirement for the Regulatory Policy Officer's (or the agency head's) authorization of the agency's "commencement of a rulemaking"?	12
33. What are the new requirements for the Regulatory Plan?	12
34. Do the revisions to the Principles of Regulation, specifically those in Section 1(b)(1) related to “market failure,” require agencies to provide more or different information to OIRA when submitting a regulation for review?.....	12
35. Does the Executive Order require an agency to consider the use of formal rulemaking?.....	13

A. General Information

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

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

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

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

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

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

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

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

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

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

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

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

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

5. What is a “significant” guidance document?

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

- (1) lead to an annual effect of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) materially alter the budgetary impacts of entitlements, grants, user fees or loan programs or the rights or obligations of recipients thereof; or
- (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

No later than July 24, 2007, agencies must:

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

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

No later than August 23, 2007, agencies must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

E. Non-Guidance provisions in Executive Order 13422

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

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

Independent agencies are encouraged to appoint a Regulatory Policy Officer.

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

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

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

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

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

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

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

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

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

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

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

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

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

Under the Executive Order, the Regulatory Policy Officer must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* * * *

Further Questions

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

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