

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

WILLIAM L. KOVACS
VICE PRESIDENT
ENVIRONMENT, TECHNOLOGY &
REGULATORY AFFAIRS

1615 H STREET, N.W.
WASHINGTON, D.C. 20062
(202) 463-5457

December 22, 2005

Mr. Paul Noe
Counselor
Office of Information and Regulatory Affairs
Office of Management and Budget
727 17th Street, NW
New Executive Office Building
Washington, DC 20503

Re: Comments on OMB's *Proposed Bulletin for Good Guidance Practices*

Dear Mr. Noe:

The U.S. Chamber of Commerce, the world's largest business federation representing more than three million businesses of every size, sector, and region is pleased to provide the following comments on the Office of Management and Budget's (OMB) *Proposed Bulletin for Good Guidance Practices* (Bulletin).¹

Introduction

The U.S. Chamber applauds OMB's efforts to develop a comprehensive policy for federal agencies concerning the development and use of guidance documents. Federal agencies issue thousands of guidance documents that provide the public and regulated community with the agencies' interpretation of key policy and technical issues. As was documented by the House of Representative's Committee on Government Reform,² agencies publish thousands of guidance documents each year, many of which are implemented as if they were agency rules having the full force and effect of law.

¹ Office of Management and Budget, *Proposed Bulletin for Good Guidance Practices*, available online at: http://www.whitehouse.gov/omb/inforeg/regpol/good_guidance_preamble.pdf, accessed December 8, 2005.

² House Report "Non-Binding Legal Effect of Agency Guidance Documents," Seventh Report by the Committee on Government Reform together with Minority and Additional Views (October 26, 2000).

An example of a guidance document masquerading as a rule would be the U.S. Environmental Protection Agency's (EPA) Environmental Justice guidelines ("Interim Guidance for Investigating Title IV Administrative Complaints Challenging Permits"), which was issued by EPA in February, 1998. In light of the legal and policy ramifications of this document, the House Government Reform Subcommittee asked the General Accounting Office (GAO) to determine if the guidance document was actually a rule. In a January 20, 1999, letter to the subcommittee the GAO confirmed that the guidance document was indeed a rule and should have gone through the formal notice and comment period of a rulemaking.³

Likewise, some agency records of decision, as well as internal memoranda, establish precedent for regulatory policy making that at times extend the regulatory reach of federal agencies far beyond the statutorily mandated powers given by Congress. A recent example of a record of decision with regulatory impact would be the EPA's decision to regulate prions.⁴

Prions are protein structures which, when infectious, are suspected of causing transmissible spongiform encephalopathy diseases, such as mad cow disease in cattle.⁵ EPA's decision to classify prions as "pests" under FIFRA stems from an internal agency memorandum asserting jurisdiction over prions,⁶ even though prions are not living things (a pre-requisite for EPA jurisdiction under FIFRA).⁷ Moreover, acting under the authority granted to itself in this memorandum, EPA issued emergency exemptions to several states to authorize the use of pesticides not registered under FIFRA to treat prion-infected surfaces. Therefore, EPA is treating this memorandum as though it is the issuance of a rule, without providing notice to the public or the opportunity to comment on the agency's interpretation of its authoritative scope.⁸ The U.S. Chamber specifically requested EPA publish its prior discussion in the *Federal Register* for notice and comment, but EPA did not respond to that request.

³ Letter from Robert P. Murphy, General Counsel, General Accounting Office, to The Honorable David M. McIntosh, U.S. House of Representatives, January 20, 1999.

⁴ S.B. Hazen, Memorandum "Consideration of Prions as a Pest under FIFRA" to the Record, April 29, 2004; accessed at: http://www.epa.gov/oppad001/records_of_decision_on_prions.pdf.

⁵ See definition of prion at <http://en.wikipedia.org/wiki/Prion>.

⁶ Memorandum from Susan B. Hazen, Principle Deputy Assistant Administrator, to the record, dated April 29, 2004. The memorandum is available on EPA's Web site at: http://www.epa.gov/oppad001/records_of_decision_on_prions.pdf.

⁷ 7 U.S.C. 136(t).

⁸ The Administrative Procedure Act defines a "rule" as ... *an agency statement of general or particular applicability and future effect designed to implement, interpret, or proscribe law or policy*...5 U.S.C. 551(4).

The U.S. Chamber believes that the Bulletin is a first step in addressing agency overreach. Moreover, the U.S. Chamber believes that every “significant guidance document,” as defined by the Bulletin, is actually a regulation and should be subject to notice and comment. Significant guidance documents include those that will have an anticipated impact of \$100 million or more on the regulated community. Setting aside for now the difficulties inherent in determining when a guidance document will have an annual effect of \$100 million—or indeed whether guidance can have **any** economic effect as it is non-binding—the U.S. Chamber believes that any guidance document with an actual economic impact would inherently constitute a regulation and, as such, must be subject to the formal procedural requirement of a rulemaking.

OMB’s proposed Bulletin is a good first step in correcting this long-standing misuse of guidance documents. For many years now the regulated community has pushed for some form of control over agencies’ unauthorized and runaway lawmaking. The Bulletin attempts to establish, for the first time, a bright-line test to distinguish between what constitutes a regulation that is subject to notice and comment rulemaking, which has the force and effect of law, and a guidance document that is merely an agency interpretation of regulatory policy or a technical matter, and does not have the force and effect of law.

The U.S. Chamber suggests several amendments to the Bulletin that would clarify OMB’s policy, help to achieve agency implementation of OMB’s policy, and better inform the public. The amendments are:

- Amendment 1: Clarify the definition of “guidance document”
- Amendment 2: Publish a list of all guidance documents on the Internet
- Amendment 3: Apply the proposed Bulletin to all existing guidance documents⁹
- Amendment 4: Provide an opportunity for administrative remedy

Amendment 1: Clarify the Definition of “Guidance Document”

OMB’s proposed Bulletin defines the term “guidance document” as one “prepared by an agency and available to the public,” which describes an agency’s “interpretation of or policy on a regulatory or technical issue.”

⁹ Those guidance documents that are currently in force and have effects on the regulated community.

Despite this relatively straightforward definition, there is still room for uncertainty and continued agency abuse. For example, agency documents that interpret policy or technical issues, but are not specifically labeled as guidance or made available to the public will not be covered by this Bulletin. Agencies will have an incentive to label a substantially greater number of documents as “internal” or “memorandum” in order to avoid the requirements of this Bulletin and thereby circumvent public scrutiny.

A more straightforward and transparent approach would be to simply state that any agency policy that is not a rule is, in fact, a guidance document if it is used by the agency as part of its efforts to manage the regulatory process. This approach would include documents that are used by agency staff to interpret regulatory policy or technical issues, or for use in the formulation of policy. That way, anything that directly provides agency interpretation of, or policy on, a regulatory or technical issue will properly fall into the category of a nonbinding guidance document. This does away with any false categorical distinctions and helps draw a bright-line between regulations and guidance documents.

Amendment 2: Publish all Guidance Documents on the Internet

The proposed Bulletin draws a distinction between three types of guidance documents: (1) guidance documents; (2) significant guidance documents; and (3) economically significant guidance documents. Each term is defined differently, with separate attending procedures about how they are made available to the public.

For example, the proposed Bulletin directs agencies to ensure that all “guidance documents” are made publicly available. This simply means that the documents must be available to the public upon request. Because of the sheer number of guidance documents and the difficulty in locating them, merely making them publicly available is not sufficient to inform the public of an agency interpretation.

“Significant guidance documents,” a subset of the first category, are not only to be made available to the public, but must also be published on an agency’s Web site. The public can submit comments through the agency Web site, but the agency is not required to consider or respond to those comments. This is a reasonable process.

Finally, there are “economically significant guidance documents.” This is the only category of guidance document that requires public notice in the *Federal Register* for draft and final documents and that mandates an agency response to any public comments. The U.S. Chamber suggests that because these guidance documents impose costs and liabilities on the regulated community, they are not guidance documents but rules and therefore need to be subject to notice and comment.

Rather than creating artificial and unnecessary distinctions between specific categories of guidance documents, and in order to make good guidance practices more transparent, consistent, and accountable, the U.S Chamber believes that a full listing of **all** guidance documents should be published on an agency’s Web site and be made available for comment. While the agency need not be required to respond to all comments, it would be the only way to assure that the public will have a voice in the regulatory process.

Amendment 3: Apply Proposed Bulletin to all Existing Guidance Documents

Federal agencies have issued thousands of guidance documents, many of which are still in full force and effect and continue to provide direction to the regulated community. Therefore, in order to make the proposed Bulletin more effective OMB should ensure that the Bulletin applies to all guidance documents in use on the effective date of the Bulletin.¹⁰

To this end, OMB will have to require agencies to ensure that all guidance documents in effect on the effective date of the Bulletin comply with the procedures set forth in §II (2) of the proposed Bulletin. This means, among other things, including the term “guidance” or its functional equivalent on every significant guidance document, and, more importantly, removing all binding language—words such as “shall,” “must,” “required,” or “requirement”—from the documents so that the public knows they are simply nonbinding interpretations to assist with regulatory compliance.

¹⁰ A comprehensive list of all guidance documents currently in effect was compiled in FY2000 and made part of the House Report referenced in footnote 2. It would simply need to be updated by the agencies from the year 2000.

Amendment 4: Provide an Administrative Remedy

OMB's proposed Bulletin does not provide for an enforcement mechanism by which regulated entities can challenge agency decisions regarding what is or is not a guidance document, whether or not a guidance document is significant, or whether a guidance document is actually operating as a rule. Leaving such decisions to the agency's discretion would be a mistake, particularly since they have done such a poor job to date of distinguishing between guidance documents and rules. Moreover, by failing to include some type of enforcement mechanism, OMB has effectively excluded the regulated community from participating in the regulatory process and left it with no recourse to challenge agency decisions.

The U.S. Chamber believes that, at the very least, the proposed Bulletin should include an administrative process whereby the public can petition an agency if the public disagrees with a specific agency decision to classify a document as a guidance document. This will help to ensure that the public has a voice in the regulatory process, that the agency will carefully consider its actions, and that poor decisions can be identified and perhaps corrected.

Conclusion

The U.S. Chamber strongly recommends that OMB consider amending its proposed Bulletin to incorporate the four suggestions set forth above in order to effectively address agency misuse of guidance documents.

Again, the U.S. Chamber applauds OMB's efforts to develop agencywide policy regarding the issuance and use of guidance documents and appreciates the opportunity to comment on the proposed Bulletin. The U.S. Chamber considers an open and transparent regulatory process to be a fundamental obligation of all federal agencies.

Please feel free to contact me if you have any questions or require additional information.

Sincerely,



William L. Kovacs