

January 9, 2006

Lisa Jones
Office of Information & Regulatory Affairs
Office of Management & Budget
725 17th Street, N.W.
New Executive Office Bldg., Room 9013
Washington, D.C. 20503

Re: Proposed Bulletin for Good Guidance Practices

Dear Ms. Jones:

The American Chemistry Council (the Council or ACC) is pleased to provide the following comments on OMB's proposed bulletin for good guidance practices (Bulletin). The Council represents the leading companies engaged in the business of chemistry.¹ Chemistry businesses are among the most heavily regulated in the United States, on subjects such as environmental protection; process safety; worker health and safety; food, drugs & cosmetics; security; tax; trade; and hazardous materials transportation. Accordingly, our members have a great deal of experience with the rulemaking and guidance practices of over a dozen federal agencies. We therefore have a keen interest in the subject matter of the proposed bulletin and significant expertise to offer OMB in connection with it.

¹ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$520 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



Responsible Care®

ACC is very pleased that OMB has undertaken to provide guidelines for federal agencies to follow in developing, issuing and using guidance documents. ACC believes guidance documents can serve very useful functions, and we further believe that it is frequently beneficial for agencies to have the flexibility to issue guidance on particular topics, rather than having to go through notice and comment rulemaking in all cases. When to proceed by rule versus guidance, and how guidance documents should be drafted, issued and implemented, however, are difficult questions that have chronically vexed the Executive Branch. Thoughtful and consistent guidelines on these issues have long been needed, and OMB deserves credit for taking on that challenge. ACC also appreciates OMB's extension of the comment period on the proposed Bulletin.

ACC broadly supports the proposed Bulletin. The Bulletin gives effect to several recommendations of the American Bar Association (ABA) and the Administrative Conference of the United States (ACUS).² The Bulletin also draws from FDA's experience with its own good guidelines practices. Some ACC members have had experience with the FDA's approach and have generally found it to be favorable.

Below, ACC recommends several ways to clarify or improve aspects of the proposed Bulletin. We follow that with a number of other recommendations regarding topics not explicitly addressed in the Bulletin that would increase its value to both federal agencies and the regulated community. In summary, our most important comments are:

- OMB should ensure that the Bulletin applies to guidance of general applicability, and does not impair the ability of agency staff to provide informal guidance addressed solely to a specific entity.
- OMB should require agencies, where practical, to seek public notice and comment on drafts of *all* significant guidance documents, not just economically significant ones. This could be accomplished via agency websites and need not involve the Federal Register. It is difficult to overstate the benefit of such prior notice and input.
- Agencies should maintain a single, consolidated guidance website that lists guidance documents (not just offering a search capability), and contains links to the documents themselves and to public comments it has received on them. Transparency and ease of location and access are key virtues.

² As OMB knows, ACUS provided a tremendous public service for several decades. By leveraging the expertise of academic and private bar experts in administrative law, ACUS was one of the most cost-effective uses of federal resources ever.

I. Scope Issues

A. Limitation to “significant guidance documents.”

ACC notes that, while the Bulletin speaks generally about “guidance documents” and contains a definition of that term, it only imposes requirements regarding “significant guidance documents.” ACC is concerned that this limitation may be interpreted so narrowly by agencies that they do not apply the Bulletin to many important guidance documents. To address this concern, we urge OMB to require agencies to provide some mechanism whereby members of the public can nominate particular guidance documents as being “significant.” Also, to clarify the Bulletin’s limited applicability (and thus reassure those concerned that the Bulletin may sweep too broadly), OMB should change the title to “OMB Bulletin for Good Practices for Significant Guidance Documents.”

B. “Significance” should include economic and practical effects on federal agencies

One of the triggers for significance is whether a guidance document would “[r]aise highly controversial issues related to interagency concerns” This phraseology implies a focus on jurisdictional, political, policy or public relations issues. This is appropriate, but incomplete. The guidance documents of one agency can also have significant financial or practical impacts on other agencies. A good example is EPA’s Integrated Risk Information System (IRIS), a toxicological database consisting of chemical files that are used to support regulatory actions, either by EPA program or regional offices, state regulatory offices or, increasingly, other national environmental regulatory bodies. Many IRIS files are highly controversial for science policy reasons, but many are equally significant because of their financial or practical impacts on other agencies. For example, recent draft IRIS files on perchlorate and naphthalene would have dramatically increased remediation costs for the Department of Defense (DoD). Even more troubling to DoD, however, is the impact that these IRIS values may have had on the continued viability of these chemicals for uses (e.g., rocket propellants) that are critical to the Department’s core mission.

ACC therefore suggests that OMB revise § I.3(ii), or add a new clause, to encompass guidance documents that “have a significant impact on other federal agencies, either by significantly increasing costs or altering an agency’s ability to fulfill its mission.”

C. \$100 million is too high a threshold for significance

As discussed below, any guidance document that is legally or practically binding on the public is really a rule and must be issued in conformance with the Administrative Procedure Act (APA). OMB was wise to recognize that there likely are many guidance documents that, while not so mandatory as to meet the ‘binding’ test, nonetheless “may [r]easonably be anticipated to lead to an annual effect on the economy” that is substantial.

For example, a cancer classification by the National Toxicology Program – which is not a rule – may have a substantial economic effect on the entities manufacturing or using the chemical in question.

ACC believes, however, that the \$100 million threshold proposed by OMB for “economically significant guidance documents” is too high. This is especially true given the relatively minor burdens imposed by the Bulletin on such guidances – Federal Register publication and response to comments. The Bulletin’s requirements are not as demanding as those of E.O. 12866, and thus a lower dollar threshold would be appropriate.

Finally in this connection, ACC urges OMB to clarify that economic impacts on “the economy” include impacts occurring outside the United States on the foreign operations of U.S. businesses. For example, U.S. cancer classifications often trigger action by foreign nations that affect the operations in those countries of U.S. companies.

D. Don’t impair issuance of informal guidance to specific entities

The preamble to the Bulletin speaks repeatedly of guidance documents being used “to inform the public” or “communicat[ing] to a broad public audience.” These statements are consistent with the intuitive notion of guidance documents – like rules – being “of general . . . applicability.”³ Under the APA, agencies can act in two basic ways: rulemaking, which is conventionally thought of as being addressed to classes of entities, and adjudication, which is conventionally thought of as being addressed to specific named parties.⁴

Similarly, it would be useful for the Bulletin to distinguish between “guidance documents,” addressed to the public or at least classes of persons, and informal guidance offered to specific entities, which would be more in the nature of (very) informal adjudication. ACC believes the Bulletin provides very helpful procedures for issuance of guidance documents. These procedures should not automatically apply, however, to informal advice, opinions or interpretations that agency officials may offer to particular entities. ACC members routinely consult with inspectors, permit writers, “hot lines” and other agency staff to obtain clarification or direction regarding the applicability of agency rules to their specific situations.⁵ Such communications need to happen quickly, and without undue process. ACC would not want to see this capability diminished by a misapplication of the Bulletin.

³ 5 U.S.C. § 551(4).

⁴ See Jeffrey S. Lubbers, *A GUIDE TO FEDERAL AGENCY RULEMAKING* 37-43, esp. 42 n.19 (3d ed. 1998).

⁵ See particularly the comments in this docket of ACC’s Biocides Panel (describing labeling decisions and other examples from the field of pesticide regulation). The comments of the American Bar Association’s Section of Administrative Law & Regulatory Practice (at 6) offer further examples (IRS letter rulings, SEC no-action letters, and waivers).

We realize that an agency interpretation issued to one person could later be cited as precedential in a subsequent case. We also realize that agencies sometimes publish compilations of hot line responses and similar informal guidance. However, it is generally understood, and OMB could confirm, such a determination does not, in fact, have any application beyond the person to whom it applies, that neither the agency nor anyone else is bound by it, and that all concerned are free to seek a different result in a different case. With such an understanding, ACC believes the world of informal guidance is functioning well at the moment, and that the Bulletin ought expressly to exclude it from coverage. To the extent an agency publishes informal determinations with the intent of offering the public its agency-wide views on a matter, then the Bulletin should apply.

II. Bulletin Procedures

A. Clarifying relationship between new and existing guidance

ACC supports the standard elements identified in Section II.2. We particularly endorse § I.2(v), which requires agencies to note if a new guidance document “is a revision to a previously issued guidance document and identify the document that it replaces.” The relationship between guidance documents has been an especially problematic issue in ACC members’ experience. For example, EPA for many years had two guidance documents concerning the RCRA status of contaminated groundwater⁶ that reached opposite conclusions.

OMB should emphasize the importance of agencies (i) determining whether older guidances exist on a topic and (ii) clarifying precisely what parts, if any, of such older guidances remain valid. OMB should discourage use of catch-all phrases like “to the extent not inconsistent” that avoid the need for this kind of analysis.⁷ Relatedly, agencies tend not to want to invalidate prior guidances, and frequently describe superseding documents as “confirming” or “explaining” prior documents.⁸ This practice should also be discouraged.

⁶ RCRA, the Resource Conservation & Recovery Act, governs management of hazardous waste. See 42 U.S.C. § 6921 et seq.

⁷ Similarly, EPA’s “RCRA Online” compendium of hazardous waste guidances contains the following disclaimer, which vitiates its reliability:

While OSW makes every effort to keep this information timely and accurate, EPA makes no expressed or implied guarantees as to the accuracy or timeliness of the information contained in this database, the documents referenced in this database, or the choice of documents referenced in this database. OSW will, however, make an effort to correct errors brought to its attention.

See <http://www.epa.gov/rcraonline/index.htm>.

⁸ For example, a 1999 EPA guidance on federally-permitted releases under the Superfund statute said it was “consistent with statements the Agency has previously made” on the topic, even though the Agency by that

B. Public access and feedback

ACC supports Section III's requirements that agencies post links to all of their currently-effective significant guidance documents, explain changes to the list in the prior year, and provide a means for the public to comment on them. Doing so would give effect to recommendations of the ABA that federal agencies:

- adopt standard procedures for disseminating information in electronic form;⁹
- explore means to maximize the availability and searchability of existing law and policy on their websites;¹⁰ and
- include within "their own searchable data bases their governing statutes, all agency rules and regulations, and all important policies, interpretations, and other like matters on which members of the public are likely to request."¹¹

As the preamble notes, Section III also implements, in part, a 1976 ACUS recommendation that agencies advise members of the public that they can submit comments on significant guidance documents after they have been issued or request that such documents be created, reconsidered or modified.¹²

ACC particularly supports OMB's proposal that guidance documents be listed and active ones accessible by links, so that their content is transparent and users can browse for guidance documents by subject, date, author, etc., without having to resort to frustrating and ineffectual government search engines. For example, EPA's "RCRA Online" compendium of hazardous waste guidances¹³ is only accessible by searching, which diminishes its usefulness. EPA's Office of Air & Radiation Policy & Guidance web page¹⁴ is better in this regard.

Further, to address the problem just noted of different agency offices or divisions having different guidance websites, agencies such as EPA should maintain a single, consolidated

time had issued three prior, inconsistent statements. See James W. Conrad, Jr., "Draft Guidance on the Appropriate Use of Rules Versus Guidance," 32 ENVTL. L. REP. 10721, 10723 (June 2002) (attached).

⁹ American Bar Association, Recommendation on Dissemination of Information in Electronic Form (Aug. 1991).

¹⁰ ABA, Recommendation on Federal Agency Web Pages (Aug. 2001); see also ABA Section of Administrative Law & Regulatory Practice, *Improving the Federal Administrative Process: A Report for the President-Elect*, 52 ADMIN. L. REV. 1099, 1106-07 (2000).

¹¹ ABA, Recommendation on Federal Agency Web Pages (Aug. 2001).

¹² Administrative Conference of the United States, Interpretive Rules of General Applicability and Statements of General Policy (Recommendation 76-5), available at <http://www.law.fsu.edu/library/admin/acus/305765.html>. According to the ACUS recommendation, "[w]hen there has been no prepromulgation notice and opportunity for comment, the publication of an interpretive rule of general applicability or a statement of general policy ... should include ... an invitation to interested persons to submit written comments"

¹³ See <http://www.epa.gov/rcraonline/index.htm>.

¹⁴ See <http://www.epa.gov/ttn/oarpg/>.

website so that a member of the public need only go to one site to look for guidance documents issued by that agency.

OMB should also require each central agency guidance website to contain links from each guidance document to any comments filed by members of the public on it. Doing so would be a simple matter technically. This degree of transparency would enable members of the public to determine the degree and range of views being expressed regarding a particular document.

Finally, agencies should be required, in any revised or final guidance document, to address any significant comments on the prior version of the document. A good example is EPA's final Guidelines for Carcinogen Risk Assessment, which discussed a wide range of issues that had been raised by commenters on prior drafts.

C. Afford public notice and comment on all draft significant guidance documents

While post-issuance comment can be valuable, ACC strongly urges OMB to go further and encourage internet publication of, and public comment on, *drafts* of *all* significant guidance documents. As a general rule, where time permits, it is always beneficial for all concerned when agencies solicit public input before finalizing a guidance document -- as it is with rules. Public consultation becomes increasingly beneficial as the subject of the guidance becomes more technically complicated -- as guidance documents tend to be (in comparison to rules). The more complex or operationally-oriented a document is, the more likely that it will need some amount of tweaking to deal with unforeseen effects or simply to make it more idiomatic for the audience (i.e., to ensure that it uses concepts and terminology that are familiar to them).

In ACC's experience, agency guidances have uniformly benefited when members of the public have been afforded an opportunity to comment on them. A good example is EPA's *Guide for Industrial Waste Management*.¹⁵ EPA's efforts to issue guidance regarding federally-permitted releases under the Superfund statute provides two illustrative, contrasting examples: a 1999 guidance, issued without public input, that was challenged in court, and a 2002 guidance developed through settlement negotiations that is well-regarded and has proven workable.¹⁶

¹⁵ EPA530-C-99-001 (June 1999), available at <http://www.epa.gov/epaoswer/non-hw/industd/order.htm>.

¹⁶ See discussion of "The Federally Permitted Release Saga" in "Draft Guidance," *supra* note 8, 32 ENVTL. L. REP. at 10723.

For these reasons, ACUS in 1976 recommended that federal agencies implement a notice and comment process for the most significant guidance documents.¹⁷ The ABA has made a similar recommendation.¹⁸

Accordingly, ACC strongly urges OMB to revise the Bulletin to encourage agencies – where practical – to solicit public comment informally on draft significant guidance documents, just as OMB has done here. Agencies need not use the Federal Register, but could solicit comments via their guidance websites. EPA has already implemented a somewhat comparable mechanism in its Information Products Bulletin,¹⁹ which EPA describes as “the source for upcoming significant information products” being developed by EPA and states. As noted earlier, agency guidance websites should contain links from particular guidance documents to any comments it receives on that document, for all to see. Doing so is not complicated, either technologically or administratively.

D. Distinguish between “approval procedures” and “implementation rules”

While § II.1 is entitled “approval procedures,” only one of its three paragraphs (§ II.1.b) actually relates to the process by which agencies approve guidance documents. Section II.1.a has to do with when agency staff may depart from a guidance document, and Section II.1.c limits agencies from circumventing the Bulletin. These two paragraphs really belong in a separate subsection entitled “Implementation.” Leaving them under “approval procedures” may, for example, create the misimpression that agency staff can depart from the *Bulletin* with supervisory approval, which we trust was not OMB’s intent.

In connection with § II.1.a, ACC recommends that OMB clarify that “appropriate . . . supervisory concurrence” generally should mean an employee’s immediate supervisor. The flexibility needed by agency officials to depart from guidance would be frustrated if agencies could routinely require concurrence by very high-level officials. Also, OMB should clarify that this approval process is not intended to make it significantly more difficult for agencies with appropriate justification to depart from pre-Bulletin guidance than is currently the case.

In connection with § II.1.c, OMB should clarify that this anticircumvention mandate applies to *all* guidances, not just those issued after the effective date of the final Bulletin. ACC trusts this is OMB’s intent, but it would be preferable to make the point explicitly.

¹⁷ Recommendation 76-5, *supra* note 12. ACUS recommended that “[b]efore an agency issues, amends, or repeals an interpretive rule of general applicability or a statement of general policy which is likely to have a substantial impact on the public, the agency normally should utilize the procedures set forth in Administrative Procedure Act subsections 553(b) and (c), by publishing the proposed interpretive rule or policy statement in the Federal Register, with a concise statement of its basis and purpose, and an invitation to interested persons to submit written comments . . .”

¹⁸ ABA, Rulemaking Procedures for Non-Legislative Rules (Aug. 1993).

¹⁹ <http://www.epa.gov/ipbpages>.

E. Exemptions for notice and comment

Section IV.2 says that agencies may, “in consultation with OMB,” exempt particular guidance documents or classes thereof from the Bulletin’s requirement of notice and comment on economically significant guidances. Because of the incentive agencies have to avoid this requirement, ACC believes such determinations should require OMB *concurrence*.

III. Other Recommendations for Improving the Bulletin

A. OMB should warn agencies about the consequences of issuing illegal rules in the form of guidance documents

The Bulletin's Introduction notes that, “[b]ecause it is procedurally easier to issue guidance documents, there . . . may be an incentive for regulators to issue guidance documents in lieu of regulations.” It supports this point by quoting at length from the *Appalachian Power* decision.²⁰ Yet the guidance never warns agencies of the consequences of issuing guidance that has legally or practically binding effect without complying with the APA’s procedural requirements: courts may invalidate the guidance document as an illegal rule – as indeed occurred in *Appalachian Power*. The D.C. Circuit has been quite aggressive in striking down guidance documents that it finds to be rules, and OMB would be doing agencies a favor if it alerted them to that danger and the importance, therefore, of hewing to requirements established by the APA and cases construing it. The most important of these requirements, which the Bulletin contains, are:

- Explaining how agency employees may depart from the guidance (§ II.1(a)); and
- Avoiding mandatory language (§ II.2(vii)).

B. OMB should discuss when agencies should proceed by rulemaking vs. guidance

Relatedly, while the Bulletin’s Introduction highlights the choice that agencies often have to issue rules or guidance, it provides no guidance on when an agency should pursue one approach or the other. OMB should revise the Bulletin to state, at the outset, that on subjects where an agency is authorized to issue legislative rules, it should make a conscious choice whether to issue a rule or a guidance document. Considerations relevant to this choice are described in the literature,²¹ but briefly include the following.

An agency should proceed by rulemaking if:

- It wants to bind the members of the public;
- Its action has the practical effect of binding members of the public;

²⁰ *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000).

²¹ See, e.g., “Draft Guidance,” *supra* note 8, 32 ENVTL. L. REP. at 10722-26.

- It wants to bind itself;
- It has already initiated a rulemaking process or said it would do so; or
- The issue involves controversial legal calls.

An agency should proceed by guidance if:

- The subject matter is highly technical and case-specific; or
- The subject, or the agency's understanding of it, is evolving rapidly or likely to do so.

C. OMB should address the question of reliance by private parties

The comments of the ABA Section on Administrative Law & Regulatory Practice (at 6-7) highlight two related issues:

- "How to communicate effectively to the public that policy statements are not binding on regulated entities or the agency that issued them."
- "Whether an agency should advise members of the public that they may rely on the guidance – that is, that the agency will use its prosecutorial discretion not to take enforcement action against someone who relies in good faith on the guidance."

The first issue has to do with explaining to the regulated community that they may *act at variance* with a guidance document without automatically triggering enforcement action, and that the agency must have an "open mind" and allow regulated parties the opportunity to persuade it of positions contrary to those laid out in the guidance. The second issue has to do with when regulated entities *conform to* the guidance, and the extent to which doing so can be a "safe harbor" from enforcement. Agencies should explain that if parties reasonably rely on guidance, agencies must explain any departure from the guidance and allow such parties to request relief.

D. OMB should address the relationship of this Bulletin to OMB's Information Quality Act Guidelines

There appears to be some degree of overlap between the proposed Bulletin and OMB's Information Quality Act Guidelines, especially the IQA Peer Review Bulletin. But the IQA is never mentioned in the proposed Bulletin. It would be helpful if OMB articulated that relationship explicitly.

For example, the scope of the proposed Bulletin is clearly broader than the IQA Guidelines, as the Bulletin reaches any document that is subject to release under the Freedom of Information Act, whereas the IQA guidelines only apply to "agency initiated or sponsored distribution[s] of information to the public."²² This is probably appropriate, since many influential guidances are internal agency directions that nonetheless can have

²² 67 Fed. Reg. 8460 (Feb. 22, 2002).

substantial impacts on persons outside the agency (for example, binding instructions to permitting officials to impose certain permit limits²³).

The clearest case of overlap appears to be the case of highly influential scientific assessments, which would be subject to the more demanding peer review requirements of the Peer Review Bulletin,²⁴ and which may also be considered “significant guidance documents” under the proposed Bulletin. It may be helpful for OMB to clarify that the proper focus of the peer review process under the Peer Review Bulletin is the scientific and technical correctness and quality of the information a document contains. By contrast, questions about the applicability and wisdom of legal and policy choices made in the document are legitimate subjects of the proposed Good Guidance Bulletin and the comment process it establishes. This distinction is not intended to limit in any way the range of issues that may be addressed under the Information Quality Act, but simply to delineate the relative purviews of the Peer Review and Good Guidance Bulletins.

E. Need for interagency review processes

Earlier, ACC noted its support for “interagency concerns” as being a basis for classifying a guidance document as “significant.” In the Bulletin’s Introduction, OMB notes that one of the procedures applicable to rulemaking is “interagency review through OMB” under Executive Order 12866. Yet the Bulletin does not propose a comparable interagency review process, even for economically significant guidance documents – even though, de facto, such review does occur from time to time and can be valuable. ACC proposes that, in cases where a guidance document is deemed “significant” because of its effect on other federal agencies, those agencies ought to be able to request an interagency review, overseen by either OMB or OSTP.

F. Technical issues

ACC recommends that OMB redraft § I.1 to read: “The term ‘agency’ has the same meaning *it has under* the Paperwork Reduction Act, 44 U.S.C. § 3502(1), *but excludes* those *entities* considered”

ACC recommends that OMB change “should” to “must” in the first two lines of page 7 of the Introduction, where OMB is paraphrasing the mandatory requirements of § IV.

²³ See “Draft Guidance,” *supra* note 8, 32 ENVTL. L. REP. at 10724.

²⁴ See 70 Fed. Reg. 2675-76 (Jan. 14, 2005).

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The Council appreciates the opportunity to submit these comments. If you have any questions or comments regarding these comments, please feel free to contact Jamie Conrad at 703-741-5166 or james_conrad@americanchemistry.com.

Sincerely,

Michael P. Walls
Managing Director,
Regulatory & Technical Affairs