

VIA EMAIL

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Re: Proposed Bulletin for Good Guidance Practices, 70 *Federal Register* 71866, November 30, 2005

The American Petroleum Institute (API) is pleased to present these comments to the U.S. Office of Management and Budget (OMB) on its Proposed Bulletin for Good Guidance Practices (“Proposed Bulletin”).<sup>1</sup> API is the primary trade association of America’s oil and natural gas industry and represents more than 400 member companies involved in all aspects of the industry. API’s members are significantly affected by many of the guidance documents issued by federal agencies. Such guidance documents often substantially affect the nature and magnitude of regulatory burdens. In many cases, the impact of guidance documents has been so strong as to constitute “regulation through guidance,” i.e., implementation in practice of standards or requirements that are different than those enumerated in the underlying statute and/or regulations.

In the comments below, API agrees with the need for a bulletin for good guidance practices and expresses its support for OMB’s development of the bulletin, including offering some specific examples of agency guidance problems with which we are familiar. Although API is generally supportive of this effort, below we urge OMB to allow for exceptions to the proposed notice and comment requirements (for guidance documents deemed significant and economically significant) where necessary and appropriate. We also explain several suggestions for enhancing the Proposed Bulletin in areas of:

- Which guidance documents should be subject to public notice and comment;
- Guidance document compliance with the Information Quality Act;
- The need to address existing (not just future) guidance; and
- Suggestions for specific sections of the Proposed Bulletin.

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<sup>1</sup> 70 *FR* 71866. November 30, 2005.

## **Need for Bulletin for Good Guidance Practices**

API strongly supports OMB's development of the Proposed Bulletin. OMB states that the purpose of the new bulletin is to "ensure that agency guidance documents are developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as binding requirements."<sup>2</sup> API agrees with OMB that agency guidance practices need to be more transparent, consistent, and accountable. These concerns, as mentioned in the Supplementary Information for the Proposed Bulletin, have been raised by other authorities in addition to OMB, including Congress and the Courts.<sup>3</sup>

In its discussion of the need for the Proposed Bulletin, OMB states that guidance documents may not be afforded the benefit of careful consideration under the procedures for federal regulatory development and review, and that the absence of procedural mechanisms for guidance documents can undermine the lawfulness, quality, fairness, and accountability of agency policymaking.<sup>4</sup> Additional direction from OMB regarding guidance documents is necessary for OMB to effectively oversee and coordinate regulatory policy. In the Introduction section of the Proposed Bulletin, OMB elaborates on the need for Good Guidance Practices, and API generally agrees with OMB's analysis. We will not reiterate here the points already made by OMB, but we would like to offer some examples to substantiate them. API and its members have reviewed numerous federal agency guidance documents over the course of many years, and below are a few recent examples related to guidance issued by the U.S. Environmental Protection Agency (EPA).

### ***OWSER Draft Subsurface Vapor Intrusion Guidance***

The EPA Office of Solid Waste and Emergency Response (OSWER) Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance) was issued in November 2002. Prior to its release, EPA held a number of public workshops and subjected the draft to internal review. EPA published notice in the *Federal Register* of its release and solicited public comments on it. Since publication of the draft guidance, EPA has reviewed the comments but not posted a response. Several additional public workshops have been held and the guidance again is undergoing internal EPA review.

Although there has been internal review and public notice and comment, the draft contains overly-conservative screening levels that states are adopting. This has led to unnecessary, costly site investigations. The impact of the *Draft* Subsurface Vapor Intrusion Guidance becomes increasingly significant as more and more states use the draft guidance to implement their requirements, despite the fact that EPA is still reviewing that draft.

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<sup>2</sup> *OMB Proposed Bulletin for Good Guidance Practices*. <http://www.whitehouse.gov/omb/inforeg/regpol.html>. p. 3.

<sup>3</sup> *OMB Proposed Bulletin for Good Guidance Practices*. <http://www.whitehouse.gov/omb/inforeg/regpol.html>. p. 2.

<sup>4</sup> *OMB Proposed Bulletin for Good Guidance Practices*. <http://www.whitehouse.gov/omb/inforeg/regpol.html>. p. 2.

This example highlights the need for OMB to incorporate a quality standard into the Bulletin. As discussed below, an appropriate standard would be to apply Information Quality Act (IQA) requirements to guidance documents. Even if a rigorous process for review and comment is established for all significant and economically significant guidance documents, inclusion of incorrect information in guidance documents—*draft or final*—can introduce significant problems into the regulatory framework.

***ANPRM on the Clean Water Act Regulatory Definition of “Waters of the United States”***

On January 15, 2003, the EPA and the U.S. Army Corps of Engineers (COE) jointly issued an Advance Notice of Proposed Rulemaking (ANPRM) on the Clean Water Act Regulatory Definition of "Waters of the United States."<sup>5</sup> The purpose of this rulemaking was to develop regulations that "will further the public interest by clarifying what waters are subject to Clean Water Act (CWA) jurisdiction and affording full protection to these waters through an appropriate focus of Federal and State resources consistent with the CWA."<sup>6</sup> Rulemaking is appropriate because various court decisions have interpreted the scope of CWA jurisdiction as it relates to agency CWA regulatory activities, and the federal agencies have not engaged in a review of the regulations with the public to address the court decisions and the confusion now surrounding the scope of jurisdiction.

Simultaneously with the ANPRM, EPA and COE issued clarifying guidance to address jurisdictional issues under the CWA. Then, on December 16, 2003, EPA and COE issued a joint memorandum announcing that they would *not* issue a new rule on federal regulatory jurisdiction over "isolated wetlands." However, the guidance document remains in effect. The guidance was not subject to public comment and leaves many questions unanswered on the issue of determining whether jurisdiction under the CWA applies to a specific location, including what is "adjacent," what is sufficient to create a "significant nexus," whether a groundwater connection is sufficient to create a nexus, and other complex issues. This is an example of federal agencies relying upon guidance, instead of rulemaking, to carry out regulatory programs. In this case, the lack of rulemaking leaves the regulated community and state and national governments with a vague understanding of jurisdiction under the regulatory scheme of the CWA.

As discussed below, API suggests that OMB expand the “Basic Agency Standards” section of the Proposed Bulletin to explicitly state that Agencies may not use guidance in lieu of rulemakings where rulemaking is required or more appropriate.

***Spill Prevention, Control and Countermeasure (SPCC) Guidance for Regional Inspectors***

On December 2, 2005, EPA released the Spill Prevention, Control and Countermeasure (SPCC) Guidance for Regional Inspectors. On December 12, 2005, EPA published a

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<sup>5</sup> 68 *FR* 1991. January 15, 2003.

<sup>6</sup> 68 *FR* 1991. January 15, 2003.

proposed rule on SPCC amendments in the Federal Register.<sup>7</sup> The proposed rule included a notice of publication of the guidance document with a 60-day comment period from date of publication of the proposed rule.<sup>8</sup> The intent of the guidance document is “to assist regional inspectors in reviewing a facility's implementation of the Spill Prevention, Control, and Countermeasure (SPCC) rule at 40 CFR part 112 and understanding the rule's applicability, and to help clarify the role of the inspector in the review and evaluation of the performance-based SPCC requirements.”

The guidance document includes interpretations that are more stringent than existing requirements. For example, Chapter 4 of the guidance document (Role of the EPA Inspector in Evaluating “Sufficiently Impervious”) includes: “The EPA inspector may ask to see any calculations/engineering justifications used in determining levels of imperviousness; this information, including calculations, should be maintained with the Plan to facilitate the inspector’s review” (pp. 4-23). 40 CFR 112 does not contain any provision that requires imperviousness “calculations” be maintained with the Plan.

Chapter 4 of the guidance document also states: “In certain geographic locations the native soil (e.g., clay) may be determined as sufficiently impervious by the PE. However, there are many more instances where good engineering practice would generally not allow the use of a facility’s native soil alone as secondary containment because the soil is not homogenous” (pp. 4-22, 4-23). Such a statement implies that the majority of existing facilities will presumably have to implement secondary containment liners, in contradiction to the preamble to the July 17, 2002 final rule that states “Liners are an option for meeting the secondary containment requirements, but are not required by the rule.”<sup>9</sup>

In both instances, the interpretations in the guidance document are more stringent than the final rule, thus confounding the regulatory requirements and illustrating the need for OMB review of significant and economically significant guidance documents.

#### ***Guidance in the TRI Program***

Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 requires owners/operators of subject facilities to submit annual reports on the amounts of listed “toxic chemicals” released into the environment or transferred to other facilities.<sup>10</sup> The list of toxic chemicals includes over 600 chemicals and chemical categories. Data submitted by companies on EPA's “Form R” or “Form A” comprise EPA's TRI database. In addition to major notice and comment rulemaking expansions, EPA has changed the TRI program through the issuance of “guidance,” particularly in the question and answer (“Q&A”) format. EPA's web site for TRI guidance currently contains links to over 40

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<sup>7</sup> 70 FR 73523. December 12, 2005.

<sup>8</sup> 70 FR 73527. December 12, 2005.

<sup>9</sup> 67 FR 47102. July 17, 2002.

<sup>10</sup> Subject facilities are those in specified SIC codes and that have 10 or more full-time equivalents.

separate EPA guidance documents. These documents are provided in addition to the TRI "Form R" and its instructions, which are over 100 pages long. The extensive use of guidance in the TRI program has the effect of imposing an additional layer of requirements on the regulated community.

API found numerous examples of "regulation by guidance" in EPA's last "Q&A," a 300-page "EPCRA Section 313 Questions and Answers" document, last revised in 1998 ("1998 Q&A"). This document replaced and significantly revised a 1997 Q&A document. Although EPA published a notice of availability in the Federal Register for the 1998 Q&A document<sup>11</sup>, the Agency did not take comments on the extensive revisions. Between the 1997 and 1998 versions of the Q&A document, EPA changed more than 400 Q&As from the 1997 document and added 150 new Q&As. Some of the Q&As had the effect of increasing requirements, for example: narrowing the motor vehicle exemption at 40 CFR 372.38(c)(4)); stating that ammonia present in human waste (sewage) is manufactured as a result of waste decomposition and that "the facility should report that it has manufactured ammonia as a byproduct;" and stating that metal scraps sent off-site (to be remelted and reused) are repackaged and distributed and thus that chemicals in the metal scraps must be counted toward the facility's processing threshold. There were various other examples in the document that API can provide upon request.

EPA's process for issuing TRI guidance has been characterized by confusion and bad timing, such as issuing guidance two weeks before the due date of TRI reports.<sup>12</sup> EPA has also rushed to issue TRI rulemakings and left significant issues to be addressed in guidance. This was most notable in the PBT rulemaking, which lowered reporting thresholds and eliminated the *de minimis* exemption for a number of chemicals. In comments on the rulemaking, API and others raised pertinent issues in the areas of assumptions to be made regarding *de minimis* quantities of chemicals in mixtures; how to account for trace amounts of PBTs in complex variable composition mixtures such as petroleum streams; how to handle dioxin thresholds below practical ability to measure; how to segregate background levels from amounts "manufactured"; and what assumptions facilities would be expected to make regarding chemicals potentially present in trace amounts in fuels. Avoiding these issues in the rulemaking process, EPA issued a final rule and then drafted guidance documents, which were not finalized until activities for reporting year 2000 were virtually complete. By inappropriately relying on post-

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<sup>11</sup> 64 FR 32232-32234. June 16, 1999.

<sup>12</sup> When EPA issued its 1998 overhaul of the TRI "Q&A" guidance and six new industry guidance documents, it announced the availability of the documents in a *Federal Register* notice published on June 16, 1999 (64 FR 32232-32234). This was two weeks before TRI reports for the 1998 reporting year were due, when facilities would have already completed most or all of the work necessary for 1998 reporting. The notice stated that the documents were effective beginning with the 1999 reporting year. However, EPA also stated, "to ensure consistency in reporting and the integrity of the data, the Agency would prefer that covered facilities use these documents as guidance for the 1998 reporting year as well." In addition, at that time, the previous versions of guidance documents were no longer available from EPA. Both EPA's web site and the EPCRA Hotline would provide only the revised 1998 Q&A.

rulemaking guidance, agencies can avoid resolving difficult issues in the rulemaking process.

The four examples above illustrate the need for more public and OMB review of significant and economically significant federal guidance documents, and for more standards for the development and issuance of guidance deemed significant or economically significant. Increasingly, the details of federal regulation are contained in guidance documents. In many instances, these guidance documents confound regulatory program requirements, expand current regulations, and impose significant costs on the regulated community with no apparent public benefit.

### **All Significant and Economically Significant Guidance Documents Should Be Published in the Federal Register for Review and Comment and Require Agency Response**

The Proposed Bulletin distinguishes among three different types of guidance documents: non-significant; significant; economically significant. Under the proposal: (1) *non-significant guidance documents* have to only be made available to the public by the agency or required to be disclosed under the Freedom of Information Act; (2) *significant guidance documents* have to be published on the governing agency's website; and (3) *economically significant guidance documents* have to be published in the Federal Register inviting public comment on the draft guidance document and the governing agency is required to respond.

The Proposed Bulletin requires that agencies maintain web site lists of all *significant guidance documents* and establish a means on the web site for the public to submit comments. However, there is no requirement for formal notice and comment and agencies are not required to respond at all to public comments. The Proposed Bulletin does require more formal notice and comment for the subset of guidance documents within the definition of *economically significant guidance document*.

For the Proposed Bulletin to achieve its intended purposes, as discussed above, API suggests that OMB require all significant guidance documents (not just the subset of economically significant ones) to be published in the Federal Register (with a public docket), with an opportunity for public comment, and requiring an agency response to comments. Many documents that fall within the definition of significant guidance document but are not "economically significant" merit notice and comment as much or more than economically significant ones—including documents within categories I.3.(ii) [raise highly controversial issues], I.3.(iii) [set forth initial interpretations of statutory or regulatory requirements]; and I.3.(iv) [concern novel or complex scientific or technical issues].

In the past, some of the biggest impacts caused by guidance appear to have been unrecognized by agencies when the documents were first drafted. It is likely that, for many guidance documents that do lead to an annual effect of \$100 million or more, agencies will not think they

meet this criterion when they are first issued. Furthermore, it is not clear how agencies would make the determination of whether a guidance document will lead to an annual effect of \$100 million or more, since there are not specified economic analyses required for guidance documents as there are for actual rulemakings. One of the main benefits of the notice and comment period for guidance documents will be to allow reviewers to identify aspects and impacts of the guidance that agencies might not otherwise appreciate.

Another reason to apply notice and comment requirements to all significant guidance documents is to encourage less proliferation of guidance. It is particularly difficult for the regulated community when agencies issue numerous and voluminous guidance (see TRI example above). Requiring notice and comment for all significant guidance documents would help advance the goal of “quality, not quantity” for guidance documents.

Further, the Proposed Bulletin should require that all *non-significant guidance documents* be published on the governing agency’s website. In addition, OMB should establish a public notification process to allow the public to identify *non-significant guidance documents* that are not currently listed on the respective agency’s website and require the agency to update their site within 30 days to include a guidance document identified by the public.

Although API is generally supportive of this effort, we urge OMB to allow for exceptions to the proposed notice and comment requirements (for guidance documents deemed significant and economically significant) where necessary and appropriate.

### **All Guidance Documents Should Comply with the Information Quality Act**

API strongly supported OMB’s publication and implementation of the Information Quality Guidelines,<sup>13</sup> and we believe that the OMB’s effort to develop clear and consistent agency practices for developing, issuing, and using guidance documents furthers the general goal of the Information Quality Guidelines—ensuring that federal guidance documents are of high quality.

To further the intent and goals of the Information Quality Act, API urges OMB to state in Section III of the Proposed Bulletin that guidance documents are subject to the provisions of the Information Quality Act and all guidelines developed pursuant to the Information Quality Act. Guidance documents often contain much scientific and technical information (e.g., emissions factors), and this information should be held to standards as high as for any type of information disseminated by agencies.

OMB also should consider requiring agencies to establish data quality criteria for data used in guidance documents (e.g., concentration data, emissions factors, and other information). Only data that meet the quality criteria should be included in guidance documents. Data quality

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<sup>13</sup> *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*; 67 FR 8451-8460, February 22, 2000.

standards should ensure that all data and information in guidance documents are properly attributed (i.e., original source clearly noted).

### **OMB Should Consider a Mechanism for Evaluating Existing Guidance**

The Proposed Bulletin as drafted would apply to guidance developed by agencies in the future. This would leave unresolved the issue of existing guidance that does not meet the standards of the Bulletin. API suggests that OMB develop a mechanism for applying the standards and procedures in the bulletin to existing guidance that continues to be used by agencies.

### **Specific Concerns by Section of Proposed Bulletin**

#### ***Section I: Definitions***

In Section I.3 of the Proposed Bulletin, we suggest that OMB state that the term “significant guidance document” should include any guidance document that may: (1) Contradict common practices used by the regulated sector(s) of the economy to implement a statutory or regulatory requirement, in place for more than one year, which may raise the possibility of civil penalties for practices employed by the regulated sector(s) prior to the issuance of the guidance; and (2) Contradict any guidance document by a state that has been in place for more than one year. These are in addition to the four definitions of “significant guidance document” provided in the proposal.<sup>14</sup>

#### ***Section II: Basic Agency Standards***

OMB notes that one of the purposes of the Bulletin is to reduce the misuse of guidance. It is particularly important that agencies not engage in “regulation by guidance” and the bulletin should address this directly. API recommends that the Basic Agency Standards section include a statement to the effect that agencies may not issue guidance when rulemaking is required or appropriate, if the effect of issuing the guidance is to in any way delay or displace the rulemaking process.

Under Section II.1.a “Approval Procedures,” the Proposed Bulletin states: “Agency employees may depart from significant guidance documents only with appropriate justification and supervisory concurrence.” This statement appears to suggest that employees can depart from the guidance approval process with supervisor concurrence. API does not believe that this was the original intent of the above-quoted language. Thus, we suggest that this language be clarified or placed in a different section.

Under Section II.1.c “Approval Procedures,” the Proposed Bulletin states: “Agencies may not circumvent the significant guidance document requirements by using alternate means of communication to disseminate new or different regulatory expectations to a

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<sup>14</sup> These revisions will address the issue of guidance documents that carry reasonably anticipated retroactive compliance concerns and the issue of problems that arise when federal agency guidance documents contradict state guidance that is already followed by the regulated community.



broad audience for the first time...” While this statement should help prevent agencies from going around the requirements of the Proposed Bulletin, it does not explicitly address the issue of revisions to existing guidance documents. As such, we suggest that OMB change the language to “Agencies shall not...” and expand the statement to include any substantive revisions made to existing documents covered under the Proposed Bulletin.

Under Section II.2 “Standard Elements,” API recommends that OMB note in the Proposed Bulletin that a “draft” guidance document issued by an agency may not be implemented by the agency—only final guidance may be implemented. We have experienced multiple problems with the imposition of “draft” guidance (e.g., as noted previously regarding OSWER Draft Subsurface Vapor Intrusion Guidance).

***Section III: Public Access and Feedback***

OMB should address the issue of timing for issuing guidance in the public access and feedback section. API suggests that the Bulletin include a statement that guidance must be issued at least 60 days in advance of its date of expected use by the regulated community absent exigent circumstances requiring less leadtime.

API and its members have experienced difficulty with the timing of the issuance of agency guidance. One very current example is the development of instructions and a Q&A document for Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR) reports, which are due in 2006 for data from calendar year 2005. Many companies are beginning to work on these reports, with difficulty, because EPA has not yet issued final guidance documents. Another example is the TRI guidance discussed above.

***Section IV: Notice and Public Comment for Economically Significant Guidance Documents***

API suggests that OMB add to Section IV of the Proposed Bulletin the requirement that agencies must provide an adequate time period for public comment (i.e., more time for guidance documents with significant impact) and that the Agency must clearly indicate the timing for comment.

API disagrees with the blanket exemption provision that agencies can determine unilaterally which guidance documents can be exempted from the provisions of the Proposed Bulletin. Under Section IV.2, “Agencies may, in consultation with OMB, identify particular guidance documents or classes of guidance documents for which the procedures of this Section [Section IV] are not feasible and appropriate.” We believe that this should be a joint determination between the agency and OMB. Further, we disagree that the agency (in consultation with OMB) should be permitted to exempt whole “classes” of guidance documents from the Good Guidance Practices discussed in the Proposed Bulletin. The exemption should be limited to a “named” guidance document, not a whole “class” of documents.

Also, as stated in the Supplemental Information for the Proposed Bulletin (Section II. E), “the agency is not required to seek public comment before it implements an economically significant guidance document if prior publication is not feasible or appropriate. For example, it may not be feasible or appropriate for an agency to seek public comment before implementing a significant guidance document if there are public health, safety, environmental or other emergencies requiring implementation of the guidance document, or there is a statutory requirement, Executive order, or court order that required immediate implementation.” OMB has appropriately required that agencies must still post these guidance documents on their website for comment. However, agencies are not required to respond to any public comments received. To illustrate, the Supplemental Information for the Proposed Bulletin (Section II. E) states: “If the Agency received comments on one of the expected guidance documents, the agency should review those comments and revise the guidance document, where appropriate.” In the event that comments are solicited, API urges OMB to require agencies to respond to comments received on guidance documents. Requiring agencies to respond to solicited public comments is clearly warranted given the importance of an exempt document (as it is defined). Failure to require agencies to respond to solicited public comment allows agencies the opportunity to ignore potentially important public feedback.

## Conclusion

API applauds OMB’s efforts to improve the transparency, consistency, and accountability of agency practices for developing, issuing, and using guidance documents. Addressing the concerns raised above will further the goals of this initiative and ultimately improve the quality and utility of the guidance issued by federal agencies. Again, API believes that there may be cases where exceptions to the proposed notice and comment requirements (for guidance documents deemed significant and economically significant) are necessary and appropriate. As such, we urge OMB to recognize the need for exceptions in the bulletin.

Please contact Derek Swick of my staff at 202-682-8341 or [swickd@api.org](mailto:swickd@api.org) if you have any questions about our comments, or would like additional information from API.

Sincerely,



cc: Lakeisha R. Harrison, API  
Derek D. Swick, API  
Environmental Information/Right-to-Know Task Force, API