NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

January 9, 2006

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

FILED BY ELECTRONIC MAIL:
OMB_GGP@omb.eop.gov

Re: Proposed Bulletin for Good Guidance Practices

Dear Ms. Jones:

The Natural Resources Defense Council (NRDC), a national non-profit public interest organization, offers these comments in response to OMB's Nov. 30, 2005 notice in the *Federal Register*[1] inviting comments on OMB's Proposed Bulletin for Good Guidance Practices (Bulletin).[2]

The views expressed herein are presented on behalf of NRDC's over 1 million members and activists, who help us protect our nation's public health, safety, and environmental safeguards. Such safeguards were born from a deliberative public process, and although these protections may come at some cost, they deliver tremendous benefits from decreased risks of cancer, to safer automobiles, and increased energy savings. Thus, we believe those who wish to change these safeguards should engage in the same deliberative process used to create them.

NRDC supports OMB's stated goal of ensuring greater transparency, public participation, and accountability with regard to the proper development, issuance, and use of guidance documents. Agency guidance is an invaluable tool in helping industry and the public understand and comply with requirements under existing safeguards. Consequently, both industry and the public have an interest in bringing accountability and regularity to this important area of administrative law.

---

[1] Proposed Bulletin for Good Guidance Practices, 70 Fed. Reg. 71,866 (Nov. 30, 2005).

[2] Office of Info. & Reg Affs., OMB, Proposed Bulletin for Good Guidance Practices (2005), available at <http://www.whitehouse.gov/omb/inforeg/regpol/good_guidance_preamble.pdf> (hereinafter "Bulletin").

While we agree that in many cases public comment on significant agency guidance documents would be beneficial, OMB's proposal fails to meet its stated goals, and instead would make matters worse at the expense of harming the public's health, safety, and environment. OMB's Bulletin would have this unfortunate effect because it would require agencies to engage in time-consuming public deliberation over insignificant and routine non-binding guidance that is already exempt from public notice and comment under the Administrative Procedure Act (APA). This will produce harmful consequences. First, it will likely chill the issuance of further guidance by agencies so as to avoid those time-consuming burdens, encouraging the development of unwritten or underground policies, and undermining the very goals of transparency and participation OMB had hoped to achieve. Second, and most troubling, the time-consuming burdens contemplated by this proposal for insignificant or routine guidance will divert agency resources from more pressing matters, and greatly impair an agency's ability to do its job of protecting our public safeguards.

In support of OMB's stated goal of increasing the transparency, public participation, and accountability of agency guidance, NRDC appreciates the opportunity to offer the following comments. Because of the short comment period afforded by OMB on its sweeping proposal on this highly complex and controversial web of issues, NRDC is unable to offer comprehensive comments. We therefore urge, in the strongest possible terms, that OMB provide additional opportunity for comment from the public, academic experts, and Congress before finalizing any Bulletin.

While by necessity our comments must be preliminary, our analysis has identified a number of troubling issues that merit OMB's careful consideration. It is our view that OMB's proposal fails for the following reasons:

1) OMB's proposal will make matters worse by greatly impairing the government's ability to protect the public's health, safety, and environment by requiring time-consuming processes for insignificant and routine guidance.

2) OMB has not presented a compelling empirical justification for its proposed solution, because it has failed to describe or document the nature and extent of the problem, and it has failed to justify the efficacy of its one-size-fits-all solution.

3) OMB has not presented any legal basis giving it the authority to effectively amend the Administrative Procedure Act.

4) OMB's proposal appears to impermissibly require agencies to engage in cost-benefit analysis for guidance, even under certain statutes under which it is unlawful to do so.

5) OMB's solution is in certain respects incoherent, because it sets up a process that is inconsistent with the law and internally contradictory.

I. OMB's proposal will make matters worse by greatly impairing the government's ability to protect the public's health, safety, and environment by requiring time-consuming processes for insignificant and routine guidance.

Agency guidance documents are an invaluable tool in helping industry and the public understand and comply with requirements under existing safeguards. They are used in various contexts for various purposes. For example, a guidance document can be a policy on how to implement and enforce an environmental protection, or merely an internal instruction to an agency employee on how to maintain an electronic database. While some agency guidance documents are significant in nature, others are not. Taken together, guidance documents encompass a vast universe of variability. No one definition can adequately describe the various types or impacts of guidance documents.

As currently drafted, the Bulletin's definitions for various guidance documents are so sweeping and ambiguous that they can be reasonably interpreted to apply to an immense number of agency materials. Moreover, the Bulletin fails to adequately distinguish among the different types and impacts of guidance documents. For example, OMB defines "significant guidance document" to include a guidance document that "set[s] forth *initial* interpretations of statutory or regulatory requirements, or *changes* in interpretation of policy."[3] Thus, OMB appears to sweep up into this category all initial agency statements on a law or regulation, regardless of whether the guidance concerns routine, insignificant, or significant matters. Similarly, all changes to initial guidance, no matter how insignificant, also appear to fall within the scope of this category, thereby effectively eviscerating the generally accepted meaning of the term "significant." Given the inherent complexity in defining the scope of various guidance documents, it may be that there is no easy solution for distinguishing between those that are significant and insignificant, but it is clear that requiring comment on the most mundane, routine, or insignificant agency interpretations or statements would cause agencies to grind to a halt. By failing to make such a distinction, the Bulletin becomes a blunt, burdensome, and counterproductive instrument.

Moreover, under the Bulletin, all "significant" guidance documents are subject to notice and comment procedures, even though timely protection of the public may depend upon prompt issuance of such guidance, and even though such guidance is exempt from those procedures under the Administrative Procedure Act (APA). Consequently, the Bulletin would appear to sweep into its notice and comment procedures time-sensitive changes to FAA air travel safety notices, USDA poultry and beef cooking advisories, National Weather Service heat advisories, or EPA's Integrated Risk Information System database, which contains thousands of technical studies and data points on the toxicity of numerous chemicals.

The time-consuming burden created by this requirement would exceed the benefits in most cases and have drastic consequences. First, it will likely chill the issuance of further guidance to avoid those time-consuming burdens. Agency guidance, however, gives industry and the public greater clarity with regard to how an agency

[3] *Id.*, *supra* note 2, § I(3)(iii), at 9 (emphasis added).

intends to implement and enforce existing rules and statutes. Implementing a policy that chills guidance would have the effect of keeping the public and industry in the dark about agency intentions, undermining the very goals of the Bulletin itself. Second, and most troubling, the time-consuming burdens contemplated by this proposal will greatly impair an agency's ability to do its job. By overwhelming an agency's limited resources, it will be unable to focus on its primary responsibility – protecting the public's health, safety, and environment. Consequently, it is our view that OMB's proposal does not meet its goals and would make matters worse.

II. OMB has not presented a compelling empirical justification for its proposed solution, because it has failed to describe or document the nature and extent of the problem and it has failed to justify the efficacy of its one-size-fits-all solution.

OMB insists on empirical evidence in the rulemaking process. But the Bulletin lacks any empirical evidence about the nature and extent of the problems with guidance practices in each of the agencies. The Bulletin only contains general pronouncements of the need for establishing standards for the initiation, development and issuance of guidance documents to raise their quality and transparency. Without knowing the specificity of the problems that industry and the public are confronting, it becomes difficult to craft an appropriate solution.

Instead of presenting empirical evidence of the problems, OMB leaped to a solution, but again it failed to provide any evidence demonstrating the efficacy of its proposed solution. In this regard, we raise two observations. First, OMB purports to base its proposal, in part, on the Food and Drug Administration's Modernization Act of 1997 (FDAMA) and its implementing regulations.[4] The legislative history of the FDAMA reveals that Congress only contemplated a limited solution for solving specific problems with FDA practices, not all agency practices.[5] As a consequence, FDA designed their own scheme to address specific problems within their own agency. OMB, however, fails even to discuss the successes and problems FDA has experienced since its implementation nearly 10 years ago. It would be important to know if FDA's scheme created unanticipated problems or created more problems than it solved.

Second, OMB substantially modified FDA's scheme and made it applicable to all government agencies with a one-size-fits-all solution. As discussed below, Congress could have chosen to make such a requirement uniform and government-wide, but decided instead to experiment with whether its requirements would improve procedures at FDA. What works for the FDA may not be appropriate for the EPA, for example, because different agencies have important dissimilarities in their statutory and regulatory

[4] *Id*. at 3.

[5] *See* S.Rep. No 105-43, at 26 (1997).

mandates and procedural strictures. By rushing to judgment, OMB's Bulletin would effectively force the government to engage in a vast, unwieldy experiment without the benefit of broad public deliberation, or even a public evaluation of FDA's experience with these procedures. Therefore, it is our view that OMB must gather empirical evidence of the problems at each agency and then engage in a deliberative process with Congress and various stakeholders to develop an appropriate solution or solutions.

III. OMB has not presented any legal basis giving it the authority to effectively amend the Administrative Procedure Act.

Although NRDC agrees there are problems with agency guidance practices, we are concerned that OMB did not present any legal basis for engaging in this reform endeavor, especially since the Bulletin effectively amends the Administrative Procedure Act (APA). When enacting the APA nearly sixty years ago, Congress intended to ensure a deliberative and publicly accountable process for agency decision-making. Section 553 of the APA requires that agencies, with limited exceptions, provide notice of proposed rulemaking through publication in the *Federal Register* and give interested parties an opportunity to participate in the rulemaking through the submission of comments.[6] Agency guidance documents properly characterized as non-binding guidance are covered within the exception that includes "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice."[7] The rationale for excluding such guidance is that it allows agencies the flexibility to announce their future intentions and to clarify how they will enforce a statute or regulation. In exchange for that flexibility, agencies essentially lose the power to bind the public to those decisions.

OMB's Bulletin, however, would require agencies to utilize notice and comment procedures when issuing certain guidance documents.[8] OMB's Bulletin states that OMB is responsible for "promoting good management practices and for overseeing and coordinating the Administration's regulatory policy."[9] Whatever authorities OMB has, it is only through a tortured interpretation of existing statutes that OMB could derive implicit authority to effectively amend the Administrative Procedure Act (APA) without an express congressional mandate. Moreover, OMB's citation of the FDAMA as a model actually undercuts its argument that it enjoys the authority to issue this Bulletin. Congress' decision to apply its procedural requirements to FDA only, and *not* to apply the FDAMA's procedures government wide, could appropriately be construed to undercut any claim that OMB can impose such procedures on all other agencies. Because Congress never implicitly or expressly empowered OMB to amend the APA by executive fiat, we therefore urge OMB to thoroughly vet the Bulletin with Congress and other

[6] 5 U.S.C. § 553(b) & (c).

[7] 5 U.S.C. § 553(b)(A).

[8] *See id., supra* note 2, §§ III & IV, at 9-10.

[9] Bulletin, *supra* note 2, at 1.

stakeholders before the adoption of any final Bulletin, and to be absolutely clear that the procedural provisions of the Bulletin are non-binding.

IV. OMB's proposal appears to impermissibly require agencies to engage in cost-benefit analysis for guidance, even under certain statutes under which it is unlawful to do so.

Assuming arguendo that OMB has authority to issue this Bulletin, we must note that OMB's definition of "economically significant guidance document" is highly problematic. Under the Bulletin, such a document is a "guidance document that may . . . reasonably be anticipated to lead to an annual effect of $100 million or more or adversely affect in a material way the economy or a sector of the economy," except that such documents do not include "documents on Federal expenditures and receipts."[10] OMB needs to provide further clarification of this puzzling provision. As a general matter, agency guidance is non-binding and thus by definition it has no monetary impact. Moreover, the Bulletin goes to great lengths to instruct agencies to omit the magic words "shall," "must," "required," or "requirement" from the guidance document itself to avoid any suggestion that the guidance is binding in nature.[11] Thus, the Bulletin appears to create a conundrum, whereby it appears to treat an economically significant guidance document as both binding and non-binding at the same time. OMB needs to explain this contradiction.

Assuming that OMB can adequately explain its intent, we strongly object to defining a category of guidance documents that are significant in solely monetary terms. This is unlawful as drafted because it will require agencies to analyze guidance in economic terms, even when doing so is in direct contravention of the underlying statute that prohibits such considerations. The Clean Air Act is such a statute. Section 109 of the Clean Air Act instructs EPA to use a health-based standard for setting ambient air quality standards. In setting the levels, the U.S. Supreme Court has consistently held that the statute and its legislative history make clear that economic considerations should play no part. Consequently, it would be unlawful for OMB to require the agency to evaluate the monetary impacts for any guidance issued under Section 109. Furthermore, if OMB is suggesting that agencies should engage in a cost-benefit analysis of agency guidance in order to determine whether it is significant, we further object because it will create undue burdens on agency resources to conduct extensive economic analyses for non-binding guidance documents, which will ultimately impair our public protections.

In addition, again assuming arguendo that OMB has the authority to issue this Bulletin, NRDC is concerned that major, significant guidance documents that could have large adverse impacts on public health, safety or the environment may not be included in the comment requirements. This would make the Bulletin a one-way street in favor only of review of guidance that has economic impacts but not those with major adverse health or environmental impacts. Therefore, we would recommend the addition of the phrase,

[10] *See* Bulletin, *supra* note 2, §§ I(5) & I(3)(i), at 9.

[11] *See* Bulletin, *supra* note 2, § II(2), at 10.

"or adversely impact health, safety or environment protections" in the definition of an economically significant guidance document—and perhaps a revision of the entire term "economically significant."

V. OMB's solution is in certain respects incoherent, because it sets up a process that is inconsistent with the law and internally contradictory.

It is also our view that OMB has designed a highly flawed solution, because its proposal is both inconsistent with the law and internally contradictory. To illustrate this, we focus on OMB's treatment of agency letters to individuals or firms, a tool that is frequently employed by agencies to explain how an agency will typically enforce a statute or regulation in a particular instance. The FDA's scheme expressly excludes "other communications directed to individual persons or firms" from the definition of guidance documents. As a result, under FDA's scheme, such communications do not require notice and comment.

OMB's Bulletin, however, is silent on this issue. OMB enumerates various guidance documents that are excluded from the scope of the term "significant guidance document," borrowing significant portions of its language from FDA's regulation.[12] Like FDA's scheme, these excluded documents do not trigger notice and comment. Unlike FDA's regulations, however, the Bulletin does not mention or use the phrase "other communications directed to individual persons or firms." So it is unclear if OMB has chosen to treat such communications in a manner that is similar or dissimilar to FDA's scheme.

Undoubtedly, there are instances when agency letters should not require notice and comment because they are routine in nature and the burdens of notice and comment would far outweigh the benefits. There are some instances, however, where agency letters to individuals and firms should trigger formal notice and comment. The bulletin, however, does not always reach that result.

There are instances where an agency letter would trigger formal notice and comment as a matter of law, but not under the Bulletin. For example, if an agency goes beyond making a mere policy statement and changes the interpretation of an existing regulatory requirement, formal notice and comment would be triggered under the APA. *See Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997) (agency violates APA if it makes a "fundamental change in its interpretation of a substantive regulation without notice and comment"). Under section III of the Bulletin,

[12] *Compare* 21 C.F.R. 10.115(a)(b)(3) (excluding from the definition of guidance documents those "[d]ocuments relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professions, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or *other communications directed to individual persons or firms*") (emphasis added) *with* section I(3) of the Bulletin (excluding from the definition of significant guidance documents "contractor instructions, legal advisory opinions for internal Executive Branch deliberations, briefs and other litigation positions, speeches, journal articles, editorials, media interviews, press materials, memoranda of understanding, or warning letters").

however, a significant guidance document that changes an interpretation of a statute or rule would only trigger informal notice and comment.[13] This would create a conundrum by requiring an agency to simultaneously engage in formal notice and comment processes under the APA and informal notice and comment under the Bulletin. The case law concerning interpretive rules and policy statements is among the most complex in administrative law. Therefore, it is particularly important that OMB carefully explain how its proposal will treat this complex issue and how the Bulletin will conform to both the APA and case law without creating further confusion in an already complex area.

Extending the above example further, the Bulletin forces a similar contradictory result when an agency letter can be characterized as both a significant guidance document (e.g., setting forth a change in interpretation) and an economically significant guidance document (e.g., adversely affecting a sector of the economy in a material way)? Under section III of the Bulletin, the agency must publish the significant guidance document on their Web at least 30 days from issuance to allow public comment, but an agency does not have to respond to those comments. However, under section IV of the Bulletin, the agency generally must publish a draft of the economically significant guidance document in the *Federal Register*, on the Internet, and in hard copy, invite public comment, and then must respond to those comments.

Inevitably, there will be a temptation under the Bulletin to follow the least burdensome route by foregoing notice and comment for mere publication, undermining OMB's intent to increase transparency, consistency, and accountability. This conundrum does not occur under FDA's scheme, because the various categories of guidance documents are defined in mutually exclusive terms,[14] unlike OMB's proposal where the various guidance documents are subsets of one another.[15] Under FDA's scheme, a guidance document will either fall within the meaning of a "level 1 guidance document," requiring formal notice and comment before allowing agency implementation, or within the meaning of "level 2 guidance document," requiring public notice and comment but allowing immediate agency implementation.[16] OMB, therefore, needs to eliminate the confusion by either reshaping the definitions or clarifying how the agency should make its choice.

---

[13] Only an economically significant guidance document triggers formal notice and comment. *See* Bulletin, *supra* note 2, § IV, at 10-11. Significant guidance documents do not trigger formal notice and comment. *See id.*, § III, at 10.

[14] *See* 21 C.F.R. section 10.115(c) (defining "level 1 guidance documents" as guidance documents that "(i) set forth initial interpretations of statutory or regulatory requirements; (ii) set forth changes in interpretation of policy that are of more than a minor nature; (iii) include complex scientific issues; or (iv) cover highly controversial issues" and "level 2 guidance documents" as guidance documents that "set forth *existing* practices or *minor changes* in interpretation or policy. Level 2 guidance documents *include all guidance documents that are not classified as Level 1*" (emphasis added).

[15] *See* Bulletin, *supra* note 2, § I, at 9.

[16] *See* 21 C.F.R. 10.115(g)(1) & (g)(4).

The overall treatment of agency communications to firms or individuals warrants OMB's careful consideration. We make this recommendation because it is our view that agency communications directed to individual persons or firms are frequently the source of much mischief, resulting in back-door deregulation at the expense of public health, safety, and environmental protections. For example, in a December 13, 2005 guidance document sought by industry, EPA contravened the Clean Air Act by declaring in an agency letter, without notice or opportunity for public comment, that a company proposing to build a new coal-fueled power plant need not even evaluate the feasibility of using the cleanest available methods of generating electricity from coal. It is our hope that OMB can properly craft a solution to prevent such a scenario from occurring again. But crafting a solution will not come easily under OMB's present scheme.

If OMB chooses to include within the scope of the Bulletin all or most agency communications directed to individuals or firms, it will impose significant burdens. As discussed above, the Bulletin appears to sweep in both significant and insignificant guidance documents under its present scheme. By adding yet another category of guidance documents to an already large universe requiring notice and comment, OMB would further undermine an agency's capacity to carry out its existing responsibilities to protect public safeguards.

If, however, OMB chooses to exempt agency communications from the scope of the Bulletin, it will create a large loophole. At best, the loophole would give agencies an incentive to issue guidance documents in lieu of regulations, because it would be procedurally easier to do so. This would defeat the intent of the Bulletin. At worst, the loophole would allow unscrupulous agency officials and corporate lobbyists to work in concert to engineer back-door deregulation through the use of letters without opportunity for notice or public comment. In light of the various difficulties we have highlighted above, we again recommend in the strongest terms that OMB expand the opportunities to comment, and consult widely with all agencies, academic experts, stakeholders, and Congress before arriving at an appropriate response.

VI. Recommendations

NRDC supports the goals of greater accountability, transparency, and consistency for agency guidance. However, we reiterate our position that OMB's Bulletin, as drafted, should not take final effect, because it is a flawed solution that won't achieve its goals and will make matters worse. Accordingly, we offer the following recommendations:

1) NRDC recommends that OMB take time to consult widely with Congress, agencies, and a broad array of stakeholders before issuing another proposal and soliciting additional comment. The public has had only a short time to review OMB's current proposal, given that it was released the day prior to Thanksgiving and the comment period included major religious and national holidays. Typically, agencies will afford the public 60 to 90 days for public comment when issuing

sweeping proposals. Not doing so here would undermine the legitimacy of the Bulletin's stated intentions. Agency guidance is a complex area of administrative law and the public would be ill-served by a proposal that has not benefited from more extensive public input.

2) NRDC recommends that OMB provide a further legal and empirical basis for its Bulletin, including a fully-documented review of the problems it seeks to solve and the efficacy of OMB's proposed solutions, so the Bulletin can be evaluated in a proper fashion.

3) NRDC recommends that OMB design a solution that is internally coherent and consistent with the current state of the law. Careful consideration should be given to confining and clarifying its definitions to avoid confusion and undue burdens. More attention needs to be given to the distinction between significant and insignificant guidance to avoid creating undue burdens. Additionally, more attention needs to be given to the meaning of economically significant guidance by expanding the current definition to expressly include health, safety, and environmental protections.

Respectfully submitted,

Wesley Warren
Director of Programs

&

Chris Murray
Consulting Attorney