

March 31, 2009

Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budget (OMB)
Room 10102
New Executive Office Building
725 17th Street, NW
Washington, DC 20503

Re: New Executive Order on Federal Regulatory Review, Request for Comments
(74 *Federal Register* 8819, February 26, 2009)

To Whom It May Concern:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) appreciates the opportunity to comment on the process for reviewing federal regulations currently governed by Executive Order 12866 (September 30, 1993). HSIA represents manufacturers and some users of chlorinated solvents and has participated in several reviews conducted by the Office of Information and Regulatory Affairs (OIRA) in recent years.

HSIA strongly believes that OMB's central role in ensuring coordination and consistency in the federal regulatory process should not be diminished in an effort to address perceived excesses of the Office's authority. We echo the White House's view reflected in the recent Memorandum for Heads of Executive Departments and Agencies that, when properly conducted, "centralized review is both legitimate and appropriate as a means of promoting regulatory goals."¹

OMB has responsibility under multiple statutes² to "ensure consistency with Presidential priorities, to coordinate regulatory policy, and to offer a dispassionate and analytical 'second opinion' on agency actions."³ Of primary significance is OMB's role in coordinating the overlapping mandates of the various federal agencies to ensure consistency and to mediate disputes between agencies about the rationale for, and the potential impacts of, regulation and other significant agency activity.

¹ 74 *Fed. Reg.* 5977, February 3, 2009.

² These statutes include the Regulatory Flexibility Act, Paperwork Reduction Act, Unfunded Mandates Reform Act, Data Quality Act, National Technology Transfer Act, Regulatory Right to Know Act, and the Congressional Review Act.

³ 74 *Fed. Reg.* 5977.

Scope of OMB Review

Although E.O. 13422, and its explicit expansion of OMB's review authority to agency guidance documents, was recently rescinded,⁴ E.O. 12866 itself casts a broad net around agency activities by defining regulation as:

an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.⁵

It is reasonable to interpret the intent of the 1993 Executive Order as including guidance documents and agency risk assessments that play a significant role in the regulatory process and, thus, should be subject to OMB review. Without appropriate oversight, agency guidance documents may wrongly define or expand regulations, may potentially alter the original purpose of regulations, or even may serve as *de facto* regulations themselves.

The U.S. Court of Appeals for the DC Circuit explained its concern with the potential impact of agency guidance documents in *Appalachian Power Co. v. EPA* as follows:

The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on . . . Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.⁶

Because of the potential significance of agency guidance, the scope of agency actions that are addressed in the new Executive Order on federal regulatory review should be as broad as that in E.O. 12866 or, preferably, should include specific reference to "significant" guidance and other documents developed by federal agencies.

Relationship between OIRA and the Agencies

OIRA plays a critical role in coordinating policy developed by the federal agencies, particularly in rationalizing potential overlaps in the regulatory responsibilities of the various agencies.⁷ The significance of this role is likely to increase as important national and global

⁴ E.O. 13422 (January 18, 2007) was rescinded by E.O. 13497 on January 30, 2009.

⁵ E.O. 12866, Section 3(d).

⁶ *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1019 (D.C. Cir., 2000) (striking down emissions monitoring guidance as a spurious rule requiring notice and comment through legislative rulemaking procedures).

⁷ The role of the Small Business Administration in OMB review is discussed in greater detail later in this letter.

policy issues (e.g., climate change) require the participation of multiple agencies with varying responsibilities and jurisdiction. Essential to effective fulfillment of this role is the ability to identify potential areas of overlap and conflict early in the regulatory process.

Although OIRA's involvement in recent high profile risk assessments prepared by the Environmental Protection Agency (EPA)⁸ has been criticized, for example, the interagency discussions on these assessments coordinated by OMB have led to –

- reviews by the National Academy of Sciences that have, thus far, been sharply critical of EPA's methodologies and failure to follow its own guidelines, and
- a coordinated single cleanup standard for one compound (trichloroethylene) to replace an inconsistent patchwork of recommendations by EPA regions.

The problem with the review of the EPA assessments has not been OMB's attempt to coordinate agency input, but that such coordination occurred too late in the development of the assessment. Earlier coordination of agency activities related to the interpretation of the available scientific information is essential to recognizing the challenge in separating science from policy and the need for better integration of the two.⁹

Public Participation

It is not clear that additional efforts to encourage public participation in the OMB review process would significantly improve the quality or timeliness of federal regulations. Additional opportunity for public participation, in fact, would likely result in undue delay in the completion of OMB's review.

The notice and comment process, as specified by the Administrative Procedures Act, affords sufficient opportunity for public participation in federal rulemaking. OMB review is not intended, nor should it become, an occasion for additional public comment. OMB should continue to focus on consistency and coordination among the federal agencies. To the extent that interested parties have information to provide in these areas, they should continue to be afforded an opportunity to interact with OMB, within the constraints of established OMB policy.

Neither is it clear that additional public participation in agency priority-setting would enhance regulatory planning or implementation. Many federal regulatory activities are prescribed by statute, leaving agencies less control over their own priorities. All significant

⁸ While not regulations, EPA risk assessments are the basis for regulatory activities within the Agency and can have considerable impact on the activities of other federal agencies, state and local entities, and the private sector.

⁹ Recent changes to the risk assessment process under EPA's Integrated Risk Information System (IRIS) are intended, in part, to facilitate earlier discussion among the agencies. Additional revision may be necessary, but it is clear that the current IRIS review process takes far too long.

regulatory activities planned by an agency, whether mandated by statute or not, are summarized in the Unified Regulatory Agenda published at least once a year. Publication provides ample opportunity for interested parties to evaluate agency priorities and, where not mandated by Congress, to inquire with the agency and OMB about a particular action. Aside from making the agenda more readily available on agency web sites, there appears to be no practical value in encouraging more public participation in the process.

In both cases, additional public participation could delay the review process unnecessarily without contributing appreciably to the result. HSIA supports efforts to increase public awareness of regulatory activity (e.g., information on agency web sites), but only to the extent that they do not delay the review process.

Disclosure and Transparency

The disclosure provisions governing OIRA review under Section 6(b)(4) of E.O. 12866 provide a comprehensive basis for ensuring transparency in the regulatory decision-making process. OIRA has taken steps, moreover, to improve implementation of the public disclosure provisions by increasing the amount of information available on its website, adopting an open-door approach to meetings with outside parties, and accepting electronic submission of comments on certain policies and reports.

Consistent with HSIA's support for public awareness of regulatory activities, HSIA encourages OMB to explore additional ways to use the Internet and other communication technologies to make more information available sooner to facilitate public debate on regulatory approaches and to explore regulatory alternatives.

The Role of Cost-Benefit and Risk-Risk Analysis

A comprehensive cost-benefit analysis is critically important to an effective regulatory process and, often, is specifically required by statute. While not the only tool necessary, cost-benefit analysis provides a systematic way to evaluate the effectiveness of a regulatory proposal and to compare regulatory alternatives. Such analysis can reveal the most promising alternatives to achieve statutory goals, as suggested in OMB's first Report to Congress on the Costs and Benefits of Federal Regulation which concluded:

The only way we know how to distinguish between the regulations that do good and those that cause harm is through careful assessment and evaluation of their benefits and costs. Such analysis can also often be used to redesign harmful regulations so they produce more good than harm and redesign good regulations so they produce even more net benefits.¹⁰

¹⁰ OMB, Office of Information and Regulatory Affairs, *Report to Congress on the Costs and Benefits of Federal Regulation* (Sept. 30, 1997), at 10.

Perhaps the most important function of OIRA review of agency decision-making is the fact that it is the only oversight authority with the ability to review rulemaking across agency programs and across different agencies. This unique perspective allows OIRA to determine whether, for example, a delay in registering a toxic fumigant will cause increased stratospheric ozone depletion by the currently registered, and equally toxic, fumigant. As another example, OIRA is the only entity capable of assessing how restrictions on a widely used solvent, methylene chloride, have resulted in increased use of a more toxic but unlisted compound, n-propyl bromide, resulting in serious injuries to affected workers. Cost-benefit and risk-risk analysis are critical in ensuring that limited resources are used to address the most serious problems and to understand the unintended consequences that may occur.

E.O. 12866 requires agencies to provide an assessment of the potential costs and benefits of a regulatory action designated as significant, including the "underlying analysis." This requirement enables affected parties to develop meaningful comments on a proposal, and should be preserved in any new Executive Order.

Distributional Concerns and Fairness

Small businesses often bear a disproportionate share of the costs of regulatory actions. The importance of assessing the impacts on small businesses is recognized in the provisions of the Regulatory Flexibility Act ("RFA"), as amended by Small Business Regulatory Enforcement and Fairness Act ("SBREFA"). The RFA requires agencies to conduct a regulatory flexibility analysis for regulations that are determined to have a significant impact on a substantial number of small entities. Ensuring compliance with the RFA is an important responsibility of OIRA, in consultation with the Small Business Administration's (SBA) Office of Advocacy.¹¹

An agency can escape compliance with RFA by certifying in its rulemaking that the proposal would not have a significant impact on a substantial number of small entities, along with a statement providing the factual basis for the certification.¹² In response to improper certifications, OIRA and SBA's Advocacy Office signed a Memorandum of Understanding (MOU) in 2002, providing for Advocacy comments to OIRA on whether an agency should have prepared a regulatory flexibility analysis.¹³ E.O. 13272 (August 13, 2002) also provides for additional Advocacy input to OIRA on draft rules. The problem continues, however, as evidenced by EPA's certification that national emissions standards it adopted for perchloroethylene drycleaners in 2006 would not have a significant impact on a substantial number of small entities.¹⁴ EPA is now seeking, belatedly, to reconsider this rule, the impact of which falls almost entirely on small entities.

¹¹ The RFA specifically recognizes the importance of ensuring compliance with its provisions. It provides that SBA's Office of Advocacy shall report on agency compliance "at least" annually to the President and Congressional Committees. 5 U.S.C. § 612(a).

¹² 5 U.S.C. § 605(b).

¹³ The MOU expired in 2005.

¹⁴ 71 *Fed. Reg.* 42724, 42742, July 27, 2006.

Ensuring proper consideration of small business impacts in agency rulemaking, as required by the RFA, is critical to effective review by OMB. It is important, therefore that the new Executive Order on regulatory review incorporate aspects of the 2002 MOU and E.O. 13272 regarding the involvement of SBA's Office of Advocacy. Additionally, the new Order should provide for timely notification to Advocacy of certification under § 605(b),¹⁵ to allow an opportunity to comment on the certification to OIRA. Similarly, the Order should specify that agencies provide an advance copy of a draft final rule to Advocacy prior to sending it to OIRA.

Such revisions to E.O. 12866 will appropriately strengthen the role of Advocacy in commenting on rules affecting small businesses undergoing regulatory review by OIRA, ensuring the full compliance with the RFA as intended by Congress.

Conclusion

OMB/OIRA review of regulatory and other significant activities of the federal agencies has been a valuable tool for facilitating consistency and coordination since the implementation of E.O. 12866. Revision of the process for OMB review should preserve the fundamental provisions of 12866, while –

- clarifying that the review process is intended to include the review of significant guidance documents and agency risk assessments that can serve to interpret agency policy or impact future regulations,
- ensuring early coordination of activities related to the interpretation of scientific information,
- preserving a central Executive Branch office responsible for cost-benefit and risk-risk analysis, and
- providing for more timely input from SBA's Office of Advocacy concerning potential small business impacts and compliance with the RFA.

Sincerely,

Steve Risotto

Stephen P. Risotto
Executive Director

¹⁵ While § 605(b) requires that the agency provide the Office of Advocacy a copy of the certification, it does not specify that the certification be provided far enough in advance to allow Advocacy time to comment.