June 1, 2012

BY ELECTRONIC MAIL
The Honorable Cass R. Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Old Executive Office Building
Washington, DC 20503
Electronic Address: http://www.regulations.gov (Docket ID OMB 2012-0003)

Re: Comments on Request for Information on Federal Participation in the Development and Use of Voluntary Consensus Standards and In Conformity Assessment Activities

Dear Administrator Sunstein:

The U.S. Small Business Administration's (SBA) Office of Advocacy (Advocacy) submits the following comments on the Office of Management and Budget's (OMB's) request for information on *Federal Participation in the Development and Use of Voluntary Consensus Standards and In Conformity Assessment Activities*.[1] The request for information invites interested parties to comment on current issues regarding Federal agencies' standards and conformity assessment related-activities, as well as for input on whether and how OMB should revise or supplement existing OMB Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.[2] A more detailed discussion of the request for information is provided below. Advocacy believes that OMB has raised a number of significant issues and welcomes the opportunity to offer recommendations to better protect the interests of small entities.

Office of Advocacy

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within SBA, so the views expressed by Advocacy do not necessarily reflect the views of SBA or the Administration. The Regulatory Flexibility Act (RFA),[3] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[4] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives. Moreover, Executive Order

[1] 77 Fed. Reg. 19357 (March 30, 2012).
[2] *Id.*
[3] 5 U.S.C. § 601 et seq.
[4] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

(EO) 13272[5] requires federal agencies to notify Advocacy of any proposed rules that are expected to have a significant economic impact on a substantial number of small entities and to give every appropriate consideration to any comments on a proposed or final rule submitted by Advocacy. Further, both EO 13272 and a recent amendment to the RFA, codified at 5 U.S.C. 604(a)(3), require the agency to include in any final rule the agency's response to any comments filed by Advocacy and a detailed statement of any change made to the proposed rule as a result of the comments.

Background

The National Technology Transfer and Advancement Act (NTTAA) requires Federal agencies to "use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities," except when an agency determines that such use "is inconsistent with applicable law or otherwise impractical."[6] In other words, NTTAA requires federal agencies to use private technical standards rather than developing their own government-unique standards whenever possible, or explain why they cannot. These private technical standards are developed by a wide array of standards development organizations (SDOs), and it is difficult to generalize about their make-up, as they cover a broad spectrum of issues, involve varied stakeholders, and operate under differing policies and procedures. Further, many of the SDO materials are copyrighted and many SDOs fund their operations by selling these materials to the public.

In response to the enactment of the NTTAA, OMB in 1998 issued (after a public comment process) OMB Circular A-119,[7] which establishes the federal government's policy with respect to adopting private technical standards (or voluntary consensus standards) through the process of Incorporation by Reference (or "IBR"). IBR refers to federal agencies' adopting materials, such as industry consensus standards, into their regulations by simply referencing them in the Federal Register. However, the Federal Register is not allowed to publish IBRs unless they are "reasonably available" to affected persons.[8]

There is currently a great deal of activity concerning the IBR issue. For example, the Administrative Conference of the United States (ACUS) recently issued a Recommendation on IBR that, among other things, calls on federal agencies that are considering incorporating by reference "to ensure that the materials will be reasonably available both to regulated and other interested parties."[9] Further, following the ACUS Recommendation, a group of legal scholars affiliated with ACUS filed a petition with the Office of the Federal Register (OFR) asking OFR to define the term "reasonably available" – including the possibility that all IBR materials should be available on the internet for free. In addition, the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011[10] prohibits the Secretary of Transportation from issuing guidance or

[5] EO 13272, *Proper Consideration of Small Entities in Agency Rulemaking* (67 Fed. Reg. 53461) (August 16, 2002).
[6] 77 Fed. Reg. 19358.
[7] 63 Fed. Reg. 8546 (February 19, 1998).
[8] Under a provision of the Freedom of Information Act, 5 U.S.C. 552(a), matters incorporated by reference and published in the Federal Register with the approval of the Director of the Federal Register are deemed to be reasonably available to the class of persons affected thereby. 5 U.S.C. 552 (a)(1).
[9] Administrative Conference Recommendation 2011-5, Incorporation by Reference, p. 5.
[10] Pub. L. 112-90 (January 3, 2012).

regulation on pipeline safety "that incorporates by reference any documents or portions thereof unless those documents or portions thereof are made available to the public, free of charge, on an Internet Web site." OMB now requests public comment on whether and how it should revise or supplement Circular A-119 to reflect recent developments, changes in technology, and other practices.

Small Entities Have Expressed a Strong Interest in Federal Use of Private Technical Standards

A number of small entity representatives have contacted Advocacy and expressed concerns with agency use of private technical standards, both through IBR and in procurement. In response, Advocacy hosted a small business roundtable on May 9, 2012 to discuss the broad issue of IBR as well as the OFR petition referenced above. Attendees at the roundtable included small businesses, small entity representatives, representatives from several private SDOs, the OFR, and several other federal agencies. Many of the small entity representative attendees are active participants in some of these SDOs and have broad experience with them. Further, Advocacy and a group of small entity representatives met with OMB on May 30, 2012 to discuss these issues. The following comments reflect the views expressed during the roundtable and OMB meeting, as well as in other conversations with small entity representatives.

1. There is no uniform small entity perspective on the questions OMB has presented.

Small entities, including for-profit businesses, non-profits, and small governmental jurisdictions, are as diverse as the rest of the U.S. economy. In addition, many private SDOs themselves are small entities. It is therefore not surprising that small entities have a wide diversity of opinions on the Federal use of private technical standards. As a result, there is no single policy on issues such as "reasonably available" that will benefit all small entities in all cases.

Nonetheless, all parties agree that Federal use of private technical standards can be of great benefit to the Federal government and small entities. IBR is a useful tool for Federal rulemaking that helps improve the quality and efficiency of rulemaking and the resulting rules. Adoption of industry consensus standards in other contexts, such as procurement, can align Federal interests with industry best practices and improve communication and outcomes.

However, whether a particular use of a private technical standard is good for small entities is highly dependent on the particulars of each use and the standard to be adopted. There is no "one-size-fits-all" policy that can ensure positive outcomes for all small entities. Fairness to small entities can only be evaluated on a case-by-case basis.

2. There are significant risks to small entities if their interests are not adequately considered when Federal agencies use private technical standards.

While the Federal use of private technical standards can have significant benefits, OMB and Federal agencies should be aware that small entities do have concerns about the use of private technical standards. These concerns include their ability to participate in the standards development process, access to standards in proposed rules and during federal procurement

contract development, and access to standards after promulgation and citation of standards not incorporated in enforcement actions.

- Participation in the standards development process.

The interests of small entities may not have been considered during the development of a private technical standard and could thus be harmed by the adoption of the standard. Small entities have noted the great commitment of time and resources it takes to participate in a standard development process, including traveling to and attending meetings, participating in working groups, and reviewing and recommending changes to draft documents. At best, many must rely on trade associations that represent all of an industry rather than just the small entities in an industry. Even for voluntary consensus standards bodies, few of which include small entities as an "interest" to be balanced, small entities are at a disadvantage.

Small entities have also expressed concern that "consensus," as implemented by major SDOs, can be manipulated to achieve standards that advance a particular policy preference or create market opportunities for select providers but do not reflect a consensus among regulated entities. Although the definition of a voluntary consensus standards body in OMB Circular A-119 requires openness and balance of interest, each standards committee has the discretion to make their own rules about participation, and committee leadership can identify a diversity of interests that serves to dilute the voice of those parties most directly affected. Since the status of each standard as a "consensus" is only subject to the self-certification of the "voluntary consensus standards body," small entities often lack the opportunity to challenge the result. This can be particularly harmful to the interests of small entities, which already tend to be underrepresented in such deliberations.

Of course, for non-consensus standards, such as those developed by consortia or a single firm, small entities often have no representation and are ensured no opportunity to express their views before a standard is adopted.

Standards produced by processes that do not adequately consider small entity interests have a greater likelihood of being disproportionately harmful to small entities and creating unreasonable barriers to future entry. In extreme cases, these standards create *de facto* monopolies.

Small entities need a reasonable opportunity to participate in key decisions and express their views during the standards development process (including at the working group level) and have those views fairly considered and accommodated. In some cases, this will require additional efforts to recruit small entity participants, including monetary incentives and other resource support.

- Access to standards in proposed rules and during federal procurement contract development.

Inadequate access to private technical standards and the underlying data and analysis upon which they are based can undermine notice and comment processes. Few small entities are financially able to expend significant resources to participate fully in rulemaking processes. Access to

standards can be a barrier to that participation, and small entities may be reluctant to invest in access if there is no guarantee that the standard eventually will be adopted. In the case of rulemaking, small entities that do not have access to standards are unable to comment on the accuracy of the required analyses under the RFA or the availability of regulatory alternatives if they do not understand precisely what the regulation would require. For procurement, small entities without access to mandated standards must incur an additional cost before being able to respond to the Federal request for proposals.

Small entities also need the opportunity to inform Federal agencies of substantive problems with the standards. These include issues with the quality of data or analysis upon which standards are based, conflicts between the standards and existing business practices, or anticompetitive effects of adopting the standard.

- Access to standards after promulgation and citation of standards not incorporated in enforcement actions.

Small entities need to know what the law is. Any barrier to understanding obligations under Federal regulations presents a risk. For IBR standards, "reasonably available" will depend greatly on the industry and its business practices.

However, small entities also have concerns about the use of private technical standards to interpret regulations in enforcement actions. In these circumstances, regulations make no reference to a private technical standard, but the enforcement action cites failure to comply with a particular standard. In other cases, the private technical standard is cited as a benchmark. This practice is unfair to small entities, since private technical standards can be revised (and thus made significantly more stringent) without notice and comment and the universe of available standards is too large for anyone to fully anticipate, let alone purchase.

3. Regulated small entities want a seat at the table and easy access to the law.

Fairness to small entities includes a full consideration of the issues discussed above: participation in the standards development process, access to standards in proposed rules and during federal procurement contract development, and access to standards after promulgation and citation of standards not incorporated in enforcement actions.

Each of these steps represents both a potential cost to regulated small entities and a potential revenue stream to small SDOs. SDOs balance these factors in their business models. Since fair and equitable treatment in the standards development process is so important, many small entities are hesitant to call for universal free access to IBR standards. They understand that free access would likely lead to significantly higher costs to participate in SDO processes, which would further hinder small entity participation.

This balancing of interests goes beyond the traditional limit of regulatory analysis, since only the cost of access to standards in final rules would appear in a cost-benefit accounting. Overall fairness to small entities should be the touchstone, which requires Federal agencies to exercise reasonable judgment.

4. SDOs want a reliable set of rules that values the service they provide to industry and the Federal government.

Small entities generally favor the adoption of voluntary consensus standards, and thus favor the continued existence of a vibrant and robust SDO community. The Federal government should avoid actions that jeopardize this community.

Federal policies on IBR and other uses of private technical standards should therefore accommodate the wide range of SDOs. In Advocacy's brief review of the issue, we now understand that SDOs have varied relationships with regulated entities, cost structures, policies on small business participation, and cooperative relationships with the regulating agency. "Reasonably available" might mean very different things to different SDOs.

However, since development of voluntary consensus standards is a complex and resource-intensive exercise, SDOs need confidence in their future revenue streams in order to engage in the exercise. However, the Federal government is not well positioned to replace revenue from sale of copyrighted materials on a universal basis. SDOs are similarly concerned that electronic piracy will cut into sales of standards if free, read-only versions are mandated. Doubts about the revenue stream will discourage development of these voluntary consensus standards. In their absence, the Federal government may choose non-consensus standards, to the disadvantage of small entities, or to develop its own. Neither of these outcomes is necessarily desirable.

Recommendations

1. OMB Circular A-119 should establish policies that will mitigate the risks to the interests of small entities.

- "Voluntary consensus" should define each particular standard rather than the SDO.

Although many standards development processes work well and produce high-quality products, small entities have raised significant concerns about the consistency of procedures across standards, and question whether self-certification is appropriate. Advocacy therefore recommends that the standards of openness, balance of interest, due process, and an appeals process should be applied to each particular standard rather than to the SDO.

- OMB should provide additional guidance on openness, balance of interest, and due process.

Small entities want to ensure that the standards development process includes a consensus of parties directly affected by the standards, rather than the opportunity to advance policy preferences or market opportunities. Advocacy suggests that private technical standards that require regulated industries to make significant changes beyond existing business practice might be better suited to a standard developed by the agency through normal rulemaking.

- Federal agencies should prefer a voluntary consensus standard over a non-consensus standard.

Although there are circumstances when non-consensus standards best reflect existing industry practice, agencies should be discouraged from selecting a non-consensus standard when a voluntary consensus standard alternative exists.

- Information Quality Act guidelines should apply to the data and analysis upon which a private technical standard is based when Federal agencies use the standard.

Data and analysis included in a public record in support of rulemaking is subject to the Information Quality Act,[11] which requires agencies to ensure the quality, objectivity, utility, and integrity of information they disseminate. Data and analysis that support a private technical standard used by a Federal agency should be held to the same standard. Therefore, Advocacy recommends that this information should be subject to each agency's Information Quality guidelines,[12] even if the data and analysis originates from a nonfederal party. If an agency is unable to provide reasonable access to the data and analysis or unable to resolve significant Information Quality challenges to a standard, it should not use that standard.

- No enforcement action should rely on or cite to private technical standards unless they are explicitly incorporated by reference through rulemaking.

The continuing advancement of private technical standards makes it increasingly important that agencies only use these standards after notice and comment and adequate consideration of the interests of small entities.

2. Agencies should have an affirmative obligation to consider and request comment on small entity issues with private technical standards.

Advocacy recommends that agencies explicitly consider small entity participation in the standards development process, access to standards in proposed rules and during contract development, and access to standards after promulgation. Agencies should document this consideration and request comment on the following:

- Whether the private technical standard meets the definition of "voluntary consensus," including whether small entities were included in the "balance of interests" and had adequate opportunity to participate.

- Whether standards are "reasonably available" in each proposed rule, and incorporate the cost of access and training into their analyses required under the RFA, the Paperwork Reduction Act, and EOs 12866 and 13563.

[11] Section 515 of the Consolidated Appropriations Act, 2001 (Pub. L. 106-554).
[12] See, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, Office of Management and Budget, 67 Fed. Reg. 8452 (February 22, 2002) (available at http://www.whitehouse.gov/sites/default/files/omb/fedreg/reproducible2.pdf).

- Reasonable alternatives to adopting private technical standards.

When there are concerns about the fairness to small entities, agencies should adopt alternate standards or safe harbors not otherwise reliant on the standard.

3. OMB Circular A-119 should include guidance on consideration of small entity interests through the RFA.

The RFA requires federal agencies to assess the impact of their regulatory proposals on small entities and consider significant alternatives that are feasible, meet the agencies objectives, and minimize the burden on small entities. Advocacy recommends the following to enhance agency RFA compliance when using private technical standards in rulemaking:

- Impacts include the cost of access to private technical standards.

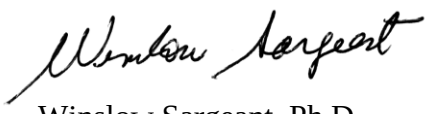
- To ensure agencies adequately consider the potential disproportionate effects of its rules on small entities, agencies should not assume that voluntary consensus standards universally reflect existing business practice. If an agency certifies a rule under section 605(b) of the RFA, the agency must have a factual basis that does not rely on the existence of the private technical standard.

- Agencies should consider and request comment on regulatory alternatives that do not rely on private technical standards, particularly if the agency proposes to use a non-consensus standard.

Conclusion

Thank you for the opportunity to comment on OMB's Request for Information on *Federal Participation in the Development and Use of Voluntary Consensus Standards and In Conformity Assessment Activities*. One of the primary functions of the Office of Advocacy is to assist federal agencies in understanding the impact of their regulatory programs on small entities. As such, we hope these comments are helpful and constructive to OMB and others considering this issue. Please feel free to contact me or either Bruce Lundegren (at (202) 205-6144 or bruce.lundegren@sba.gov) or David Rostker (at (202) 205-6966 or david.rostker@sba.gov) if you have any questions or require additional information.

Sincerely,



Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy