



Consumer Federation of America

June 1, 2012

Hon. Cass R. Sunstein, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Re: Docket IDs OMB 2012-0003 and NARA-12-0002-0001

Submitted through regulations.gov

Dear Mr. Sunstein:

CFA submits these comments in response to OMB's Request for Information in Docket IDs OMB 2012-0003 and NARA-12-0002-0001. CFA is a non-profit association of approximately 280 pro-consumer groups, with a combined membership of 50 million people that was founded in 1968 to advance the consumer interest through advocacy and education. CFA has participated in numerous voluntary standards activities for many years through participation in ASTM, UL and ANSI and in the policy arena.

CFA will be commenting on two topics in these comments: incorporation by reference and conformity assessment.

I. Incorporation by Reference

Standards that are incorporated by reference into federal regulations must be widely available and easily accessible to the public and must be available without charge.

CFA works within voluntary standards organizations to ensure that the voluntary standards produced by the standards development organizations reflect the interests of consumers and offer the most robust health and safety protections. It is imperative that both within the voluntary standards process and when a standard is incorporated by reference into a federal regulation, that the standard must be free of charge and easily accessible.

Without unfettered access to these standards, our democratic system will be severely limited and important constituencies such as individual consumers and public interest and consumer organizations will be unable to participate in these proceedings. Public interest involvement and consumer participation is necessary to ensure that the consumer and public interest is represented and that public health and safety is prioritized.

Access to these standards must be available through the internet, through clear and accessible mechanisms that are free of charge to the public. We urge OMB to ensure that standards incorporated by reference into federal regulations are free and accessible to the public.

II. Conformity Assessment

For the vast majority of consumers, the complexities of conformity assessment and product safety standards are far from their hectic every day agenda. Nonetheless, consumers believe that products they buy are tested by some entity to ensure that they are safe before a product is available for sale. While most consumers don't know which products are subject to mandatory or voluntary standards, whether or how these products are tested to make sure the products meet the standards, or what criteria are used to measure any of these standards, it is clear that consumers expect that products can and should be used as intended and will not cause harm to them and their families. In order for us all to have faith in the market place, product standards, whether voluntary or mandatory, must effectively address the known risks of harm. Moreover, those products must comply with all applicable standards. Critically, the relevant federal agencies must have the unfettered ability to be engaged in these processes.

This section of these comments will focus on three main issues: 1) the adequacy of the voluntary standard; 2) the need for a system in place to ensure compliance with voluntary standards; and 3) the need for accreditation to ensure that the compliance is robust and meaningful.

1. Adequacy of Voluntary Standard

Any discussion of conformity assessment must first focus upon what conformity is measured against. Regarding product safety, for example, the voluntary standard applicable to the product must adequately reduce the risk. The fact that there may be consensus and that various entities may agree on the substance of the standard does not make it adequate. The standard must reduce or eliminate the unreasonable risk of harm potentially caused by previous versions of the product. Over the years, CFA has observed numerous voluntary standards where consensus has been achieved but the resultant standard was not adequate to reduce or eliminate an unreasonable risk. A system of conformity assessment cannot be successful unless the underlying standard is adequate.

In an effort to outline criteria to measure whether a voluntary standards process provides a forum that can be relied upon, CFA suggest the following parameters for successful voluntary standards:

- 1) Adequate participation by consumer groups
- 2) Transparent process
 - a. Information must be shared with all participants
 - b. Must be transparent and understandable by the public
- 3) Clear logical process
- 4) Potential for regulatory oversight if standard fails to meet goals
- 5) Participation by regulatory agency
- 6) The standard has to be widely used and accepted to be effective

- a. It must be clear which products, institutions, etc. do or don't comply with the standards
 - b. There must be consequences for non compliance
- 7) Standard should not be wholly controlled by industry
 - 8) Any participants must have the ability to raise issues and those issues must be addressed
 - 9) Must effectively address the hazard or other consumer protection at issue

Voluntary standards must address the identified hazard. At a minimum, this means that voluntary standards are often reactive to known hazards. Once the standard is written and final, it is important that there be continual monitoring to assess the effectiveness of the standard. For consumer products, data of injury patterns must be followed to determine if the standard is effective in reducing the injuries. This type of monitoring is important to insure that the standard is adequate.

In 2007, for example, this process failed. Imported toys were recalled by the millions. Consumers didn't know what toys to buy because popular toys contained excessive levels of lead. Another toy metabolized into the date rape drug when mixed with saliva. There were voluntary standards, there was a conformity assessment system without extensive government involvement, and there was widespread non-compliance and the market suffered. In addition, more recently, there were millions of recalls of cribs that posed dangerous environments to infants. There were voluntary standards and mandatory standards in place, there was compliance to those standards, there was a conformity assessment system but again, without extensive government involvement, but the standards were inadequate in addressing hazards posed to infants. Consumers didn't know where they could put their infants safely to sleep. The standards didn't change to address the known hazards until the Consumer Product Safety Improvement Act was passed in 2008. This law, in section 104, creates the right balance between private sector standards development and the promulgation of those as mandatory standards by the CPSC.

If the safety risk is adequately addressed by a voluntary (or mandatory) standard, the standard must be associated with a system to demonstrate that products claimed to be in compliance do comply with the standard. Moreover, compliance with that standard must be clear and knowable both by the federal government and by consumers and the federal government must play a prominent role in this process.

2. System in Place to Ensure Compliance with the Standard

These examples reflect a long supply chain in which there was reliance upon agreements to conform to standards, but a lack of meaningful verification to assure compliance. In addition, the crib example illustrates a changing industry wide use of materials that the voluntary standard could not adequately take into account as well as a federal agency, the U.S. Consumer Product Safety Commission that did not have adequate authority. These factors must be taken into account for conformity assessment to be meaningful. These examples also reflect that conformity assessment conducted by a first party is not adequate. Independent third party testing is much more effective to ensure that a product meets the standards it claims to meet.

In order to be adequate, conformity assessment must also take into account predictive failures. The system in place must be robust and dynamic enough to detect such failures. A system that works well relies upon trust as well as meaningful verification.

In summary, when a mandatory or voluntary standard is relied upon to protect public health and safety, it is necessary for an effective system to be in place that ensures compliance. Federal Agencies must have the authority and the flexibility to assess the particular industry on a case by case or product by product basis (mattresses are different from lawn mowers) and that testing must be rigorous and meaningful. For the CPSC, it had adequate authority over voluntary standards and conformity assessment only since the CPSIA passed in 2008. These are principles that consumers demand and have a right to expect.

3. Accreditation of Conformity Assessment Bodies

Conformity assessment must deliver a level of confidence that Congress requires for the agency to fulfill its statutory mandate. Consumers must have confidence that this system is meaningful and rigorous. In order for conformity assessment to be meaningful for consumers, the conformity assessment body who conducts the assessment must be qualified to conduct the assessment. As such, conformity assessment bodies must be accredited. The conformity assessment body must prove that it is capable of conducting the review, that it is knowledgeable about the product at issue, about the standards at issue, as well as the testing protocol required to ensure compliance to that standard. Most important, the relevant federal agency must have the ability to be engaged and set the parameters for the accreditation process.

Accreditation, just as conformity assessment itself, must be meaningful and rigorous. An entity without adequate knowledge or skills cannot suddenly emerge as a conformity assessment body. For products under CPSC's jurisdiction, for example, third party testing conformity assessment bodies must be accredited by international accrediting bodies. The scope of the accreditation should apply only to the testing for which the conformity assessment body has demonstrated competence and good laboratory practices. The government must be able to conduct spot checks and periodic reviews in order to construct conformity assessments. Revisions to accreditation requirements must be permitted to ensure that the highest standards for laboratory accreditation are being followed. Standards should be applied to ensure impartiality if a 1st party conformity assessment is permitted. Conflicts of interest should always be protected against and such 1st party assessment should be limited. Self declarations for conformity assessment should be the rare exception rather than the rule.

As a final clarifying example, the CPSIA required CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies to assess children's products for conformity with children's product safety rules. Many of these rules are being promulgated by CPSC based upon reliance on ASTM standards that CPSC is strengthening. Under this law, each manufacturer or private labeler of products subject to the children's product safety rules is required to be tested by a third party conformity assessment body accredited to conduct such testing and must issue a certificate of compliance with the appropriate standard based on that testing. Certification must be based on a test of each general use consumer product or a reasonable testing program and third party testing of sufficient samples of the product. CPSC requires that conformity assessment bodies must be accredited by a signatory to the International

Laboratory Accreditation Cooperation- Mutual Recognition Agreement and uses ISO/IEC 17025:2005 “General Requirements for the Competence of Testing and Calibration Laboratories,” as the standard for accrediting conformity assessment bodies. From the consumer perspective, this exemplifies a conformity assessment system that appropriately engages the federal government to ensure the effectiveness of compliance with the safety standards at issue.

Conclusion

As OMB considers reopening Circular A- 119, we urge OMB to ensure that voluntary standards incorporated by reference in federal regulations are available to the public at no cost and to continue to provide agencies with the authority, responsibility and flexibility to ensure that the voluntary standard, the conformity assessment body, and the accreditation process are robust enough to protect consumers from unsafe products. Consumer confidence in our markets suffers as a consequence of a failure of these systems.

Sincerely,

A handwritten signature in black ink that reads "Rachel Weintraub". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Rachel Weintraub
Director of Product Safety and Senior Counsel