Consumers Union * Consumer Federation of America
*** Kids in Danger * Public Citizen ***
*** U.S. Public Interest Research Group ***

July 6, 2010

Office of the Secretary
Consumer Product Safety Commission
Room 820
4330 East-West Highway
Bethesda, Maryland 20814
Via e-mail: http://www.regulations.gov
Docket No. CPSC-2009-0064

Comments of Consumers Union, Consumer Federation of America, Kids in Danger, and the U.S. Public Interest Research Group to the U.S. Consumer Product Safety Commission
on
"Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1215 of Title 16, Code of Federal Regulations"

Introduction

Consumers Union of U.S., Inc. (CU), Consumer Federation of America (CFA), Kids in Danger, and the U.S. Public Interest Research Group (jointly "We") submit the following comments in response to the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") in the above-referenced matter ("Notice of Requirements" or "Notice").[1] The CPSC has issued this Notice of Requirements pursuant to section 14(a)(3)(B)(vi) of the Consumer Product Safety Act (CPSA) (15 U.S.C 2063(a)(3)(B)(vi)), as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. In this Notice, the CPSC publishes the requirements for accreditation of 'third party' laboratories, termed conformity assessment bodies to assess the

[1] "Third Party Testing for Certain Children's Products: Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1215 of Title 16, Code of Federal Regulations" as Established by the Consumer Product Safety Commission," 75 Fed. Reg. 31688 (June 4, 2010).

conformity of certain products with safety rules.[2] We submit these comments in response to the CPSC's Notice of Requirements.

Background

Section 14(a)(3)(B)(vi) of the CPSA, as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-3144, directs the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies to assess children's products for conformity with "other children's products safety rules." A children's product safety rule is defined as a consumer product safety rule (for products designed or intended primarily for children 12 years of age or younger) under the CPSA or similar rule, regulation, standard, or ban under any other Act enforced by the Commission, including a rule declaring a consumer product to be a banned hazardous product or substance. Under section 14(a)(3)(A) of the CPSA, each manufacturer (including the importer) or private labeler of products subject to these regulations must have products subject to those regulations that are manufactured more than 90 days after the Federal Register publication date of a notice of the requirements for accreditation, tested by a third party conformity assessment body accredited to conduct such testing, and must issue a certificate of compliance with the appropriate regulation based on that testing. Certification must be based on the testing of "sufficient samples" of the product, or samples that are identical in all material respects to the product. Irrespective of certification, the product in question must comply with applicable CPSC requirements.[3]

The Commission seeks comments on the notice of requirements as they apply to accreditation of third party conformity assessment bodies.

[2] Section 14(f)(1) of the CPSA.
[3] See e.g. section 14(b) on the CPSC, as added by section 102(b) of the CPSIA.

Recommendations

We urge the CPSC to adopt the following recommendations in its implementation of the accreditation requirements for third party conformity assessment bodies.

We support the requirements (described in section II.A. of the Notice) that conformity assessment bodies be accredited by a signatory to the International Laboratory Accreditation Cooperation - Mutual Recognition Agreement (ILAC-MRA). This helps establish an internationally recognized consortium for organizations qualified to provide accreditation services.

In addition, we support the use of ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," as the standard for accrediting conformity assessment bodies. However, we must emphasize the importance of ensuring that the scope of the accreditation apply to only the testing for which the conformity assessment body has demonstrated competence and good laboratory practices. In particular, they must demonstrate competence and be specifically accredited to test to the method for testing infant bath seats included in 16 CFR part 1215, *Safety Standard for Infant Bath Seats*.

We recommend that the Commission conduct periodic reviews and revise accreditation requirements to ensure that the highest standards for laboratory accreditation are followed. For example, if the ISO/IEC 17025: 2005 is superseded by a more stringent accreditation standard, then the Commission should, at minimum, adopt the more stringent standard.

It is important that the Commission apply rigorous standards to ensure that impartiality is maintained within firewalled conformity assessment bodies. We support the requirement that these laboratories submit copies of their training documents to the Commission and the accreditation body for review showing

how employees are trained to notify the Commission immediately and confidentially of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over the laboratory's test results. The Commission should also develop a stringent standard for such training documents to meet. Standards for impartiality are addressed in ISO/IEC Guide 65 – "General Requirements for Bodies Operating Product Certification Systems," which could, as a starting place, be applied for this purpose. This standard requires a documented structure designed to safeguard impartiality, including provisions to ensure the impartiality of the operations of the certification body. Other standards or best practices that are more protective of laboratory and test result integrity should also be considered for the development of a training document standard. As part of the accreditation process, the laboratory should be required to show proof of its compliance with the ISO/IEC Guide 65 or the stringent standard regarding impartiality protections developed by the CPSC.

We also have concerns that the additional accreditation requirements for firewalled conformity assessment bodies may not protect against potential conflict-of-interest when the conformity assessment body is owned, managed, or controlled by the manufacturer or private labeler of a children's product. We recommend that the Commission establish safeguards to ensure that employees engaged in conformity assessment activities are not rewarded monetarily or otherwise for positive outcomes of testing. In addition, the product sampling schedule for determining on-going compliance with established regulations should be double that of independent, accredited conformity assessment bodies.

Furthermore, should it be demonstrated that a firewalled conformity assessment body has certified a product later found to be non-complaint with applicable regulations, the conformity assessment body should temporarily lose their accreditation. We recommend that temporary suspension of their accreditation be 3 months for the first offense, 6 months for the second offense, and 12

months for the third offense. Four our more offenses over a two year period should result in permanent loss of accreditation status.

The recommendations described above should apply as well to the additional accreditation requirements for Governmental Conformity Assessment Bodies as described in section II.C in the Notice.

We also recommend a similar scheme for suspending accreditation for independent conformity assessment bodies that certify a product that is later found to be out of compliance with applicable regulations. In the case of an independent laboratory, the suspension scheme should be less rigorous than that for firewalled laboratories since it is essential for those independent labs to maintain certification in order to stay in business. We recommend a scheme that includes a written warning after the first offense, a 1 month suspension after the second offense, and a 3 month suspension after the third offense. Four or more offenses should result in a revaluation of the laboratory's practices by commission staff and then reassessment by the ILAC accreditation body.

The Commission should establish a defined system for suspending accreditation of any conformity assessment body for just cause. Examples of reasons for delisting and accredited lab might include, but are not limited to:

- evidence of conflict-of-interest or where there is undue influence by a manufacturer, a common parent company, or other party that could have affected test results; or
- a laboratory has been found to be incompetent to conduct required testing due to personnel or laboratory equipment changes; or
- the prescribed schedule for sampling sufficient products to demonstrate on-going compliance with applicable regulations is not being followed (see below).

Although not directly related to accreditation requirements, the CPSC has not been specific about the meaning of “sufficient samples” to meet the certification requirements in a test program conducted by the conformity assessments body. Since the word “sufficient” is subject to interpretation, we anticipate that different conformity assessment bodies will require vastly different sampling schedules. Producers are then apt to work with those conformity assessment bodies that require the least onerous sampling schedule. We strongly recommend that the Commission prescribe a specific, consistent testing schedule based on a statistical scheme for sample product runs of the children’s products. The number of samples selected for testing should be based on both the size and the duration of the production run. The accreditation body can confirm that the recommended sampling schedule is being followed by the conformity assessment body.

We also recommend that the Commission define a specific procedure for filing certificates of compliance. The Commission should specify not only who should “own” the certificates, but also the amount of time that they need to be kept on file.

Respectfully submitted,

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