
The Consumer Product Safety Improvement Act of 2008 (CPSIA) requires every manufacturer (defined to include an importer) of a consumer product subject to a rule, ban, standard or regulation under any Act enforced by the CPSC (applicable standard) to certify compliance with each applicable standard before importing the product or distributing it in commerce. With limited exceptions, such certification of a children’s product (a consumer product designed or intended primarily for children 12 years or younger) must be based on testing of the product by a third party laboratory accepted by CPSC to test to the applicable standards (Third Party Lab). The certification requirement has become effective for individual standards on a rolling basis since 2008, and the following regulations detailing requirements for testing and certification were published in November 2011:

- 16 C.F.R. Part 1109, which permits a manufacturer to base certification on component part testing or certification, or another party’s finished product testing or certification, went into effect in December 2011.
- 16 C.F.R. Part 1107, which specifies additional requirements concerning the certification, ongoing testing and labeling of children’s products, goes into effect February 8, 2013 for products manufactured after that date.¹

We summarize key provisions of these regulations below, to help avoid traps for the unwary.

Third Party Testing for Certification (16 C.F.R. § 1107.20)

A manufacturer “must submit a sufficient number of samples of a children’s product, or samples that are identical in all material respects to the children’s product,” to a Third Party Lab for testing to support certification. The number of samples selected must “provide a high degree of assurance that the tests … accurately demonstrate the ability” of the product — not just the tested samples — to comply with all applicable standards. The number of samples submitted for testing therefore may vary depending on the uniformity of the products in question. If a sample fails certification testing, the manufacturer must investigate the reasons for the failure and take corrective action, even if other samples

have passed the same certification test. A manufacturer may not certify the product “until the manufacturer establishes, with a high degree of assurance,” that the finished product complies with all applicable standards.

**Periodic Testing (16 C.F.R. § 1107.21)**

A manufacturer must have representative samples of a children’s product subject to continuing production tested pursuant to a periodic testing plan at least once per year, absent limited exceptions. The periodic testing plan must be specific to each manufacturing site, specify the tests to be conducted, the testing interval(s) (e.g., a period of time or a number of units produced) and the number of samples tested, and must “ensure with a high degree of assurance” that products manufactured after certification or since the previous periodic testing continue to comply with all applicable standards. The procedure used to select the samples must provide an adequate basis for inferring that the untested products produced during the periodic testing interval are compliant, and the manufacturer must document both the selection procedure and basis for such inference.

**Material Change (16 C.F.R. § 1107.23)**

If a children’s product undergoes a material change in product design or manufacturing process—including the sourcing of component parts—that a manufacturer exercising due care knows or should know could affect the product’s ability to comply with an applicable standard, the manufacturer must issue a new certificate based upon new testing by a Third Party Lab, as described above. If a material change is limited to a component part and does not otherwise affect the product’s compliance with applicable standards, a manufacturer may issue a certificate based on the earlier certification tests and on new test results of the changed component part.

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2 If a manufacturer implements an adequate production testing plan, including, e.g., process management techniques and/or testing, periodic testing must be conducted at least once every two years. A manufacturer may conduct periodic testing at least once every three years if it uses an ISO/IEC 17025-2005-accredited lab for production testing, and uses the same test methods to ensure continued compliance as it uses for certification testing.

3 If a manufacturer conducts certification testing for each shipment or production lot of a children’s product, it need not conduct periodic testing, as each shipment or lot is considered a discrete product rather than continuing production.

**Undue Influence Policy (16 C.F.R. § 1107.24)**

Each manufacturer of a children’s product must establish procedures to safeguard against the exercise of undue influence by the manufacturer on a Third Party Lab. The required procedures must include the following, at a minimum:

- Safeguards against attempts to exercise undue influence, including a written policy statement from company officials stating that the exercise of undue influence is not acceptable, and directing that appropriate staff receive training on avoiding undue influence and sign a statement attesting to participation in such training;
- A requirement that CPSC be notified immediately of any attempt by the manufacturer to hide or exert undue influence over test results;
- A requirement to inform employees that allegations of undue influence may be reported confidentially to the CPSC and describe the manner in which such a report can be made; and
- A requirement that staff be retrained if the requirements of the undue influence regulation change substantively.

**Recordkeeping (16 C.F.R. § 1107.26)**

A children’s product manufacturer must maintain specified records for five years and make them available to CPSC for inspection upon request. Records may be maintained in languages other than English if the manufacturer can provide them immediately to CPSC and translate them accurately into English within 48 hours of a request or longer period negotiated with the CPSC staff. The manufacturer must maintain the following records:

- A children’s product certificate for each product. The children’s product covered by the certificate must be clearly identifiable and distinguishable from other products;
- Records of each third party certification test. The manufacturer must have separate certification tests records for each manufacturing site;
- Periodic testing records, including both the periodic or production test plan, as applicable, and test results;
- Records documenting the testing of representative samples for periodic testing, including the number
selected, the procedure used to select them, and the basis for inferring compliance of the product manufactured during the periodic testing interval from the results of the tested samples;

- Descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values; and

- Undue influence procedures, including training materials and training records of all employees trained on these procedures, including attestations.

**Labeling Consumer Products to Indicate Compliance (16 C.F.R. § 1107.30)**

Once a manufacturer certifies that its consumer product complies with all applicable standards, the manufacturer may place a “uniform label” on the product stating: “Meets CPSC Safety Requirements.” A manufacturer may use an additional label as long the label does not alter the meaning of the uniform label or mislead consumers. In addition, a manufacturer “must not imply that the CPSC has tested, approved, or endorsed the product.”

**Reliance on Component Part Testing or Another Party’s Testing or Certification (16 C.F.R. § 1109.5)**

A manufacturer may rely on component part testing to support certification of a children’s product if testing the component is sufficient to assess compliance of the product with the standard at issue, and the tested component parts are materially identical to those used in the finished product.

A manufacturer also may certify its children’s product based on finished product or component testing procured by another party, or another party’s finished product or component certification, if, among other things, the other party exercises “due care” to ensure test result integrity by controlling factors that could affect the finished product’s compliance, and the manufacturer exercises “due care” in relying on the other party’s certifications or test reports.

A manufacturer exercises due care by taking steps that a prudent and competent person in the same line of business would take. Due care may vary depending on the industry and circumstances, but at a minimum, due care does not permit willful ignorance and requires taking some affirmative step to ensure the validity of the test report or certification being relied upon. Thus, due care may include, for example, conducting a reasonable review of the other party’s certification or test reports and addressing any discrepancies or other concern over their validity; confirming that the testing labs have been accepted by CPSC; asking Third Party Labs to confirm the authenticity of test reports; inspecting or auditing factories to ensure that good manufacturing practices, proper sampling procedures and the periodic test plan are being followed and that the necessary records are being kept; or submitting samples to a Third Party Lab to verify compliance.

In addition, a manufacturer must not rely on another party’s certifications or test reports unless the manufacturer receives certain documentation from the other party, including the following items that could be difficult to obtain:

- Identification of a lot or batch number or other information sufficient to identify the component part or finished product to which the testing applies;

- Descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values;

- An attestation by each certifier and testing party that while the component part or finished product was in its custody, it exercised due care to ensure compliance with the test integrity requirements of 16 C.F.R. § 1109.5 (b).

**Challenges**

The certification, testing and recordkeeping requirements present significant and costly burdens to children’s product manufacturers. In addition to bearing increased testing costs, manufacturers may need to modify or create procedures and systems to help ensure compliance with these requirements and help demonstrate to CPSC that the company has acted reasonably.
The regulations also present unique challenges to importers, who may have little or no control over the manufacturing process, and to finished product manufacturers seeking to rely on testing or certification by upstream component manufacturers, over which the finished product manufacturer may have little or no control. An importer or finished product manufacturer faces two paths to compliance: (1) procure all necessary testing itself, or (2) rely on the foreign manufacturer’s (or component manufacturers’) testing or certification of the product. In considering which path to take, an importer or finished product manufacturer should consider the following challenges:

- Is it practicable to obtain all of the documentation and develop and implement the necessary procedures to demonstrate that the company has exercised due care as required to rely on another party’s test reports or certifications?
- What steps can the company reasonably take to determine when there has been a material change to a product or its components?
- Is it preferable to test products (or component parts) from each purchase order or shipment to help ensure that the products (or component parts) tested are representative of those distributed and that no material changes have been made?
- How should the company balance the logistical challenges of relying on another party’s test reports or certifications vs. the increased costs of testing itself?

There is no “one size fits all” approach. Indeed, the answers to these questions may depend on many factors including the type of product at issue, the number of different components and suppliers, the extent of the company’s experience and comfort level with the product and suppliers, the company’s control over the manufacturing process and supply chain, and the company’s internal controls and staff resources. However, whichever approach an importer or finished product manufacturer takes, the company should develop appropriate procedures to help reduce the risk of noncompliance and demonstrate that the company has acted reasonably.

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

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