



Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2017-0043]

16 CFR Part 1112

CPSC Acceptance of Third Party Laboratories: Revision to the Notice of Requirements for Prohibitions of Children's Toys and Child Care Articles Containing Specified Phthalates

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; notice of requirements.

SUMMARY: This final rule updates the notice of requirements (NOR) for the accreditation of third party laboratories to assess conformity with the prohibitions of children's toys and child care articles containing specified phthalates. The NOR provides the criteria and process for Commission acceptance of accreditation under the Consumer Product Safety Act (CPSA). This rule makes the NOR consistent with the regulated phthalates in children's toys and child care articles in the phthalates final rule published in the *Federal Register* on October 27, 2017.

DATES: This rule is effective on April 25, 2018. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register, as of April 25, 2018.

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SUPPLEMENTARY INFORMATION:

A. Background

Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) established requirements concerning concentration limits for specified phthalates in children's toys and child care articles. In accordance with section 108 of the CPSIA, on October 27, 2017, the Commission published a phthalates final rule (phthalates rule) in the *Federal Register* (82 FR 49938). That final rule made permanent the interim prohibition on children's toys that can be placed in a child's mouth and child care articles that contain concentrations of more than 0.1 percent of diisononyl phthalate (DINP). The phthalates rule extended this prohibition to cover all children's toys and child care articles containing concentrations of more than 0.1 percent of DINP. The phthalates rule also lifted the interim prohibitions on children's toys that can be placed in a child's mouth and child care articles that contain concentrations of more than 0.1 percent of di-n-octyl phthalate (DNOP) or diisodecyl phthalate (DIDP). In addition, the phthalates rule prohibited children's toys and child care articles that contain concentrations of more than 0.1 percent of diisobutyl phthalate (DIBP), Di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), and dicyclohexyl phthalate (DCHP). The permanent prohibitions on children's toys and child care articles that contain concentrations of more than 0.1 percent on the use of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP) in children's toys and child care articles in section 108 of the CPSIA were unchanged by the phthalates rule.

On October 27, 2017, in the same issue of the *Federal Register*, the Commission published a notice of proposed rulemaking (NPR) to update the existing NOR in part 1112 for prohibitions of children's toys and child care articles containing specified phthalates. As explained further below, NORs provide the criteria and process for Commission acceptance of accreditation of third party testing laboratories that test products' conformance to CPSC requirements. The Commission previously issued an NOR for the statutory phthalate provisions, 76 FR 49286 (August 10, 2011). The October 27, 2017 NPR proposed to amend part 1112 to reflect the phthalates prohibited in children's toys and child care articles in the phthalates rule. Because the phthalates rule modified the statutorily prohibited phthalates in children's toys and child care articles listed in section 108 of the CPSIA (as stated in § 1307.3), this final rule amends the existing requirements for the prohibitions of children's toys and child care articles containing specified phthalates so that part 1112 reflects those changes.

B. Notice of Requirements

Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program. Products that are subject to a children's product safety rule must be certified based on tests of a sufficient number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable requirements. The Commission's phthalates rule is considered a "children's product safety rule." 15 U.S.C. 2063(f). Thus, products subject

to the phthalates rule are subject to the testing and certification requirements of section 14 of the CPSA.

Because children's toys and child care articles are children's products, samples of these products must be tested by a third party conformity assessment body whose accreditation has been accepted by the Commission. These products also must comply with all other applicable CPSC requirements, such as the lead content requirements of section 101 of the CPSIA, the requirements of the toy standard, 16 CFR part 1250, and the tracking label requirement in section 14(a)(5) of the CPSA.

In accordance with section 14(a)(3)(B)(vi) of the CPSIA, the Commission has previously published two NORs for accreditation of third party conformity assessment bodies for testing children's toys and child care articles under section 108 of the CPSIA (76 FR 49286 (Aug. 10, 2011), 78 FR 15836 (March 12, 2013)).

As described in the NPR, the Commission will use the following process during the transition period from test method CPSC-CH-C1001-09.3 (2010) to a revised version of the method, test method CPSC-CH-C1001-09.4 (2018). CPSC will accept testing to support children's toys and child care article certifications to the new phthalates prohibitions if the laboratory is already CPSC-accepted to test to CPSC-CH-C1001-09.3 (2010). Laboratories that conduct testing to support product certifications to the new phthalates prohibitions must list in their test reports "16 CFR part 1307" and CPSC-CH-C1001-09.3 until laboratories have transitioned their accreditation scope and CPSC listing to CPSC-CH-C1001-09.4 (2018).

The CPSC will open the laboratory application process for test method CPSC-CH-C1001-09.4 (2018) on the date this final rule is published in the *Federal Register*.

Laboratories that seek CPSC acceptance to the revised prohibitions for children's toys and child care articles in 16 CFR part 1307 will be required to update their accreditation scope. To be CPSC-accepted, a laboratory's scope of accreditation must include the reference to CPSC-CH-C1001-09.4 (2018). Laboratories that are currently CPSC-accepted to CPSC-CH-C1001-09.3 (2010) are instructed to update their accreditation scope to include CPSC-CH-C1001-09.4 (2018) as soon as possible, and submit their application for CPSC acceptance. Laboratories that were not previously CPSC-accepted to CPSC-CH-C1001-09.3 (2010) are instructed to work with their accreditation bodies to include "CPSC-CH-C1001-09.4 (2018)" in their scope documents.

CPSC will accept testing results to the new phthalates prohibitions in 16 CFR part 1307 from laboratories that are CPSC-accepted to CPSC-CH-C1001-09.3 (2010) for two years from the date of publication of this final rule in the *Federal Register*. This should allow adequate time for laboratories to work with their accreditation bodies to make official updates to their accreditation scope document to include the revised CPSC method "CPSC-CH-C1001-09.4 (2018)" and submit applications to the CPSC. On [Insert date 2 years after publication in the FEDERAL REGISTER], the CPSC will no longer accept laboratory applications that reference CPSC-CH-C1001-09.3 (2010), and any application to CPSC must reference "CPSC-CH-C1001-09.4 (2018)."

C. Comments on the NPR

We received four comments on the NPR. Three comments addressed the DRAFT CPSC procedure CPSC-CH-C1001-09.4 (2017) that was published with the October 2017 NPR briefing package. The first comment requested clarification of the final list of prohibited phthalates. The second comment

highlighted “that dissolved PVC-samples can be precipitated by adding hexane. The phthalates remain in solution. The centrifuged solution can then be measured in the GC.” The third comment came from a testing laboratory representative who recommended a few changes to add clarity and more specificity to the CPSC procedure. The fourth comment was outside the scope of the rule.

Staff made editorial clarifications to the DRAFT CPSC procedure based on the comments. Staff revised the test procedure to clarify the final list of eight prohibited phthalates. Also, staff made several additions to the test equipment and supplies section of the test method reflected in test method CPSC-CH-C1001-09.4 (2018) in response to comment.

Staff did not accept some of the commenters’ suggested changes to the test method. The revised test method does not add a temperature specification to the sonication reference in the extraction steps because the extraction is not heat dependent. Additionally, the revised test method does not include suggested additional elements to the Table 1 Conditions for Gas Chromatography-Mass Spectrometry (GC-MS). Staff did not make changes to Table 1, as well as other recommended quality assurance changes to the analysis section of the test method, in order to allow accredited laboratories flexibility in setting up their internal standard operating and quality assurance procedures. Adding the suggested requirements to Table 1 might have forced accredited laboratories to alter already suitable quality assurance programs, thus reducing flexibility. The comment relating to use of hexane for PVC samples did not warrant a change to the test method because the test method already permits the use of hexane.

D. Description of the Rule

The final rule amends 16 CFR 1112.15(b)(31) introductory text, (b)(31)(i), and (c)(3)(i) to update the references to reflect the promulgation of 16 CFR part 1307 and revised CPSC test method CPSC-CH-C1001-09.4 (2018). CPSC test method CPSC-CH-C1001-09.4 (2018), has, among other things, been updated to reflect the list of phthalates prohibited in children's toys and child care articles in 16 CFR part 1307 (DEHP, DBP, BBP, DNOP, DIBP, DPENP, DHEXP, or DCHP). CPSC test method CPSC-CH-C1001-09.4 (2018) provides detailed information on the test methods that will be used by the CPSC testing laboratory for the analysis of phthalate content in children's toys and child care articles covered by the standard set forth in section 108 of the CPSIA and 16 CFR part 1307. The test method provides detailed information regarding equipment and supplies, the procedure for the measurement of phthalate concentration, sample preparation, the phthalate extraction method, and instrument parameters. The test method CPSC-CH-C1001-09.4 (2018) is substantially the same as the current testing procedure.

E. Incorporation by Reference

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to the final rule, ways that the materials the agency incorporates by reference are reasonably available to interested persons and how interested parties can obtain the materials. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, section D of this preamble summarizes CPSC test method CPSC-CH-C1001-09.4 (2018) that the Commission incorporates by reference into 16 CFR part 1112. The test method is reasonably available to interested parties, and interested parties may obtain a copy of the test method from CPSC National Product Testing and Evaluation Center, 5 Research Place, Rockville, MD 20850; www.cpsc.gov. The test method is also available on the CPSC website. <https://cpsc.gov/Business--Manufacturing/Testing-Certification/Lab-Accreditation/Test-Methods/>. A copy of the test method can also be inspected at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923.

F. Effective Date

The APA generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). The NPR proposed a 30-day effective date because the rule allows testing to continue under the existing testing method by testing laboratories that meet certain criteria for a period of up to two years after the publication of a final rule. However, to avoid possible confusion if the effective date for this rule differed from the effective date for the underlying phthalates rule, we

are setting the effective date for the rule on April 25, 2018, the same date the phthalates rule takes effect. This is consistent with past practice setting the effective date for NORs for durable nursery products under section 104 of the CPSIA and updates to the mandatory toy standard ASTM F963 on the same date the underlying rule takes effect.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the APA, or any other statute, unless the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603 and 605. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The Commission certified, in the NPR, that the rule would not have a significant impact on a substantial number of small entities because the revised testing method is substantially the same as the method that laboratories are already using, qualified testing laboratories should be able to adopt the new method without difficulty, and the 2-year window allowed to amend the accreditation scope documents would allow testing laboratories to time the amendments with their periodic reassessments by their accreditation bodies, which should result in minimal (if any) additional cost. The Commission did not receive any public comments that addressed the potential impact on small entities, nor has the Commission staff become aware of any new information that would change its previous determination regarding the impact on small entities.

H. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

List of Subjects in 16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Incorporation by reference, Reporting and recordkeeping requirements, Third party conformity assessment body.

For the reasons discussed in the preamble, the Commission amends title 16 CFR chapter II, as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend § 1112.15 by:

- a. Revising the introductory text to paragraph (b)(31);
- b. Revising paragraph (b)(31)(i); and
- c. Revising paragraph (c)(3)(i).

The revisions read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(31) 16 CFR part 1307, Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates. For its accreditation to be accepted by the Commission to test for phthalates in children’s toys and child care articles, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope:

(i) CPSC Test Method CPSC-CH-C1001-09.4, “Standard Operating Procedure for Determination of Phthalates”;

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(c) * * *

(3) * * *

(i) CPSC-CH-C1001-9.4, “Standard Operating Procedure for Determination of Phthalates”, January 17, 2018;

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Alberta E. Mills,
Acting Secretary,
U.S. Consumer Product Safety Commission.

[FR Doc. 2018-01452 Filed: 1/31/2018 8:45 am; Publication Date: 2/1/2018]