



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

The contents of this document will be discussed
at the Commission Meeting scheduled for
October 11, 2017.

This document has been electronically
approved and signed.

DATE: September 13, 2017

**THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.
A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: October 18,
2017**

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
David M. DiMatteo, Attorney, OGC

SUBJECT: Notice of Proposed Rulemaking: *Revision to the Notice of Requirements for Prohibitions of Children's Toys and Child Care Articles Containing Specified Phthalates*

Staff is forwarding to the Commission a memorandum recommending that the Commission issue a notice of proposed rulemaking (NPR) to revise the existing notice of requirements (NOR) for phthalates to make the NOR consistent with staff's recommendation for a final phthalates rule under section 108 of the Consumer Product Safety Improvement Act of 2008. The Office of the General Counsel is providing for the Commission's consideration the attached draft NPR for publication in the *Federal Register*.

Please indicate your vote on the following options:

- I. Approve publication of the attached document in the *Federal Register*, as drafted.

(Signature)

(Date)

II. Approve publication of the attached document in the *Federal Register*, with changes.
(Please specify.)

(Signature)

(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice of Proposed Rulemaking: *Revision to the Notice of Requirements for Prohibitions of Children’s Toys and Child Care Articles Containing Specified Phthalates*

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2017-00XX]

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: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking (NPR) would update the existing notice of requirements (NOR) for prohibitions of children’s toys and child care articles containing specified phthalates that provide the criteria and process for Commission acceptance of accreditation pursuant to section 14(a)(3)(B)(vi) of the Consumer Product Safety Act (CPSA). The proposed NOR would revise the current NOR to be consistent with the final phthalates rule, which is published elsewhere in this same issue of the *Federal Register* and will be codified at 16 CFR part 1307.

DATES: Submit comments by [Insert date 75 days after publication in the *Federal Register*].

ADDRESSES: You may submit comments, identified by Docket No. CPSC- _____, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments.

The Commission does not accept comments submitted by electronic mail (e-mail), except

through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number CPSC-_____, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Scott R. Heh, Project Manager, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-504-7646; email: sh@cpsc.gov.

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 this same issue of the *Federal Register*, the

Commission is publishing a final rule that changes some of the statutory phthalate restrictions currently in place pursuant to section 108(b)(3) of the CPSIA. 15 U.S.C. 2063c(a). The Commission's phthalates rule makes 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 extends 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 lifts 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 prohibits 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 are unchanged by the phthalate rule.

Because the phthalates rule revises the list of statutorily prohibited phthalates in children's toys and child care articles in section 108 of the CPSIA, this NPR proposes to amend the existing NOR for the prohibitions of children's toys and child care articles containing specified phthalates to reflect 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 or, for children's products, 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 "consumer product safety standard." 15 U.S.C. 2063c(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 toys and child care articles under section 108 of the CPSIA (76 FR 49286 (Aug. 10, 2011), 78 FR 15836 (March 12, 2013)).

If the Commission finalizes the NOR as proposed, the following process would be used during the transition period from test method CPSC-CH-C1001-09.3 (2010) to a

revised version of the method, currently titled, draft test method CPSC-CH-C1001-09.4 (2017). CPSC would 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.

The CPSC would open the laboratory application process for draft test method CPSC-CH-C1001-09.4 (2017) on the date the final NOR 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 would be required to update their accreditation scope. To be CPSC-accepted, a laboratory's scope of accreditation must include the reference to draft CPSC-CH-C1001-09.4 (2017). Laboratories that are currently CPSC-accepted to CPSC-CH-C1001-09.3 (2010) would be instructed to update their accreditation scope to include draft CPSC-CH-C1001-09.4 (2017) 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) would be instructed to work with their accreditation bodies to include "CPSC-CH-C1001-09.4 (2017)" in their scope documents.

CPSC would 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 the final rule NOR 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 (2017)” and submit applications to the CPSC. Two years after the date the final rule NOR publishes 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 (2017).”

C. Description of the Proposed Rule

The proposed rule would amend 16 CFR part 1112(b)(32) and (c)(i) to update the references to reflect the promulgation of 16 CFR part 1307 and draft CPSC test method CPSC-CH-C1001-09.4 (2017). Draft CPSC test method CPSC-CH-C1001-09.4 (2017), among other things, has been updated to reflect the list of phthalates prohibited in children’s toys and child care articles in 16 CFR part 1307 ((di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), butyl benzyl phthalate (BBP), di-*n*-octyl phthalate (DNOP) diisobutyl phthalate (DIBP), di-*n*-pentyl phthalate (DPENP), di-*n*-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP)). The draft test method CPSC-CH-C1001-09.4 (2017) is substantially the same as the current testing procedure. The Commission encourages comments on draft CPSC test method CPSC-CH-C1001-09.4 (2017). We note that the draft test method could change in the final rule.

D. 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). Because the proposed rule would allow 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, the Commission proposes a 30 day effective date for the final rule.

E. 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 impact of the proposed rule on small testing laboratories would be minimal. The only laboratories that would be impacted are those that offer to test children's toys and child care articles for prohibited phthalates. These laboratories are already accredited by one or more accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) and have had their accreditations accepted by the Commission. These laboratories would have to revise their procedures for testing for phthalate content to be consistent with the revised phthalate test method (CPSC-CH-C1001-09.4) which would replace the current phthalate test method (CPSC-CH-C1001-09.3) if the proposed NOR is finalized. Staff expects that the impact of revising testing procedures will be low for qualified laboratories because the same sample preparation, extraction methods, and equipment is used in for both methods. Moreover, the additional phthalates included in draft CPSC-CH-C1001-09.4 can be isolated at unique elution times by gas chromatography and, therefore, the analysis should not be a burden for those qualified to perform such testing.

Additionally, within two years of the publication of the final NOR rule, laboratories would need to update their scope accreditation documents to include the

revised phthalate test method (CPSC-CH-C1001-09.4). Staff expects that the burden of this requirement will also be low because testing laboratories typically must undergo a reassessment every two years in order to maintain their accreditations. Updating the accreditation scope documents to include the revised phthalate test method is a minor change and should result in little or no additional cost to a testing laboratory if completed during the periodic reassessment, which the 2-year window would allow testing laboratories to do.

After considering the economic impacts of this proposed rule on small entities, the Commission certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

F. 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

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 proposes to amend 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 introduction to paragraph (b)(32);
- b. Revising paragraph (b)(32)(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) * * *

(32) 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-1001-09.4, “Standard Operating Procedure for Determination of Phthalates;

* * * * *

(c) * * *

(3)(i) CPSC-CH-C1001-9.4, “Standard Operating Procedure for Determination of Phthalates”, September 1, 2017.

* * * * *

Dated: _____

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



Staff Briefing Package

Notice of Proposed Rulemaking: Amendment to the Notice of Requirements for 16 C.F.R. Part 1112 for CPSC Acceptance of Third Party Laboratories for Prohibited Phthalates in Children's Toys and Child Care Articles

September 13, 2017

Table of Contents

Briefing Memorandum.....1

TAB A - DRAFT Test Method: CPSC-CH-C1001-09.4 Standard Operating Procedure for Determination of Phthalates5

TAB B - Impact on Small Entities of the Amendment to the Notice of Requirements for CPSC Acceptance of Third Party Laboratories for Prohibited Phthalates in Children’s Toys and Child Care Articles.....14

BRIEFING MEMORANDUM



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

This document has been electronically
approved and signed.

September 13, 2017

TO : The Commission
Alberta E. Mills, Acting Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director
J. DeWane Ray, Deputy Executive Director for Safety Operations

FROM : George A. Borlase, Ph.D., P.E., Assistant Executive Director
Office of Hazard Identification and Reduction
Scott R. Heh, Program Manager, Third Party Laboratory Accreditation
Directorate for Laboratory Sciences

SUBJECT : Notice of Proposed Rulemaking: Amendment to the Notice of Requirements in
16 C.F.R. part 1112 for CPSC Acceptance of Third Party Laboratories for
Prohibited Phthalates in Children's Toys and Child Care Articles

I. Introduction

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. Pursuant to direction in section 108 of the CPSIA, CPSC staff recommends that the Commission issue a final rule that would change some of the phthalate restrictions currently in place. If the Commission promulgates the draft phthalates rule, the interim prohibition on the use of diisononyl phthalate (DINP) would become permanent and would prohibit concentrations of more than 0.1 percent of DINP in children's toys and child care articles. The draft phthalates rule also prohibits the use of 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) in children's toys and child care articles. On the other hand, the draft rule would lift the interim prohibitions on the use of di-n-octyl phthalate (DNOP) and diisodecyl phthalate (DIDP) in children's toys that can be placed in the mouth and child care articles. CPSIA's permanent prohibition 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 would be unchanged by the draft final phthalate rule.

Section 14 of the Consumer Product Safety Act (CPSA) requires manufacturers of children's products to certify that their products comply with all applicable children's product safety rules. Certification must be based on third party testing. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party testing laboratories to assess whether a children's product conforms to the applicable children's product safety rule. The Commission's requirements for CPSC acceptance of third party testing laboratories are found in 16 C.F.R. part 1112. Currently, part 1112 states the criteria for laboratory acceptance and certification timing for the determination of prohibited phthalates in children's toys and child care articles that section 108 established. Should the Commission approve the draft final rule on the prohibition of certain phthalates in children's toys and child care articles, the Commission must revise the current NOR to reflect the changes to the phthalates prohibitions in children's toys and child care articles and to allow for third party testing laboratories to transition to an updated CPSC testing method to determine whether the specified phthalates are present in children's toys and child care articles.

This memorandum presents staff's recommendation for revising the existing NOR found in part 1112 to establish the rules for CPSC acceptance of accreditation of testing laboratories for the determination of phthalates in children's toys and child care articles so that the NOR reflects the provisions of the draft final rule. The recommendation for revising the NOR also addresses the transition to an updated version of "Test Method: CPSC-CH-C1001-09 Standard Operating Procedure for Determination of Phthalates." The version number for the CPSC test method will be updated from CPSC-CH-C1001-09 .3 to CPSC-CH-C1001-09.4

II. Laboratory Competence and CPSC Acceptance of Accreditation

The regulation at 16 C.F.R. part 1112 establishes a baseline requirement that, to be considered for CPSC acceptance, a laboratory must be accredited to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Standard ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories" (ISO/IEC 17025). The laboratory's accreditation body must be a signatory to the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA). Laboratories that are ISO/IEC 17025 accredited have been assessed to have the technical and managerial competence to conduct testing in accordance with the standards and test methods that are listed in the laboratory's scope of accreditation. The scope of accreditation is issued and made publically available by the laboratory's accreditation body.

Currently, the CPSC accepts the accreditation of over 400 laboratories to conduct testing in accordance with the CPSC procedure "CPSC-CH-C1001-09.3 - Standard Operating Procedure for Determination of Phthalates, April 1st, 2010."

CPSC staff developed the procedure to support the first NOR for phthalates in children's toys and child care articles prohibited under the CPSIA.

CPSC staff in the Laboratory Sciences Directorate, Division of Chemistry, has developed a revised and updated version of the CPSC Standard Operating Procedure for Determination of Phthalates, CPSC-CH-C1001-09.4 (2017) [Tab A]. The revised testing procedure is substantially the same as the current version. The revision reflects changes in the list of prohibited phthalates and includes updates to ASTM and other standards that are referenced within the CPSC method.

CPSC staff considers testing laboratories that have been CPSC-accepted for CPSC-CH-C1001-09.3 to have the competency to conduct testing to a newly issued and revised CPSC method, CPSC-CH-C1001-09.4.

III. Acceptance of Accreditation and Third Party Testing to Support Certification to the Revised Phthalates Prohibition

Staff recommends that the Commission approve an approach for acceptance of testing that supports certification to the revised phthalates prohibitions in children's toys and child care articles, and acceptance of laboratory accreditation, that takes into account testing laboratories that are currently CPSC-accepted for testing in accordance with CPSC-CH-C1001-09.3 (2010).

Staff also recommends that the CPSC accept testing results to the new phthalates prohibition at 16 C.F.R. part 1307 by laboratories that are CPSC-accepted to CPSC-CH-C1001-09.3 (2010) for a period not to exceed 2 years after publication of the final NOR. This should allow adequate time for testing 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 (2017¹)" and submit applications to the CPSC.

The CPSC will open the laboratory application process for CPSC-CH-C1001-09.4 (2017) when a final rule NOR is published in the *Federal Register* as an amendment to 16 C.F.R. part 1112. Testing laboratories that seek CPSC acceptance to the revised prohibitions for children's toys and child care articles 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 (2017). Laboratories that are currently CPSC-accepted to CPSC-CH-C1001-09.3 (2010) will be instructed to update their accreditation scope to include CPSC-CH-C1001-09.4 (2017) 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) and request CPSC acceptance to

¹ The year 2017, or the year that CPSC-CH-C1001-09.4 is finalized and posted on the CPSC website.

CPSC-CH-C1001-09.4 (2017) will be instructed to work with their accreditation bodies to include “CPSC-CH-C1001-09.4 (2017)” in their scope documents.

Beginning 2 years after the date of the final rule NOR publication, the CPSC will no longer accept laboratory applications that reference CPSC-CH-C1001-09.3 (2010). At that time, the scope document submitted with applications to CPSC must reference “CPSC-CH-C1001-09.4 (2017).”

The CPSC would provide notice of these requirements through *Federal Register* notices of the NPR and the final NOR and through direct email to all current CPSC-accepted laboratories and their accreditation bodies.

This approach should allow for a practicable transition from CPSC-CH-C1001-09.3 (2010) to CPSC-CH-C1001-09.4 (2017) for testing laboratories, children’s products manufacturers, and other interested parties.

IV. Recommendation

Staff recommends that the Commission publish a notice of proposed rulemaking (NPR) with a proposed amendment to the NOR in 16 C.F.R. part 1112. The NPR will have a 75-day comment period. The Office of the General Counsel will provide a draft *Federal Register* notice for the NPR.

The staff recommends an effective date for required third party testing to the new phthalates prohibition to be 30 days after publication of a final rule amendment to 16 C.F.R. part 1112.

TAB A - DRAFT Test Method: CPSC-CH-C1001-09.4 Standard Operating Procedure for Determination of Phthalates



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
DIRECTORATE FOR LABORATORY SCIENCES
DIVISION OF CHEMISTRY
5 RESEARCH PLACE
ROCKVILLE, MD 20850**

**DRAFT Test Method: CPSC-CH-C1001-09.4
Standard Operating Procedure for Determination of Phthalates
September 2017**

This document provides detailed information on test methods that will be used by the U.S. Consumer Product Safety Commission's (CPSC) testing laboratory (LSC) for the analysis of phthalate content in children's toys and child care articles covered by the standard set forth in the Consumer Product Safety Improvement Act Section 108 as amended by section 5 of H.R. 2715, Pub. L. No. 112-28 (August 12, 2011). In 2017, the Commission issued a rule on prohibited phthalates in children's toys and child care articles at 16 C.F.R. part 1307. Guidance regarding the law can be found at: <https://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information>.

CPSC staff has determined that using an appropriate combination of the methods of extraction and analysis presented here is sufficient to determine the concentration of the six regulated phthalates in most consumer products. Adjustments may be necessary for products made from certain materials and should be based on sound chemistry and materials science knowledge, as well as appropriate solvents for the materials. The general approach is to dissolve the sample completely in tetrahydrofuran, precipitate any PVC polymer with a second solvent, then analyze by Gas Chromatography-Mass Spectrometry (GC-MS).

Definitions

- 1. Sample** – An individual consumer product or a group of identical consumer products from a batch to be tested.
- 2. Component Part** – Individual sub-unit within a product.
- 3. Laboratory Reagent Blank (LRB)** – An aliquot of solvents that is treated exactly as a sample including exposure to glassware, apparatus and conditions used for a particular test, but with no added sample. LRB data are used to assess contamination from the laboratory environment.
- 4. Stock Standard** – Phthalate(s) purchased from reputable commercial source at the highest available purity, used to prepare calibration standards. Replace before expiration date.
- 5. Calibration Standard** – Solutions containing the phthalate(s) of interest. Each standard should contain 20 µg/ml of internal standard when running a 20:1 split injection. A minimum of four calibration standards are used. Calibration standards should be

prepared, as needed, from the stock solution and may be stored at room temperature. Record weight of solutions before and after use to monitor for solvent evaporation. Standards should be replaced when experimental data demonstrates a decrease in quality or significant loss in solvent weight.

6. Quality Control Sample (QCS) – Solutions containing known amounts of phthalates that are used to evaluate the performance of the analytical instrument system. QCSs are obtained from a source external to the laboratory and are not made from the Stock Standard solutions. For example, certified reference materials (CRMs) are available from the National Institute of Standards and Technology (NIST), such as those listed in the Equipment and Supplies section below.

Equipment and Supplies

The materials used for sampling and analyses are as follows:

1. Tetrahydrofuran (C₄H₈O, THF), GC grade or higher.
2. Hexane (C₆H₁₄), GC grade or higher.
3. Cyclohexane (C₆H₁₄), GC grade or higher.
4. Acetonitrile (C₂H₃N), GC grade or higher.
5. Sealable glass vials with PTFE or silicone liner, size 20 ml or larger.
6. Cryogenic-mill (or suitable alternative to grind samples to powder).
7. PTFE filters, 0.45 µm.
8. Gas Chromatograph-Mass Spectrometer (GC-MS) with an auto-sampler, split/splitless inlet, programmable GC oven, and capable of selective ion monitoring.
9. CRMs containing phthalates (such as NIST SRM 3074 or Korea Research Institute of Standards and Science CRM 113-03-006).
10. Benzyl Benzoate (C₁₄H₁₂O₂, BB), analytical grade or higher.
11. Dibutyl Phthalate (C₁₆H₂₂O₄, DBP), CAS No. 84-74-2, analytical grade or higher.
12. Diisobutyl phthalate (C₁₆H₂₂O₄, DIBP), CAS No. 84-69-5, analytical grade or higher.
13. Di-n-pentyl phthalate (C₁₈H₂₆O₄, DPENP), CAS No. 131-18-0, analytical grade or higher.
14. Di-n-hexyl phthalate (C₂₀H₃₀O₄, DHEXP), CAS No. 84-75-3, analytical grade or higher.
15. Dicyclohexyl phthalate (C₂₀H₂₆O₄, DCHP), CAS No. 84-61-7, analytical grade or higher.
16. Di(2-ethylhexyl) phthalate (C₂₄H₃₈O₄, DEHP), CAS No. 117-81-7, analytical grade or higher.
17. Benzyl Butyl Phthalate (C₁₉H₂₀O₄, BBP), CAS No. 85-68-7, analytical grade or higher.
18. DINP (C₂₆H₄₂O₄):
 - 1,2-Benzenedicarboxylic acid, 1,2-diisononyl; CAS No. 28553-12-0, analytical grade or higher.
 - 1,2-Benzenedicarboxylic acid, di-C₈₋₁₀ branched alkyl esters, C₉-rich; CAS No. 68515-48-0, technical grade.

Measurement of Phthalate Concentration

The procedure to be used for all CPSC Compliance determinations, as described below, consists of three sections: sample preparation, extraction, and analysis. In addition to the procedure described here, certain alternative methods listed below are acceptable to CPSC staff for phthalate content certification testing. Note that some methods require adaptation to be sufficient; most notably, some methods do not specifically include all of the phthalates that are

regulated in use in children's toys and child care items in the United States. As such, the methods must be modified to ensure the inclusion of all phthalates of interest.

Standalone methods: These methods are acceptable to CPSC staff for phthalate content certification testing as written, and require no adaptations beyond including all phthalates of interest:

- CPSC-CH-C1001-09.3 or CPSC-CH-C1001-09.4
- Health Canada Method C34 and C34.2
- EN 14372:2004
- EN 71-5:1993/A1:2006
- ASTM D7823-16
- GB/T 22048-2015
- ISO 8124-6 2014
- ISO 14389:2014 (*for textiles only*)
- California Department of Toxic Substances Control Method²

Extraction only: The following methods are only suitable for the extraction portion of certification testing. They must be combined with an analysis method from a standalone method listed above, or an *analysis only* method listed in the following section.

- EPA 3540C, 3541, 3545A, 3546 and 3550C
- ASTM D2124-99 (2011)

Analysis only: The following methods must be combined with a sample preparation and extraction method from a standalone method or extraction only method.

- EPA 8270D (must be modified appropriately to include all phthalates of interest)

References: The following standard guide is recommended to assist users interpreting results.

- ASTM D7993-15

Precautions

These methods require the use of hazardous materials. It is paramount to properly handle all hazardous materials safely in a ventilated fume hood with adequate personal protective equipment.

Phthalates are a common contaminant. Even low levels of contamination can impact quantitative results. Avoid plastic materials and use only scrupulously cleaned glassware and equipment. All solvents should be tested for any phthalate content. Solvent blanks should be run through the GC-MS periodically to monitor for potential contamination. Disposable glassware is recommended where practical.

Sample Preparation

² Ting et al.; GC/MS Screening Method for Phthalate Esters in Children's Toys, Journal of AOAC International, Vol. 92, No. 3, 2009

Prior to analysis, each plasticized component part should be cut into small pieces (no dimension larger than 2 mm), or milled/ground into a representative powder. Each cut/milled plasticized component part will be considered a sample for testing as described below. At minimum, prepare the amount required to constitute a sufficient sample size.

Phthalate Extraction Method

Testing lab shall determine how many replicate samples are necessary to meet their quality assurance requirements. Prepare LRB concurrently with samples.

1. Weigh out a minimum of 0.05 ± 0.005 g of sample into a sealable glass vial (weighed to an accuracy of $\pm 0.5\%$ relative); if sample is not uniform, collect more to reduce sample variance.
2. Add 5 ml of THF to the sample. For samples larger than 0.05 g, add 10 ml of THF for every 0.1 g of sample (or a reasonable amount to dissolve sample*). Shake, stir, or otherwise mix sample for at least 30 minutes to allow dissolution*. Sample may be sonicated to expedite dissolution.
**Note: Some materials may not dissolve completely. In this case, add an additional 2 hours to mixing time and then proceed.*
3. Precipitate any PVC polymer with 10 ml of hexane or acetonitrile for every 5 ml of THF used in Step 2. Shake vigorously and allow at least 5 minutes for polymer to settle (longer times may be necessary to minimize clogging of filters in subsequent step).
4. *(Optional)* Filter solution through a $0.45 \mu\text{m}$ PTFE filter. Collect a few ml of filtered solution in separate vial. This step is optional, but recommended when using hexane for Step 3.
5. Transfer solution to GC vial for analysis.

Instrument Parameters

A GC-MS system with an auto-sampler is suggested for the sample analysis. Related instrumentation, such as GC or liquid chromatography (LC) with advanced MS options (e.g., ion trap or tandem mass spectrometry) can be used for qualitative assessment. The following GC conditions are used (Table 1):

Table 1. GC Conditions

Column	DB-5MS; 30 m x 0.25 mm ID x 0.25 μm
Flow Mode	1 ml/min, constant flow (He or H ₂ gas)
Inlet Mode	20:1 Split
Injection Amount	1 μl
Inlet Temperature	290° C
Solvent Delay	4.5 minutes
Initial Oven Temp, Hold Time	150° C, 1 min
Ramp 1	30° C/min, 280° C
Ramp 2	15° C/min, 310° C
Final Hold Time	3 minutes or longer

Samples are analyzed using both full scan mode and the Selective Ion Monitoring (SIM) program listed in Table 2. Monitor for corresponding ions of each compound listed in a time segment (e.g., set Group 3 to monitor for 149, 167, 249, 279, and 293 m/z). The retention times listed are based on CPSC data, and must be confirmed by analyzing stock standards. The last column indicates the identification (ID) ion, and the relative abundance of this ion to 149 m/z . An example chromatogram is shown in Figure 1.

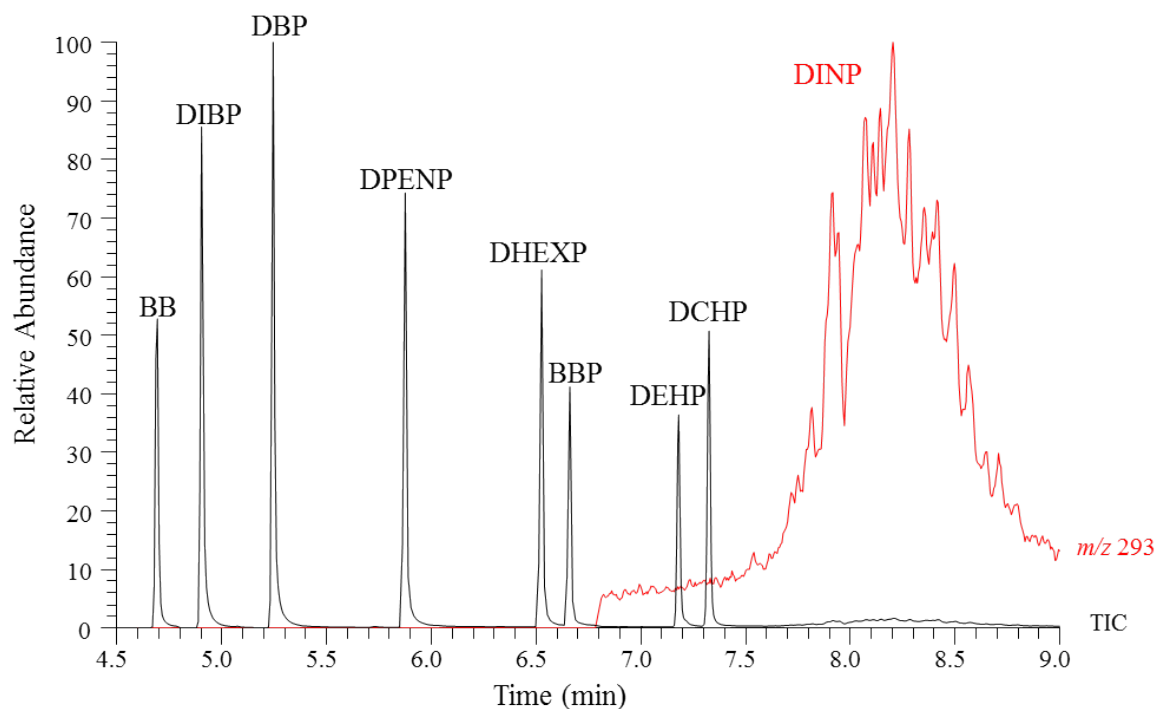
If the instrument to be used has limited SIM abilities, monitor for only those ions in **bold**.

Table 2. SIM Settings

	<i>Estimated Retention Time (min)</i>	Corresponding Ions (m/z)	Published Relative Abundance of ID Ion to 149 m/z³
<i>SIM Group 1:</i>	<i>4.5 – 5.3 minutes</i>		
BB (Internal Standard)	4.69	91.1, 105 , 194, 212	
DIBP	4.91	149, 167, 205, 223	223 : 9.6
DBP	5.25	149, 167, 205, 223	223 : 4
<i>SIM Group 2:</i>	<i>5.5 – 7.0 minutes</i>		
DPENP	5.88	149, 219, 237	237 : 6.1
DHEXP	6.53	149, 233, 251	251 : 4.5
BBP	6.66	91.1, 149, 206	206 : 27
<i>SIM Group 3:</i>	<i>7.0 – End</i>		
DEHP	7.18	149, 167, 279	279 : 32
DCHP	7.33	149, 167, 249	249 : 4.5
DINP	7.8-8.9	149, 167, 293	293 : 26

³ Bolgar, M; Hubball, J; Groeger, J; Meronek, S; *Handbook for the Chemical Analysis of Plastic and Polymer Additives*, CRC Press, Boca Raton, FL, 2008.

Figure 1. Total ion chromatogram (TIC) of the internal standard and all phthalates of interest, overlaid with an extracted ion chromatogram isolating DINP (red, m/z 293).



Analysis

1. Prepare at least four calibration standards for each of the eight phthalates of interest along with one calibration blank (cyclohexane). Each calibration standard should have an internal standard concentration of 20 $\mu\text{g}/\text{ml}$.
2. Analyze standards and blank with the GC-MS in both full-scan mode and SIM. Qualitatively analyze the results to ensure proper retention times and no contamination.
3. Integrate the peak area from valley to valley (approximate retention times are listed in Table 2) for each standard. Compounds monitored in SIM Groups 1 and 2 can be quantified by extracted ion chromatograph (EIC) or the ion chromatograph (suggested quantitative ions are in **bold**). The phthalates monitored in SIM Group 3 overlap and **must** be quantified using their quantitative ions (again, in **bold**).
4. Construct a calibration curve using normalized phthalate responses. The normalized phthalate response (Pht_n) is calculated by:

$$Pht_n = \frac{Pht}{ISTD}$$

Where Pht is the phthalate response and $ISTD$ is the internal standard response.

5. Analyze a CRM to ensure a proper calibration. The analyzed value should be within $\pm 15\%$ of the expected value. If not, prepare new standards and re-run calibration.
6. Analyze the LRB and all samples. Analyze a CRM if time has passed since the last calibration check.
7. Qualitatively evaluate full-scan results. Phthalates of interest should be identified by matching with retention times and mass spectra of standards. Potential non-regulated chemicals which may have mass ions of interest and/or similar retention times and must be qualitatively eliminated from consideration based on their spectra and chromatograms include, but are not limited to, linear C9 and C10 phthalates, and terephthalates.

8. Quantitate SIM results. If the results are out of the calibration range, prepare additional calibration standards or dilute the sample for re-analysis.

Calculations and Results

Results can be reported as follows:

$$\text{Percentage [Phthalate]} = \% \text{ Phthalate (w/w)} = [(C \times V) / (W \times 1000)] \times 100$$

Where

C = Concentration of phthalate in GC-MS sample (in µg/ml)

V = Total volume of THF and hexane/acetonitrile added from steps 2 and 3 of phthalate extraction method

W = Weight of sample collected (in mg)

Repeat calculation for each phthalate present in sample

Example

A small, homogeneous PVC toy was cut into small pieces and ground to a powder. 50 mg of sample powder was dissolved in 5 ml THF; next 10 ml of hexane were added (total of 15ml of solvent). The GC-MS results found 20 µg/ml of DEHP and 5 µg/ml of DINP. Therefore, the sample contained 0.60% DEHP and 0.15% DINP by weight.

W	C	V	$[(C \times V) / (W \times 1000)] \times 100$
Sample weight	Measured DEHP Concentration by GC-MS	Original Volume	% DEHP (w/w)
50 mg	20 µg/ml	15 ml	$[(20 \mu\text{g/ml} \times 15 \text{ ml}) / (50 \text{ mg} \times 1000 \mu\text{g/mg})] \times 100\% = \mathbf{0.60\%}$
	Measured DINP Concentration by GC-MS		% DINP (w/w)
	5 µg/ml		$[(5 \mu\text{g/ml} \times 15 \text{ ml}) / (50 \text{ mg} \times 1000 \mu\text{g/mg})] \times 100\% = \mathbf{0.15\%}$

Summary of Changes in Revision CPSC-CH-C1001-09.4

- Page 1; added link to CPSC website for guidance.
- Page 2; updated list to reflect currently prohibited phthalates; additional clarity provided for DINP and DIDP definitions.
- Page 3; updated acceptable alternative methods section to improve clarity and include new options, including reference section.
- Page 4; removed optional IR pre-screen due to modification of test method.
- Page 5; alternative technical options are listed under **Instrument Parameters**.
- Page 5; new GC parameters are listed in **Table 1** to decrease analysis time.
- Page 6; **Table 2** is updated with new retention times to reflect the updated GC parameters and current prohibited phthalates.
- Page 7; **Figure 1** has updated to reflect the updated GC parameters and current prohibited phthalates.

TAB B - Impact on Small Entities of the Amendment to the Notice of Requirements for CPSC Acceptance of Third Party Laboratories for Prohibited Phthalates in Children's Toys and Child Care Articles



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: July 27, 2017

TO : Scott Heh
Program Manager
Directorate for Laboratory Sciences

THROUGH: Gregory B. Rodgers, Ph.D.
Associate Executive Director
Directorate for Economic Analysis

FROM : Robert Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

SUBJECT : Impact on Small Entities of the Amendment to the Notice of Requirements for CPSC Acceptance of Third Party Laboratories for Prohibited Phthalates in Children's Toys and Child Care Articles

Consumer Product Safety Commission (CPSC) staff is recommending that the Commission issue a notice of proposed rulemaking (NPR) that would revise the existing notice of requirements (NOR) for accepting the accreditations of laboratories for testing children's toys and child care articles for the presence of prohibited phthalates. The revision to the NOR would update the methodology for determining the prohibited phthalates in children's toys and child care articles to reflect the change in the specific phthalates that would be prohibited should the Commission vote to promulgate the draft final rule on phthalates. If the Commission promulgates the draft phthalates rule, the interim prohibition on the use of diisononyl phthalate (DINP) would become permanent and would prohibit concentrations of more than 0.1 percent of DINP in children's toys and child care articles. The draft phthalates rule would also prohibit the use of concentrations of more than 0.2 percent of diisobutyl phthalate (DIBP), Di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), and dicyclohexyl phthalate (DCHP) in children's toys and child care articles. On the other hand, the draft rule would lift the interim prohibitions on the use of di-n-octyl phthalate (DNOP) and diisodecyl phthalate (DIDP) in children's toys and child care articles. The CPSIA prohibition 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 would be unchanged by the draft final phthalate rule.

This memorandum presents an analysis of the impact of the draft proposed rule on small entities as required by the Regulatory Flexibility Act. As explained in the analysis below, the

draft proposed rule revising the NOR for accepting the accreditation of laboratories for testing for the presence of the prohibited phthalates will not have a significant economic impact on a substantial number of small entities and the Commission could so certify.

Small Entities Subject to the Draft Proposed Rule or NOR

The draft proposed rule or revised NOR would apply only to third party conformity assessment bodies (testing laboratories) that desire to have their accreditations accepted by the Commission for testing children's toys and child care articles for conformance with the prohibition of specific phthalates in children's toys and child care articles. Testing laboratories are classified in the North American Industrial Classification System under code 54138, which includes establishments that perform physical, chemical, and other testing services. In 2014, there were 5,241 firms classified as testing labs in the United States.⁴ According to the criteria used by the Small Business Administration (SBA), testing laboratories with annual revenue of less than 15 million dollars are considered small.⁵

As of July 2017, the Commission had accepted the accreditations of just over 40 testing laboratories whose accreditation scope documents include current methodology for testing for prohibited phthalates. Of these laboratories fewer than 25 would be considered small laboratories according to the SBA criteria. Thus, assuming that the total number of testing laboratories in the United States is about the same as it was in 2014, the small testing laboratories that would be impacted by the draft proposed rule represent less than one percent of the testing laboratories in the country.

Impact of the Draft Proposed Rule on Small Entities

The impact of the draft proposed rule on small testing laboratories would be minimal. As noted above, the only laboratories that would be impacted are those that offer to test children's toys and child care articles for prohibited phthalates. These laboratories are already accredited by one or more accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) and have had their accreditations accepted by the Commission. These laboratories would have to revise their procedures for testing for phthalate content to be consistent with the revised phthalate test method (CPSC-CH-C1001-09.4) which will replace the current phthalate test method (CPSC-CH-C1001-09.3) in the NOR. CPSC staff expects that the impact of revising their test procedure will be low for qualified laboratories. This is because the same sample preparation and extraction methods are used in both methods and the same equipment is also used in in both methods. Moreover, the additional phthalates included in the CPSC-CH-C1001-09.4 can be isolated at unique elution times by gas chromatography and, therefore, the analysis should not be burden for those qualified to perform such testing (Dreyfus, 2014).

⁴ United States Census Bureau, 2014 County Business Patterns (release date: 9/29/2016).

⁵ A table of the size standards used by the SBA is available at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf

Within 2 years of the publication of a final NOR, the draft proposed rule would require laboratories to have their accreditation scope documents updated to include the revised phthalate test method (CPSC-CH-C1001-09.4). CPSC staff expects that the burden of this requirement will also be low because testing laboratories typically must undergo a full reassessment every 2 years in order to maintain their accreditations. Updating the accreditation scope documents to include the revised phthalate test method is a minor change and should result in little or no additional cost to a testing laboratory if completed during the periodic reassessment, which the 2-year window allowed by the draft proposed rule would allow testing laboratories to do.

Conclusion

Fewer than 25 small testing laboratories would be impacted by the draft proposed rule. This is less than one percent of the testing laboratories in the United States. Moreover, the impact on these small testing laboratories will be insignificant because the revised phthalate testing method is similar to the current method and qualified testing laboratories should be able to follow it without difficulty. Also, the 2-year window allowed by the draft NPR 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 additional cost, if any. The Commission could certify that the draft proposed rule would not have a significant impact on a substantial number of small entities.

Reference

Dreyfus, Matthew (2014), CPSC Memorandum to Michael Babich, "Summary of Phthalate Testing Results and Potential Modifications to the Testing Method," U.S. Consumer Product Safety Commission, Bethesda, Maryland (October 27, 2014).