



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

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DATE: January 17, 2018

BALLOT VOTE SHEET

TO: The Commission
 Alberta E. Mills, Acting Secretary

THROUGH: Patricia M. Hanz, General Counsel
 Patricia H. Adkins, Executive Director

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

SUBJECT: Draft direct final rule: *Prohibition of Children’s Toys and Child Care Articles
 Containing Specified Phthalates: Revision of Determinations Regarding Certain
 Plastics* Ballot Vote Due - Tuesday, January 23, 2018

Staff is forwarding to the Commission a memorandum recommending that the Commission issue a direct final rule (DFR) to revise the determinations rule regarding certain plastics and additives in 16 C.F.R. part 1308 to reflect the phthalates prohibited in children’s toys and child care articles in the phthalates final rule published on October 27, 2017. The Office of the General Counsel is providing for the Commission’s consideration the attached draft DFR 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* Direct final rule: *Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates: Revision of Determinations Regarding Certain Plastics*

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2016-0017]

16 CFR Part 1308

Prohibition of Children’s Toys and Child Care Articles Containing Specified

Phthalates: Revision of Determinations Regarding Certain Plastics

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: On August 30, 2017, the Commission issued a final rule determining that certain plastics and additives would not contain the phthalates that the Consumer Product Safety Improvement Act of 2008 (CPSIA) prohibits from use in children’s toys and child care articles. Subsequently, the Commission issued a final rule that removes some phthalates from the statutory prohibition and adds others. This direct final rule revises the determinations rule to cover the phthalates that the phthalates final rule prohibits from use in children’s toys and child care articles.

DATES: The rule is effective on April 25, 2018, unless we receive significant adverse comment by **[insert date 30 days after publication in the FEDERAL REGISTER]**. If we receive timely significant adverse comment, we will publish notification in the *Federal Register*, withdrawing this direct final rule before its effective date.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2016-0017, by any of the following methods:

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail), except through www.regulations.gov.

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, 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 electronically. Such information should be submitted in writing.

FOR FURTHER INFORMATION CONTACT: For information, contact: John W. Boja, Lead Compliance Officer, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408; telephone: 301-504-7300; email: jboja@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Statutory Prohibitions. Section 108 of the CPSIA established permanent and interim prohibitions that prohibited the use of certain phthalates in children's toys and

child care articles. 15 U.S.C. 2057c(a) and (b). The CPSIA also directed the Commission to issue a rule deciding whether to make the interim prohibitions permanent and whether to prohibit other children's products containing any phthalates. *Id.* 2057c(b)(3). In the following discussion, we refer to rulemaking under section 108 of the CPSIA as the phthalates rule or rulemaking.

Third Party Testing and Burden Reduction

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). For children's products, certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* Public Law 112-28 (August 12, 2011) amended the CPSA and directed the CPSC to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation." Public Law 112-28 also authorized the Commission to issue new or revised third party testing regulations if the Commission determines "that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." 15 U.S.C. 2063(d)(3)(B).

The Commission may issue determinations that specific materials do not contain prohibited substances such as lead or phthalates. Based on such a determination, the specified material would not require third party testing for compliance with the applicable mandatory prohibition.

The determinations only relieve the manufacturer's obligation to have the specific materials tested by a CPSC-accepted third party conformity assessment body. Children's products must still comply with the applicable substantive requirements, regardless of any relief from third party testing requirements. Additionally, the manufacturer must issue a certificate stating that the product complies with CPSC requirements.

Determinations Rule

On August 30, 2017, the Commission published a final rule determining that specified plastics and additives would not contain materials subject to the prohibition of children's toys and child care articles containing specified phthalates. 82 FR 41163. The rule created a new part 1308 for "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics." The rule determined that the specified plastics and accompanying additives do not contain the statutorily prohibited phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP) in concentrations above 0.1 percent, and thus, are not required to be third party tested to assure compliance with section 108 of the CPSIA. At the time the Commission issued the determinations rule, the Commission had issued a proposed rule in the phthalates rulemaking, but had not yet promulgated a final rule in that proceeding. The preambles of both the NPR and final rule for the determinations noted that the research providing the basis for the determinations covering the six phthalates subject to the statutory prohibition, applied as well to the additional four phthalates the Commission had proposed prohibiting in children's toys and child care articles in the phthalates NPR. In the preamble to the final determinations rule, the Commission indicated that when the Commission published the final phthalates rule, the Commission would amend the

determinations rule to reflect the phthalates regulated in the phthalates final rule. 82 FR 41163, at 41164.

Phthalates Final Rule

On October 27, 2017, the Commission published the final phthalates rule in the *Federal Register*. 82 FR 49938. The phthalates rule, which is codified at 16 CFR part 1307, makes permanent the interim statutory prohibition on diisononyl phthalate (DINP) and expands that restriction to prohibit all children's toys and child care articles that contain 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). Additionally, the phthalates rule also 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. The phthalates rule takes effect on April 25, 2018.

B. Revisions to 16 CFR part 1308

This direct final rule amends 16 CFR 1308.1 to cover the phthalates listed in the phthalates final rule discussed in section A of the preamble. This action will bring the determinations into alignment with the phthalates final rule so that firms will be able to

use the determinations to reduce testing burdens related to the final phthalates rule as they have with the statutory prohibitions. The amendment does not make any other changes to the determinations rule.

C. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. The Administrative Procedure Act (APA) generally requires notice and comment rulemaking. 5 U.S.C. 553. The direct final rule process is an appropriate way to satisfy this requirement in certain circumstances. In Recommendation 95-4, the Administrative Conference of the United States (ACUS) endorsed direct final rulemaking as an appropriate procedure to expedite promulgation of rules that are noncontroversial and that are not expected to generate significant adverse comment. *See* 60 FR 43108 (August 18, 1995). The Commission concludes that a direct final rule is appropriate here. The Commission is taking the limited action of amending the determinations rule at 16 CFR part 1308 to reflect the phthalates that are restricted under the Commission's phthalates rule. The previous determinations rule explained that the reports supporting the determinations regarding the phthalates that are covered by the statutory prohibitions in section 108 of the CPSIA also apply to the phthalates covered by the Commission's phthalates rule. We also note that this determination rule is separate from the Commission's phthalates rulemaking which was concluded with the Commission's issuance of a final rule on October 27, 2017. Because this document merely updates the regulated phthalates in the determinations rule, the Commission believes this rulemaking is a non-controversial matter which is not likely to generate comments. Therefore, the Commission concludes that the direct final rule process is appropriate.

Unless we receive a significant adverse comment within 30 days, the rule will take effect on April 25, 2018. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be one where the commenter explains why revising the list of regulated phthalates would be inappropriate. We note that comments on either the underlying determinations or phthalates final rules are not considered significant adverse comments because the only change this rule makes is to revise the list of covered phthalates.

Should the Commission receive significant adverse comment, the Commission would withdraw this direct final rule. Depending on the comments and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603 and 604. CPSC conducted a final regulatory flexibility analysis (FRFA) for the determinations rule that the Commission issued in August 2017. The FRFA found that "the impact of the determinations on small businesses would be to reduce the burden of third party testing for phthalate content and would be expected to be entirely beneficial." 82 FR 41171. As explained above, this direct final rule takes the limited action of revising the list of covered phthalates to bring the determinations rule into line with the phthalates rule so

that companies will be able to use the determinations to reduce third party testing under the phthalates rule as they have under the statutory prohibitions.

E. Effective Date

As discussed in section C of this preamble, this is a direct final rule. Unless we receive a significant adverse comment within 30 days, the rule will take effect on April 25, 2018.

List of Subjects in 16 CFR Part 1308

Business and industry, Consumer protection, Imports, Infants and children, Product testing and certification, Toys.

Accordingly, the Commission amends Title 16 of the Code of Federal Regulations by adding part 1308 to read as follows:

PART 1308— Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics

1. The authority citation for part 1308 continues to read as follows:

Authority: Sec. 3, Pub. L. 110-314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

2. Revise § 1308.1 to read as follows:

§ 1308.1 Prohibited children’s toys and child care articles containing specified phthalates and testing requirements.

Section 108(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits any children’s toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). In accordance with section 108(b)(3)

of the CPSIA, 16 CFR part 1307 prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisobutyl phthalate (DIBP), di-*n*-pentyl phthalate (DPENP), di-*n*-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP) is prohibited. Materials used in children's toys and child care articles subject to section 108(a) of the CPSIA and 16 CFR part 1307 must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA), unless listed in § 1308.2.

* * * * *

Dated:

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



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

This document has been electronically
approved and signed.

Date: January 11, 2018

Memorandum

TO : The Commission
Alberta E. Mills, Acting Secretary

THROUGH: Patricia H. Adkins, Executive Director
Patricia M. Hanz, General Counsel
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

Patricia K. Adair, Director, Risk Management Group
Office of Hazard Identification and Reduction

Randy Butturini, P.E., SCPM, Project Manager,
Office of Hazard Identification and Reduction

SUBJECT : ***Amending the rule *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics*, to be consistent with the rule, *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates****

1. Purpose of the Draft Direct Final Rule

This draft direct final rule (DFR) is intended to amend 16 C.F.R. part 1308 (the determinations rule) to align with the phthalates listed in 16 C.F.R. part 1307 (the phthalates rule). If the Commission issues this draft DFR, phthalates that are no longer subject to the Consumer Product Safety Improvement Act's (CPSIA's) interim restriction in children's toys and child care articles (diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DnOP)) would not be listed in the determinations rule, and the phthalates added by the phthalates rule (diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), and dicyclohexyl phthalate (DCHP)), would be included in the list of phthalates determined not to require third party testing in the specified plastics.

2. Background

2.1. Third Party Testing Requirements

Section 14 of the Consumer Product Safety Act (CPSA),¹ as amended by the CPSIA,² requires third party testing of children’s products subject to an applicable children’s product safety rule. A “children’s product safety rule” is a consumer product safety rule under the CPSA, or similar rule, regulation, standard or ban under any other Act the Commission enforces.³

2.2. CPSIA Prohibitions Regarding Phthalates

Section 108 of the CPSIA established statutory prohibitions on children’s toys and child care articles that contained certain phthalates. Section 108(a) permanently prohibits the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any “children’s toy or child care article” that contains concentrations of more than 0.1 percent of three specified phthalates. Section 108(b)(1) established an interim prohibition (in effect until the Commission promulgates a final rule) that prohibited the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of “any children’s toy that can be placed in a child’s mouth” or “child care article” containing concentrations of more than 0.1 percent of three additional specified phthalates. Table 1 shows the permanent and interim prohibitions the CPSIA established.

Table 1: Phthalates Specified in Section 108 Permanent Prohibition	
Phthalates	CASRN⁴
DEHP: di-(2-ethylhexyl) phthalate	117-81-7
DBP: +dibutyl phthalate	84-74-2
BBP: benzyl butyl phthalate	85-68-7
Phthalates Specified in Section 108 Interim Prohibition	
DINP: diisononyl phthalate	28553-12-0, 68515-48-0
DIDP: diisodecyl phthalate	26761-40-0, 68515-49-1
DnOP: di-n-octyl phthalate	117-84-0

¹ <https://www.cpsc.gov/PageFiles/105435/cpsa.pdf>.

² <http://www.cpsc.gov/PageFiles/129663/cpsia.pdf>.

³ 15 U.S.C. § 2063(f).

⁴ CASRN is an acronym for *Chemical Abstracts Service Registry Number*. A CASRN is a unique identifier for a chemical.

These prohibitions are children's product safety rules. Therefore, the U.S. Consumer Product Safety Commission (CPSC, Commission) requires that children's toys and child care articles subject to the phthalates content limit have passing third party testing results from a CPSC-accepted laboratory for the manufacturer to issue a Children's Product Certificate (CPC) before the children's toys or child care articles can enter commerce.

2.3. Current Determinations Regarding Plastics

In accordance with statutory direction, the Commission has previously issued determinations that certain materials do not need to be tested by a third party to assure their compliance with CPSC requirements. Section 14(d)(3)(B) of the CPSA, as amended by Public Law 112-28, states that the Commission:

. . . may prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

The Commission published the final rule 16 CFR part 1308 (the determinations rule), *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics*, in the *Federal Register* on August 30, 2017.⁵ The rule took effect on September 29, 2017.

The rule determined that certain plastics with specified additives would not contain the specified phthalates in children's toys and child care articles. Based on these determinations, the specified plastics with specified additives will not require third party testing for compliance with the CPSIA's statutory prohibitions on children's toys and child care articles containing phthalates. The specified phthalates in the determinations rule are those listed in Table 1, above. The plastics listed in the determinations rule are:

- Polyethylene (PE);
- Polypropylene (PP);
- General purpose polystyrene (GPPS);
- Medium-impact polystyrene (MIPS);
- High-impact polystyrene (HIPS);
- Super high-impact polystyrene (SHIPS); and
- Acrylonitrile butadiene styrene (ABS).

⁵ <https://www.federalregister.gov/documents/2017/08/30/2017-18387/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates-determinations>.

The determinations were based on data submitted by Toxicology Excellence for Risk Assessment (TERA) under contract with the CPSC⁶ and additional staff research described in the briefing package, which staff prepared for the determinations' notice of proposed rulemaking (NPR).⁷ The TERA Task 11 and 12 reports and the additional staff research showed that none of the restricted phthalates are used in the specified plastics.^{8,9}

On October 27, 2017, the Commission published a final rule, to be codified at 16 CFR part 1307 (the phthalates rule), *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates*, in the *Federal Register*.¹⁰ This rule modifies the list of statutorily prohibited children's toys and child care articles under section 108 of the CPSIA whose content cannot exceed 0.1 percent of specified phthalates. The phthalates rule lifts the interim prohibitions on children's toys that can be placed in a child's mouth and child care articles containing DIDP and DnOP. The phthalates rule maintains the interim prohibition regarding DINP, but extends the prohibition to all children's toys (not just those that can be placed in a child's mouth) and child care articles. The phthalates rule also prohibits children's toys and child care articles that contain concentrations of more than 0.1 percent of four additional phthalates. Table 2 lists phthalates whose use in children's toys and child care articles is prohibited by the CPSIA's permanent prohibition and the Commission's phthalates rule. The phthalates rule becomes effective on April 25, 2018.

⁶ TERA is now part of the Risk Science Center at the University of Cincinnati. See: <https://med.uc.edu/eh/centers/rsc>.

⁷ The NPR Briefing Package can be found at: <https://ecpsc.cpsc.gov/apps/6b/Section%206b%20Tracking/Phthalates%20in%20Four%20Specified%20Plastics%20Briefing%20Package.docx>.

⁸ The TERA Task 11 Report can be found at: <https://www.cpsc.gov/s3fs-public/pdfs/TERAReportPhthalates.pdf>.

⁹ The TERA Task 12 Report can be found at: <https://www.cpsc.gov/s3fs-public/pdfs/ReportonPhthalatesinFourPlastics.pdf>.

¹⁰ <https://www.federalregister.gov/documents/2017/10/27/2017-23267/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates>.

Table 2: Phthalates Specified in the Phthalates Rule at 16 CFR part 1307 (includes those covered by Permanent Prohibition)	
Phthalates	CASRN
DEHP: di-(2-ethylhexyl) phthalate	117-81-7
DBP: dibutyl phthalate	84-74-2
BBP: benzyl butyl phthalate	85-68-7
DINP: diisononyl phthalate	28553-12-0, 68515-48-0
DIBP: diisobutyl phthalate	84-69-5
DPENP: di- <i>n</i> -pentyl phthalate	131-18-0
DHEXP: di- <i>n</i> -hexyl phthalate	84-75-3
DCHP: dicyclohexyl phthalate	84-61-7

The preamble to the determinations final rule noted that the research providing the basis for the determinations covering the six phthalates subject to the statutory permanent and interim prohibitions, applied as well to the additional phthalates listed in the phthalates rule. Additionally, the preamble to the determinations final rule noted that the Commission was in the process of promulgating a final rule prohibiting children’s toys and child care articles containing certain phthalates at the time the determinations final rule was published.

The Commission indicated in the determinations rule preamble that when the Commission published the final phthalates rule, the determinations rule would be amended to reflect the phthalates listed in the phthalates final rule. This draft DFR revises the determinations rule to cover the phthalates listed in the phthalates rule.

3. Discussion

3.1. TERA and CPSC Staff Research

Section 14(d)(3)(B) of the CPSA authorizes the Commission to issue regulations that the Commission determines “will reduce third party testing costs consistent with assuring compliance” with applicable CPSC requirements. Thus, to issue a determination, the Commission must have sufficient evidence to conclude that the material would consistently comply with the CPSC requirement so that third party testing is unnecessary to provide a high degree of assurance of compliance.

For the determinations rule NPR Briefing Package, the research conducted for the TERA Task 11 and Task 12 reports, and the additional staff research on the specified plastics included

the phthalates listed in Table 2. That research concluded that none of the phthalates listed in Table 2 are present in the specified plastics as manufactured, with a concentration greater than 0.1 percent. Additionally, none of the typical additives to the plastics (e.g., fillers, blocking agents, quenchers, nucleating agents, plasticizers) result in a plastic with greater than 0.1 percent concentration of any of the phthalates listed in Table 2.

The data in the TERA Task 11 and Task 12 Reports, and the additional staff research detailed in the determinations rule NPR Briefing Package, provided the basis for the Commission to determine in the determinations final rule that accessible component parts of children's toys and child care articles made from the specified plastics do not contain any phthalate listed in the permanent and interim statutory prohibitions (shown in Table 1 above) in concentrations above 0.1 percent. The same data and research provide a basis for the Commission to determine that accessible component parts of children's toys and child care articles made from the specified plastics do not contain any phthalate listed in the phthalates rule (shown in Table 2 above) in concentrations above 0.1 percent.

If the list of phthalates in the determinations rule is not harmonized with the list of phthalates in the phthalates rule, then third party testing for any phthalate not listed in the determinations rule will be required for component parts of children's toys and child care articles made of the specified plastics. Because one test is usually performed for all phthalates assessed, the requirement to test for the presence of one phthalate would eliminate any potential third party testing burden reduction.

4. Staff Recommendations

CPSC staff recommends that the Commission publish a direct final rule amending 16 CFR part 1308, regarding determinations for any of the specified plastics and the phthalates listed in Table 2, as described above.

Because the amended determinations for the specified plastics would reduce the testing burden on certifiers of children's toys and child care articles, and the phthalates rule does not become effective until April 25, 2018, staff recommends an effective date of April 25, 2018.

5. Conclusion

Because the phthalates rule changed the list of phthalates whose use is restricted in children's toys and child care articles, staff recommends amending the determinations rule to be consistent with the phthalates rule.