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

This document has been electronically approved and signed.

DATE: August 16, 2017

BALLOT VOTE SHEET

TO: The Commission
Todd A. Stevenson, 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: Draft Final Rule: *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics*

BALLOT VOTE DUE: Tuesday, August 22, 2017

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for determinations that certain plastics with specified additives would not contain the specified phthalates prohibited in children's toys and child care articles. Based on these determinations, the specified plastics with specified additives would not require third party testing for compliance with the mandatory phthalates prohibitions on children's toys and child care articles.

Please indicate your vote on the following options:

I. Approve publication of the attached draft final rule in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

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

_____

_____

_____

_____

_____ _____

(Signature) (Date)

III. Do not approve publication of the attached draft final rule in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice for Final Rule: Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1308

[Docket No. CPSC- 2016-0017**]**

Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (Commission, or CPSC) is issuing a final rule that determines that certain plastics with specified additives would not contain the specified phthalates prohibited 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 mandatory prohibitions on children's toys and child care articles containing phthalates.

DATES: The rule is effective on [30 days after publication in FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION:

A. Background

1. Third Party Testing and Burden Reduction

Section 14(a) of the Consumer Product Safety Act, (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that manufacturers of products subject to a consumer product safety rule or similar rule, ban, standard, or regulation enforced by the CPSC, must certify that the product complies with all applicable CPSC-enforced 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).

2. Prohibitions in Section 108 of the CPSIA

Section 108(a) of the CPSIA 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 di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or butyl benzyl phthalate (BBP). 15 U.S.C. 2057c(a). Section 108(b)(1) prohibits on an interim basis (*i.e.*, until the Commission promulgates a final rule), 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 diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-*n*-octyl phthalate (DNOP). 15 U.S.C. 2057c(b)(1). Children's toys and child care articles subject to the content limits in section 108 of the CPSIA require third party testing for compliance with the phthalate content limits before the manufacturer can issue a Children's Product Certificate (CPC) and enter the children's toys or child care articles into commerce.

The CPSIA required the Commission to appoint a Chronic Hazard Advisory Panel (CHAP) to "study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles." 15 U.S.C. 2057c(b)(2). The CHAP issued its report in July 2014[1]. Based on the CHAP report, the Commission published a notice of proposed rulemaking (NPR), [2] proposing to permanently prohibit children's toys and child care articles containing concentrations of more than 0.1 percent of DINP, and proposing to lift the interim statutory prohibitions with respect to DIDP and DnOP. In addition, the NPR proposed adding four new phthalates, DIBP, DPENP, DHEXP, and DCHP, to the list of phthalates that cannot exceed 0.1 percent concentration in accessible component parts of children's toys and child care articles. The Commission has not finalized its proposal on phthalates in children's toys and child care articles. As the determinations NPR noted, the research providing the basis for the determinations covers the six phthalates subject to the statutory prohibition, as well as the additional phthalates the Commission proposed to prohibit in children's toys and child care articles. This determinations final rule lists only the six phthalates subject to the statutory

[1] http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf.
[2] https://www.federalregister.gov/articles/2014/12/30/2014-29967/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates.

prohibition. However, when the Commission issues a final rule for the specified prohibited phthalates in children's toys and child care articles, the Commission will revise the list of prohibited phthalates in children's toys and child care articles to reflect the phthalates prohibited in the final rule.

B. The Proposed Rule

On August 17, 2016, the Commission published an NPR in the *Federal Register,* which proposed determinations that polypropylene (PP), polyethylene (PE), high-impact polystyrene (HIPS), and acrylonitrile butadiene styrene (ABS), with specified additives, would not contain the specified phthalates prohibited in children's toys and child care articles. *See* 81 FR 54754. A determination means that third party testing of the specified plastics with specified additives is not required to demonstrate compliance with the phthalates prohibitions on children's toys and child care articles. The NPR describes the CPSC's contracts with Toxicology Excellence for Risk Assessment (TERA) to conduct research on phthalates and provide CPSC with two research reports on phthalates that are the primary basis for the determinations.

C. Comments on the NPR

CPSC received 11 comments on the NPR. Below, we summarize the key issues raised by the comments and provide responses.

1. General and Technical Comments

Some commenters express support for the proposed rule as a means to reduce third party testing costs.

Comment 1: A commenter asserts that the proposed rule erroneously listed a catalyst as an additive. The commenter notes that a catalyst is not an additive and should not have been listed as such in the proposed rule.

Response 1: The commenter is correct that a catalyst is not an additive, but rather, is used to accelerate chemical reactions, and therefore, is not intended to be an additive that provides a feature (*e.g.*, color, flame resistance) to a plastic. However, plastic manufacturing processes can leave small amounts of catalyst in the resultant resin. These unrecovered catalysts can be considered trace materials or nonfunctional additives. Consequently, the Commission has changed "catalyst," used in the text of the proposed rule, to "unrecovered catalyst" in the text of the final rule, to more precisely identify any catalysts that remain in the plastic resin after manufacture.

Comment 2: Commenters suggest several editorial changes to the Task 12 report and the preamble of the final rule. The commenters suggested the following changes, among others, to the preamble of the rule:

- Use "propylene" instead of "PP monomer";
- Use "ethylene" instead of "PE monomer";
- Note that many additives are not added to virgin PE, and not all additives will be included in most plastic used by manufacturers;
- No longer list benzene as a raw material for HIPS; and
- No longer state that Ziegler-Natta catalysts are not directly used in the production of HIPS.

The commenters' did not suggest changes to the codified text of the rule.

Response 2: The Task 12 report is a completed work product that TERA produced under contract to the CPSC, and is not subject to modification. However, because the proposed rule was based on information in this report, and in the Task 11 report, we appreciate the technical comments and corrections. To the extent that the NPR relied on imprecise terminology, the preamble to the final rule uses the commenters' suggested changes in terminology. The Commission notes that several of the suggested changes to the Task 12 report have no bearing on the rule, and as such, no changes to the preamble to the rule are necessary.

Comment 3: A commenter suggests that the CPSC should list all the different types of plastics that qualify for a determination by their Chemical Abstracts Service Registry Number (CASRN) because the lack of this type of helpful guidance may lead to uncertainty and confusion over which plastics qualify for a determination. The commenter adds that many plastics have different types, not all of which may qualify for a determination that third party testing is not required.

Response 3: The Task 11 and Task 12 reports used both specific CASRNs and common chemical names (*e.g.*, polyethylene, polypropylene, HIPS, and ABS). Therefore, CPSC considers that a CASRN or a common chemical name is acceptable for use as a plastic identifier because the contractor's research indicates that none of the terms for the plastics researched showed that these plastics contain the specified phthalates in concentrations greater than 0.1 percent.

Suppliers may use the common name and not the CASRN to identify the plastics sold to component part manufacturers or children's product manufacturers. Additionally, a rule listing only CASRNs could be unnecessarily restrictive, excluding versions of the

specified plastics that are equally expected always to comply with the phthalates content limits. Conceivably, a plastic resin plus a specific combination of these additives could be assigned a unique CASRN, and would be excluded from using the third party testing determinations, if the determinations were limited to a defined set of CASRNs.

2. Contamination Risk and Continued Testing

Comment 4: A commenter states that molded plastics may become contaminated with phthalates if the molding machine used phthalate-containing plastics and the molds were not cleaned before the new plastics were introduced. The commenter provides a theoretical example of polyvinyl chloride (PVC) production followed by production using one of the specified plastics. The commenter did not provide data regarding the possible levels of phthalate transfer.

Another commenter states that hard plastics are at high risk of contamination with phthalates. The commenter asserts that they have measured the commenter has measured "high" concentrations of phthalates on ABS plastic during laboratory testing. The commenter did not provide any data or other specific information.

Response 4: These commenters appear to describe contamination, not intentional use of the specified phthalates in the plastics that are the subject of the current determinations proceeding. Neither commenter provides information about manufacturing ABS or other plastics to contradict the findings in the Task 12 report. Thus, we are unable to evaluate the commenters' claim.

Comment 5: A commenter suggests that the CPSC should conduct or procure "unbiased testing on the relevant plastics" to assure that none of the prohibited phthalates is present

in the plastics. The commenter suggests that if CPSC does not conduct such testing, then the current third party testing requirements should be maintained.

Response 5: The Commission's determination that the specified plastics do not contain the specified phthalates at concentrations above 0.1 percent is based on data and information about raw materials and manufacturing processes that show that phthalates are not used to, or not present at, concentrations above 0.1 percent in the finished plastic. Staff has not conducted a study specifically to test products made with the specified plastics for the presence of the specified phthalates. However, staff's experience with testing and screening of plastic products supports the conclusion, based on the raw material and manufacturing process information that the specified plastics do not contain the specified phthalates.

The final rule is based on information about the use and production of phthalates and about the production of the specific plastics. Therefore, a testing study is not necessary. The information shows that phthalates are not used as plasticizers for the specified plastics and do not have other uses that would result in phthalate content in the plastics at levels exceeding the specified limit for children's toys and child care articles. Thus, the final rule is not based on manufacturers' choices or promises to use non-phthalate formulations, but rather, the rule is based on technical studies demonstrating that phthalates have no function or value in the specified plastics.

3. Exclude Other Materials from Required Third Party Testing

Comment 6: A commenter states that phthalates are incompatible with polyolefins, and that the phthalates' cost will restrict their use to materials "absolutely necessary to make certain materials flexible when this cannot be achieved by other means."

Response 6: We agree that the available information supports a determination that the polyolefins do not contain phthalates. The rule specifically includes determinations for the polyolefins, polyethylene, and polypropylene.

Comment 7: A commenter recommends that the Commission include rigid vinyl in future assessments of whether specified plastics can be determined not to contain the specified phthalates in concentrations above 0.1 percent. The commenter states that rigid vinyl typically has a hardness of 70 or higher as measured using the Shore D durometer test method.

Another commenter suggests that the final rule incorporate a provision that plastics meeting a hardness specification are exempt from third party testing requirements. According to the commenter, because rigid plastics' hardness would be compromised by the addition of phthalates, plastics with Shore A hardness of 90 or greater are unlikely to contain any prohibited phthalate in concentrations above 0.1 percent with a high degree of assurance.

Response 7: The hardness of a plastic is not sufficient to determine the plastic's compliance to the prohibitions in section 108 of the CPSIA. The Shore A and D hardness tests were never intended to be used as indicators of the presence of phthalates at low concentrations in plastics. As noted in Tab B of the staff's briefing package, otherwise rigid plastics can be noncompliant with the 0.1 percent content limit for the specified phthalates. [**Insert link**].

Plasticized polyvinyl chloride (PVC) typically contains phthalates in concentrations up to 40 percent or more. "Rigid" PVC has been shown to be noncompliant to the content limit of 0.1 percent. Furthermore, PVC is often recycled into

new PVC products. Recycling of PVC provides a path for plasticized PVC to be used in a new "rigid" product that is noncompliant with the prohibitions in section 108 of the CPSIA. The determinations in the final rule for materials that do not, and will not, contain the specified phthalates at concentrations exceeding 0.1 percent are based on information about raw materials and manufacturing processes. Physical characteristics about finished products are not sufficient information to indicate that a plastic complies with the prohibitions of section 108 of the CPSIA.

Comment 8: Two commenters request that the CPSC exclude other plastic materials from required third party testing. The commenters request that the Commission determine that the materials in the following list do not contain any prohibited phthalates in concentrations above 0.1 percent, and thus, are not subject to third party testing for certification purposes, preferably by issuing a rule to that effect. The commenters provide no additional data to support the assertions that the materials on the list do not contain any prohibited phthalates:

- 1,3,5-trioxane, copolymer with 1,3-dioxolane (acetal/polyoxymethylene (POM) copolymer)
- 2,5-Furandione polymer with 1-propene (maleic anhydride grafted PP)
- 2,5-Furandione polymer with ethane (maleic anhydride grafted PE)
- Acetal/polyoxymethylene (POM) homopolymer
- Acrylic (polymethylmethacrylate and polyacrylonitrile)
- Ionomers
- Liquid crystal polymers (hydroxybenzoic acid copolymers)
- Nylon/polyamide

- Olefin thermoplastic elastomers (such as EPDM)
- Polybutene
- Polybutylene terephthalate
- Polycarbonate
- Polyesters
- Polyethylene terephthalate
- Polylactic acid
- Polyphenylene sulfide
- Polystyrene, including crystal and general-purpose (GPPS), medium-impact (MIPS) and super-high-impact (SHIPS) grades
- Polytetramethylene glycol-dimethyl terephthalate-1,4-butanediol copolymer (polyester elastomer)
- Silicone rubber (pure)
- Styrene-butadiene copolymers
- Styrene-butadiene-styrene rubbers (SBS/SBR)
- Styrene-acrylonitrile copolymers (SAN)
- Vinylidene chloride/methyl acrylate copolymers
- CMYK Process Inks
- Butadiene-ethylene resins
- Butene-ethylene copolymers
- Ethylene copolymers
- Ethylene acrylic acid copolymers
- Ethylene-propylene copolymers

- Ethylene vinyl acetate copolymers
- Ethylene vinyl acetate vinyl alcohol copolymers
- Ethylene vinyl alcohol copolymers
- Propylene-ethylene copolymers.

One of these commenters specifically requests that the Commission extend the exclusion for high-impact polystyrene (HIPS) to crystal and general-purpose polystyrene (GPPS, or GPS), medium-impact polystyrene (MIPS), and super-high-impact polystyrene (SHIPS) grades.

Another commenter urges the CPSC to continue to review other plastics for exemptions from required third party testing for phthalate content. Finally, a commenter suggests that the Commission allow suppliers of novel resin and additive combinations to warrant that the materials comply with the requirements of the CPSIA to a high degree of assurance. The commenter suggests that a third party testing exception could be granted based on "demonstrated data."

Response 8: The commenters provided no information to support their claim that the plastics they listed do not contain phthalates as a part of their manufacture or as an additive. The Commission cannot make determinations without such information.

However, after submission of the NPR to the Commission, CPSC's contractor completed another report (the Task 16 report), which included information about the additional polystyrene-based plastics, GPPS, MIPS, and SHIPS, mentioned by the

commenter. [3] The Task 16 report contains information regarding the potential for GPPS, MIPS, SHIPS, and other plastics to contain any of the specified phthalates.

Staff examined the Task 16 report and determined that GPPS, MIPS, SHIPS, and HIPS can be considered members of a family of polystyrene plastics. GPPS is the polystyrene component of HIPS, MIPS, and SHIPS, as described in the Task 12 and Task 16 reports. GPPS does not involve the use of phthalates in its manufacture, or as an additive. Because GPPS is brittle, polybutadiene rubber is added as a "shock absorber," to increase the impact resistance of the polystyrene-butadiene mixture. In the manufacturing of polybutadiene, Ziegler-Natta catalysts, which can include DBP, DIBP, and DEHP, are used, raising the possibility that these phthalate components of the catalysts could remain in the processed plastics. However, catalysts are washed from the polybutadiene, and the remaining phthalate concentrations are not likely to exceed the 0.1 percent limit.[4]

Medium-impact polystyrene consists of GPPS with about two to five percent butadiene added.[5] HIPS typically contains 6 to 12 percent butadiene.[6] The concentration of butadiene in SHIPS ranges from 40 to 60 percent.[7] All of these polystyrenes use the

[3] *Exposure Assessment: Potential for the Presence of Phthalates in Specified Materials at Concentrations Above 0.1 Percent*, Task Order 16, Contract Number CPSC-D-12-0001, August 8, 2016, Final Report. Prepared by: Toxicology Excellence for Risk Assessment (TERA) University of Cincinnati. Available at: https://www.cpsc.gov/s3fs-public/ThePotentialforPhthalatesinSelectedPlastics.pdf.
[4] Borealis, A.G. 2014. Polypropylene Products: Borealis' Position on Phthalates in PP Catalysts. Vienna, Austria. Available at: http://www.borealisgroup.com/Global/Company/Sustainability/polypropylene-products.pdf.
[5] Sastri, Vinny R., (2013). *Plastics in Medical Devices: Properties, Requirements, and Applications*. William Andrew, publisher, ISBN 0323265634, 9780323265638. P 107.
[6] Ibid.
[7] Deanin, Rudolph D., Crugnola Aldo M. (1976). *Toughness and Brittleness of Plastics*. American Chemical Society, ISBN13: 9780841202214. eISBN: 9780841223356. P239.

same materials as HIPS in their manufacture and use the same additives to achieve desired finished component part characteristics.

The Task 16 report largely referred to the information about HIPS summarized in the previous Task 12 report because of the lack of additional references for the specific polystyrene materials and the similarities among the various polystyrene materials described in the general references. No specific reference in the Task 16 report identified the use of phthalates in production of GPPS, MIPS, HIPS, or SHIPS for consumer products. Additional research by staff did not discover any more information, suggesting that phthalates may be used to produce these polystyrene-based materials.

Because the Task 12 and 16 reports and staff's research show that phthalates are not used in GPPS, MIPS, and SHIPS (except as a catalyst to make the butadiene component), and the final concentration of phthalates in the polystyrene-based materials are likely to be well below 0.1 percent, the Commission agrees with the commenter that these materials can be included in the determination, along with HIPS. The codified text of the final rule adds GPPS, MIPS, and SHIPS to HIPS and the accompanying additives.

Regarding the commenter's suggestion to allow suppliers of novel resin and additive combinations to warrant that the materials comply with the requirements of the CPSIA, section 14 of the CPSA does not allow warrants to substitute for required third party testing. The Commission could consider determinations regarding third party testing requirements for new plastics or other materials in the future, if sufficient data and other information show that third party testing is not required to assure compliance. Currently, the Commission lacks those data.

Comment 9: A commenter request that the Commission "publicly identify the many types of plastic materials that will not contain the restricted phthalates in excess of 0.1 percent and that can thus be excluded from third-party testing requirements." The commenter also suggests that the Commission consider identifying the very few types of plastic materials that may contain the specified phthalates, and presumably, restrict required third party testing to those materials only. The commenter asserts that either approach would "offer added certainty to both testing laboratories and customers, of critical importance due to the high cost of phthalates testing."

Response 9: In this rulemaking, the Commission identifies several specific plastics that do not contain the specified phthalates in concentrations greater than 0.1 percent, based on information about raw materials, manufacturing processes, and other relevant factors. Any additional recommendations for determinations would similarly require data and other information to support a conclusion that the material does not, and will not, contain the specified phthalates. At this time, staff does not have evidence supporting additional plastics determinations, and therefore, the Commission cannot make determinations for additional plastics.

Furthermore, although we understand the typical uses of phthalates and generally the types of products that may contain phthalates in concentrations exceeding 0.1 percent, we do not agree that specifying a list of products and materials that would have to be tested (as opposed to specifying materials that do not require testing to demonstrate conformance with the standard) is practical, given the range of materials that may contain phthalates and the possibility of future development of novel uses for the specified phthalates.

4. Rule Contrary to CPSC 2009 Statement of Policy and Public Law 112-28

Comment 10: A commenter asserts that the proposed rule is contrary to section 108(c) of the CPSIA (as amended by Public Law 112-28). The commenter points to a sentence in the proposed rule at § 1308.2(c):

> Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Section 108(c) of the CPSIA states:

> APPLICATION.—Effective on the date of enactment of this Act, subsections (a) and (b)(1) and any rule promulgated under subsection (b)(3) shall apply to any plasticized component part of a children's toy or child care article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates.

The commenter asserts that because this language limited required third party testing for phthalate content to accessible *plasticized* component parts, and to component parts that *may contain phthalates*, required third party testing is limited "to only component parts that have had a plasticizer added to it or to component parts that could contain phthalates." The commenter adds that required third party testing is therefore not required for component parts that have not been plasticized and materials that may not contain phthalates. The commenter states that the aforementioned sentence in the proposed rule creates a new scope by applying required phthalate testing to all plastics not specifically listed in the determinations.

The commenter suggests that the language in proposed § 1308.2(c) should state:

> Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section must still be comprised of compliant materials pursuant to section 108 of

> CPSIA, Public Law 110-314 as amended by H.R. 2714, Public Law 112-28.

The commenter asserts that this change to the language recommended above will reflect Congressional intent and be consistent with CPSC phthalate testing policy that has been effectively used by some companies to eliminate phthalate testing on materials known to be compliant.

Response 10: The commenter is correct that section 108(c) of the CPSIA applies to this rule and that compliance to section 108 of the CPSIA is limited to plasticized component parts and other materials that may contain phthalates. As noted in the NPR preamble, children's toys and child care articles are always required to comply with the requirements of section 108 of the CPSIA, regardless of any exceptions to required third party testing under section 14 of the CPSA.

We acknowledge that § 1308.2(c) of the proposed rule could be interpreted as conflicting with section 108(c) of the CPSIA. Thus, we have revised § 1308.2(c) in the final rule to clarify that the rule concerns accessible component parts of children's toys and child care articles made from materials that are plasticized or may contain phthalates.

We are making this change because, if a manufacturer or importer (*i.e.*, a certifier) of a children's toy or child care article has accessible component parts that have been plasticized, or are composed of a material that may contain phthalates, third party testing is required to assure compliance to section 108 of the CPSIA. Examples of materials that may contain phthalates include, but are not limited to, plastics (for which a determination has not been made), inks, solvents, surface coatings, adhesives, and some rubberized materials.

Comment 11: Two commenters claim that the NPR reverses the Commission's 2009 *Statement of Policy*, which, according to the commenters, lists a number of plastic materials other than the four plastics in the NPR that are not subject to third party testing for certification purposes. Another commenter states that the proposed rule "appears to negate the flexibility afforded in the 2009 *Statement of Policy* document on phthalates." The commenter suggests that "the flexibility granted by the CPSC's *Statement of Policy* should be maintained." The commenter asserts that this flexibility allows suppliers with supply chain knowledge to use their discretion when determining which materials to subject to third party testing.

Response 11: The Commission's 2009 guidance document, *Statement of Policy: Testing of Component Parts With Respect To Section 108 of the Consumer Product Safety Improvement Act*,[8] was intended to provide general guidance. It listed a number of materials that *might not* require third party testing. In contrast, the determination rule specifies that third party testing is not required for specified plastics with accompanying additives. The determination does not remove flexibility, but provides a clear pathway for manufacturers to know that third party testing is not required if they use the specific plastics and additives listed in the determination.

5. Due Care and Certification

Comment 12: A commenter suggests that the Commission state whether a Certificate of Compliance (COC) is required for plastics for which a third party testing determination has been made. The commenter states that if a COC is required when third party testing

[8] https://cpsc.gov/s3fs-public/pdfs/blk_media_componenttestingpolicy.pdf.

is not necessary, additional due diligence would be needed to ensure that the plastic material qualifies for a determination. The commenter suggests adding to the final rule a "due care" provision, similar to the provision in 16 CFR part 1109 (the component part testing rule).[9] The commenter contends that the due care requirement should apply to the phthalates determinations because of the inherent complexity involved with properly identifying the specific plastics and additives that would be exempt from testing.

Another commenter states that importers often have limited knowledge of their products' materials and lack the evidence to demonstrate compliance without testing. The commenter suggests that manufacturers use an Attenuated Total Reflectance (ATR) sensor to identify materials that do not contain prohibited phthalates.

The commenter requested that the preamble clarify that manufacturers must use due diligence to ensure that their products only have plastics that are covered by the determination. The commenter states that screening tests, conducted on a first party basis, would reduce third party testing costs while ensuring compliance to the CPSIA.

Response 12: The final rule addresses third party testing requirements for specified plastics to assure compliance to section 108 of the CPSIA. Certification of products subject to a children's product safety rule is required, regardless of whether third party testing is required. A certifier or testing party must exercise due care to ensure that no action or inaction after testing, and before distribution in commerce, would affect compliance, including contamination or degradation, while a component part or finished product is in its custody. Thus, the component part testing rule establishes due care

[9] http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title16/16cfr1109_main_02.tpl, Section 1109.4 (g) states: "Due care means the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Due care does not permit willful ignorance."

requirements for certifiers or testing parties. To repeat the requirements in this rule would be redundant and unnecessary.

Comment 13: A commenter suggests that the final rule clarify that when certifying parties are relying on third party testing determinations for certification purposes, laboratories do not have the responsibility for:

- Determining the type of plastic;
- Verifying that the plastic is what a supplier declares;
- Confirming that there has been no contamination; and
- Confirming there have been no material changes through supply chain traceability and production safeguards.

The commenter asserts that these responsibilities reside with the certifying party (domestic manufacturer or importer).

Response 13: We agree with the commenter that the manufacturer or importer of a children's product is responsible for the product's certification. Laboratories have limited responsibilities regarding certification issues. Unless a laboratory, on behalf of a manufacturer or importer, voluntarily chooses to be a children's product or component part certifier, the laboratory is not responsible for the compliance of a tested product to the applicable children's product safety rules. The manufacturer or importer is responsible for meeting the requirements of 16 CFR parts 1107 and 1109, which generally include the responsibilities listed by the commenter.

6. Research Does Not Demonstrate High Degree of Assurance

Comment 14: A commenter asserts that the research does not provide a high degree of assurance that the specified plastics do not contain any of the specified phthalates in concentrations above 0.1 percent because data are lacking on how phthalates are used, where they occur, and their migration. The commenter also expresses concern about phthalates in recycled materials.

The commenter provides as examples:

- The presence or concentration of the specified phthalates in polyethylene was not reported in TERA report.
- Other studies cited in the Task 12 report and patents for toys and child care products did not include information on the presence of phthalates in ABS."[10]
- Zeigler-Natta catalysts (which can contain the prohibited phthalates) could remain in high-impact polystyrene at a concentration of 0.0001 percent, but no test data had been supplied to support that claim.
- There is a lack of information on phthalates in recycled plastics; and
- Information on the possibility of a plastic's contamination with a specified phthalate is also lacking.

Response 14: CPSC disagrees with the assertion that data are lacking to support the determination. The available information identifies how and where phthalates are used, and also shows the chemicals and processes used to manufacture the specified plastics. Therefore, the Commission considers the available information provides support for the conclusion that the specified plastics do not contain phthalates at levels exceeding the specified limit for children's toys and child care articles.

[10] TERA Task 12 report, page 57.

We agree that few studies directly measured phthalate content in the specified plastics. However, we expected that such studies might be rare, given that the available information does not indicate that phthalates might be present.

We acknowledge that the literature on recycling is not as extensive as the data on phthalates and plastics manufacturing. Nonetheless, we consider all of the information about phthalates' use and occurrence to indicate that recycling could result in plastics that contain traces of phthalates. We expect that residual levels would be well below the maximum-allowed concentration in children's toys and child care articles.

In work done by a contractor and presented in the Task 12 and 16 reports, the contractor was faced with "proving a negative," *i.e.*, showing that phthalates are not present in the specified plastics. The contractor employed a tiered approach to research the specified plastics. This approach narrowed the field of possible sources and assisted in identifying information that was not available (data gaps) so that focused efforts could be directed in those areas. In the Task 12 report, from a "universe" of more than 109 million sources, the contractor screened 119,800 articles for relevant information on the four plastics and phthalates. The contractor states:

> Given the search strategy and its success at getting the other information, we can be confident that if there had been information on the phthalate content of the four plastics we would have found it. In fact, the consistent lack of information amongst the many places we searched, both secondary authoritative web and library sources and primary literature sources made us highly confident that there was very little information on the specified phthalates in the four plastics.[11]

[11] Tera Task 12 report, page 55.

In the Task 16 report, the contractor screened more than 179,000 sources for relevant information on the specified plastics and phthalates in a nonbiased manner that was representative of the world wide literature on this subject matter. As in the Task 12 report, the contractor states that its Task 16 report search strategy and its success at obtaining other information gives them confidence that, if there had been information on the phthalate content of the specified plastics, then they would have found it.

Thus, for the reasons discussed above, CPSC considers the Task 12 and 16 reports to provide a high degree of assurance that the specified plastics do not contain any prohibited phthalates in concentrations above 0.1 percent.

Comment 15: A commenter recommends that the Commission exercise "extreme caution and skepticism with unproved claims of compliance with CPSC requirements." The commenter expresses concern about unintentional or unknown factors that could result in the presence of phthalates. The commenter claims that many toys have disconnected and global supply chains, and that as a consequence, U.S. toy importers often rely on laboratory test results from foreign suppliers. The commenter cites the alleged failure of an importer to meet a state standard as evidence that CPSC should exercise caution and skepticism.

Response 15: The rule is primarily based on information in the TERA Task 11, 12, and 16 reports about use and production of phthalates, and about the production of specified plastics. The available information shows that phthalates are not used as plasticizers for the specified plastics, and are not otherwise found in the plastics at levels exceeding the specified limits for children's toys and child care articles. The determinations in this rule are not based on suppliers' assertions, manufacturer's laboratory test results, or other

industry attestations. We consider the information in the TERA Task 12 and 16 reports, and the additional staff research, to be sufficient to make a determination with a high degree of assurance that the specified plastics are compliant with section 108 prohibitions without requiring third party testing.

Regarding the commenter's concerns about unintentional or unknown factors, we note that manufacturers and importers are required to have a high degree of assurance that their products are compliant to the applicable children product safety rules. Furthermore, manufacturers and importers are responsible for exercising due care to ensure their children's products comply with the applicable children's product safety rules. 16 CFR 1109.5(b)(3).

Comment 16: A commenter states that the contractor (TERA) engaged by the CPSC to study phthalate use and investigate the presence of phthalates in four specified plastics may have a conflict of interest. The commenter notes TERA's past litigation support for regulated industries. The commenter asserts TERA's potential conflict of interest is exemplified in a 2016 paper sponsored by a chemical manufacturers' trade group.[12]

The commenter adds that TERA is a founding member of the Alliance for Risk Assessment (ARA). The ARA's Standing Panel includes the TERA founder, two industry consultants, employees of Dow Chemical and ExxonMobil, and two government employees. The commenter alleges that, in light of TERA's relationship with ExxonMobil, TERA's conclusions should be viewed with caution.

[12] *Approaches for describing and communicating overall uncertainty in toxicity characterizations: U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) as a case study*. The publication can be found at: https://www.ncbi.nlm.nih.gov/pubmed/26827183.

Response 16: We consider TERA to be an independent organization[13] that focuses on advancing the science of toxicology and risk assessment. We do not agree that work by TERA or individual TERA staff in scientific projects, workshops, or publications concerning industrial chemicals or products or that include chemical firms, industry employees, or trade organizations necessarily indicates unreliable performance or improper influence in CPSC contract work.

As standard procedure, CPSC reviews potential conflicts of interest before awarding a contract or task order. We did not identify any conflicts for TERA related to the investigation of the production and use of phthalates or the production of the specified plastics.

We do not agree that the membership in ARA is evidence of a potential conflict of interest. Rather, we consider ARA to be a transparent, multi-stakeholder scientific collaboration to develop risk assessment information to advance public health activities. Furthermore, the commenter does not specify any projects by the ARA that suggest that the contracted TERA work is affected by potential conflicts of interest.

In summary, the commenter did not provide any specific information that shows that the reports produced by TERA under contract with CPSC have been affected by potential conflicts of interest. Nor did the commenter show that the reports contain inaccurate or misleading data or information.

7. Out of Scope Comments

[13] Staff notes that after the contract work discussed here, TERA reorganized as the Risk Science Center at the University of Cincinnati: https://med.uc.edu/eh/centers/rsc.

We also received comments on issues such as random spot checking for certificates of compliance, developing a procedure for petitioning the Commission for determinations, identifying statistical averaging and margins of error under which products could still be considered compliant, allowing other techniques beyond materials determinations for lead content testing that could reduce third party testing costs, asking Congress for authority to implement commenter's suggestions, determinations for lead content, and the inclusion of supply chain controls when noncompliant products are found. This rulemaking is limited to determinations regarding phthalate content in specified plastics. The aforementioned comments are outside the scope of this rulemaking.

D. Determinations for Specified Plastics with Certain Additives

1. Legal Requirements for a Determination

As noted above, section 14(a)(2) of the CPSA requires third party testing for children's products that are subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Children's toys and child care articles must comply with the phthalates prohibitions in section 108 of the CPSIA. 15 U.S.C. 2057c. In response to statutory direction, the Commission has investigated approaches that would reduce the burden of third party testing while also assuring compliance with CPSC requirements. As part of that endeavor, the Commission has considered whether certain materials used in children's toys and child care articles would not require third party testing.

To issue a determination that a plastic (including specified additives) does not require third party testing, the Commission must have sufficient evidence to conclude that the plastic and specified additives would consistently comply with the CPSC

requirement to which the plastic (and specified additives) is subject so that third party testing is unnecessary to provide a high degree of assurance of compliance. Under 16 CFR 1107.2, "a high degree of assurance" is defined as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."

For a material determination, a "high degree of assurance of compliance" means that the material will comply with the specified chemical limits due to the nature of the material or due to a processing technique that reduces the chemical concentration below its limit. For materials determined to comply with a chemical limit, the material must continue to comply with that limit if it is used in a children's product subject to that requirement. A material on which a determination has been made cannot be altered or adulterated to render it noncompliant and then used in a children's product.

The determinations will only relieve the manufacturer's obligation to have the specified plastics and accompanying additives tested by a CPSC-accepted third party conformity assessment body. Children's toys and child care articles must still comply with the substantive phthalates content limits in section 108 of the CPSIA, regardless of any relief from third party testing requirements. Additionally, the manufacturer must issue a certificate stating that the product complies with CPSC requirements.

Phthalates are not naturally occurring materials, but are intentionally created and used in specific applications (*e.g.*, plastics, surface coatings, solvents, inks, adhesives, and some rubberized materials). One application of phthalates in children's toys and

child care articles is as a plasticizer, or softener for plastic component parts.[14] The addition of a plasticizer converts an otherwise rigid plastic into a more flexible form, such as in a child's rubber duck or a soft plastic doll. Because plastics used in children's toys and child care articles can contain the prohibited phthalates, third party testing is required before a CPC can be issued for children's toys and child care articles with accessible plastic component parts. However, some specific plastics with certain additives might not use any of the prohibited phthalates as a plasticizer, or for any other purpose. For these specific plastics and accompanying additives, compliance with the requirements of section 108 of the CPSIA can be assured without requiring third party testing. To reduce the third party testing burden on children's product certifiers while continuing to assure compliance, the CPSC has determined with a high degree of assurance that the specified plastics with certain additives comply with the phthalate content requirements of section 108 of the CPSIA, based on evidence indicating that such materials will not contain the prohibited phthalates. These determinations mean that third party testing for compliance with the phthalates prohibitions is not required for certification purposes for the specified four plastics. The Commission makes these determinations to reduce the third party testing burden on children's product certifiers while continuing to assure compliance.

2. Statutory Authority

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. Public Law 110-314, sec. 3,

[14] The Merriam-Webster online dictionary defines a plasticizer as "a chemical added especially to rubbers and resins to impart flexibility, workability, or stretchability."

Aug. 14, 2008. As noted previously, section 14 of the CPSA, as amended by the CPSIA, requires third party testing for children's products subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Section 14(d)(3)(B) of the CPSA, as amended by Public Law 112-28, gives the Commission the authority to "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." *Id.* 2063(d)(3)(B). These statutory provisions authorize the Commission to issue a rule determining that specified plastics and additives will not exceed the phthalates prohibitions of section 108 of the CPSIA, and therefore, specified plastics do not require third party conformity assessment body testing to assure compliance with the phthalates limits in section 108 of the CPSIA.

The determinations will relieve the specified plastics and accompanying additives from the third party testing requirement of section 14 of the CPSA to support the required certification. However, the determinations would not apply to any other plastic or additives beyond those listed in the rule.

3. Description of the Final Rule

The rule creates a new part 1308 for "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics." The rule determines 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.

Section 1308.1 of the rule explains the statutorily created requirements for children's toys and child care articles under section 108 of the CPSIA and the third party testing requirements for children's products. This section is unchanged from the proposed rule. As discussed in section A.2 of the preamble, currently, the agency is involved in rulemaking to determine whether to continue the interim prohibitions in section 108 and whether to prohibit any other children's products containing any other phthalates. At the time of publication of this final rule in the *Federal Register*, the Commission has not issued a final rule in the phthalates rulemaking. Therefore, this determinations rule lists the phthalates that are statutorily prohibited from being in children's toys and child care articles under section 108 of the CPSIA.

Section 1308.2(a) of the rule establishes the Commission's determinations that the following seven plastics do not exceed the phthalates content limits with a "high degree of assurance" as that phrase is defined in 16 CFR part 1107. Section 1308.2(a) of the rule is being finalized as proposed, except for the following changes. The final rule:

- Adds "naphthenic oil" to the list of PP plasticizers in § 1308.2(a)(1)(i). Naphthenic oil is a nonphthalate plasticizer listed with paraffinic and mineral plasticizing oils in a Task 12 report reference and should have been included in the proposed rule but was inadvertently omitted;
- Adds the word "unrecovered" before "catalysts" in §§ 1308.2(a)(1)(iii), (a)(2)(iv), (a)(3)(i), (a)(4)(vii) of the final rule to clarify that this additive refers to small amounts of catalyst that may remain in a plastic resin after manufacture;
- Adds general purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), and super high-impact polystyrene (SHIPS) to § 1308.2(a)(3), to high-impact

polystyrene (HIPS) that was listed in the proposed rule, to the list of materials that can be determined not to require third party testing in order to assure compliance with section 108 of the CPSIA. This change is made based on a commenter's suggestion and supporting information from the Task 16 report. These three plastics, along with HIPS, can be considered members of a family of polystyrene plastics manufactured with the same raw materials and processes. The potential additives for GPPS, MIPS, and SHIPS are the same as those for HIPS;

- Replaces the term "phosphate esters" in § 1308.2(a)(4)(i) with "hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), and oligomeric phosphate" to more precisely identify the ABS plasticizers listed. The specific phosphate esters added were listed and discussed in the preamble of the NPR and the underlying staff briefing package, but were inadvertently left out of the codified text in the NPR; and
- Deletes "hydrocarbon solvents" from the list of additives for PP in § 1308.2(a)(1)(ii) and ABS in § 1308.2(a)(4)(ii) because hydrocarbon solvents are not additives but rather are used in the production of resin. The list of additives in §§ 1308.2(a)(1)(ii) and (a)(4)(ii) has been renumbered to reflect this change.

Section 1308.2(b) of the rule states that accessible component parts of children's toys and child care articles made with the specified plastics, and specified additives listed in paragraph (a) of this section, are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107. Section 1308.2(b) is included in the rule to make clear that when the listed plastics and accompanying additives are used in children's toys and child care articles, manufacturers and importers are not required to

conduct the third party testing required in section 14(a)(2) of the CPSA and 16 CFR part 1107. This provision is unchanged from the proposed rule.

Section 1308.2(c) of the rule has been revised to add the phrase "that are plasticized or may contain phthalates" between "in paragraph (a) of this section" and "are required to be third party tested." The new language tracks the statutory language of section 108(c) of the CPSIA regarding component parts of children's toys or child care articles that are plasticized or may contain phthalates. If a manufacturer or importer (*i.e.*, a certifier) of a children's toy or child care article has accessible component parts that have been plasticized, or are composed of a material that may contain phthalates, third party testing is required to assure compliance to section 108 of the CPSIA. This change has been made because the language of § 1308.2(c) of the proposed rule could be interpreted as conflicting with section 108(c) of the CPSIA.

E. Effective Date

The Administrative Procedure Act (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 Commission proposed a 30-day effective date because the rule provides relief from existing testing requirements under the CPSIA. No comments were received regarding the effective date. The effective date for the rule is 30 days from the date of publication of the rule in in the *Federal Register*.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed and final rules on small entities, including small businesses. Section 604 of the RFA requires that agencies prepare a final regulatory

flexibility analysis (FRFA) when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The FRFA must describe the impact of the rule on small entities. CPSC staff prepared a FRFA. See Tab C of staff's briefing package at [**Insert link**]. We provide a summary below.

The rule is intended to reduce the burden of third party testing on manufacturers of children's toys and child care articles consistent with assuring compliance with CPSC requirements under section 14 of the CPSA, as amended by section 2 of Public Law 112-28. The final rule would reduce the burden of third party testing on manufacturers and importers of children's toys and child care articles by establishing determinations for certain plastics (PP, PE, GPPS, MIPS, HIPS, SHIPS, and ABS) and accompanying additives. Based on these determinations, the specified plastics with specified additives will not require third party testing for compliance with the mandatory prohibitions on children's toys and child care articles containing phthalates.

Although comprehensive estimates of the number of products that contain components made from the specified plastics are not available, there is some evidence that these plastics are extensively used in children's toys. One source stated that polypropylene and high-density polyethylene are used in 38 and 25 percent, respectively, of injection-molded toys.[15] The same source also stated that low-density polyethylene, polystyrene, and acrylonitrile butadiene styrene, are each used in less than 10 percent of injection-molded toys.

[15] Donald V. Rosato, Plastics End Use Applications, Springer, New York, (2011).

Based on the number of domestic toy manufacturers that are classified as small businesses by the U.S. Bureau of the Census, and evidence that the specified plastics are used extensively in toys, staff believes a substantial number of small entities would be impacted positively by this regulation.

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. The cost of third party testing for phthalates is between approximately $125 and $350 per test, depending on where the testing is conducted and any discounts that might be applicable.[16] Because one product might have several component parts that require testing, the cost to test a finished product for phthalate content may be substantially higher. To the extent that small entities have lower production volumes than larger entities, these determinations would be expected to have a disproportionately beneficial impact on small entities because the costs of the tests are distributed over fewer units. Additionally, some laboratories may offer their larger customers discounts that might not be available to small entities that need fewer third party tests. However, the benefit of making the determinations could be less than might be expected. For example, some manufacturers might have already substantially reduced their third party phthalate testing costs by using the component part testing under 16 CFR part 1109. Therefore, the marginal benefit that might be derived from making the determinations might be low. Some importers might not be certain of what materials are actually being used in each component part and might not be able to use the determinations without testing.

[16] The cost estimates of third party phthalate testing are based on information provided both by consumer product manufacturers and by testing laboratories.

Under section 604 of the Regulatory Flexibility Act, a FRFA should include a "statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected." The final rule is itself, the result of CPSC's efforts to reduce third party testing costs consistent with assuring compliance with all applicable consumer product safety rules. Therefore, CPSC considered few alternatives, other than expanding the list of plastics for which determinations could be made. We note that the final rule includes determinations for three additional polystyrenes (GPPS, MIPS, and SHIPS) that were not included in the NPR.

G. Environmental Considerations

The Commission's regulations provide a categorical exclusion for Commission 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. The Commission's regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

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 proposes to amend 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

Sec.

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

§ 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-ethylhexl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Section 108(b)(1) of the CPSIA prohibits on an interim basis any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP). Materials used in children's toys and child care articles subject to section 108(a) and (b)(1) of the CPSIA 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.

§ 1308.2 Determinations for specified plastics.

(a) The following plastics do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Polypropylene (PP), with any of the following additives:

(i) The plasticizers polybutenes, dioctyl sebacate, isooctyl tallate, paraffinic, naphthenic, and mineral plasticizing oils, and polyol;

(ii) Unrecovered catalysts;

(iii) Fillers;

(iv) Primary and secondary antioxidants;

(v) Neutralizing agents;

(vi) Antistatic agents;

(vii) Slip agents;

(viii) Metal deactivators;

(ix) Quenchers;

(x) UV stabilizers;

(xi) Nucleating agents;

(xii) Flame retardants;

(xiii) Blowing or foaming agents;

(xiv) Antiblocking agents;

(xv) Lubricants; or

(xvi) Colorants.

(2) Polyethylene (PE), with any of the following additives:

(i) The plasticizers glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer;

(ii) Initiators;

(iii) Promoters;

(iv) Unrecovered catalysts;

(v) Fillers;

(vi) Antistatic agents;

(vii) Flame retardants;

(viii) Anti-blocking agents;

(ix) Slip agents;

(x) Blowing agents;

(xi) Cross-linking agents;

(xii) Antioxidants;

(xiii) Carbon black; or

(xiv) Colorants.

(3) General purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), and super high-impact polystyrene (SHIPS) with any of the following additives:

(i) Unrecovered catalysts;

(ii) Internal lubricants;

(iii) Chain transfer/transition agents;

(iv) Stabilizers;

(v) Diluents;

(vi) Colorants;

(vii) Aluminum chloride, ethyl chloride, hydrochloric acid;

(viii) Iron oxide, potassium oxide, chromium oxide; or

(ix) Bifunctional peroxides.

(4) Acrylonitrile butadiene styrene (ABS), with any of the following additives:

(i) The plasticizers hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, long chain fatty acid esters and aromatic sulfonamide;

(ii) Stabilizers;

(iii) Lubricants;

(iv) Antioxidants;

(v) Molecular weight regulators;

(vi) Initiators/unrecovered catalysts,

(vii) Activators;

(viii) Emulsifiers; or

(ix) Colorants.

(b) Accessible component parts of children's toys and child care articles made with the specified plastics, and specified additives, listed in paragraph (a) of this section are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

(c) Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section that are plasticized or may contain phthalates are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Dated:

_____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

Staff Briefing Package

Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics

July 14, 2017

The views expressed in this report are those of the CPSC staff, and they have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Contents

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

This document has been electronically approved and signed.

Memorandum

Date: July 14, 2017

TO : The Commission
Todd A. Stevenson, Secretary

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

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

SUBJECT : **Final Rule Briefing Package: *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics***

1. Introduction: Third Party Testing Requirements

Section 14 of the Consumer Product Safety Act (CPSA),[1] as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA),[2] requires third party testing of children's products subject to an applicable rule, ban, standard or regulation. Section 108 of the CPSIA prohibits children's toys and child care articles that contain any of six specified phthalates in concentrations above 0.1 percent in "accessible plasticized component parts and other component parts made of materials that may contain phthalates." The specified phthalates are listed in Table 1. Thus, children's toys and child care articles subject to the phthalates content limit require 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.

[1] https://www.cpsc.gov/PageFiles/105435/cpsa.pdf.
[2] http://www.cpsc.gov/PageFiles/129663/cpsia.pdf.

Table 1: Specified Phthalates	
Phthalates in prohibited children's toys and child care articles	**CASRN[3]**
DEHP: di-(2-ethylhexyl) phthalate	117-81-7
DBP: +dibutyl phthalate	84-74-2
BBP: benzyl butyl phthalate	85-68-7
Phthalates in prohibited children's toys that can be placed in a child's mouth and in child care articles	
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

Section 14(d)(3)(B) of the CPSA 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.

On August 17, 2016, a notice of proposed rulemaking (NPR) was published in the *Federal Register* (81 FR 54754) to determine that certain plastics with specified additives would not contain the specified phthalates in children's toys and child care articles in concentrations above the limit in section 108 of the CPSIA. If the Commission finalizes the proposal, the specified plastics with specified additives would not require third party testing for compliance with the mandatory phthalates prohibitions on children's toys and child care articles.

In this package, CPSC staff discusses the public comments received in response to the NPR, and recommends issuing the draft final rule.

2. Discussion: Public Comments

The CPSC received 11 comments in response to the NPR published in the *Federal Register*. Summaries of the comments and CPSC staff's responses are provided in Tab A. Table 2 identifies the commenters.

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

Several commenters expressed support for the proposed rule. The significant topics covered in the comments included:

- suggested editorial changes to the proposed rule to improve its clarity;
- suggestions to the Commission of a list additional materials that do not require third party testing to assure compliance with section 108 of the CPSIA;
- a recommendation for the use of hardness testing as a screening method to identify plastics that do not require third party testing to assure compliance with section 108 of the CPSIA;
- the assertion that the proposed rule is contrary to section 108(c) of the CPSIA, as amended by Public Law No. 112-28, or negates the flexibility afforded by the Commission's 2009 guidance document, *Statement of Policy: Testing of Component Parts With Respect To Section 108 of the Consumer Product Safety Improvement Act;*[4]
- an assertion that the research supporting the proposed rule is insufficient to assure a high degree of assurance; and
- an allegation that the contractor engaged by the CPSC to study phthalate use and investigate the presence of phthalates in specified plastics may have a conflict of interest.

In response to the comments suggesting the use of hardness testing as a screening method to identify plastics that do not require third party testing to assure compliance, staff prepared the memorandum, *Hardness testing on plastics with more than 0.1 percent of specified phthalates*, which is included in Tab B of this Briefing Package. No comments were received regarding the proposed effective date of 30 days after the final rule's publication in the *Federal Register*.

[4] https://cpsc.gov/s3fs-public/pdfs/blk_media_componenttestingpolicy.pdf.

Table 2: Commenters on Docket CPSC-2016-0017	
Comment identification	**Commenter**
CPSC-2016-0017-0002	Anonymous Manufacturer/Importer
CPSC-2016-0017-0003	Raymond YU
CPSC-2016-0017-0004	Briana Baker
CPSC-2016-0017-0005	SPI: The Plastics Industry Trade Association
CPSC-2016-0017-0006	American Chemistry Council
CPSC-2016-0017-0007	The International Federation of Inspection Agencies, Inc. (IFIA)
CPSC-2016-0017-0008	Toy Industry Association, Inc.
CPSC-2016-0017-0009	Actus Analytical
CPSC-2016-0017-0010	The Vinyl Institute
CPSC-2016-0017-0011	Anonymous
CPSC-2016-0017-0012	Natural Resources Defense Council

Note: The public comments may be found in docket CPSC-2016-0017 at: http://www.regulations.gov.

3. Recommended Changes to the Proposed Rule Based on Comments

3.1. Addition of GPPS, MIPS, and SHIPS to List of Materials Determined not to Contain the Specified Phthalates

Based on a commenter's suggestion, staff recommends adding general purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), and super high-impact polystyrene (SHIPS) to the list of materials that do not require third party testing to assure compliance with section 108 of the CPSIA. These materials, along with high-impact polystyrene (HIPS), which was one of the subjects of the NPR, can be considered members of a family of polystyrene plastics manufactured with the same raw materials and processes. The potential additives for GPPS, MIPS, and SHIPS are the same as those for HIPS.

Information about these additional plastics is included in the Task 16 Report[5] produced under contract with CPSC, after the contractor reports that provided technical support for the NPR. The Task 16 Report was finalized after staff completed its analysis and transmitted its recommendations for the proposed rule to the Commission. This report contains information regarding the potential for GPPS, MIPS, SHIPS, and other plastics to contain any of the specified phthalates. GPPS is the polystyrene component of HIPS, MIPS, and SHIPS; and as described in the Task 12 and Task 16 Reports, GPPS does not use phthalates in its manufacture or as an additive. MIPS, HIPS, and SHIPS consist of GPPS with varying amounts of polybutadiene

[5] *Exposure Assessment: Potential for the Presence of Phthalates in Specified Materials at Concentrations Above 0.1 Percent*, Task Order 16, Contract Number CPSC-D-12-0001, August 8, 2016, Final Report. Prepared by: Toxicology Excellence for Risk Assessment (TERA) University of Cincinnati. Available at: https://www.cpsc.gov/s3fs-public/ThePotentialforPhthalatesinSelectedPlastics.pdf.

added.[6] The Task 12 Report shows that the polybutadiene used in manufacturing HIPS does not contain any of the specified phthalates in concentrations greater than 0.1 percent. Thus, varying the amount of polybutadiene, a compliant material added to GPPS cannot render the resultant material noncompliant.

Staff notes that in the Task 16 Report, the contractor largely referred to the information summarized in the previous Task 12 contractor report for HIPS because of the lack of additional references for the specific polystyrene materials and the similarities among the various polystyrene materials described in the general references. Both the Task 12 and Task 16 Reports for polystyrene include references to the presence of phthalates or the potential use of phthalates in their manufacture. Staff reviewed these references in preparing its recommendations for the proposed rule. The most specific reference to phthalates in polystyrene materials concerns the use of Ziegler-Natta catalysts in the production of the polybutadiene. The Zeigler-Natta catalysts include an internal electron donor to accelerate the chemical reactions that may be a phthalate, such as DBP, DIBP, or DEHP. Based on the available information on the use of these catalysts, the concentration of any phthalate in the polybutadiene and the final polystyrene-based product is expected to be well below 0.1 percent, irrespective of the specific polystyrene material. No other references in either the Task 12 or Task 16 reports identified use of phthalates in production of GPPS, MIPS, HIPS, or SHIPS for consumer products. Additional research by staff did not locate any other information that suggests phthalates may be used to produce these polystyrene-based materials.

3.2. Requirements for Third Party Testing Stated in Section 1308.2(c) of the Draft Rule

Staff recommends replacing this phrase in the proposed rule:

> Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

With the following text:

> Accessible component parts of children's toys and child care articles made with a material not listed in paragraph (a) of this section *that are plasticized or may contain phthalates* are required to be third party tested pursuant to section 14(a)(2) of the CPSA, and 16 C.F.R. part 1107.

(emphasis added for revised language)

Staff acknowledges that the language of § 1308.2(c) of the proposed rule could be interpreted to be overly restrictive with regard to section 108 of the CPSIA, as amended by Public Law No. 112-28, which states that the phthalate prohibitions apply to plasticized component parts and other materials that may contain phthalates. Staff recommends this change because, if a manufacturer or importer (i.e., a certifier) of a children's toy or child care article has accessible component parts that have been plasticized, or are composed of a material that may contain

[6] MIPS contains about 2 to 5 percent butadiene; HIPS contains about 6 to 12 percent butadiene; and SHIPS contains from 40 to 60 percent butadiene.

phthalates, third party testing is required to assure compliance to section 108 of the CPSIA. Examples of materials that may contain phthalates include, but are not limited to, plastics (for which a determination has not been made), inks, solvents, surface coatings, adhesives, and some rubberized materials. Irrespective of testing, compliance of accessible component parts subject to section 108 of the CPSIA is always required.

3.3. Editorial Changes

Staff recommends the following changes to be incorporated into codified text of the draft final rule:

- Changing "catalyst" to "unrecovered catalyst" to clarify that this additive refers to small amounts of catalyst that may remain in a plastic resin after manufacture;
- Adding naphthenic oil to the list of PP plasticizers. Naphthenic oil is a non-phthalate plasticizer listed with paraffinic and mineral plasticizing oils in a Task 12 Report reference;
- Adding hydrocarbon processing oil to the list of ABS plasticizers, and replacing "phosphate esters" with "triphenyl phosphate, resorcinol bis(diphenyl phosphate), and oligomeric phosphate" as ABS plasticizers, which were included in the NPR preamble, but was inadvertently omitted from the proposed codified text; and
- Deleting "hydrocarbon solvents" from the list of additives to PP and ABS because the solvents are used in resin production and are not additives.

Based on the comments submitted, staff clarified the terminology, as follows:

- Using "propylene," instead of "PP monomer," in describing the component parts of polypropylene;
- Using "ethylene," instead of "PE monomer," in describing the component parts of polyethylene;
- Emphasizing that many additives are not added to virgin PE during resin manufacturing, and that not all additives will be included in most plastic used by manufacturers;
- Not listing benzene as a raw material for HIPS because benzene is used in the manufacture of the butadiene component of HIPS, and not in the production of HIPS itself; and
- Not listing Ziegler-Natta catalysts as being used in the production of HIPS because the Zeigler-Natta catalysts can be used in the production of the butadiene component of HIPS, and not in the production of HIPS itself.

4. Impact on Small Entities

As detailed in Tab C, the draft final rule would reduce the burden of third party testing on manufacturers and importers of children's toys and child care articles by eliminating the requirement to certify, based on third party testing, that accessible PE, PP, GPPS, MIPS, HIPS,

SHIPS, and ABS component parts do not contain any of the specified phthalate in concentrations above 0.1 percent. The cost of third party testing for phthalates is approximately $125 to $350 per test, depending upon where the testing is conducted and any applicable discounts.[7] Because one product might have several component parts that require testing, the cost to test a finished product for phthalate content may be substantially higher. If small entities have lower production volumes than larger entities, these determinations would be expected to have a disproportionately beneficial impact on small entities because the costs of the tests are distributed over fewer units. Additionally, some laboratories may offer their larger customers discounts that might not be available to small entities that need fewer third party tests.

Although the cost of third party phthalate testing is relatively high on a per-test or per-product basis, the total amount by which the third party testing costs would be reduced cannot be estimated reliably with the information available. For example, although the number of manufacturers of children's toys and child care articles is available from the U.S. Bureau of the Census, the number of manufacturers that actually use PE, PP, GPPS, MIPS, HIPS, SHIPS, or ABS in their products is unknown. Likewise, the number of children's toys and child care articles that contain these plastics is also unknown.

Although comprehensive estimates of the number of products that contain components made from the specified plastics are not available, there is some evidence that these plastics are used extensively in children's toys. One source stated that polypropylene and high-density polyethylene are used in 38 percent and 25 percent, respectively, of injection-molded toys.[8] The same source also stated that low-density polyethylene, polystyrene, and acrylonitrile butadiene styrene, are each used in less than 10 percent of the injection-molded toys.

Based on the number of domestic toy manufacturers classified as small businesses by the U.S. Bureau of the Census and evidence that the specified plastics are used extensively in toys, staff believes that a substantial number of small entities would be affected positively by this regulation.

5. Conclusions and Recommendations

CPSC staff recommends that the Commission approve the draft final rule for publication in the *Federal Register* with an effective date 30 days after publication.

5.1. Staff Recommendations

CPSC staff recommends that the Commission determine that the following plastics, with any of the additives listed for each plastic, do not contain any of the specified phthalates in concentrations greater than 0.1 percent, and thus, are not required to be third party tested to assure compliance with section 108 of the CPSIA:

Polypropylene (PP), with any of the following additives:

[7] The cost estimates of third party phthalate testing are based on information provided both by consumer product manufacturers and by testing laboratories.
[8] Donald V. Rosato, Plastics End Use Applications, Springer, New York, (2011).

- The following plasticizers: polybutenes, dioctyl sebacate, isooctyl tallate, paraffinic naphthenic, and mineral plasticizing oils, and polyol;
- Unrecovered catalysts;
- Fillers;
- Primary and secondary antioxidants;
- Neutralizing agents;
- Antistatic agents;
- Slip agents;
- Metal deactivators;
- Quenchers;
- UV stabilizers;
- Nucleating agents;
- Flame retardants;
- Blowing or foaming agents;
- Antiblocking agents;
- Lubricants; or
- Colorants.

Polyethylene (PE), with any of the following additives:

- The following plasticizers: glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer;
- Initiators;
- Promoters;
- Unrecovered catalysts;
- Fillers;
- Antistatic agents;
- Flame retardants;
- Anti-blocking agents;
- Slip agents;
- Blowing agents;
- Cross-linking agents;
- Antioxidants;
- Carbon black; or
- Colorants.

General purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), or super high-impact polystyrene (SHIPS), with any of the following additives:

- Unrecovered catalysts;
- Internal lubricants;
- Chain transfer/transition agents;
- Stabilizers;
- Diluents;
- Colorants;
- Aluminum chloride, ethyl chloride, hydrochloric acid;
- Iron oxide, potassium oxide, chromium oxide, or

- Bifunctional peroxides.

Acrylonitrile butadiene styrene (ABS), with any of the following additives:

- The following plasticizers: hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, , long chain fatty acid esters and aromatic sulfonamide;
- Stabilizers;
- Lubricants;
- Antioxidants;
- Molecular weight regulators;
- Initiators/unrecovered catalysts;
- Activators;
- Emulsifiers; or
- Colorants.

5.2. Commission Options

The following options are available for Commission consideration:

1. Publish the final rule, as drafted by the Office of the General Counsel (OGC).
2. Publish the final rule, with changes, as directed by the Commission.
3. Specify other options, as directed by the Commission.

CPSC staff recommends that the Commission publish the draft final rule, as drafted by OGC. Because the draft final rule provides relief from existing testing requirements under the CPSIA, and staff did not receive any comments on the 30 day effective date proposed in the NPR, CPSC staff recommends that the rule become effective 30 days after publication of the notice of final rulemaking in the *Federal Register*.

Tab A: Response to Comments on the Proposed Rule: Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics

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

Memorandum

Date: July 14, 2017

TO: George A. Borlase, Ph.D., P.E., Assistant Executive Director, Office of Hazard Identification and Reduction

THROUGH: Patricia K. Adair, Manager, Risk Management Group
Alice Thaler, DVM, Associate Executive Director, Directorate for Health Sciences

FROM: Randy Butturini, P.E., SCPM, Project Manager, Office of Hazard Identification and Reduction
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : **Response to Comments on the Proposed Rule: *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics***

1. Introduction

On August 17, 2016, a notice of proposed rulemaking (NPR) was published in the *Federal Register* (81 FR 54754) that would determine that certain plastics, with or without specified additives, would not contain the specified phthalates prohibited in children's toys and child care articles in concentrations above the limit in section 108 of the CPSIA. The docket number for the proposed rule is CPSC-2016-0017. The CPSC received 11 comments in response to the notice published in the *Federal Register*. Summaries of the comments and CPSC staff's responses are provided below.

2. Comments on the Proposed Rule

2.1. General and Technical Comments

Some commenters express support for the proposed rule as a means to reduce third party testing costs.

Comment 1: A commenter suggests that CPSC allow review and comment on future technical reports before drafting future NPRs.

Response 1: The technical reports[9,10] produced under contract with CPSC, on which the proposed rule was based, were posted on the CPSC website before publication of the NPR. Comments regarding the reports can be (and were) received during the comment period for the proposed rule. In general, interested parties can submit comments on reports and other items posted on the CPSC website. Staff reviewed the comments on the technical report and addressed the issues raised in the comments in the preparation of the draft final rule, as described in staff responses to specific comments below.

Comment 2: A commenter suggests removing the description of additives from Section C, parts 1–4 of the proposed rule. The commenter asserts that there are errors in the descriptions and that, with the exception of plasticizers, the material is irrelevant to the proposed rule. The only error mentioned by the commenter is that a catalyst is not an additive.

Response 2: Section C, parts 1–4 of the NPR is a discussion in the proposed rule's preamble that lists common additives that manufacturers add to plastic resins to aid manufacturing and add features to the finished component part. We assume that the commenter also wants the list of additives removed from the codified text of the rule.

The list of additives for each plastic was included in the proposed rule to indicate that any determination applies not only to the pure plastic resin, but also to the resin and any combination of listed additives. Commonly, an intermediate manufacturer will acquire plastic resin, and add one or more additives, before selling the resultant product to a manufacturer of children's toys or child care articles. The children's toy or child care article manufacturer (the certifier) can rely on a determination for the resin and any listed additives to support a Children's Product Certificate (CPC), instead of being required to test each component part or constituent of the product.

The commenter is correct that a catalyst is used to accelerate chemical reactions, and is not intended to be an additive that provides a feature (e.g., color, flame resistance) to a plastic. However, plastic manufacturing processes can leave small amounts of catalyst in the resultant resin. These unrecovered catalysts can be considered as trace materials or nonfunctional additives. To clarify the rule, staff has replaced "catalyst" with "unrecovered catalyst" to identify more precisely any catalysts that remain in the plastic resin.

Comment 3: Commenters suggest editorial changes for the final rule and for the Task 12 Report. The suggested corrections are as follows:

- Using "propylene" instead of "PP monomer";
- In polypropylene manufacturing:
    - Noting that for isotactic polypropylene, all the methyl groups are oriented on the same side of the polymer backbone;
    - Deleting details about nucleation as not relevant;
    - Noting that many additives are not added during virgin resin manufacturing, but are added in secondary steps, and that many additives would not be found in food packaging, toy, or child care applications;

[9] The Task 11 Report can be found at: https://www.cpsc.gov/s3fs-public/pdfs/TERAReportPhthalates.pdf.
[10] The Task 12 Report can be found at: https://www.cpsc.gov/s3fs-public/pdfs/ReportonPhthalatesinFourPlastics.pdf.

    - Noting that the information provided by Saravanan and Sulaiman (2014) describing polypropylene production methods is dated;
- In raw materials used in polyethylene:
    - Correcting the use of "PE monomer" to "ethylene";
    - Emphasizing that many additives are not added to virgin polyethylene, and that not all additives will be included in polyethylene plastics frequently;
- Noting that a reference (Brydson, 1999) is an outdated source and does not describe the current manufacturing processes well;
- Deleting the inclusion of benzene as a raw material for HIPS;
- Deleting the use of Ziegler-Natta catalysts for HIPS;
- Correcting the manufacturing processes for HIPS to exclude processes that are not used for the production of polystyrene;
- Correcting a seeming confusion between HIPS and styrene-block copolymers; and
- Adding medical lab ware, refrigerators, and building insulation to the application list for HIPS.

Response 3: The Task 12 Report is a completed work product of another party under contract to the CPSC, and therefore, is not subject to modification. However, because the proposed rule was based on material in this report, and in the Task 11 Report, staff appreciates the commenter's technical comments and corrections; to the extent that staff relied on imprecise terminology, staff has clarified the preamble of the draft final rule, as listed below. Staff notes that several of the suggested changes to the Task 12 Report have no bearing on the proposed rule, and as such, no revisions to the rule are necessary for those suggestions.

Regarding commenters' editorial changes and suggestions for the draft final rule, staff has made the following changes:

- Using "propylene" instead of "PP monomer";
- Using "ethylene" instead of "PE monomer";
- Emphasizing that many additives are not added to virgin PE, and that not all additives will be included in most plastic used by manufacturers, will help avoid confusion;
- Not listing benzene as a raw material for HIPS; and
- Not listing the Ziegler-Natta catalysts as catalysts of HIPS.

Comment 4: A commenter suggests that the CPSC should list all the different types of plastics that qualify for a determination by their Chemical Abstracts Service Registry Number (CASRN) because the lack of this type of helpful guidance may lead to uncertainty and confusion over which plastics qualify for a determination. The commenter adds that many plastics have different types, not all of which may qualify for a determination that third party testing is not required. The commenter states that adding the CASRNs will reduce uncertainty and confusion over which plastics qualify for a testing exclusion.

Response 4: The Task 11 and Task 12 reports used both specific CASRNs and common chemical names (e.g., polyethylene, polypropylene, HIPS, and ABS) in their research. Therefore, staff considers that either a CASRN or a common chemical name is acceptable for use as a

plastic identifier, because the contractor's research indicates that none of the terms for the plastics researched showed that these plastics contain the specified phthalates in concentrations greater than 0.1 percent.

Suppliers may use the common name, and not the CASRN, to identify the plastics sold to component part manufacturers or children's product manufacturers. Additionally, a rule listing only CASRNs could be unnecessarily restrictive, excluding versions of the specified plastics that are equally expected always to comply with the phthalates content limits. That is, staff's recommendations are for the plastic resin, or the resin, plus any combination of one or more of the listed additives in the rule. Conceivably, a plastic resin, plus a specific combination of these additives, could be assigned a unique CASRN, and would be excluded from the third party testing exemption, if a determination were limited to a defined set of CASRNs. Thus, staff declines to change the draft final rule based on this comment.

2.2. Contamination Risk and Continued Testing

Comment 5: A commenter states that molded plastics may become contaminated with phthalates if the molding machine used phthalate-containing plastics and the molds were not cleaned before the new plastics were introduced. The commenter provides a theoretical example of polyvinyl chloride (PVC) production followed by production using one of the specified plastics. The commenter did not provide any data regarding the possible levels of phthalate transfer.

Another commenter states that hard plastics are at high risk of contamination with phthalates. The commenter asserts that they have measured "high" concentrations of phthalates on ABS plastic during laboratory testing. No data or other specific information was provided.

Response 5: These commenters appear to describe contamination, not intentional use of the specified phthalates in the plastics that are the subject of the current determinations proceeding. Neither commenter provides information about manufacturing ABS or other plastics that contradicts the findings in the Task 12 Report. Thus, staff is unable to evaluate further the commenter's claim.

Because the commenters appear to describe contamination issues and situations involving lack of due care and do not provide evidence of the manufacture of one or more of the specified plastics with the specified phthalates, staff declines to change the draft final rule based on these comments.

Comment 6: A commenter suggests that the CPSC, before proceeding with rulemaking, should procure "unbiased testing on relevant plastics" to ensure that none of the specified phthalates is present in concentrations above 0.1 percent.. The commenter adds that regular, continuing testing by the CPSC should be conducted to ensure that any material changes have not resulted in the introduction of a specified phthalate.

The commenter states that if a CPSC testing program is not implemented, the CPSC should leave the current third party testing requirements in place, or require that "manufacturers certify the absence of the covered phthalates in their products in a manner that is open to scrutiny by the public."

Response 6: Staff's recommendations concerning a determination that the specified plastics do not contain the specified phthalates at concentrations above 0.1 percent are based on data and

information about raw materials and manufacturing processes that show that phthalates are not present at concentrations above 0.1 percent in the finished plastic. Staff has not conducted a study specifically to test products made with the specified plastics for the presence of the specified phthalates. However, staff's experience with testing and screening of plastic products supports the conclusion based on the raw material and manufacturing process information that the specified plastics do not contain the specified phthalates.

Additionally, this rule addresses determinations regarding required third party testing. Issues concerning additional certification requirements, such as requiring certification methods that are "open to scrutiny by the public," are beyond the scope of this rule.

A testing study or continued testing requirements are not necessary because the staff recommendations are based on information about the use and production of phthalates and about the production of the specific plastics. The information shows that phthalates are not used as plasticizers for the specified plastics, and do not have other uses that would result in phthalate content in the plastics at levels exceeding the specified limit for children's toys and child care articles. Thus, the staff recommendations are not based on manufacturers' choices or promises to use non-phthalate formulations, but rather, are based on technical studies that show that phthalates have no function or value in the specified plastics. Therefore, staff declines to change the draft final rule based on this comment.

2.3. Exclude Other Materials from Required Third Party Testing

Comment 7: A commenter states that phthalates are incompatible with polyolefins, and that the phthalates' cost will restrict their use to materials "absolutely necessary to make certain materials flexible when this cannot be achieved by other means."

Response 7: Staff agrees that the available information supports a determination that the polyolefins do not contain phthalates. The NPR and the draft final rule specifically include determinations for the polyolefins polyethylene and polypropylene.

Comment 8: A commenter recommends that the Commission include rigid vinyl in future assessments of whether specified plastics can be determined not to contain the specified phthalates in concentrations above 0.1 percent. The commenter states that rigid vinyl typically has a hardness of 70 or higher, as measured using the Shore D durometer test method. The commenter states that adding phthalates to vinyl intended to be rigid reduces the desired rigidity by plasticizing, or softening the material. The commenter adds that the "plastification" of vinyl relies on the porosity of the vinyl resin to absorb the plasticizer; vinyl intended to be rigid has low porosity, and is not suitable for absorbing plasticizers in significant amounts.

Another commenter suggests that the final rule incorporate a provision that plastics meeting a hardness specification are to be exempt from third party testing requirements. According to the commenter, because rigid plastics' hardness would be compromised by the addition of phthalates, plastics with Shore A hardness of 90 or greater are, with a high degree of assurance, unlikely to contain any of the specified phthalates in concentrations above 0.1 percent.

Response 8: Staff notes that the hardness of a plastic is not sufficient to determine the plastic's compliance to the prohibitions in section 108 of the CPSIA. The Shore A and D hardness tests were never intended to be used as indicators of the presence of phthalates at low concentrations in plastics. As noted in the Tab B memorandum on hardness testing of plastics

with known phthalate concentrations, otherwise rigid plastics can be noncompliant with the 0.1 percent content limit for the specified phthalates.

Staff notes that plasticized polyvinyl chloride (PVC) typically contains phthalates in concentrations of up to 40 percent or more. "Rigid" PVC has been shown to be noncompliant to the content limit of 0.1 percent. Furthermore, PVC is often recycled into new PVC products. PVC recycling provides a path for plasticized PVC to be used in a new "rigid" product that is noncompliant with the prohibitions in section 108 of the CPSIA. Staff recommendations regarding determinations for materials that do not and will not contain the specified phthalates at concentrations exceeding 0.1 percent are based on information about raw materials and manufacturing processes. Physical characteristics about finished products are not sufficient information to indicate the compliance of a plastic with the prohibitions of section 108 of the CPSIA. Thus, staff declines to change the draft final rule based on these comments.

Comment 9: Two commenters request that CPSC exclude other plastic materials from required third party testing. The commenters request that the Commission determine, preferably by issuing a rule to that effect, that the materials in the list below do not contain any of the specified phthalates in concentrations above 0.1 percent, and are thus, not subject to third party testing for certification purposes:.

The plastics listed by the commenters are:

- 1,3,5-trioxane, copolymer with 1,3-dioxolane (acetal/polyoxymethylene (POM) copolymer);
- 2,5-Furandione polymer with 1-propene (maleic anhydride grafted PP);
- 2,5-Furandione polymer with ethane (maleic anhydride grafted PE);
- Acetal/polyoxymethylene (POM) homopolymer;
- Acrylic (polymethylmethacrylate and polyacrylonitrile);
- Ionomers;
- Liquid crystal polymers (hydroxybenzoic acid copolymers);
- Nylon/polyamide;
- Olefin thermoplastic elastomers (such as EPDM);
- Polybutene;
- Polybutylene terephthalate;
- Polycarbonate;
- Polyesters;
- Polyethylene terephthalate;
- Polylactic acid;
- Polyphenylene sulfide;
- Polystyrene, including crystal and general-purpose (GPPS), medium-impact (MIPS) and super-high-impact (SHIPS) grades;
- Polytetramethylene glycol-dimethyl terephthalate-1,4-butanediol copolymer (polyester elastomer);
- Silicone rubber (pure);

- Styrene-butadiene copolymers;
- Styrene-butadiene-styrene rubbers (SBS/SBR);
- Styrene-acrylonitrile copolymers (SAN);
- Vinylidene chloride/methyl acrylate copolymers;
- CMYK process inks;
- Butadiene-ethylene resins;
- Butene-ethylene copolymers;
- Ethylene copolymers;
- Ethylene acrylic acid copolymers;
- Ethylene-propylene copolymers;
- Ethylene vinyl acetate copolymers;
- Ethylene vinyl acetate vinyl alcohol copolymers;
- Ethylene vinyl alcohol copolymers; and
- Propylene-ethylene copolymers.

The commenters provided no additional data to support their assertions that the materials on the list do not contain any of the specified phthalates.

One of these commenters specifically requests that the Commission extend the exclusion for high-impact polystyrene (HIPS) to crystal and general-purpose polystyrene (GPPS, or GPS), medium-impact polystyrene (MIPS) and super-high-impact polystyrene (SHIPS) grades.

Another commenter urges the CPSC to continue to review other plastics for exemptions from required third party testing for phthalate content.

Finally, a commenter suggests that the Commission allow suppliers of novel resin and additive combinations to warrant that the materials comply with the requirements of the CPSIA to a high degree of assurance. The commenter suggests that a third party testing exception could be granted based on "demonstrated data."

Response 9: The commenters provided no information to support their claim that the plastics they listed do not contain phthalates as a part of their manufacture or as an additive. For those plastics, for which no information was made available, staff is unable to recommend a determination that third party testing is not required to assure their compliance to section 108 of the CPSIA.

Staff notes that the additional polystyrene-based plastics, GPPS, MIPS, and SHIPS, mentioned by the commenter were included in work[11] (the Task 16 Report) produced under contract with CPSC, after the contractor reports supporting the NPR. The Task 16 Report was finalized after staff completed its analysis and transmitted its recommendations to the

[11] *Exposure Assessment: Potential for the Presence of Phthalates in Specified Materials at Concentrations Above 0.1 Percent*, Task Order 16, Contract Number CPSC-D-12-0001, August 8, 2016, Final Report. Prepared by: Toxicology Excellence for Risk Assessment (TERA) University of Cincinnati. Available at: https://www.cpsc.gov/s3fs-public/ThePotentialforPhthalatesinSelectedPlastics.pdf.

Commission. The Task 16 Report contains information regarding the potential for GPPS, MIPS, SHIPS, and other plastics to contain any of the specified phthalates.

Staff examined the Task 16 Report regarding GPPS, MIPS, and SHIPS. These materials and HIPS can be considered to be members of a family of polystyrene plastics. GPPS is the polystyrene component of HIPS, MIPS, and SHIPS, and as described in the Task 12 and Task 16 Reports, GPPS does not involve the use of phthalates in its manufacture or as an additive. Because GPPS is brittle, polybutadiene rubber is added as a "shock absorber" to increase the impact resistance of the polystyrene-butadiene mixture. In the manufacturing of polybutadiene, Ziegler-Natta catalysts, which can include DBP, DIBP, and DEHP, are used, raising the possibility that these phthalate components of the catalysts could remain in the processed plastics. However, catalysts are washed from the polybutadiene, and the remaining phthalate concentrations are not likely to exceed the 0.1 percent limit.[12]

Medium-impact polystyrene consists of GPPS with about 2 percent to 5 percent butadiene added.[13] HIPS typically contains 6 percent to 12 percent butadiene.[14] The concentration of butadiene in SHIPS ranges from 40 percent to 60 percent.[15] All of these polystyrenes use the same materials as HIPS in their manufacture and the same additives to achieve desired finished component part characteristics.

The Task 16 Report largely referred to the information about HIPS summarized in the previous Task 12 Report by the contractor, because of the lack of additional references for the specific polystyrene materials and the similarities among the various polystyrene materials described in the general references. No specific reference in the Task 16 Report identified the use of phthalates in the production of GPPS, MIPS, HIPS, or SHIPS for consumer products. Additional research by staff did not reveal any additional information suggesting that phthalates may be used to produce these polystyrene-based materials.

Because the Task 12 and 16 Reports, and additional staff research, show that phthalates are not used in GPPS, MIPS, and SHIPS, except as a catalyst in the production of the butadiene component, and that the final concentration of phthalates in the polystyrene-based materials is likely to be well below 0.1 percent, staff agrees with the commenter that these materials can be included with the recommendation to determine that HIPS is not required to be third party tested to assure compliance with section 108 of the CPSIA. The draft final rule includes this change.

Regarding the commenter's suggestion to allow suppliers of novel resin and additive combinations to warrant that the materials comply with the requirements of the CPSIA, section 14 of the CPSA does not allow warrants as a substitute for required third party testing. The Commission could consider determinations regarding third party testing requirements for new plastics or other materials in the future, if sufficient data and other information show that third

[12] Borealis, A.G. 2014. Polypropylene Products: Borealis' Position on Phthalates in PP Catalysts. Vienna, Austria. Available at: http://www.borealisgroup.com/Global/Company/Sustainability/polypropylene-products.pdf.
[13] Sastri, Vinny R., (2013). *Plastics in Medical Devices: Properties, Requirements, and Applications*. William Andrew, publisher, ISBN 0323265634, 9780323265638. P 107.
[14] Ibid.
[15] Deanin, Rudolph D., Crugnola Aldo M. (1976). *Toughness and Brittleness of Plastics*. American Chemical Society, ISBN13: 9780841202214. eISBN: 9780841223356. P239.

party testing is not required to assure compliance. Thus, staff declines to change the draft final rule based on this suggestion.

Comment 10: A commenter requests that the Commission "publicly identify the many types of plastic materials that will not contain the restricted phthalates in excess of 0.1 percent and that can thus be excluded from third-party testing requirements." The commenter also suggests that the Commission consider identifying the very few types of plastic materials that may contain the specified phthalates, and presumably, restrict required third party testing to those specific materials. The commenter asserts that either approach would "offer added certainty to both testing laboratories and customers, of critical importance due to the high cost of phthalates testing."

Response 10: For this rulemaking, staff identified several specific plastics that do not contain the specified phthalates in concentrations greater than 0.1 percent, based on information about raw materials, manufacturing processes, and other relevant factors. Any additional recommendations for determinations would similarly require data and other information to support a conclusion that the material does not and will contain the specified phthalates. At this time, staff has not completed evaluations of additional plastics, and therefore, we cannot recommend determinations for additional plastics.

Furthermore, although staff understands the typical uses of phthalates and generally the types of products that may contain phthalates in concentrations exceeding 0.1 percent, staff does not agree that specifying a list of products and materials that would have to be tested (as opposed to specifying materials that do not require testing to demonstrate conformance with the standard) is practical, given the range of materials that may contain phthalates and the possibility of future development of novel uses for the specified phthalates. Thus, staff concludes that requiring testing only for specified materials would not be consistent with a high degree of assurance of compliance, and therefore, we decline to change the draft final rule based on this comment.

2.4. Variance with CPSC 2009 Statement of Policy and Public Law No. 112-28

Comment 11: A commenter asserts that the proposed rule is contrary to section 108(c) of the CPSIA (added by Public Law No. 112-28). The commenter points to a sentence in the proposed rule at § 1308.2(c):

> Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

The commenter refers to section 108(c) of the CPSIA, which states:

> APPLICATION.—Effective on the date of enactment of this Act, subsections (a) and (b)(1) and any rule promulgated under subsection (b)(3) shall apply to any plasticized component part of a children's toy or child care article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates.

The commenter asserts that because this language limited required third party testing for phthalate content to accessible *plasticized* component parts, and to component parts that *may contain phthalates*, required third party testing is limited "to only component parts that have had a plasticizer added to it or to component parts that could contain phthalates." The commenter adds that required third party testing, therefore, is not required for component parts that have not been plasticized and materials that may not contain phthalates. The commenter stated that the sentence mentioned above in the proposed rule creates a new scope by applying required phthalate testing to all plastics not specifically listed in the determinations.

The commenter proposes that the language in proposed 16 C.F.R. § 1308.2(c) state:

> Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section must still be comprised of compliant materials pursuant to section 108 of CPSIA, Public Law 110-314 as amended by H.R. 2714, Public Law 112-28.

The commenter asserts that this change to the language recommended above will reflect congressional intent and be consistent with the CPSC phthalate testing policy that has been used effectively by some companies to eliminate phthalate testing on materials known to be compliant.

Response 11: The commenter is correct that section 108(c) of the CPSIA applies to this rule and that compliance to section 108 of the CPSIA is limited to plasticized component parts and other materials that may contain phthalates. However, the commenter's suggestion to revise the language of section § 1308.2(c) of the proposed rule is unnecessary. The Commission already noted in the NPR that children's toys and child care articles are always required to comply with the requirements of section 108 of the CPSIA, regardless of any exceptions to required third party testing under section 14 of the CPSA.

However, staff acknowledges that § 1308.2(c) of the proposed rule could be interpreted as overly restrictive regarding section 108(c) of the CPSIA. Thus, staff has changed proposed § 1308.2(c) so that the draft final rule states:

> Accessible component parts of children's toys and child care articles made with a material not listed in paragraph (a) of this section that are *plasticized or may contain phthalates* are required to be third party tested pursuant to section 14(a)(2) of the CPSA, and 16 CFR part 1107.
>
> (emphasis added for revised language)

Staff recommends this change because, if a manufacturer or importer (i.e., a certifier) of a children's toy or child care article has accessible component parts that have been plasticized, or are composed of a material that may contain phthalates, third party testing is required to assure compliance to section 108 of the CPSIA. Examples of materials that may contain phthalates include, but are not limited to, plastics (for which a determination has not been made), inks, solvents, surface coatings, adhesives, and some rubberized materials. Irrespective of testing, compliance of accessible component parts subject to section 108 of the CPSIA is always required.

Comment 12: Two commenters claim that the NPR reverses the Commission's 2009 Statement of Policy which, according to the commenters, lists a number of plastic materials other than the four plastics in the NPR that are not subject to third party testing for certification purposes. Another commenter states that the proposed rule "appears to negate the flexibility afforded in the 2009 Statement of Policy document on phthalates." The commenter suggests that "the flexibility granted by the CPSC's *Statement of Policy* should be maintained." The commenter asserts that this flexibility allows suppliers with supply chain knowledge to use their discretion when determining which materials are subject to third party testing.

Response 12: The Commission's 2009 *Statement of Policy: Testing of Component Parts with Respect to Section 108 of the Consumer Product Safety Improvement Act*,[16] a guidance document, listed a number of materials that might not require third party testing. The 2009 *Statement of Policy* did not create determinations for the listed materials that would exclude those materials from required third party testing.

The specified phthalates are commonly used in some plastics, inks, adhesives, paints, some rubberized materials, sealants, air fresheners, and scented products. However, the 2009 *Statement of Policy* did not state that the use of the specified phthalates was limited to the listed materials only. The draft final rule does not reverse the 2009 *Statement of Policy*. Rather, the draft final rule establishes a list of materials that are not subject to required third party testing to assure compliance with section 108 of the CPSIA.

However, staff acknowledges that the proposed rule may be interpreted as negating the flexibility of the 2009 *Statement of Policy*. As discussed in response to Comment 11, staff has now phrased § 1308.2(c) of the draft final rule to emphasize that materials other than the specified plastics listed in the draft final rule that are plasticized or may contain phthalates are required to be third party tested. Section 108(c) of the CPSIA requires third party testing (with some exceptions) of accessible component parts for plasticized component parts or other materials that may contain phthalates.

Staff notes that this rule, if approved by the Commission, would supersede any conflicting statements contained in the 2009 statement of policy.

2.5. Due Care and Certification

Comment 13: A commenter suggests that the Commission state whether a Certificate of Compliance is required for plastics for which a third party testing determination has been made. The commenter states that if third party testing is not required, but that a Certificate of Compliance must still be issued by the certifier, additional due diligence is required to ensure that the plastic material is one that qualifies for a testing exclusion. The commenter suggests adding a "due care" provision, similar to the provision in 16 C.F.R. part 1109 (the component part testing rule),[17] to the Final rule. The commenter contends that the due care requirement should be extended to a certificate's reliance on the proposed phthalates determinations given the

[16] https://cpsc.gov/s3fs-public/pdfs/blk_media_componenttestingpolicy.pdf.

[17] http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title16/16cfr1109_main_02.tpl, Section 1109.4 (g) states: "Due care means the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Due care does not permit willful ignorance."

inherent complexity involved with properly identifying the specific plastics and additives that would be exempt from testing. The commenter asserts that adding this requirement to the rule would result in manufacturers and importers taking steps to have confidence that their plastics qualify for third party testing determinations. If certification is required, the commenter requests that the Commission should:

> provide guidance as to what is an acceptable basis for such a certification in the absence of third party testing. The agency should also explain how such a certification requirement would intersect with the ability of manufacturers and importers to rely on certificates from upstream suppliers.

Another commenter states that importers often have limited knowledge of their products' materials and lack the evidence to demonstrate compliance without testing. The commenter asserts:

> Employing an Attenuated Total Reflectance (ATR) sensor and identification models for the determination of plastics, it is quite easy to arrive at the required "high degree of assurance" that the products are manufactured from one of the four exempted plastics – and, by extension, a "high degree of assurance" that the materials contain no banned ortho-phthalates – for a minimal investment in technology and thus saving substantial third-party lab testing costs.

The commenter proposes that language added to the preamble of a final rule to "strengthen" the rule and make it more consistent with the provision in Public Law No. 112-28.[18] The commenter suggests that the proposed preamble text stating:

> The proposed determinations would only relieve the manufacturers' obligation to have the specified plastics and accompanying additives tested by a CPSC accepted third-party conformity assessment body. Children's toys and child care articles must still comply with the substantive phthalates content limits in section 108 of the CPSIA regardless of any relief on third-party testing requirements.

be supplemented with the text below:

> As such, manufacturers and importers of these products must exercise "due diligence," which would include screening of its plastic supplies to ensure that their products are manufactured only from an exempt plastic, otherwise their products must be third-party tested for the presence of any banned phthalate.

The commenter states that screening tests, conducted on a first party basis, would reduce third party testing costs while ensuring compliance to the CPSIA.

Response 13: The draft final rule addresses third party testing requirements for specified plastics to ensure compliance with section 108 of the CPSIA. Certification of products subject to

[18] CPSA section 14(i)(3)(B), as amended by Public Law No. 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." See https://www.cpsc.gov/s3fs-public/pdfs/blk_media_cpsa.pdf?epslanguage=en.

a children's product safety rule is required irrespective of whether third party testing is required. As discussed in response to Comment 5, a certifier or testing party must exercise due care to ensure that no action or inaction after testing and before distribution in commerce has occurred that would affect compliance, including contamination or degradation, while a component part or finished product is in its custody. Thus, the component part testing rule establishes due care requirements for certifiers or testing parties. To repeat the requirements in this proposed rule would be redundant and unnecessary.

In a similar manner, adding a "due diligence" mandate to the proposed rule to require screening plastic supplies is redundant to 16 C.F.R. part 1109. Screening or testing (first party or third party) unnecessarily restricts the methods that certifiers may use to ensure that the plastics used in their children's products are plastics for which testing determinations have been made. Several methods are available to certifiers to ensure compliance, such as quality assurance/quality control processes, factory/supplier evaluations, design reviews, manufacturing process controls, process auditing or similar controls, raw material validation and controls, testing programs (first party and/or third party), and risk identification and management actions.

Because the requirement for certifiers to use due care has been established in the component part testing rule, staff declines to change the draft final rule based on this comment.

Comment 14: A commenter suggests that any final rule clarify that when certifying parties are relying on third party testing determinations for certification purposes, laboratories do not have the responsibility for:

- Determining the type of plastic;
- Verifying that the plastic is what a supplier declares;
- Confirming that there has been no contamination; and
- Confirming there have been no material changes through supply chain traceability and production safeguards.

The commenter asserts that these responsibilities reside with the certifying party (domestic manufacturer or importer).

Response 14: We agree with the commenter that the manufacturer or importer of a children's product is responsible for its certification. Laboratories have limited responsibilities regarding certification issues. Unless a laboratory, on behalf of a manufacturer or importer, voluntarily chooses to be a children's product or component part certifier, the laboratory is not responsible for the compliance of a tested product to the applicable children's product safety rules. The manufacturer or importer is responsible for meeting the requirements of 16 C.F.R. parts 1107 and 1109, which generally include the responsibilities listed by the commenter. Because other regulations include the responsibilities listed by the commenter, staff declines to change the draft final rule based on this comment.

2.6. Research Does not Show High Degree of Assurance of Compliance

Comment 15: A commenter asserts that the research does not provide a high degree of assurance that the specified plastics do not contain any of the specified phthalates in concentrations above 0.1 percent. The commenter states:

> the research conducted so far does not demonstrate "consistent performance" of the product due to the overwhelming lack of available data on how phthalates are used, where they occur, and their migration across products and out of materials.

The commenter points to the lack of data on phthalate content in the specified plastics, and provides examples. One example is that for products made with polyethylene, "the presence or concentration of the specified phthalates was not reported."[19] Another example cited is "Other studies and patents for toys and child care products did not include information on the presence of phthalates in ABS."[20] The commenter adds that the TERA Task 12 Report states that Zeigler-Natta catalysts (which can contain some of the specified phthalates) could remain in high-impact polystyrene at a concentration of 0.0001 percent, but that no test data had been supplied to support that claim. The commenter provides other examples of the lack of information on phthalates in recycled plastics or the possibility of a plastic's contamination with a specified phthalate.

The commenter states:

> Given the complete lack of data on phthalates in recycled materials and on migration into and out of products, and the almost complete lack of data overall, CPSC cannot support moving away from its legal obligations to require third party product testing.

Response 15: Staff disagrees with the assertion " . . . overwhelming lack of available data on how phthalates are used, where they occur . . .." The available information identifies how and where phthalates are used, and also shows the chemicals and processes used to manufacture the specified plastics. Therefore, staff considers that the available information supports a conclusion that the specified plastics do not contain phthalates at levels exceeding the specified limit for children's toys and child care articles.

Staff agrees that few studies directly measured phthalates content in the specified plastics. However, we expected that such studies might be rare, given that the available information does not indicate that phthalates might be present.

Staff agrees that the literature on recycling is not as extensive as the data on phthalates and plastics manufacturing. Nonetheless, staff considers that all of the information about phthalate use and occurrence indicates that recycling could result in plastics that contain traces of phthalates, although staff expects that residual levels would be well below the maximum allowed concentration in children's toys and child care articles.

[19] TERA Task 12 Report, page 56.
[20] TERA Task 12 Report, page 57.

In the work done by a contractor, and presented in the Task 12 and 16 reports, the contractor was faced with "proving a negative," or showing that phthalates are not present in the specified plastics. The contractor employed a tiered approach to research the specified plastics. This approach narrowed the field of possible sources and assisted in identifying information that was not available (data gaps) so that focused efforts could be directed in those areas. In the Task 12 Report, from a "universe" of more than 109 million sources, the contractor staff screened 119,800 articles for relevant information on the four plastics and phthalates. The contractor stated:

> Given the search strategy and its success at getting the other information, we can be confident that if there had been information on the phthalate content of the four plastics we would have found it. In fact, the consistent lack of information amongst the many places we searched, both secondary authoritative web and library sources and primary literature sources made us highly confident that there was very little information on the specified phthalates in the four plastics.[21]

For the Task 16 Report, the contractor screened more than 179,000 sources for relevant information on the specified plastics and phthalates in a nonbiased manner that was representative of the worldwide literature on this subject matter. As in the Task 12 Report, the contractor states that its Task 16 Report search strategy and its success at obtaining other information, gives them confidence that, if there had been information on the phthalate content of the specified plastics, it would have been found.

Thus, for the reasons discussed above, staff considers the Task 12 and 16 reports to provide a high degree of assurance that the specified plastics do not contain any of the specified phthalates in concentrations above 0.1 percent. Staff declines to change the draft final rule based on this comment.

Comment 16: A commenter recommends that the Commission exercise "extreme caution and skepticism with unproved claims of compliance with CPSC requirements." The commenter expressed concern about unintentional or unknown factors that could result in the presence of phthalates. The commenter claims that many toys have disconnected and global supply chains, and that as a consequence, U.S. toy importers often rely on laboratory test results from foreign suppliers. As evidence of their argument to exercise caution and skepticism, the commenter cites the alleged failure of an importer to meet a state standard.

Response 16: Staff recommendations are primarily based on information in the TERA Task 11, 12, and 16 reports about use and production of phthalates, and about the production of specified plastics. The available information shows that phthalates are not used as plasticizers for the specified plastics or otherwise found in the plastics at levels exceeding the specified limits for children's toys and child care articles. The recommendations for the determinations in this rule are not based on supplier assertions, manufacturer's laboratory test results, or other industry attestations. Staff considers the information in the TERA Task 12 and 16 reports, along with the additional staff research, to be sufficient to make a determination with a high degree of assurance that the specified plastics are compliant with section 108 prohibitions without requiring third party testing.

[21] Tera Task 12 Report, page 55.

Regarding the commenter's concerns about unintentional or unknown factors, staff notes that manufacturers and importers are required to have a high degree of assurance that their products comply with the applicable product safety rules. Furthermore, manufacturers and importers are responsible for exercising due care to ensure that their children's products comply with the applicable children's product safety rules. As described in section 1109.5(b)(3) of 16 C.F.R. part 1109, due care includes actions after product testing and before product distribution in commerce to ensure against noncompliance through contamination or degradation. Staff declines to change the draft final rule based on this comment.

Comment 17: A commenter states that the contractor (TERA) engaged by the CPSC to study phthalate use and investigate the presence of phthalates in four specified plastics may have a conflict of interest. The commenter notes TERA's past litigation support for regulated industries. The commenter asserts that TERA's potential conflict of interest is exemplified in a 2016 paper sponsored by a chemical manufacturers' trade group.[22]

The commenter adds that TERA is a founding member of the Alliance for Risk Assessment (ARA). The ARA's Standing Panel includes the TERA founder, two industry consultants, employees of Dow Chemical and of ExxonMobil, and two government employees.

The commenter alleges that, in light of TERA's relationship with ExxonMobil, TERA's conclusions should be viewed with caution.

Response 17: In CPSC staff's assessment, TERA is an independent organization[23] that focuses on advancing the science of toxicology and risk assessment. Staff does not agree that work by TERA or individual TERA staff in scientific projects, workshops, or publications that relate to industrial chemicals or products, or that include chemical firms, industry employees, or trade organizations necessarily indicates unreliable performance or improper influence in CPSC contract work.

As a standard procedure, CPSC reviews potential conflicts of interest before awarding a contract or task order. Staff did not identify any conflicts for TERA related to the investigation of the production and use of phthalates or the production of the specified plastics.

Staff does not agree that the membership in ARA is evidence of a potential conflict of interest. Rather, staff considers the ARA to be a transparent, multi-stakeholder scientific collaboration to develop risk assessment information to advance public health activities. Furthermore, the commenter did not specify any projects by the ARA that suggest that the contracted TERA work is affected by potential conflicts of interest.

In summary, the commenter did not provide any specific information demonstrating that the reports produced by TERA under contract with CPSC have been affected by potential conflicts of interest. Nor did the commenter show that the reports contain inaccurate or misleading data or information.

---

[22] *Approaches for describing and communicating overall uncertainty in toxicity characterizations: U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) as a case study.* The publication can be found at: https://www.ncbi.nlm.nih.gov/pubmed/26827183.

[23] Staff notes that subsequent to the contract work discussed here, TERA reorganized as the Risk Science Center at the University of Cincinnati: https://med.uc.edu/eh/centers/rsc.

2.7. Out of Scope

Comment 18: A commenter suggests that the CPSC substitute "random spot checking" for Certificates of Compliance, to ensure that children's toys (and presumably child care articles) do not contain any of the specified phthalates in concentrations over 0.1 percent.

Response 18: This rulemaking is limited to determinations regarding required third party testing. Recommendations to substitute "random spot checking" for certificates of compliance are beyond the scope of this rule.

Comment 19: A commenter proposes that CPSC develop a system to permit manufacturers to petition the Commission for exclusion from third party phthalate testing for compliant materials that will be innovated in the future and for which no testing determinations have been made. The commenter suggests that upon receipt of specified "background information" on the novel material, the Commission could respond with a determination within a fixed time.

Response 19: This rulemaking is limited to determinations regarding required third party testing. Developing a process for petitioning for potential future testing exclusions is beyond the scope of this rulemaking.

Comment 20: A commenter urges the Commission to identify statistical averaging and margins of error under which products could still be considered compliant to avoid the need to destroy an entire lot or batch.

Response 20: This rulemaking is limited to determinations regarding phthalate content in specified plastics. Proposals regarding product testing are beyond the scope of this rulemaking.

Comment 21: A commenter advises the Commission to consider allowing other techniques that could reduce third party testing costs. The commenter states: "The CPSC could allow finished children's product producers to rely on supplier assurances that lead is not included in the raw material, much as a manufacturer of a children's product made of leather or wood can rely on exemptions for those products." The commenter cites the example of the U.S. Food and Drug Administration's (FDA) use of Good Manufacturing Practices to control lead content in food-grade materials. The commenter states that guarantees by raw material producers do not need to be subjected to independent verification by third party testing laboratories.

A second commenter suggests that the Commission adopt required third party testing exclusions for lead for food-grade plastic resins accompanied by a supplier assurance of compliance with FDA requirements.

Response 21: This rulemaking is limited to determinations regarding phthalate content in specified plastics. Proposals regarding product testing and certification, or lead testing, are beyond the scope of this rulemaking. In the absence of a determination or registration as a small batch manufacturer, section 14 of the CPSA requires third party testing to ensure compliance. Supplier assurances are not allowed to replace required third party testing. Similarly, "good manufacturing practices" types of processes are not allowed to replace required third party testing.

Comment 22: A commenter suggests that, to the extent the Commission believes that it lacks authority to adopt the commenter's recommendations, the Commission should request such authority from Congress under Section 14(d)(3)(C) of the Consumer Product Safety Act, as amended by Section 2 of Public Law No. 112-28.

Response 22: This rulemaking is limited to determinations regarding phthalate content in specified plastics. Requests for additional authority are beyond the scope of this rulemaking.

Comment 23: A commenter suggests that when noncompliant products are found in the marketplace, the CPSC's investigation should include supply chain controls to confirm that any due care or similar requirements needed for a manufacturer or importer to rely on a phthalate determination have been satisfied. The commenter suggests that if during the investigation, a certifier's reliance on a determination is not indicated expressly on the laboratory test report, the Commission should still ask whether a determination was claimed by the certifying party before concluding there was an error in testing.

Response 23: This rulemaking is limited to determinations regarding phthalate content in specified plastics. Compliance activities are beyond the scope of this rulemaking.

Comment 24: A commenter recommends that the Commission to continue to require third party testing for phthalates in polyvinyl chloride (PVC), especially flexible grades.

Response 24: This rulemaking is limited to determinations regarding phthalate content in specified plastics; polyvinyl chloride is not included among these plastics. Currently, third party testing is required and would remain required for toys and child care articles with accessible component parts manufactured from PVC.

Tab B: Hardness testing on plastics with more than 0.1 percent of specified phthalates.

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

Memorandum

Date: June 6, 2017

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

THROUGH: Andrew G. Stadnik, Associate Executive Director
Directorate for Laboratory Sciences

Aaron Orland, Director
Division of Chemistry, Directorate for Laboratory Sciences

FROM : Richard Uhl, Chemist
Directorate for Laboratory Sciences

SUBJECT : Hardness testing on plastics with more than 0.1 percent of specified phthalates

During the U.S. Consumer Product Safety Commission (CPSC) Workshop on Reducing Third Party Testing Burdens Through Determinations, held on April 3, 2014, representatives from the Toy Industry Association (TIA) and the Fashion Jewelry and Accessories Trade Association (FJATA) asserted: "materials with a Shore A hardness rating of 90 or above . . . are not likely to contain phthalates." However, no testing data were provided to support the assertion by the representatives. In response to the notice of proposed rulemaking (NPR), *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics*,[24] two commenters recommended that the final rule incorporate a provision that plastics meeting a hardness specification be exempt from third party testing requirements.[25,26] The commenters provided no data to support their recommendations. If a hardness test could be used to screen plastic component parts that do not contain greater than 0.1 percent phthalates, expensive third party testing could be avoided without affecting the compliance of the children's product to section 108 of the CPSIA[27] (the phthalate content requirements).

In plastics, phthalates are used as plasticizers, or softeners, of component parts. CPSC staff initiated an activity to confirm whether the hardness of plastic component parts can be used as an indication of their compliance to the prohibition of certain phthalates in children's toys and child care articles. Section 108 of the CPSIA prohibits children's toys and child care articles with more than 0.1 percent content of three phthalates (DEHP, DBP, and BBP), and prohibits children's

[24] https://www.federalregister.gov/documents/2016/08/17/2016-19464/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates-determinations.
[25] See: https://www.regulations.gov/document?D=CPSC-2016-0017-0005.
[26] See: https://www.regulations.gov/document?D=CPSC-2016-0017-0010.
[27] https://www.cpsc.gov/regulations-laws--standards/statutes/the-consumer-product-safety-improvement-act/.

toys that can be placed in the mouth and child care articles with more than 0.1 percent content of three additional phthalates (DINP, DIDP, and DnOP).

"Hardness" is defined as a material's resistance to permanent indentation. For plastics, hardness is commonly measured by Shore[28] (durometer) hardness methods. Shore durometer is often preferred for softer materials, such as soft polymers, elastomers, and rubbers. ASTM D2240-15, *Standard Test Method for Rubber Property – Durometer Hardness*,[29] is the method used to measure the hardness of plastics. The Shore A scale is used to measure hardness in softer plastics; the Shore D scale is used for harder plastics. The Shore hardness for each scale is a value between 0 and 100, with higher values representing harder plastics.

The industry representatives at the CPSC workshop and one NPR commenter asserted that plastic component parts with a Shore A hardness rating of 90 or above would not contain a quantity of regulated phthalates at concentrations greater than 0.1 percent. Another NPR commenter stated that rigid vinyl with Shore D hardness greater than 70 would not contain any of the specified phthalates in concentrations greater than 0.1 percent.

CPSC staff measured the Shore hardness of various plastic samples with a Shore type-A durometer. Measurements were also made with a type-D durometer, which was recommended by CPSC subject matter experts because a type-D durometer can differentiate harder plastics. CPSC staff also measured the phthalate content of the plastic samples. The results of the testing are shown in Table 1, and in Graphs 1 and 2 for the Shore A tests.

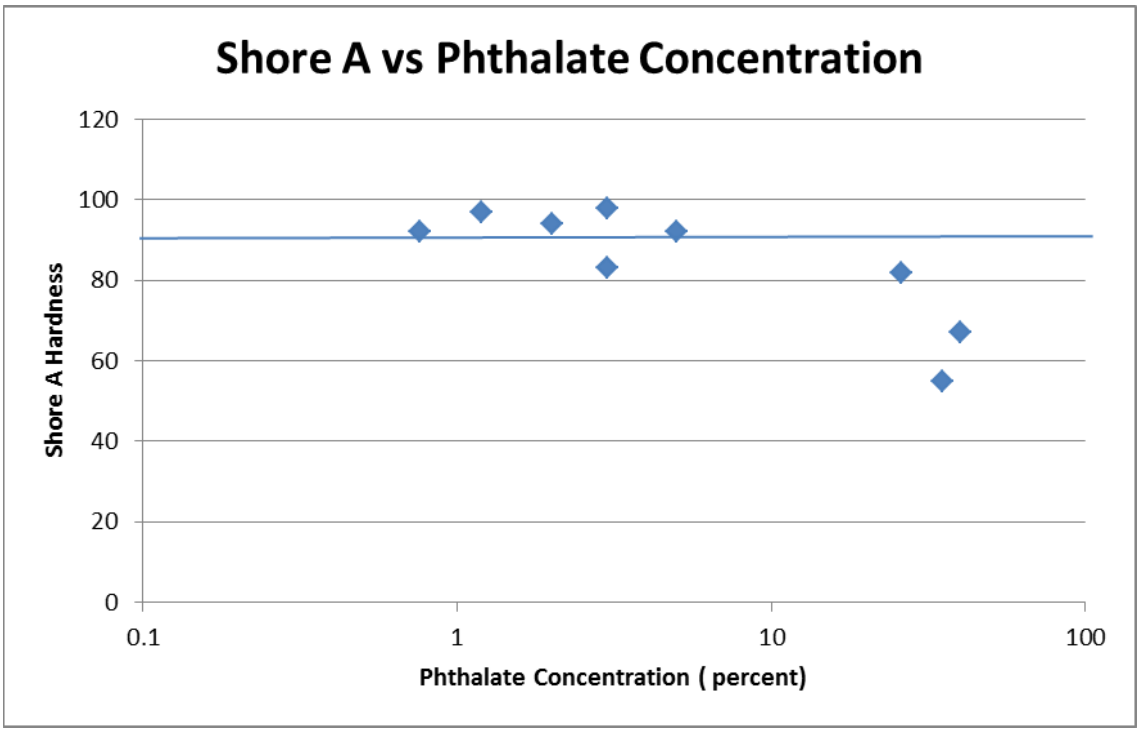
[28] https://en.wikipedia.org/wiki/Shore_durometer.
[29] https://www.astm.org/Standards/D2240.htm.

Table 1: Shore Hardness (A and D) results for plastic samples with various percentages of a specified phthalate:

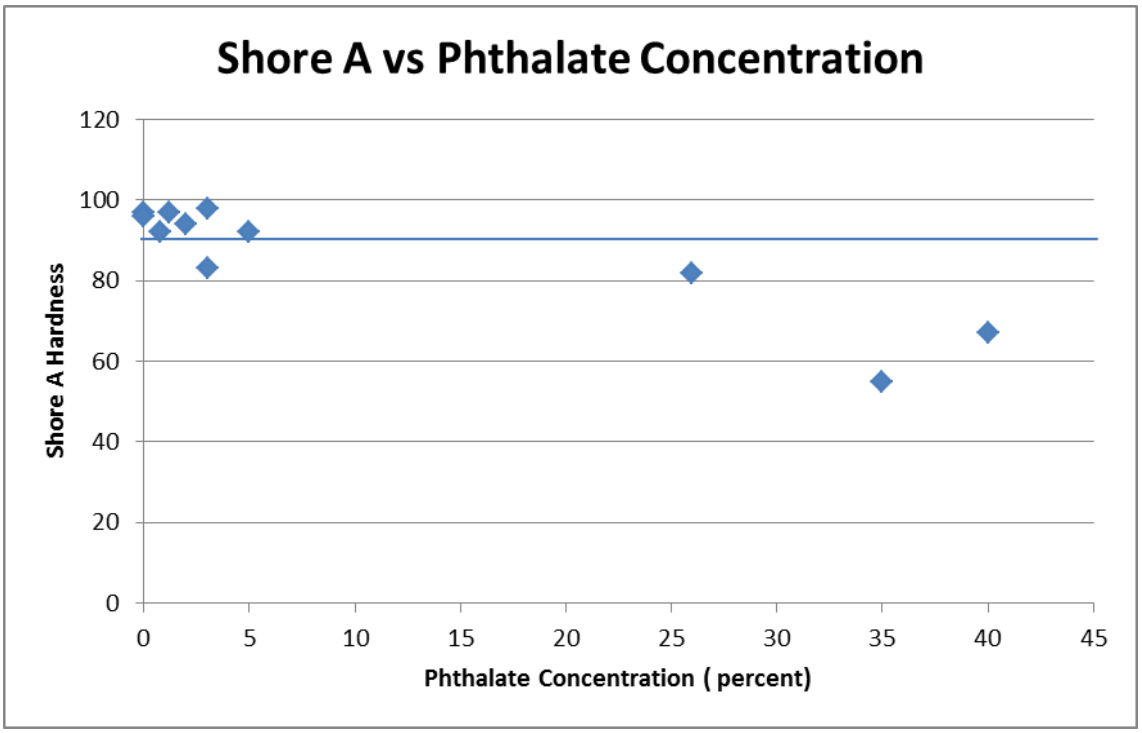
Sample	Material Composition	Specified Phthalate concentration (percent)	Shore A*	Shore D	Notes
Pink ball	Polyvinyl chloride	40	67		Sample folded over to 4-layer thickness for testing
Ducky	Polyvinyl chloride	35	55		Two layers tested
Pink arm	Polyvinyl chloride	2	94	44	Side of arm
Pink leg	Polyvinyl chloride	3	98	55	Side of leg
Red shoe	Polyvinyl chloride	3	83	21	Sole
Clear Tire	Polyvinyl chloride	0.76	92	48	Sample previously analyzed (0.76 percent DEHP)
PVC Pipe	Polyvinyl chloride	0	97	82	
PLA	Polylactic acid	0	96	83	
Doll head	Polyvinyl chloride	26	82		
Doll arm	Polyvinyl chloride	5	92		
Doll leg	Polyvinyl chloride	1.2	97		

* Durometer readings below 20 or above 90 are not considered reliable per ASTM D2240 section 9.3, and are included here as reference only.

Graph 1: Shore A Hardness Versus Phthalate Concentration (logarithmic):*



Graph 2: Shore A Hardness Versus Phthalate Concentration (linear):*



* The blue line in both graphs represents a Shore A hardness value of 90.

Three samples with high phthalate content (26 percent, 35 percent and 40 percent phthalates) were found to have Shore A hardness measurements of less than 90, and two samples purported to contain no phthalates, were found to have Shore A hardness values higher than 90. However, **five out of six samples** containing "lower" levels of a specified phthalates (0.76 percent to 5 percent) had Shore A hardness values of greater than 90. All five of these samples contained phthalates in concentrations significantly higher than the 0.1 percent content limit, which would apply if those components were accessible components of toys or child care articles. These initial examples indicate that using a Shore A hardness rating of 90 or above is unreliable as a definitive analysis for determining regulated phthalate content of not greater than 0.1 percent, and should not be used to assess compliance with section 108 of the CPSIA.

The Shore D measurement results appear to show that small concentrations of phthalates reduce the hardness of the component part, such that the plasticized component parts had Shore D hardness measurements less than 70. Two non-plasticized samples had hardness measurements greater than 70. However, because of the small sample size, these results cannot be used to draw any definitive conclusions regarding the relationship of polyvinyl chloride hardness to phthalate concentration. Thus, staff cannot support the claim that a Shore D hardness measurement of greater than 70 can be used to conclude that a plastic product or component part does not contain any of the phthalates that are prohibited in children's toys and child care articles.

The Shore hardness test was never intended to be used to infer the chemical content of a tested plastic. The data show that for a phthalate concentration of 3 percent, the Shore D hardness varied by more than a factor of two. This variation implies that factors other than chemical content (e.g., composites with varying hardness, work hardening during testing, sample non-homogeneity, surface pollution) can have a significant impact on the hardness measurement.

In conclusion, staff cannot, at this time, support the use of Shore hardness testing as a replacement for third party testing requirements for phthalate content of children's toys and child care articles. This conclusion is based on the characteristics and purpose of the Shore hardness testing, the results of Shore A tests that show that plasticized materials can show high hardness measurements, contrary to expectations, and the variable results for limited Shore D testing that does not clearly define the performance of the test regarding conclusions about phthalate content.

Tab C: Determinations that Certain Plastics Will Not Contain Specified Phthalates: Regulatory Flexibility Analysis

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: June 26, 2017

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

THROUGH: Gregory B. Rodgers, Ph.D., Associate Executive Director
Robert L. Franklin, Senior Staff Coordinator
Directorate for Economic Analysis

FROM: Charu S. Krishnan
Directorate for Economic Analysis

SUBJECT: **Determinations that Certain Plastics Will Not Contain Specified Phthalates: Regulatory Flexibility Analysis**

Background

The U.S. Consumer Product Safety Commission (CPSC, Commission) is considering a draft final rule that would make determinations that specific plastics do not and will not contain any of six specified phthalates in concentrations greater than 0.1 percent. If the Commission promulgates the final rule, as drafted, manufacturers of children's toys and child care articles will not have to obtain third party tests for accessible component parts made of these plastics to certify that the component parts do not contain the specified phthalates in excess of the allowable level. The plastics for which the CPSC staff recommendations have been made are: polyethylene (PE), polypropylene (PP), acrylonitrile butadiene styrene (ABS), general purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), and super high-impact polystyrene (SHIPS).

Based on an extensive literature review seeking information on the raw materials used in the manufacture of the specified plastics, the worldwide manufacturing practices of the plastics, the typical applications, and the potential for exposure to the specified phthalates through the use of recycled materials or due to contamination, CPSC staff has concluded that there is a high degree of assurance that these plastics will not contain any of the specified phthalates in concentrations above 0.1 percent. Therefore, third party testing would not be necessary to ensure that children's toys and child care articles with component parts made from these plastics do not contain those phthalates. The draft final rule is one result of the Commission's ongoing efforts to find opportunities to reduce the cost of the third party testing

requirements consistent with assuring compliance with the applicable children's product safety rules.

The Regulatory Flexibility Act (RFA) requires that agencies review rules for their potential economic impact on small entities, including small businesses. Section 604 of the RFA calls for agencies to prepare a final regulatory flexibility analysis, describing the impact of the rule on small entities. The final regulatory flexibility analysis is to contain:

1) a statement of the need for, and objectives of, the rule;

2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the draft Final Rule as a result of the comments;

4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for the preparation of the report or record; and

6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the draft Final Rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

According to the U.S. Small Business Administration's (SBA) Office of Advocacy,

> Congress considered the term 'significant' to be neutral with respect to whether the impact is beneficial or harmful to small businesses. Therefore, agencies need to consider both beneficial and adverse impacts in an analysis.[30]

The SBA guidance may seem counterintuitive in that burden reduction, although beneficial, could still be found to have a significant economic impact on a substantial number of small businesses. However, the SBA guidance states, " . . . an agency cannot certify a proposed rule if the economic impact will be significant but positive."[31] Therefore, although the draft final

[30] SBA Office of Advocacy "A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act", May 2012, p. 23
[31] Id. p.20

rule would have a positive impact on small entities, staff has prepared a final regulatory flexibility analysis, which is summarized below.

Objectives and Legal Basis of the Final Rule

The objective of the draft final rule is to reduce the burden of third party testing on manufacturers of children's toys and child care articles consistent with assuring compliance with CPSC requirements. The legal basis is section 2 of Public Law No. 112-28.

Significant Issues Raised by Public Comments or by the Chief Counsel for Advocacy of the Small Business Administration

Two commenters stated that the rule appeared to limit the flexibility provided in the Commission's 2009 *Statement of Policy: Testing of Component Parts with Respect to Section 108 of the Consumer Product Safety Improvement Act*.[32] One commenter stated that this could actually significantly increase the costs for some companies. One commenter stated that the 2009 *Statement of Policy* "lists a number of other plastic materials, beyond PP, PE, ABS, and HIPS[33] that will not contain the restricted phthalate esters." The other commenter expressed a belief that the *2009 Statement of Policy* made manufacturers responsible "for knowing what is in, and what is not in their products while allowing them discretion on how to comply with the testing requirements mandated by the CPSC."

We believe that these commenters are misinterpreting the *2009 Statement of Policy*. As noted in Response 12 of Tab A, the *2009 Statement of Policy* document did not create determinations for the listed materials that would exclude those materials from required third party testing. The specified phthalates are commonly used in some plastics, inks, adhesives, paints, some rubberized materials, sealants, air fresheners, and scented products. However, the 2009 guidance did not state that the use of the specified phthalates was limited to only those listed materials. The draft final rule does not reverse the 2009 guidance. Rather, the draft final rule establishes a list of materials for which third party testing is not required for certifying compliance with section 108 of the CPSIA. Staff has rephrased §1308.2(c) of the draft final rule to emphasize that materials other than the specific plastics listed in the draft final rule that are plasticized or may contain phthalates are required to be third party tested. Section 108 of the CPSIA requires third party testing (with some exceptions) of accessible component parts for plasticized component parts or other materials that may contain phthalates.

It is possible that some manufacturers might have misinterpreted the *2009 Statement of Policy* and perhaps have conducted less third party testing than they should have. However, because this rule is not imposing additional restrictions, it will not increase costs for companies that had properly been conducting third party testing as required by section 102 of the CPSIA and 16 C.F.R. parts 1107 and 1109.

[32] https://cpsc.gov/s3fs-public/pdfs/blk_media_componenttestingpolicy.pdf

[33] PP, PE, ABS, and HIPS are polypropylene, polyethylene, acrylonitrile butadiene styrene, and high-impact polystyrene, respectively.

Small Entities to Which the Final Rule Would Apply

The rule would apply to small entities that manufacture or import children's toys or child care articles that contain accessible polyethylene, polypropylene, acrylonitrile butadiene styrene, general-purpose polystyrene, medium-impact polystyrene, high-impact polystyrene, and super high-impact polystyrene component parts. Toy manufacturers are classified in North American Industry Classification System (NAICS) category 339930 (Doll, Toy, and Game Manufacturing). According to the U.S. Bureau of the Census, in 2014 there were 556 toy manufacturers in the United States, of which 548 had fewer than 500 employees and would be considered small entities according to the SBA criteria.[34] Of the small manufacturers, 339 had fewer than five employees.

Toy importers may be either wholesale merchants or retailers. The draft final rule would not apply to toy wholesalers or retailers if they obtain their merchandise from domestic manufacturers or importers and do not import toys or child care articles themselves. Toy wholesalers are classified in NAICS category 423920 (Toy and Hobby Goods and Supplies Merchant Wholesalers). According to the U.S. Bureau of the Census, there were 2,033 firms in this category.[35] Of these, 1,959 had fewer than 100 employees and would be considered small businesses, according to SBA criteria. Toy retailers are classified in NAICS category 451120 (Hobby, Toy, and Game Stores). There could be about 4,632 toy retailers that would meet the SBA criteria to be considered a small entity.[36] Although importers are responsible for the certification of the children's products that they import, they may rely upon third party testing performed by their foreign suppliers for purposes of certification. The number of small toy wholesalers or retailers that import toys, as opposed to obtaining their product from domestic sources is not known. Also unknown is the number of small importers that must obtain or pay for the third party testing of their products.

The phthalate regulations also apply to manufacturers and importers of child care articles. Child care articles include many types of products for which the CPSC has recently promulgated or proposed new or amended mandatory safety standards. These include toddler beds, full size and non-full size cribs, bassinets and cradles, bedside sleepers, high chairs, hook-on-chairs, and booster seats. Other child care articles include sleepwear and crib or cradle bumpers. In its ongoing market research, CPSC staff has identified 364 suppliers of these products that would be considered small according to criteria established by the SBA. Additionally, there could be other child care articles, not listed above, for which CPSC has not

[34] U.S. Bureau of the Census, "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2014," 2014 County Business Patterns.
[35] Ibid.
[36] The SBA considers a toy retailer (NAICS 451120) to be a small entity if its annual sales are less than $27.5 million. According to the U.S. Bureau of the Census, in 2012, the average receipts for toy manufacturers with more than 500 employees was almost $900 million. The average receipts for the next largest category for which summary data were published, toy retailers with at least 100 but fewer than 500 employees, was about $10 million. There were 4,647 firms in this NAICS category, of which 4,632 had fewer than 500 employees. (U.S. Census Bureau, Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2012.)

yet developed a mandatory or proposed standard, but which nevertheless are covered by the phthalate requirements.

Child care articles would also include products such as pacifiers and bottle nipples. Manufacturers of these products are classified in NAICS category 326299 ("All other rubber product manufacturing"). There are 565 firms classified in this NAICS code of which 513 are considered to be small.[37] However, this NAICS category includes many other products and most of these firms probably do not manufacture child care articles.

Although, as discussed above, while the number of small companies that supply children's toys or child care articles to the U.S. market might be close to 10,000, the number that actually supply products with accessible polyethylene, polypropylene, general purpose polystyrene, medium-impact polystyrene, high-impact polystyrene, super high-impact polystyrene, or acrylonitrile, butadiene styrene component parts is not known. Also not known is the number of children's toys and child care articles that contain these plastics.

While comprehensive estimates of the number of children's toys and child care articles that contain components made from the specified plastics are not available, there is some evidence that these plastics are extensively used in children's toys. One source stated that polypropylene and high-density polyethylene are used in 38 percent and 25 percent, respectively, of injection-molded toys. Low-density polyethylene, acrylonitrile butadiene styrene, and polystyrene are each used in less than 10 percent of the injection-molded toys.[38]

Based on the number of domestic toy manufacturers that are classified as small businesses by the U.S. Bureau of the Census and evidence that the specified plastics are extensively used in toys, staff believes a substantial number of small entities would be positively impacted by this regulation.

Reporting, Recordkeeping and Other Compliance Requirements and Impact on Small Businesses

The draft final rule would not impose any reporting, recordkeeping, or other compliance requirements on small entities. In fact, because the draft final rule would eliminate a testing requirement, there would be a small reduction in some of the recordkeeping burden under 16 C.F.R. parts 1107 and 1109 because manufacturers would no longer have to maintain records of third party phthalate tests for the component parts manufactured from these plastics.

CPSC staff is recommending that the Commission make determinations that there is a high degree of assurance that the specific plastics will not contain any of the specified phthalates in concentrations above 0.1 percent. If the Commission promulgates a rule making the determinations, manufacturers, importers, and private labelers of children's toys and child care

[37] U.S. Bureau of the Census, "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2014," 2014 County Business Patterns.
[38] Donald V. Rosato, Plastics End Use Applications, Springer, New York, (2011).

articles that have accessible component parts consisting of these plastics will not have to obtain third party tests to certify that the components do not contain the specified phthalates in concentrations above 0.1 percent. The specific plastics for which the determinations could be made are:

- Polypropylene (PP), including the following plasticizers: polybutenes, dioctyl sebacate, isooctyl tallate, paraffinic naphthenic, and mineral plasticizing oils, and polyol, and any of the following additives: unrecovered catalysts, fillers, primary and secondary antioxidants, neutralizing agents, antistatic agents, slip agents, metal deactivators, quenchers, UV stabilizers, nucleating agents, flame retardants, blowing or foaming agents, antiblocking agents, lubricants, or colorants that may be added to the plastic;
- Polyethylene (PE), including the following plasticizers: glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer, and any of the following additives, initiators, promoters, unrecovered catalysts, fillers, antistatic agents, flame retardants, anti-blocking agents, slip agents, blowing agents, cross-linking agents, antioxidants, carbon black, or colorants. that may be added to the plastic;
- General purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), and super high-impact polystyrene (SHIPS), including unrecovered catalysts, internal lubricants, chain transfer/transition agents, stabilizers, diluents, colorants, aluminum chloride, ethyl chloride, hydrochloric acid, iron oxide, potassium oxide, chromium oxide, or bifunctional peroxides that may be added to the plastic. It should be noted that only HIPS was included in the proposed rule. GPPS, MIPS, and SHIPS were added to this list since the publication of the notice of proposed rulemaking; and
- Acrylonitrile butadiene styrene (ABS), including the following plasticizers: hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, long chain fatty acid esters and aromatic sulfonamide, and any of the following additives, stabilizers, lubricants, antioxidants, molecular weight regulators, initiators/ unrecovered catalysts, activators, emulsifiers; or colorants. that might be added to the plastic.

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. The cost of phthalate testing is relatively high: between approximately $125 and $350 per test, depending upon where the testing is conducted and any discounts that are applicable. Because one product might have multiple component parts that require testing, the cost of testing a single product for phthalates could exceed $1,000 in some cases. Moreover, more than one sample might have to be tested to provide a high degree of assurance of compliance with phthalate requirements during a year. To the extent that small businesses have lower production or sales volumes than larger businesses, these determinations would be expected to have a disproportionately beneficial impact on small businesses. This beneficial impact is because the testing costs are spread over fewer units; and the benefit of the Commission making the determinations would be greater on a per unit basis for small businesses. Additionally, some laboratories may offer their larger customers discounts that might not be available to small

businesses that need fewer third party tests. Given the relatively high cost of phthalate testing and evidence that these plastics may be extensively used in children's toys and child care articles, making the determinations could potentially significantly benefit a substantial number of firms.

On the other hand, there are reasons to believe that the benefit of making the determinations could be less than might be expected. For example, some manufacturers might have been able to substantially reduce their third party phthalate testing costs by using component part testing as allowed by 16 C.F.R. part 1109, so the marginal benefit that might be derived from making the determinations might be low. The volume of children's toys or child care articles that contain PE, PP, GPPS, MIPS, HIPS, SHIPS, or ABS that are manufactured or imported might be substantially higher than average and therefore, the testing costs per unit might be low compared to the revenue per unit. Some importers might not be certain of what materials are actually being used in each component part. Therefore, these importers might have to undertake testing to determine the material from which component parts are made before they can decide that third party testing for phthalate content is not required. Doing so would reduce the beneficial impact of the Commission making the determinations.

Based on staff's research, staff cannot rule out the possibility that the burden reduction from this determination rule could result in testing cost reductions that exceed 1 percent of the gross revenues for a substantial number of toy manufacturers or importers.

Steps the Agency Has Taken to Minimize the Significant Impact on Small Entities

Under section 604 of the Regulatory Flexibility Act, a final regulatory flexibility analysis should include a "statement of the factual, policy, and legal reasons for selecting the alternative adopted in the draft Final Rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected." The draft Final Rule is itself the result of efforts of the CPSC to reduce third party testing costs consistent with assuring compliance with all applicable consumer product safety rules. Therefore, few alternatives, other than expanding the list of plastics for which determinations could be made were considered. We note that the draft Final Rule includes determinations for three additional polystyrenes (GPPS, MIPS, and SHIPS) that were not included in the Proposed Rule for this determination rule since the publication of the NPR.