information associated with the Class C airspace surface area and shelf.

Lastly, this action would update the El Paso International Airport geographic coordinates to reflect the current ARP information in the FAA’s aeronautical database from “lat. 31°48′24″ N., long. 106°22′40″ W.” to “lat. 31°48′26″ N., long. 106°22′35″ W.”

Class C airspace areas are published in paragraph 4000 of FAA Order 7400.9Z, dated August 6, 2015 and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class C airspace area modification proposed in this document would be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F. “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 4000—Subpart C—Class C Airspace

ASW TX C El Paso International Airport, TX (Amended)

El Paso International Airport, TX
(Lat. 31°48′26″ N., long. 106°22′35″ W.)

That airspace extending upward from the surface to and including 8,000 feet MSL within a 5-mile radius of the El Paso International Airport, excluding that airspace west of long. 106°27′02″ W., and that airspace within Mexico; and that airspace extending upward from 5,200 feet MSL to and including 8,000 feet MSL within a 10-mile radius of the El Paso International Airport, excluding that airspace west of long. 106°27′02″ W., and that airspace within Mexico.

Issued in Washington, DC, on August 10, 2016.

M. Randy Willis,
Acting Manager, airspace Policy Group.
[FR Doc. 2016–19556 Filed 8–16–16; 8:45 am]

BILLING CODE 4910–13–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


ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (Commission, or CPSC) is proposing a rule to determine 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.

DATES: Submit comments by October 31, 2016.

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

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written comments by mail/hand delivery/ courier to: Office of the Secretary, Consumer Product Safety Commission, Room 512, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

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

FOR FURTHER INFORMATION CONTACT:
Randy Butturini, Project Manager, Office of Hazard Identification and Reduction U.S. Consumer Product Safety Commission, 4330 East West Hwy., Room 814, Bethesda, MD 20814; telephone (301) 504–7923.

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) 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.” Id. 2063(d)(3)(B).

2. Prohibitions in Section 108 of the CPSIA

Section 108 of the CPSIA prohibits children’s toys and child care articles that contain 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 prohibited phthalates in section 108 of the CPSIA are listed in Table 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.

Table 1—Statutorily Prohibited Phthalates

<table>
<thead>
<tr>
<th>Phthalates</th>
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<tbody>
<tr>
<td>DEHP: di-(2-ethylhexyl) phthalate</td>
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<tr>
<td>DBP: dibutyl phthalate</td>
</tr>
<tr>
<td>BBP: benzyl butyl phthalate</td>
</tr>
<tr>
<td>DIMP: diisononyl phthalate</td>
</tr>
<tr>
<td>DIBP: diisobutyl phthalate</td>
</tr>
<tr>
<td>DNOP: di-n-octyl phthalate</td>
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</tbody>
</table>

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.” The CHAP issued its report in July 2014. Based on the CHAP report, the Commission published a notice of proposed rulemaking (NPR) proposing to make the interim prohibition on DINP in children’s toys and child care articles permanent, and proposing to lift the interim statutory prohibitions on DIDP and DnOP in children’s toys and child care articles. In addition, the NPR proposed adding four new phthalates to the prohibited list of phthalates that cannot exceed 0.1 percent concentration in accessible component parts of children’s toys and child care articles. Table 2 contains the list of phthalates that the NPR proposed to prohibit in children’s toys and child care articles.

Table 2—Proposed Prohibited Phthalates

<table>
<thead>
<tr>
<th>Phthalates</th>
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<tbody>
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<td>DEHP: di-(2-ethylhexyl) phthalate</td>
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</tr>
</tbody>
</table>

B. Contractor’s Research on Phthalates in Consumer Products

CPSC contracted with Toxicology Excellence for Risk Assessment (TERA) to conduct research on phthalates and provide CPSC with two research reports on phthalates relevant to this rulemaking. TERA conducted a literature search on the production and use of 11 specified phthalates in consumer products (Task 11 Report). The 11 phthalates researched by TERA are based on the phthalates assessed by the CHAP and the recommendations made in the CHAP report. Additionally, the CPSC contracted with TERA to conduct a literature search on whether specified plastics could be determined not to contain any of the 11 phthalates in concentrations above the CPSIA limit of 0.1 percent (Task 12 Report). TERA used a tiered literature research approach to identify sources for review from among the “universe” of available data. The plastics researched by TERA were:

• Polypropylene (PP);
• Polyethylene (PE);
• High-impact polystyrene (HIPS); and
• Acrylonitrile butadiene styrene (ABS).

TERA’s research included the following factors:

• The raw materials used in the production of the specified plastics;
• The manufacturing processes used worldwide to produce the plastics;
• Typical applications for the specified plastics in consumer products, especially toys and child care articles, focusing on circumstances where the plastic could contain phthalates at concentrations greater than 0.1 percent;
• The potential use of recycled materials containing the specified phthalates in the production of the plastics; and
• The potential for phthalate contamination during packaging, storage, use, or other factors.

C. CPSC Staff Analysis

1. Polypropylene (PP)

TERA’s research indicated the production of PP plastic uses a PP monomer, ethylene, and other monomers, a hydrocarbon solvent, catalysts, nucleating agents or fillers, and a number of other additives, depending on the type of PP and other manufacturing considerations. Additives can be included in PP to achieve various chemical and mechanical characteristics. PP can include the following additives:

• Hydrocarbon solvents: Examples of solvents used are hexane and heptane;

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### Polyethylene (PE)

#### Catalysts:
Catalysts used in producing PP are the Ziegler-Natta catalysts;^6^&^7^ fillers; fillers are added to plastics to enhance their performance (e.g., impact resistance, shrink resistance), and reduce manufacturing costs. Examples of fillers used in PP include talc, calcium carbonate, and fiberglass;

- **Primary antioxidants**: Antioxidants inhibit oxidative deterioration of a material. Primary antioxidants donate hydrogen atoms to prevent free radical creation. Examples of primary antioxidants include hindered phenol, such as butylated hydroxytoluene, and hindered amine light stabilizers;
- **Secondary antioxidants**: Secondary antioxidants prevent degradation by breaking down free radicals and hydroperoxides, and synergize with the primary antioxidants. Examples of secondary antioxidants include phosphites and thioesters;
- **Neutralizing agents**: Neutralizing agents adjust the acidity of the chemicals during production, and can include calcium and zinc stearate, zeolites, calcium and zinc oxides, and metallic salts of lactic or benzoic acid;
- **Antistatic agents**: Antistatic agents reduce the buildup of static electricity, and can include cationic compounds, anionic compounds, and nonionic compounds;
- **Slip agents**: Slip agents are added to a plastic surface’s coefficient of friction. Examples of slip agents include modified fatty acids or fatty amides;
- **Metal deactivators**: Transition metals like copper and iron can accelerate plastic degradation. Metal deactivators, such as N,N'-dibenzaloxaldihydrazide, combine with the metal ions and prevent catalytic degradation of the plastic;
- **Quenchers**: Quenchers scavenge stray free radicals and decompose unwanted peroxides. Examples of quenchers are organic nickel complexes, nickel salts of thio carbonate, and nickel complexes with alkylated phenol phosphonates;
- **UV stabilizers**: Ultraviolet (UV) stabilizers are added to PP to protect the plastic from degradation in sunlight. Examples of UV stabilizers are hindered amine light stabilizers, carbon black, titanium dioxide, zinc oxide, derivatives of benzophenone, benzotriazoles, phenoxy, or acrylic esters, formamidines, and oxanilides;

#### Nucleating agents:
Nucleating agents are additives that increase the crystallization of a plastic from a liquid solution. Examples of nucleating agents for PP include carboxylic acids, benzyl sorbitols, and salts of organic phosphates;

- **Flame retardants**: Examples of flame retardants include brominated flame retardants, cycloaliphatic chlorines; antimony trioxide, ferric oxide, zinc oxide, zinc borate, barium metaphosphates; phosphorus flame retardants, magnesium hydride, and aluminum hydride;

- **Blowing or foaming agents**: Blowing and foaming agents create gas bubbles during molding, resulting in a foamed plastic. Examples of blowing and foaming agents include sodium bicarbonate, sodium borohydride, polycarboxic acid, citric acid, 4,4'-oxybis(benzensulfonyl hydrazide), azodicarbonamide, or para-toluenesulfonyl semicarbazide;

- **Antiblocking agents**: Antiblocking agents are used to prevent plastic films from sticking together through cold flow or static electricity. Examples of antiblocking agents include natural and manufactured waxes, metallic salts of fatty acids, silica compounds, and some polymers (e.g., polyvinyl alcohol, polyamides, polyethylene, polysiloxanes, and fluoroplastics);

- **Lubricants**: Lubricants are used in PP (and other plastics) to lower the molten plastic’s coefficient of viscosity and prevent the plastic from sticking to metal surfaces. The lubricants allow the plastic’s hydrocarbon chains to slip past each other in the melt. Examples of lubricants include metal soaps, hydrocarbon waxes, polyethenes, amide waxes, fatty acids, and fatty alcohols, (e.g., calcium or zinc stearates); or

- **Colorants**: Colorants for plastics typically consist of dyes, in which the color-producing material is dissolved in a carrier medium, and pigments, in which very small particles of the color-producing material are suspended in the carrier medium. Examples of colorants used in PP include heavy metal-based oxides, sulfides, chromates, and other complexes, including cadmium, zinc, titanium, lead, molybdenum; and ultramines (sulfide-silicate complexes containing sodium and aluminum; azo pigments).

The research showed that among all of these raw materials and additives, only Ziegler-Natta catalysts may contain one or more of the prohibited phthalates. Ziegler-Natta catalysts are generally titanium-based catalyst systems in combination with an organoaluminum co-catalyst, and an internal donor (a molecule that contributes an electron to the chemical reaction), such as DBP, DIBP or DEHP.

As described in the Task 12 Report, these catalysts may survive the plastic’s polymerization process, and the phthalates may be present in the final plastic pellets, theoretically at concentrations of about 1 mg/kg (0.15 ppm), and are often below the measurement threshold of the analytical method of 0.01 mg/kg (0.01 ppm).

#### Blowing or foaming agents:

**Notes:**

^5^The Merriam-Webster online dictionary defines a “catalyst” as “a substance that causes or accelerates a chemical reaction without itself being affected.” A catalyst is not consumed, altered, or incorporated into one of the reaction’s products.

^6^A Ziegler–Natta catalyst, named after Karl Ziegler and Giulio Natta, is a class of catalyst used in the production of some plastics.

^7^The Task 12 Report indicated that several prohibited phthalates are used as plasticizers in PE. CPSC staff reviewed the report’s references for this information. As cited in the Task 12 Report, Bhunia et al. (2013) reported several phthalates used in food packaging plastic film, including PE, referencing Sablani and Rahman (2007). In the latter reference, staff did not find any support for the claimed uses of phthalates. In fact, in the section on plasticizers, Sablani and Rahman (2007) stated that most plasticizers are used in PVC and that as a result of studies on migration of plasticizers from food packaging, “. . . industry has replaced PVC with other polymers, such as PE or regenerated cellulose not associated with plasticizers.” (emphasis added)
• Flame retardants: PE flame retardants include antimony trioxide, and halogenated substances; • Anti-blocking agents: Fine silicas are an example of a PE antiblocking agent; • Slip agents: PE slip agents include fatty acid amides such as oleamide and erucamide; • Blowing agents: PE blowing agents include 4,4′-oxybisbenzenesulphonohydrazine and azocarbonamide; • Cross-linking agents: Cross-linking agents set up chemical bonds between the plastic macromolecules and assists in “curing” the plastic. Examples of cross-linking agents include dicumyl peroxide, and vinyl silanes; • Antioxidants: PE antioxidants include 4-methyl-2,6-t-butyl phenol, 1,1,3-tris-(4-hydroxy-2-methyl-5-butylphenyl)butane, bis-[2-hydroxy-5-methyl-3-(1-methylcyclohexyl)phenyl]methane, and dilauryl-β,β′-thiodipropionate; • Carbon black; or • Colorants: PE colorants are often based on cobalt, cadmium, and manganese.

As with PP, PE catalysts include an internal donor, such as DBP, DIBP, or DEHP, although the phthalate concentration in the final plastic is generally well below 0.15 mg/kg (0.15 ppm).

One reference in the Task 12 report indicated that DOP can be used as a plasticizer in PE. Staff reviewed the cited references, as well as citations within the references, and found that uses of DOP in PE are mentioned in patents for specialized materials with no known current consumer product application, or may be used in materials, such as pavement marking, which are not children’s products. One cited patent described use of phthalates in a PE microporous film used as an internal separator for lithium ion batteries.

The Task 12 Report cited a patent for a material made with PE plastic and DBP for use as a surface for outdoor athletic track, basketball, volleyball, and playgrounds. CPSC staff found no information indicating that such a product has been manufactured and marketed for consumer use. Furthermore, the applications for the material do not include children’s toys or child care articles that are subject to the phthalate content restrictions.

3. High-Impact Polystyrene (HIPS)

TERA’s research indicated that HIPS is a plastic blend generally produced from styrene, polybutadiene rubber, benzene, and a number of other substances. Additives can be included in HIPS to achieve various chemical and mechanical characteristics. HIPS can include the following additives:

- Catalysts: The Ziegler-Natta catalysts;
- Internal lubricant: Zinc stearate is a lubricant for HIPS;
- Chain transfer/transition agent: Chain transfer/transition agents regulate the length of the HIPS macromolecules. HIPS chain transfer/transition agents include terdodecylmercaptan and liquid paraffin;
- Stabilizer: tert-butylcatechol is a stabilizer for HIPS;
- Diluents: Diluents are used to reduce the concentration of a plastic as a means to reduce the plastic’s viscosity and to modify its processing conditions. Examples of HIPS diluents include ethylbenzene, and toluene; or • Colorants: HIPS colorants include azo dyes, anthraquinone dyes, perinone dyes, dioxazine, and xanthene dyes.
- Other additives: Additional materials used in the manufacture of HIPS include:
  - Aluminum chloride, ethyl chloride, hydrochloric acid;
  - Iron oxide, potassium oxide, chromium oxide; and
  - Biphenol peroxides.

As with PP and PE, the polybutadiene used in HIPS production is made with the use of catalysts that include an internal donor, such as DBP, DIBP, or DEHP. Although no testing for phthalate content was located, because the use of phthalate in HIPS is as a catalyst, the concentration in the final product is expected to be well below 0.1 percent.

4. Acrylonitrile Butadiene Styrene (ABS)

TERA’s research indicated that ABS plastic is manufactured with specific monomers, such as acrylonitrile, butadiene, and styrene, trans-1,4-butadiene, cis-1,4-butadiene, and 1,2-butadiene. Additives are included in ABS to achieve various chemical and mechanical characteristics. ABS can include the following additives:

- Plasticizers: ABS plasticizers include hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, long chain fatty acid esters, and aromatic sulfonamide;
- Hydrocarbon solvents: hexane, heptane, and ethyl benzene;
- Stabilizers against heat or light degradation: Stabilizer examples include phenolic antioxidants, thiol-containing antioxidants, phosphites, thioesters, substituted benzophenones and benzotriazoles, and hindered amines;
- Lubricants: ABS lubricants include metallic steareas, montan waxes or amide waxes;
- Antioxidants: Phenolic-based or phosphate-based antioxidants are used in the manufacture of ABS;
- Molecular weight regulator: An example of an ABS molecular-weight regulator is tert-dodecyl mercaptan;
- Initiators/catalysts: ABS initiators and catalysts include potassium persulfate, sodium persulfate, oil-soluble initiators in a redox system (cumene hydroperoxide, sodium pyrophosphate, dextrose, and iron (II) sulfate);
- Activators: Activators prepare the ABS surface for electroplating. The activators in ABS are often palladium and tin salts in an acid solution; • Emulsifiers: Emulsifiers are chemicals that promote the mixing of hydrophilic and hydrophobic materials. ABS emulsifiers include salts of rosin, fatty sodium, lauryl sulfate, and oleate;
- Colorants: ABS colorants include phthalocyanines, perylenes, cromophitals, titanium dioxide, carbon black, black iron oxide, ultramarine blue, red iron oxide, and aluminum flake.

5. Additional CPSC Staff Research

TERA’s research did not include an examination of the colorants in polyethylene, high-impact polystyrene, or acrylonitrile butadiene styrene. TERA’s research also did not include an examination of the lubricants, activators, and antioxidants that could be used in the production of ABS. CPSC staff conducted additional research into these component parts of the plastics.

6. Potential Phthalate Use in the Four Plastics

The Task 11 Report indicates that phthalates are used generally as plasticizers or softeners of certain plastics, primarily polyvinyl chloride (PVC), as solvents, and as components of inks, paints, adhesives, and sealants. Except for the general category of inks and colorants, the Task 11 Report did not indicate uses of the prohibited phthalates in any of the four plastics, in the raw materials, or in the types of additives that might be used in the four plastics. The four plastics may also be used as ingredients in a variety of materials. For
example, PP may be used in formulations for concrete, paints, and lubricating grease. These materials would not be considered to be PP plastic. PE, HIPS, ABS also may be used as additives in materials that would not be considered plastics.

The TERA Task 11 and Task 12 Reports indicate that the phthalates researched are not associated with the chemistry and applications of the plastics PP, PE, HIPS, or ABS. When these plastics are plasticized, materials other than the phthalates are used as plasticizers (e.g., hydrocarbon processing oil, phosphate esters, long chain fatty acid esters, and aromatic sulfonamide for ABS). TERA found one reference in which DnOP (also referred to as DOP) was used as a plasticizer for PE. However, the only application cited was a patent for a microporous plastic film used in the production of lithium-ion batteries. TERA’s research included references prior to and after the enactment of the CPSIA, none of which indicated any phthalate use in the four plastics.

7. Studies Where Phthalates Were Detected

TERA’s investigation of the uses of the four plastics shows that all four are used to make plastic consumer products and component parts. None of these applications specifically includes phthalates, although a few studies of the phthalate content of products were located.

Several studies evaluated food, beverage, and cosmetics packaging made with PP, PE, and polystyrene (PS). These studies generally measured migration of specified chemicals, including phthalates, from products purchased in retail stores. The references provided few or no details about all the materials used in the products, including whether other plastics were present, whether other component parts were present such as coatings, finishes, inks, or adhesives, or whether residues of the contained products were present.

The Task 12 Report also cited a Korean study of various products that reported low levels of phthalates in a toy car made with ABS. The study provided no details about other materials used in the product, including whether other plastics were present, or whether other component parts were present such as coatings, finishes, inks, or adhesives.

The Task 12 Report’s detailed description of the raw materials and manufacturing processes for PP, PE, HIPS, and ABS plastics showed that phthalates are not present after these plastics are produced. However, the Task 13 Report describes uses of phthalates in materials on these plastics, such as coatings, inks, and adhesives. Because consumer products purchased in stores likely consist of a number of different component parts, some of which may have contained phthalates, the studies described above should not be considered to be evidence that phthalates were used in the manufacture of the PP, PE, HIPS, or ABS plastic component parts of consumer products subject to the phthalate content restrictions.

8. Phthalates in Recycled Materials

All four plastics may be recycled and reprocessed into new products. However, degradation of the original plastics during the recycling process and mixing with other plastics or materials in the recycling stream can reduce the quality of the recovered plastic and limit further commercial uses. In some cases, recovered plastics are mixed with virgin plastics to improve the products’ quality and utility. The Task 12 Report indicated that few studies were located for analysis of phthalates in recycled plastics. One study found no phthalates in recycled PP carpet. Two studies analyzed solid waste consisting of PP or PE. One study reported detection of phthalates in recovered waste PP and PE material, but not in samples of virgin PP or PE plastic. The other study reported phthalates in recovered PE. The authors of the latter study suggested that the source of phthalates could have been the products that had been in contact with the plastic.

HIPS and ABS are generally used as rigid materials; available information does not indicate use of phthalates in such materials or associated with recycled HIPS or ABS.

Some studies indicated the potential for low, but detectable, levels of phthalates in plastics, such as PP or PE packaging that contained or had been in contact with a phthalate-containing product. Products made with such materials could contain residual phthalates, although at levels well below the maximum allowed concentration in children’s products. 12

9. Staff Conclusions Based on TERA Research

With the exception of the catalysts for polymerization, and certain, specific uses of phthalates in products without consumer product applications, neither of the TERA task reports, nor research by CPSC staff found that phthalates are used as a component part of the four plastics. In the case of the phthalate catalysts used in plastics manufacturing, the phthalate concentration in finished plastics is significantly below the maximum allowable concentration.

The two TERA task reports and CPSC staff research show that very little information exists that indicates that manufactured PP, PE, HIPS, and ABS plastics could contain the researched phthalates. The research located references, including patents, for uncommon and specialized products, and products that generally do not have applications to children’s toys and child care articles.

Staff found no evidence that phthalates are present at concentrations above 0.1 percent in any of the four plastics (either virgin or using recycled material) for consumer products, especially children’s products.

D. Determinations for Specified Plastics

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 CPSA, 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 CPSA 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 part 1107 section 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 or additive, a high degree of assurance of compliance means that the material will comply

12 The highest level recorded by Huber and Franz was 200 ppm for one sample of DBP. The other samples’ concentrations ranged from 3.1 to 96.3 ppm.
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.

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.13 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 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. As a means to reduce the third party testing burden on children’s product certifiers while continuing to ensure compliance, the CPSC is proposing to make determinations that 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.

Based on the discussion in section C of this preamble, the Commission proposes to determine that the specified four plastics and accompanying additives would comply with the phthalates prohibitions with a high degree of assurance. These determinations mean that third party testing for compliance with the phthalates is not required for certification purposes for the specified four plastics. The Commission proposes to make 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, Aug. 14, 2008. As noted previously, section 14 of the CPSA, which was 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 proposed determinations would relieve the four specified plastics and accompanying additives from the third party testing requirement of section 14 of the CPSA for purposes of supporting the required certification. However, the proposed determinations would not be applicable to any other plastic or additives beyond those listed in the proposed rule.

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.

3. Description of the Proposed Rule

This proposed rule would create a new Part 1308 for “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics.” The proposed rule would determine that the specified four plastics and accompanying additives do not contain the statutorily prohibited phthalates (DEHP, DBP, BBP, DNP, 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. As discussed in section A.2 of the preamble, the agency is currently 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. TERA’s examination covered all phthalates that are subject to the current permanent and interim prohibitions, as well as the additional phthalates the Commission proposed restricting in the phthalates proposed rule. If the Commission issues a final rule in the phthalates rulemaking before finalizing this determinations rulemaking, the Commission would modify the determinations proposed rule so that the determinations rule covers the same phthalates restricted by the final phthalates rule.

Section 1308.1 of the proposed 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.

Section 1308.2(a) of the proposed rule would establish the Commission’s determinations that 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:

- Polypropylene, with any of the following additives:
  - the plasticizers polyybutenes, dioctyl sebacate, paraffinic oil, isooyctallate, minearr plasticizing oils, and polyols;
  - hydrocarbon solvents;
  - catalysts;
  - fillers;
  - nucleating agents;
  - primary and secondary antioxidants;
  - neutralizing agents;
  - antistatic agents;
  - slip agents;
  - metal deactivators;
  - quenchers;
  - UV stabilizers;
  - flame retardants;
  - blowing or foaming agents;
  - antiblocking agents;
  - lubricants; or
  - colorants.

- Polyethylene, with any of the following additives:
  - the plasticizers glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerol, EPDM rubber, and EVA polymer.

- Polyvinyl chloride, with any of the following additives:
  - the plasticizers polyvinyl acetate, dioctyl phthalate, paraffinic oil, tallate, mineral plasticizing oils, and polyols;
  - hydrocarbon solvents;
  - catalysts;
  - fillers;
  - nucleating agents;
  - primary and secondary antioxidants;
  - neutralizing agents;
  - antistatic agents;
  - slip agents;
  - metal deactivators;
  - quenchers;
  - UV stabilizers;
  - flame retardants;
  - blowing or foaming agents;
  - antiblocking agents;
  - lubricants; or
  - colorants.

- Polyvinyl acetate, with any of the following additives:
  - the plasticizers polyvinyl acetate, dioctyl phthalate, paraffinic oil, tallate, mineral plasticizing oils, and polyols;
  - hydrocarbon solvents;
  - catalysts;
  - fillers;
  - nucleating agents;
  - primary and secondary antioxidants;
  - neutralizing agents;
  - antistatic agents;
  - slip agents;
  - metal deactivators;
  - quenchers;
  - UV stabilizers;
  - flame retardants;
  - blowing or foaming agents;
  - antiblocking agents;
  - lubricants; or
The Commission is proposing this NPR to reduce the burden of third party testing on toy and child care article manufacturers, especially the burden on those that are small entities. 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, the Commission concludes that there is a high degree of assurance that polypropylene, polyethylene, high impact polystyrene, and acrylonitrile butadiene styrene with the accompanying additives in the proposed rule will not contain any of the prohibited phthalates in concentrations above 0.1 percent when used in children’s toys and child care articles. Therefore, third party testing is not necessary to assure that children’s toys and child care articles with accessible component parts made from these plastics and accompanying additives do not contain the prohibited phthalates.

3. Small Entities To Which the Proposed Rule Would Apply

The proposed rule would apply to small entities that manufacture or import children’s toys or child care articles that contain accessible polyethylene, polypropylene, high impact polystyrene, or acrylonitrile butadiene styrene with the accompanying additives in component parts. Toy manufacturers are classified in North American Industry Classification System (NAICS) category 33993 (“Doll, Toy, and Game Manufacturing”). According to the U.S. Bureau of the Census, in 2012 there were 559 toy manufacturers in the United States, of which 552 had fewer than 500 employees and would be considered small entities according to the Small Business Administration (SBA) criteria. Of the small

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14 2012 County Business Patterns.
manufacturers, 326 had fewer than five employees.

Toy importers may be either wholesale merchants or retailers. The proposed rule would not apply to toy wholesalers or retailers if they obtain their merchandise from domestic manufacturers or importers. Toy wholesalers are classified in NAICS category 42392 (“Toy and Hobby Goods and Supplies Merchant Wholesalers”). According to the U.S. Bureau of the Census, there were 2,096 firms in this category. Of these, 2,021 had fewer than 500 employees and would be considered small businesses according to SBA criteria. Toy retailers are classified in NAICS category 45112 (“Hobby, Toy, and Game Stores”). There could be about 5,800 toy retailers that would meet the SBA criteria to be considered a small entity. The number of these small toy retailers that import toys, as opposed to obtaining their product from domestic sources is not known.

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.14 These products 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 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 teethers (if they are not medical devices), pacifiers, and bottle nipples. Manufacturers of these products are classified in NAICS category 326299 (“All other rubber product manufacturing”). There are 617

firms classified in this NAICS code of which 573 are considered to be small.15 However, this NAICS category includes many other products and most of these firms probably do not manufacture child care articles.

Although, as discussed above, 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, high impact polystyrene, or acrylonitrile butadiene styrene and analyze the parts is not known. Also not known is the number of children’s toys and child care articles that contain these plastics. To develop comprehensive estimates of the number of products that contain these plastics and the number of firms that supply the products it would probably be necessary to survey a representative sample of toy and child care article suppliers to solicit information on their use of the four plastics or to collect a representative sample of children’s toys and child care articles and accessible components to determine which ones contained one or more of the four plastics.

Although comprehensive estimates of the number of children’s toys and child care articles that contain components made from the four 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. Low density polyethylene and acrylonitrile butadiene styrene, are each used in less than 10 percent of the injection molded toys. Polystyrene may also be used in injection molded toys, but the source does not specify the proportion that is high impact polystyrene.16 The Commission requests comments to better determine the impact the proposed determinations would have on small entities.

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

The proposed rule would determine that there is a high degree of assurance that four specific plastics with any of the accompanying additives will not contain any prohibited phthalates at concentrations above 0.1 percent prohibition level. As a result of the proposed determinations, manufacturers, importers, and private labelers of children’s toys and child care articles that have accessible components that consist of these plastics and any accompanying additives will not have to obtain third party tests to certify that the accessible components do not contain the prohibited phthalates in concentrations above 0.1 percent.

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

A determination that specified plastics with accompanying additives used in children’s toys and child care articles do not require third party testing is expected to be entirely beneficial to manufacturers and importers using those plastics in accessible component parts because manufacturers and importers could forego testing they otherwise would be required to conduct. However, staff believes the magnitude of that benefit is uncertain and could depend on factors such as:

- The extent to which manufacturers have already reduced their testing costs by using component part testing (as allowed in 16 CFR part 1109);
- the volume of children’s toys and child care articles that contain PE, PP, HIPS, or ABS;
- whether importers who certify children’s products are unsure what plastics are being used in the toys and child care articles they import, so they could not take advantage of the determinations without additional testing to assure that a component part is composed of one of the four plastics.

The Commission welcomes comments on the potential impact of the proposed rule on small entities. Comments are especially welcome on the following topics:

- The extent to which PP, PP, HIPS, or ABS are used in children’s toys and child care articles, especially those manufactured or imported by small firms;
- The potential reduction in third party testing costs that might be provided by the Commission making the determinations, including the extent to which component part testing is already being used.
Any situations or conditions in the proposed rule that would make it difficult to make use of the determinations to reduce third party testing costs; and

Although the Commission expects that the impact of the proposed rule will be entirely beneficial, any potential negative impacts of the proposed rule.

5. Other Federal Rules

We have not identified any Federal rules that duplicate or conflict with the proposed rule.

6. Alternatives Considered To Reduce the Burden on Small Entities

Under section 603(c) of the RFA, an initial regulatory flexibility analysis should “contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities.” Because the proposed rule is intended to reduce the cost of third party testing on small businesses and will not impose any additional burden, the Commission did not consider alternatives to the proposed rule that would reduce the burden of this rule on small businesses.

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.

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

1308.2 Determinations for specified plastics.


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

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

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

(ii) Initiators;

(iii) Promoters;

(iv) 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.

(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 are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Dated: August 11, 2016.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

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