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BILLING CODE 4910-13-P

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Parts 1112 and 1234

[Docket No. CPSC-2015-0019]

#### Safety Standard for Infant Bath Tubs

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is issuing a safety standard for infant bath tubs in response to the direction of section 104(b) of the CPSIA. In addition, the Commission is amending its regulations regarding third party conformity assessment bodies to include the mandatory standard for infant bath tubs in the list of notices of requirements (NORs) issued by the Commission.

**DATES:** This rule will become effective October 2, 2017. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of October 2, 2017.

**FOR FURTHER INFORMATION CONTACT:** Keysha Walker, Compliance Officer, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-6820; email: [kwalker@cpsc.gov](mailto:kwalker@cpsc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Statutory Authority

The CPSIA was enacted on August 14, 2008. Section 104(b) of the CPSIA, part

of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) Examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. Standards issued under section 104 are to be “substantially the same as” the applicable voluntary standard or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” Section 104(f)(2) of the CPSIA lists examples of durable infant or toddler products, including products such as “bath seats” and “infant carriers.” Although section 104(f)(2) does not specifically identify infant bath tubs, the Commission has defined an infant bath tub as a “durable infant or toddler product” in the Commission’s product registration card rule under CPSIA section 104(d).<sup>1</sup>

On August 14, 2015, the Commission issued a notice of proposed rulemaking (NPR) for infant bath tubs. 80 FR 48769. The NPR proposed to incorporate by reference the voluntary standard, ASTM F2670-13, *Standard Consumer Safety Specification for Infant Bath Tubs*, with several modifications to strengthen the standard, as a mandatory consumer product safety rule. In this document, the Commission is issuing a mandatory consumer product safety standard for infant bath tubs. As required by section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this proposed

standard, largely through the ASTM process. Based on modifications to the voluntary standard since the NPR published, the final rule incorporates by reference the most recent voluntary standard, developed by ASTM International, ASTM F2670-17, without modification.

Additionally, the final rule amends the list of NORs issued by the Commission in 16 CFR part 1112 to include the standard for infant bath tubs. Under section 14 of the CPSA, the Commission promulgated 16 CFR part 1112 to establish requirements for accreditation of third party conformity assessment bodies (or testing laboratories) to test for conformity with a children’s product safety rule. Amending part 1112 adds an NOR for the infant bath tub standard to the list of children’s product safety rules.

## II. Product Description

### A. Definition of Infant Bath Tub

Paragraph 3.1.2 of ASTM F2670-17 defines an “infant bath tub” as a “tub, enclosure, or other similar product intended to hold water and be placed into an adult bath tub, sink, or on top of other surfaces to provide support or containment, or both, for an infant in a reclining, sitting, or standing position during bathing by a caregiver.” Paragraph 1.1 of the voluntary standard specifically excludes “products commonly known as bath slings, typically made of fabric or mesh” from the scope of the standard.

Infant bath tubs within the scope of the final rule include products of various designs, such as “bucket style” tubs that support a child sitting upright, tubs with an inclined seat for infants too young to sit unsupported, inflatable tubs, folding tubs, and tubs with spa features, such as handheld shower attachments and even whirlpool settings. Paragraph 6.1 of ASTM F2670-17 permits infant bath tubs to have “a permanent or removable passive crotch restraint as part of their design,” but does not permit “any additional restraint system(s) which requires action on the part of the caregiver to secure or release.”

### B. Market Description

Typically, infant bath tubs are produced and/or marketed by juvenile

<sup>1</sup> Requirements for Consumer Registration of Durable Infant or Toddler Products; Final Rule, 74 FR 68668, 68669 (Dec. 29, 2009); 16 CFR 1130.2(a)(16).

product manufacturers and distributors. Currently, at least 25 manufacturers and importers supply infant bath tubs to the U.S. market, including 22 domestic firms: 14 are domestic manufacturers, seven are domestic importers, and one firm has an unknown supply source. Three foreign companies export directly to the United States via Internet sales or to U.S. retailers.<sup>2</sup>

According to preliminary data collected with the CPSC's 2013 Durable Products Nursery Exposure Survey, households with children under 6 years old own approximately 8.9 million infant bath tubs. Of those, approximately 4.4 million are currently in use.

### III. Incident Data

#### A. Overview of Incident Data

The Commission is aware of a total of 247 incidents (31 fatal and 216 nonfatal) related to infant bath tubs that were reported to have occurred from January 2004 through December 2015. This total includes 45 new infant bath tub-related incidents reported since the NPR<sup>3</sup> (collected between May 20, 2015 and December 31, 2015). None of the newly reported incidents is a fatality. All of the new incidents fall within the hazard patterns identified in the NPR. Just over half (146 out of 247 or 59 percent) of the reports were submitted to the CPSC by retailers and manufacturers through the CPSC's "Retailer Reporting System." The remaining 101 incident reports were submitted to the CPSC from various sources, such as the CPSC Hotline, Internet reports, newspaper clippings, medical examiners, and other state/local authorities.

More recently, staff also reviewed the incident data for 2016 and identified an additional 34 incidents with no fatalities. Staff did not identify any new hazard patterns in the 2016 data. The

<sup>2</sup> Staff made these determinations using information from Dun & Bradstreet and Reference USA Gov, as well as firm Web sites.

<sup>3</sup> Data discussed in the NPR was collected from January 1, 2004 through May 20, 2015.

more detailed discussion of incident data that follows does not include year 2016 incidents.

#### 1. Fatalities

Of the 31 decedents in the fatal incidents, 29 of the victims were between the ages of 4 months and 11 months old; the other two fatalities were a 23-month-old and a 3-year-old. The fatalities were evenly split with 16 males and 15 females. In 30 of the 31 fatalities, a parent or guardian was not present at the time the incident occurred. Drowning was the cause of death reported for 30 of the 31 fatalities. The remaining fatality involved a child with ventricular septal defect, and the coroner listed that the immediate cause of death was attributed to pneumonia.

#### 2. Nonfatal Incidents

Thirty-two injuries were reported among the 216 nonfatal incidents. Eight of nine hospitalizations were due to near-drowning, and one was due to a scalding water burn. In all eight near-drowning hospitalizations, the parent or guardian had left the child alone for at least a short period of time when the incident occurred. Five additional near-drowning incidents required emergency department treatment. The remaining incidents ranged from rashes, upper respiratory infections due to mold on the product, slip and fall injury, laceration by sharp edge, a hit on head by toy accessory, and a concussion from falling from a tub.

#### 3. National Injury Estimates<sup>4</sup>

Commission staff estimates a total of 2,300 injuries (sample size = 89, coefficient of variation = 0.18) related to

<sup>4</sup> The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system. NEISS injury data is gathered from emergency departments of hospitals that are selected as a probability sample of all the U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

infant bath tubs occurred from 2004 to 2015, which were treated in U.S. hospital emergency departments.<sup>5</sup> The injury estimates for individual years are not reportable because they fail to meet publication criteria.<sup>6</sup>

One drowning death was reported through the NEISS and is included in the fatality counts for infant bath tubs. About 94 percent of the estimated emergency department visits during the 11-year period involved infants 12 months of age or younger, and all but three cases involved children 24 months of age or younger. The cases involving children older than 2 years of age included: A 5-year-old who received a laceration while playing with the infant bath tub, a 3-year-old falling off an infant tub, and a 6-year-old landing in a straddle position on an infant tub while getting out of a bathtub.

The estimated emergency department visits were split almost evenly among male (48%) and female (52%) children. For the emergency department-treated injuries related to infant bath tubs, the following characteristics occurred most frequently:

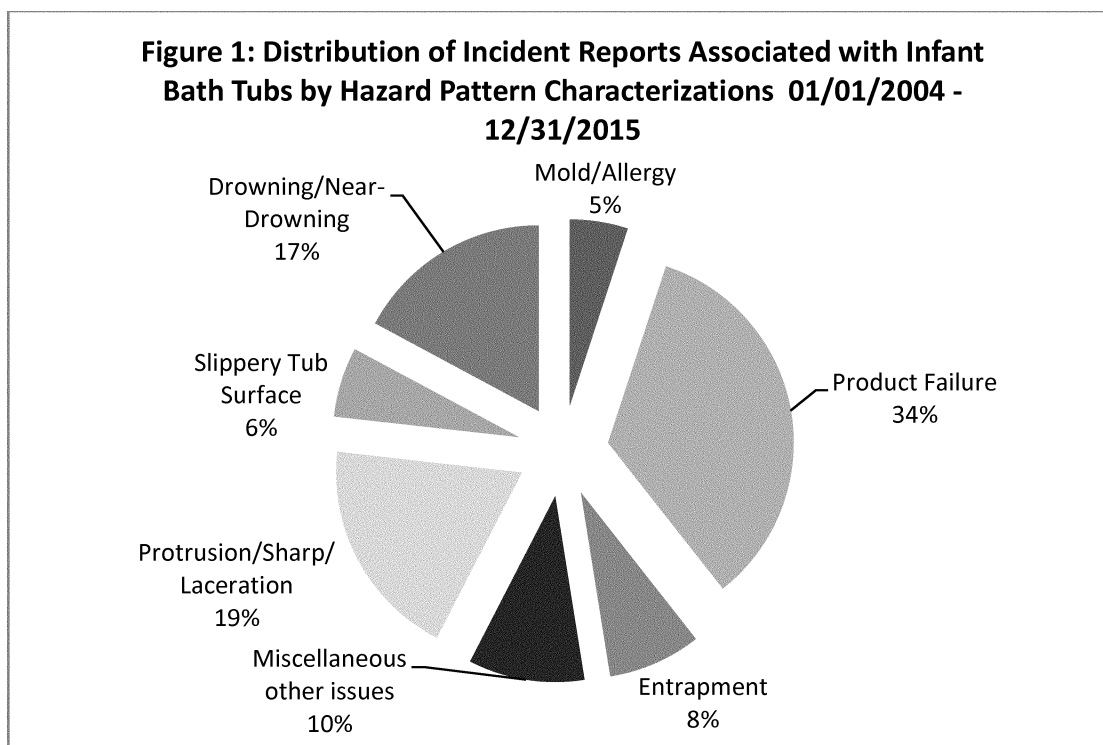
- Hazard—falls (35%); a majority of the reports did not specify the manner or cause of fall;
- Injured body part—head (37%), all/over half of body (20%), and face (18%);
- Injury type—internal organ injury (included closed head injuries) (29%), drowning or nearly drowning (20%), and contusions/abrasions (18%);
- Disposition—treated and released (83%) and admitted or transferred to a hospital (14%).

#### B. Hazard Pattern Characterization Based on Incident Data

Figure 1 shows the distribution of hazard patterns for infant bath tubs by frequency.

<sup>5</sup> National injury estimates for 2004–2014 were presented in the NPR.

<sup>6</sup> According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.



Source: CPSC epidemiological databases IPH, INDP, DTHS, and NEISS completed investigations (NEISS IDIs). Note, percentages may not add up to 100% due to rounding.

- *Drowning/Near-Drownings* account for 17 percent (43 of 247) of reported incidents. Of the 43 drowning or near-drowning incidents, 30 were fatalities and 13 were near-drowning incidents. Because no one witnessed most of the incidents, Commission staff cannot determine a pattern that led to the submersions. However, in 38 of 43 incidents, the parent or guardian was not present at the time the incident occurred. Frequently, the child was found floating. In the other five incidents in which the parent or guardian was present, four of the children survived. Only one reported fatality was not ruled a drowning; this incident is included in the miscellaneous category.

- *Protrusion/Sharp/Laceration issues* account for 19 percent (48 of 247) of reported incidents. A protrusion is commonly a part of the product that sticks out or has a rough surface; and in the incidents reported, the child rubbed against the protruding part in some way, which caused red marks, cuts, or bruising. The injured body parts reportedly included toes, feet, bottom, genitalia, and back. In 29 of 39 incidents, the part of the infant bath tub described as a “bump” or “hump” caused a red mark on the infant’s back or discomfort to the infant in the bath tub. Typically, the bath tub “hammock/

sling” attachment was involved in this type of protrusion incident. One incident required a hospital visit, and the remaining 47 incidents involved no injury or a minor injury. The incident requiring a hospital visit involved a scratch to the child’s back, caused by a screw that penetrated the tub wall.

- *Product Failures* account for 34 percent (85 of 247) of reported incidents. Fifty-nine incidents reported the bath tub “hammock/sling” attachment collapsing, and eight additional incidents of the locking mechanism failing or breaking. The remaining 18 incidents involved various tub parts breaking. Of the 85 product failures, two incidents required a trip to the hospital, and the remaining incidents reported either no injury or a minor injury. The two children who required hospital trips were treated and released. One of these incidents was due to a toy breaking off from the tub and causing a deep cut to the victim’s forehead. The second incident was due to a leg collapsing on a tub placed on a counter top; as a result, the child fell from the counter top to the floor and suffered a concussion.

- *Entrapment issues* account for 8 percent (20 of 247) of reported incidents. Entrapment incidents involve body parts caught or stuck on parts of the tub, mostly in a pinching manner.

The body parts reportedly injured were fingers, arms, feet, legs, and genitalia. Many of these injuries occurred in tubs that fold. The most common components of the tubs causing injury were the hinges, holes, and foot area inside the tub. No reported incident required a hospital visit. All of the entrapment-related reports involved either no injury or a minor injury.

- *Slippery tub surface issues* account for 6 percent (15 out of 247) of reported incidents. Common reported incidents and concerns include scratches to the body or protrusions that contact the body, or potential submersions, including the head. One emergency room visit was due to a child slipping under water and swallowing some water; the rest of the reports involved either no injury or a minor injury.

- *Mold/Allergy issues* account for 5 percent (12 of 247) of reported incidents. Of the 12 incidents, eight were due to mold, and four were due to allergy. Reported issues included a variety of symptoms: Itching, rashes, foul odor, respiratory concerns, and a urinary tract infection. Eight incidents involved a single tub make and model, including six with mold issues and two with allergy issues. Two of the 12 incidents involved emergency room visits: One child may have developed an upper respiratory issue and one child

broke out in a rash throughout the child's back. Seven additional incidents required medical treatment: Four reported itching and rashes, one reported a urinary tract infection, and one reported mold spores on the genitalia.

- *Miscellaneous issues* account for the remaining 10 percent (24 of 247) of the reported incidents. The incidents included a fall from the tub, an unstable tub, missing pieces, leaking or overheating batteries, rust, and scalding. One incidental fatality and one hospital visit fall in this miscellaneous category. The fatality involved a child with a ventricular septal defect, with the death attributed to pneumonia. A scalding incident in which a parent poured hot water from the stove onto the foam cushion in the infant bath tub and then placed the child in the tub resulted in the hospital visit. The remaining reports were either an incident with no injury or a minor injury, including six battery-related complaints.

#### IV. Overview and Assessment of ASTM F2670

ASTM F2670, *Standard Consumer Safety Specification for Infant Bath Tubs*, is the voluntary standard that was developed to address the identified hazard patterns associated with the use of infant bath tubs. The standard was first approved by ASTM in 2009, and then revised in 2010, twice in 2011, 2012, 2013, twice in 2016, and the newest version was approved on January 1, 2017. The NPR referenced ASTM F2670–13, with the following modifications to the ASTM standard to adequately address hazard patterns identified in the incident data:

1. Revised latching or locking mechanism testing protocol.
2. Revised static load testing protocol.
3. Revised content of the warnings, markings, and instructions:
  - (a) Changed the text in the drowning warnings, and
  - (b) added fall hazard warning.
4. Specified a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product, on the packaging, and in the instructions.
5. Required that the safety alert symbol and the word "WARNING" on the drowning hazard label be "at least 0.4 in. (10mm) high unless stated otherwise, shall be the same size, and shall be in bold capital letters. The remainder of the text shall be in characters whose upper case shall be at least 0.2 in. (5 mm) high unless stated otherwise."

In the time since the NPR was published, ASTM approved and published three more versions of the voluntary standard. The most recent version, ASTM F2670–17, was approved and published on January 1, 2017. As explained below, ASTM F2670–17 addresses all of the Commission's proposed modifications and concerns described in the NPR, allowing the Commission to adopt ASTM F2670–17, without modification, as the mandatory safety standard for infant bath tubs.

##### A. Revised Latching or Locking Mechanism Requirements

The NPR proposed a modification to F2670–13 to allow more time for the latching or locking mechanism testing to accommodate more complicated mechanisms. Through the ASTM process, the wording and rationale for the latching or locking mechanism durability testing in paragraph 7.1.2 of F2670 evolved. The language is consistent with the language in the NPR and is now incorporated into ASTM F2670–17. For the final rule, the Commission is adopting the language in 7.1.2 of F2670–17, without modification.

##### B. Revised Static Load Requirements

The NPR proposed a modification to paragraph 7.4.2 of F2670–13 to change the static load test apparatus to a shot bag, which was recommended by the ASTM subcommittee, but not yet balloted through ASTM at the time of the NPR. ASTM has now balloted the revision, which is included in F2670–17. The revised language is consistent with the modifications in the NPR, and thus, the Commission adopts paragraph 7.4.2 of F2670–17 for the final rule, without modification.

##### C. Revised Content of the Warnings, Markings, and Instructions

The NPR proposed that the drowning and fall hazard warnings state:

*Drowning Hazard:* Babies have drowned while using infant bath tubs.

- Stay in *arm's reach* of your baby.
- Use in empty adult tub or sink.
- Keep drain open.

*Fall Hazard:* Babies have suffered head injuries falling from infant bath tubs.

- Place tub only [insert manufacturer's intended location(s) for safe use (e.g., in adult tub, sink or on floor; in adult tub or on floor)].

- Never *lift or carry* baby in tub.

Although ASTM F2670–13 contained warning statements for both drowning and fall hazards, the warning header only identified drowning as the hazard. The Commission proposed in the NPR

to separate the warnings to identify more clearly the drowning hazard and fall hazard and to provide guidance on how to avoid these hazards. Additionally, the NPR proposed warning language that was more personal by use of the word "baby." For example, the NPR used the word "babies" as opposed to "infant" and the phrase "stay in arm's reach of your baby" as opposed to "ALWAYS keep infant within adult's reach."

After the NPR, the warning content in the voluntary standard was revised to be consistent with the modifications in the NPR, except for one statement. ASTM F2670–17 contains a revision to the hazard statement "Keep drain open," clarifying that caregivers should keep the drain in an adult tub open during bathing, stating "Keep drain open in adult tub or sink." The Commission agrees that the added statement clarifies the direction to caregivers. Accordingly, the final rule adopts the revised warning content in ASTM F2670–17, without modification.

##### D. Warning Label Format

At the time of the NPR, F2670–13 did not require any specific formatting for warning statements. The NPR proposed specific changes to the format of warning statements consistent with ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*. CPSC staff regularly cites ANSI Z535.4 as a baseline in developing warning materials. Since the NPR was published, ASTM convened a task group, the ASTM Ad Hoc Wording Task Group (Ad Hoc TG), which consists of members of the various durable nursery product voluntary standards committees, including CPSC staff. The purpose of the Ad Hoc TG is to harmonize the wording, as well as warning format, across durable infant and toddler product ASTM voluntary standards. CPSC's Human Factors Division hazard communication subject matter expert, who also is the CPSC staff representative on the ANSI Z535 committee, represents CPSC staff on this task group. ASTM's Ad Hoc TG recommendations related to the format of warning statements were published as a reference document entitled, "Ad Hoc Wording—May 4, 2016," as part of the F15 Committee Documents. The approved Ad Hoc Wording guidance document recommends formatting requirements that are similar to the ANSI Z535.4 requirements, with modifications intended to make the Ad Hoc TG's recommendations more stringent.

After publication of the Ad Hoc Wording recommendation, the ASTM

committee for infant bath tubs balloted and approved incorporation of the Ad Hoc Wording guidance recommendations into ASTM F2670–17. Commission staff states that adopting the Ad Hoc Wording guidance document recommendations provides noticeable and consistent warning labels, including warning formatting, on infant bath tubs and across juvenile products. Therefore, for the final rule, the Commission adopts the warning formatting requirements incorporated into ASTM F2670–17, without modification.

#### E. Warning Label Font Size

The NPR proposed to increase the font size of the safety alert symbol, and the word “WARNING,” to be not less than 0.4 in. (10 mm) high and the remainder of the text with upper case characters not less than 0.2 in. (5 mm) high.<sup>7</sup> The Commission proposed this revision to align the font size for infant bath tub labeling with ASTM F1967, *Standard Consumer Safety Specifications for Infant Bath Seats*, which is already incorporated into a federal standard. Similar to bath tub incidents, bath seat incidents also include drownings associated with caregivers leaving children unattended. Currently, increased font size for warning statements is unique to the infant bath seats voluntary and mandatory standards. The Ad Hoc Wording guidance document does not include this modification. The Ad Hoc Wording guidance document recommends that the font size of the safety alert symbol, and the word “WARNING,” be not less than 0.2 in. (5 mm) high and the remainder of the text with upper case characters be not less than 0.1 in. (2.5 mm) high. ASTM F2670–17 follows the Ad Hoc Wording guidance document, and does not include the increased font size that the Commission proposed in the NPR.

The Commission recognizes that the Ad Hoc Wording guidance document improves the warning label format, and therefore, the effectiveness of the warning statements. ASTM F2670–17 contains all of the Ad Hoc Wording guidance document recommendations. As stated above, the specific formatting changes in the Ad Hoc Wording guidance follow the guidance of ANSI Z535.4, differing from what was proposed in the NPR only in terms of the specific size exception that had been proposed for the drowning warning

label. The warning label changes in F2670–17 bring the formatting and language of the warning label into close alignment with the NPR proposal, except for the size requirements. The Commission concludes that all of the formatting and wording revisions incorporated into ASTM F2670–17 improve the labeling over the labeling in F2670–13, referenced in the NPR. The Commission cannot state definitively that increasing the font size of this particular warning statement will influence caregiver behavior more than the totality of formatting changes already incorporated into ASTM F2670–17. However, in an August 10, 2016 letter to ASTM,<sup>8</sup> CPSC staff encouraged further exploration of the increased size of the warnings to determine whether these additional changes will provide even greater effect. Therefore, the final rule incorporates by reference ASTM F2670–17, without any modifications.

#### F. Infant Bath Slings

Updated incident data for the final rule demonstrates that 59 of the 85 “product failure” incidents involve the infant bath hammock or sling collapsing. No injuries or minor injuries resulted from the bath hammock/sling incidents. In October 2016, CPSC recalled the infant bath tub with a sling accessory that was involved in the majority of infant bath sling incidents.<sup>9</sup>

Currently, ASTM F2670–17 does not include provisions that will specifically address the incidents involving bath hammocks/slings. Staff advises that the ASTM subcommittee on bath tubs is working to evaluate this issue, but has not yet completed its work. CPSC staff continues to work with two ASTM task groups formed to address the risks of bath slings. One group is developing performance requirements for infant bath slings that only can be used with infant bath tubs. A second group is developing requirements for infant bath slings that are used separately or as tub accessories, which will be addressed under a new, separate standard. CPSC staff states that new requirements for bath hammocks/slings that can be used with an infant bath tub will be added to the voluntary standard in the near future, as the task group is preparing to present recommendations to the larger subcommittee during an April 2017 ASTM meeting, and anticipates balloting of the new provisions shortly after the meeting. Therefore, the Commission is proceeding with a final

rule on infant bath tubs and urges the ASTM subcommittee to finalize the inclusion of infant bath hammock/sling requirements to the ASTM standard.

If the voluntary standard for infant bath tubs is revised to include requirements for infant bath slings used with an infant bath tub and the Commission is notified of the revised standard by ASTM, CPSC staff will assess the revised voluntary standard. Staff will then make a recommendation to the Commission regarding whether to revise the mandatory standard for infant bath tubs to incorporate new provisions on infant bath slings, using the process for updating durable infant and toddler product rules pursuant to section 104 of the CPSIA. Similarly, if ASTM creates a new voluntary standard related to infant bath slings that are used separately or as tub accessories, CPSC staff will assess the ASTM standard and make a recommendation to the Commission whether to create a new mandatory durable infant and toddler standard under section 104 of the CPSIA for such products.

#### V. Response to Comments

The August 14, 2015 NPR solicited information and comments concerning all aspects of the NPR, and specifically asked about the cost of compliance with, and testing to, the proposed mandatory infant bath tub standard, the proposed 6-month effective date for the new mandatory rule and the amendment to part 1112. The Commission received 12 comments related to the NPR. Seven commenters expressed general support of the NPR, along with additional, more specific, comments. Five commenters either requested more time for the ASTM committee to consider the NPR proposals and revise the voluntary standard, as appropriate, or disagreed with some of the proposed requirements in the NPR. Comments and other supporting documentation, such as summaries of ASTM meetings, are available on: [www.Regulations.gov](http://www.Regulations.gov), by searching Docket No. CPSC–2015–0019.

We summarize the comments received on the NPR and CPSC’s responses below.

##### A. Test Requirements

(Comment 1) Two commenters recommended that the text of the static load test protocol match the ASTM F2670 standard language. The commenters noted that wording in the NPR was similar to what was balloted and approved by ASTM, but not exact.

(Response 1) At the time of the NPR, staff recommended using the exact wording that the ASTM subcommittee

<sup>7</sup> This requirement applies to a separate drowning hazard label and if the drowning and fall hazard labels are displayed together. If the fall hazard label is separate, smaller text size applies.

<sup>8</sup> <https://www.regulations.gov/document?D=CPSC-2015-0019-0023>.

<sup>9</sup> <https://www.cpsc.gov/Recalls/2017/Summer-Infant-Recalls-Infant-Bath-Tubs> (viewed on Web site 11/22/2016.)

was proposing. After the NPR, the ASTM subcommittee chairman made editorial changes to the proposal, which resulted in slight differences between the ASTM wording and the NPR wording. The Commission agrees that the static load test protocol language reflected in ASTM F2670–17 is nearly the same as the language proposed in the NPR, and will accept the ASTM F2670–17 language in the final rule, without modification.

*(Comment 2)* Two commenters recommended including the revised static load test protocol rationale (X1.2 Section 7.4.2) in the final rule.

*(Response 2)* Consistent with the response to comment 1, the Commission agrees that the rationale for the static load test protocol language reflected in ASTM F2670–17 be included in the final rule, without modification.

*(Comment 3)* Two commenters stated that the Latching or Locking Mechanism Durability test protocol in the NPR is identical to what has been balloted and approved for a revision to F2670. The commenters requested that the final rule accept this language.

*(Response 3)* The Commission agrees with the Latching or Locking Mechanism Durability test language in ASTM F2670–17 Section 7.1 and will incorporate this revision into the final rule, without modification.

*(Comment 4)* Two commenters recommended including the revised Latching or Locking Mechanism Durability test language rationale (X1.1 Section 7.1.2) in the final rule.

*(Response 4)* The Commission agrees. The final rule incorporates the rationale for the Latching or Locking Mechanism Durability test protocol language reflected in ASTM F2670–17.

*(Comment 5)* One commenter recommended that stands for bath tubs be included in the final rule. The commenter indicated that the current voluntary standard does not include stands, but stated a concern about an influx into the U.S. market of European-designed products that have matching stands.

*(Response 5)* The Commission is aware that infant bath tub stands are not covered by the current voluntary standard, ASTM F2670–17. CPSC staff advised that staff is not aware of any incident data involving bath tub stands. CPSC staff will monitor incident data and the retail market for use of these products. Currently, however, based on the lack of incident data, the Commission is not including bath tub stands in the final rule.

#### B. Incident Data

*(Comment 6)* One commenter questioned whether CPSC staff shared all of CPSC's incident data with ASTM. The NPR referenced 202 incidents related to infant bath tubs, while CPSC staff reported to ASTM an awareness of 156 incidents that occurred from 2004 to 2014. The commenter questioned whether CPSC had included "sling" data in its incident review for the NPR, noting that sling accessories are not included in the scope of the current ASTM standard.

*(Response 6)* CPSC staff included bath slings data in its incident review for the NPR and provided such data to ASTM. Inclusion of this data prompted ASTM to form two task groups to address incidents related to bath slings. One group is developing performance requirements for infant bath slings that only can be used with infant bath tubs. ASTM intends to include these requirements in ASTM F2670. A second group is developing requirements for infant bath slings that are used separately or as tub accessories, which will be addressed under a new, separate voluntary standard.

With regard to data discrepancies between CPSC and ASTM, such discrepancies may exist for several reasons. *First*, the scope of the data sets may be different. For example, the NPR data included incidents reported to CPSC involving infant bath tubs received from January 1, 2004, through May 20, 2015. The data delivered to ASTM for the fall 2014 meetings included data received by CPSC through July 24, 2014. CPSC provided an additional update to ASTM for the spring 2016 meeting.

*Second*, CPSC cannot share confidential data with ASTM. The CPSC rulemaking packages include *all* data received by staff; this includes data received through the Retailer Reporting Program (RRP). Tab A to the staff's briefing package for the final rule on infant bath tubs demonstrates that CPSC received a sizeable portion of the nonfatal incident data through RRP; the same was true for the NPR. Because RRP information is submitted confidentially, CPSC provides a general summary of RRP data for rulemaking packages, but cannot share incident details received through the RRP with ASTM, unless CPSC completes a follow-up in-depth investigation, or such reports were also received from other sources.

*Third*, the Infant Bath Tub subcommittee appears to maintain data in a manner that does not match identically to incident data supplied by CPSC staff nor to the incident data in

the NPR. Incident data maintained by the ASTM subcommittee is described by the commenter. CPSC staff provided 167 infant bath tub-related incidents to ASTM in fall 2014. Thirty incidents involved a fatality and 137 reports described a nonfatal incident. When the ASTM subcommittee prepared its data, 12 nonfatal incidents provided by CPSC staff were not included in the subcommittee's spreadsheet. CPSC document numbers for these 12 incidents (some have been investigated) are: H0430279A, I07B0418A, I1170518A, I1210049A, H1330201A, I1380526A, I1390145A, I13B0030A, I1430085A, I1430327A, I1450108A, 60318884. Of the 12 incidents, 11 involved slings, and one involved a faucet adapter, which was later determined to be out of scope for this product category.

*(Comment 7)* One commenter stated that incidents related to infant bath tubs have declined significantly over the years. The commenter stated that no urgency for a rule on infant bath tubs exists because of this decline.

*(Response 7)* CPSC is issuing the final rule for infant bath tubs to fulfill a congressional mandate under section 104 of the CPSIA to create mandatory standards for durable infant and toddler products. Moreover, NPR data consisted of incidents received by CPSC on or before May 20, 2015. Accordingly, any comparison of the number of incidents reported to CPSC that occurred in 2015 to any past years is inappropriate because the data from past years do not represent the full year of 2015 data. In the NPR, of the overall 31 fatalities, four deaths were reported in each of 2010 and 2011; two deaths were reported in 2012; and one each was reported in 2013 and 2014. In the most current infant bath tub Epidemiology memorandum, Tab A of the staff briefing package for a final rule on infant bath tubs, staff states that as of February 17, 2016, CPSC has not received any fatal incident reports for infant bath tubs. CPSC generally *does not expect* completed reporting of fatal incidents for a particular year for 2 to 3 years later, due to lag time of the many ways fatal incidents are reported to CPSC. For instance, CPSC does not expect all reported 2014 fatalities to be received by CPSC until around late 2016, or sometime in 2017. Because of the lag time in receiving incident data, CPSC does not publish or draw conclusions using the number of fatalities reported in the most recent years. It is possible, and would not be unexpected, for additional infant bath tub fatalities that occurred in 2014 or

2015, to be reported to CPSC in the future.

Recent data collection on infant bath tub incidents reported to CPSC on or before February 17, 2016 reflect an increase in the number of nonfatal incidents related to infant bath tubs for the years 2013 (26 reports), 2014 (31 reports), and 2015 (44 reports). CPSC also experiences a lag time between the date of a nonfatal incident and CPSC receiving the reports.

### C. Initial Regulatory Flexibility Act (IRFA)

(*Comment 8*) One commenter, a domestic manufacturer of inflatable infant bathtubs, stated that it would be adversely affected by defining “inflatable bathtubs” to be durable products falling within the scope of a mandatory rule. The commenter stated that the proposed rule would require the manufacturer to provide consumers with prepaid product registration cards and to provide an option for consumers to register products via the Internet. The commenter asserted that this would increase its costs by 1.5 to 2.0 percent on an ongoing basis.

(*Response 8*) The requirement that manufacturers of durable infant or toddler products provide each consumer with a product registration card was established by the Consumer Product Safety Improvement Act of 2008, and not by the this rule on infant bath tubs. In 16 CFR part 1130, the Commission determined that infant bath tubs are durable infant or toddler products. No exclusion was made for inflatable bath tubs. Therefore, the statutory and regulatory requirements concerning the provision of product registration cards to consumers already apply to manufacturers of inflatable infant bath tubs and will be unaffected by the final rule.

(*Comment 9*) One commenter stated: “in order to ensure that the lifespan of our inflatable tub would match that of the hard plastic tubs and folding tubs . . . , the thickness of the vinyl used would have to be increased to the point where the cost of manufacturing and subsequent retail price of the item would be more than the market would bear.” The commenter estimated that this would increase the cost of the product by 10 to 15 percent.

(*Response 9*) The commenter may misunderstand some of the requirements of the proposed rule and the voluntary standard. Although inflatable infant bath tubs are classified as durable infant or toddler products, ASTM F2670 does not require the products to have a minimum expected life. The standard contains requirements

that, among other things, are intended to ensure that the bath tub will not collapse or break during use and that any latching or locking mechanisms on the product are durable.

(*Comment 10*) One commenter stated that the cost of labelling is not as small as indicated in the NPR. Although the commenter agreed that the labelling costs are one-time costs, the commenter said it would take “multiple years to recoup the loss in margin.” The commenter did not provide an estimate of the labelling costs. The commenter stated that the commenter would likely “cease manufacturing inflatable infant bathtubs for sale in the U.S” if the standard is codified as it is currently written.

(*Response 10*) Although the commenter asserted that the labelling cost would be greater than indicated, the commenter did not provide any specific estimates of the expected labelling costs. Without more information, the Commission cannot provide a specific response to this comment.

### D. Performance and Labelling Requirements

(*Comment 11*) Two commenters requested that CPSC in the mandatory rule require a maximum water fill line on infant bath tubs. One commenter suggested that the “fill line demarcation be specified at depths of no greater than 2 inches.” The other commenter suggested the manufacturer be responsible for providing a maximum fill line that is in a “suitable position.”

(*Response 11*) A similar suggestion to require a water fill line was raised in the rulemaking for infant bath seats. For the same reason we gave in that rulemaking, the Commission will not include a water fill line in the infant bath tubs final rule. CPSC staff has voiced concern that a water fill line on infant bath tubs could imply a safe water level, even though staff is aware that children have drowned in very little water. Staff advises, and the Commission agrees, that the ASTM wording required in the user instruction, “Babies can drown in as little as 1 inch of water. Use as little water as possible to bathe your baby,” accurately describes the risk associated with any level of water. CPSC staff will continue to monitor this issue.

(*Comment 12*) A commenter indicated that icons for key safety messages were clearer to consumers, but the commenter did not specifically recommend that CPSC require use of icons and pictograms in the final rule for infant bath tubs.

(*Response 12*) The Commission acknowledges that icons and pictograms

can be used to convey a hazard more effectively, especially for consumers with limited or no English literacy. However, CPSC staff advises that the design of effective graphics can be difficult. For example, some seemingly obvious graphics are poorly understood and can give rise to consumer interpretations that are opposite of what the message of the graphic is intended to convey (deemed “critical confusions” in human factors literature). Use of icons and pictograms generally require a consumer study to ensure that the intended message is conveyed. However, if revised warning statements prove to be inadequate to address safety hazards associated with infant bath tubs, CPSC staff may recommend developing graphic symbols in the future to further reduce the risk of injury. Currently, however, the Commission is not mandating use of graphics for warning labels in the infant bath tubs final rule.

(*Comment 13*) A commenter stated: “any safety wording should be equally visible in Spanish as well as English.”

(*Response 13*) The NPR states that the warning label shall appear, at a minimum, in the English language. The Commission does not dismiss the usefulness of providing warnings in Spanish and other non-English languages, and recognizes that adding Spanish versions of the warnings most likely would improve warning readability among the U.S. population more than adding any other language. Nevertheless, the Commission’s incident data analyses for infant bath tubs have not revealed a pattern of incidents involving people who speak Spanish. Accordingly, the final rule does not require warnings to be in English and Spanish, but does not prohibit manufacturers from providing the required warnings in another language, in addition to English.

(*Comment 14*) Two commenters urged CPSC to monitor ASTM’s work on including infant bath sling accessories to the infant bath tub standard.

(*Response 14*) CPSC staff has been an active participant in the ASTM task group work regarding infant bath sling accessories sold with and used with infant bath tubs. Staff will continue this work. We encourage the infant bath sling task group to finalize recommended sling requirements so that the ASTM subcommittee can discuss this progress and vote for inclusion of bath sling requirements in the voluntary standard for infant bath tubs. Once this work is complete, CPSC staff will assess whether any revised voluntary standard adequately addresses incident data on bath slings

and make a recommendation to the Commission. The Commission will consider whether to incorporate such revisions into an amendment to the mandatory bath tubs standard through the revision process described in section 3 of Public Law 112–28.

(*Comment 15*) One commenter recommended that, based on the incident data, CPSC restrict the scope of the rule to cover only infant bath tubs for infants under 24 months of age.

(*Response 15*) The Commission is not including an age limit in the final rule for infant bath tubs. Section 104(f) of the CPSIA defines “durable infant or toddler products” as “durable products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” Although infant bath tubs are considered durable infant or toddler products, no age requirement or age cut-off for use of the product is included in the ASTM standard. Depending on the manufacturer’s design, infant bath tubs can accommodate users from newborns to preschoolers. Safety requirements included in the ASTM standard, and incorporated into the final rule for bath tubs, benefit infants and toddlers across all intended ages of foreseeable users.

(*Comment 16*) One commenter stated support for the “new wording as it is clearer,” and stated that the “new FALLING HAZARD is a good addition.” The commenter suggested adding an additional warning to “NOT USE ON RAISED SURFACES, SUCH AS TABLES OR WORKTOPS.”

(*Response 16*) One incident involved a skull fracture sustained when a bath tub fell from a kitchen counter. Based on the incident data, staff advises that the fall warnings included in ASTM F2670–17 adequately and succinctly convey the message of where the infant bath tub can be used safely based on the manufacturer’s intended use. Specifically, section 8.5.2.2 of the voluntary standard states:

Additional warning statements shall address the following:

- Place tub only [insert manufacturer’s intended location(s) for safe use (e.g., in adult tub, sink, or on floor)].
- Never lift or carry baby in tub.

Staff will continue to monitor incidents for use of bath tubs on elevated surfaces.

(*Comment 17*) One commenter stated: “the requirement in 16 CFR 1234.2(b)(6)(i)(C) previously proposed by CPSC was discussed by the task group; it was considered too nebulous, subjective and virtually unenforceable, and therefore was recommended to be deleted.”

(*Response 17*) Proposed 16 CFR 1234.2(b)(6)(i)(C) states: “9.3 In addition to the warnings, the instructional literature shall emphasize and reinforce the safe practices stated in the warnings.” The intent of the statement was to ensure that the instructional statements in section 9 of the voluntary standard remain consistent with the warning statements in section 8. Current wording in section 9 of ASTM F2670–17 meets this objective. Accordingly, for the final rule, the Commission adopts the wording in section 9 of ASTM F2670–17, without modification.

#### E. General and Legal

(*Comment 18*) Two commenters recommended delaying publication of the final rule until major warnings format and content revisions proposed in the NPR can be properly reviewed, balloted through the ASTM process, and then implemented into F2670.

(*Response 18*) Since the NPR was published, ASTM’s subcommittee for infant bath tubs reviewed, balloted, and published a new standard (F2670–17) with improved warning formatting and content revisions in alignment with the NPR, except for the font size of certain warning statements. For the final rule, the Commission incorporates by reference ASTM F2670–17, without modification.

(*Comment 19*) One commenter noted that the NPR contains several errors when referring to figures that show example warning labels. The Commenter stated:

- Figure 1 is missing from the NPR. The NPR starts with Figure 2;
- A reference to Figure 3 is missing in proposed section 1234.2(b)(4)(i)(F);
- A reference to Figure 3 in proposed section 1234.2(b)(6)(i)(B)(3) is inaccurate and should instead reference Figure 4; and
- A reference to Figure 4 in proposed section 1234.2(b)(6)(i)(B)(3) is inaccurate and should reference a different example warning label similar to Figure 3.

(*Response 19*) The omission of Figure 1 from the NPR was intentional. Figure 1 is referenced in paragraph 5.6 of ASTM F2670–13, which the Commission proposed to incorporate by reference without modification. The NPR only discussed sections of the proposed rule that differed from ASTM F2670–13. Reusing Figure 1 in the NPR would have created two “Figure 1” designations in the final rule. Otherwise, we agree with the comment and references to figures are corrected in the final rule by incorporation of ASTM F2670–17 without modification.

(*Comment 20*) A commenter stated that, while they appreciated CPSC staff’s work on the proposed rule, they were concerned about staff’s “ability to seemingly be able to arbitrarily change language or standards without any justification.” In addition the commenter stated: “[i]t is the role of the Commission, **not professional staff** to dictate changes in policy.” (Emphasis in original).

(*Response 20*) The Commission does not agree that staff “arbitrarily” changes language in a standard “without any justification.” In fact, staff ensures that each package for proposed and final rules contains ample explanation and thorough documentation of the appropriate engineering and/or scientific analysis to support staff’s recommendations. By voting to issue the NPR, the Commission expressed its policy decisions. Furthermore, at ASTM meetings, CPSC staff is not speaking for the Commission, but is expressing staff’s views, based on staff’s expertise.

Moreover, since the proposed rule was published, CPSC staff continued participating on the ASTM Ad Hoc TG on warning labels. The Ad Hoc TG discussed labeling issues, including formatting, and a best-practices approach for ASTM juvenile products standards warning labels moving forward. The latest version of the voluntary standard, ASTM F2670–17, incorporates the Ad Hoc TG’s recommendations. For the final rule, the Commission incorporates by reference ASTM F2670–17, without modification.

(*Comment 21*) A commenter stated that the text of the rule for infant bath tubs should be available for free and in the public domain, rather than incorporating by reference an ASTM standard that is subject to copyright restrictions. The commenter made several arguments supporting this contention, including:

- Citizens have the right “without limitation, to read, speak, and disseminate the laws that we are required to obey, including laws that are critical to public safety and commerce”;
- the right to freedom of speech is “imperiled” if citizens cannot freely communicate provisions of law with each other;
- equal protection and due process are “jeopardized” if only citizens that can afford to purchase the law have access;
- the cost of obtaining standards incorporated by reference into current CPSC regulations would be in the hundreds of dollars to purchase, and would require consultation of other agencies regulations;



- public access to the law is crucial to CPSC's mission: "rationing access to the law hurts trade, it hurts public safety, and it makes it much more difficult for the CPSC to carry out its congressionally-mandated mission."; and

- prohibiting the wide dissemination of the mandatory rules for durable infant standards makes the public less safe.

The commenter argued that, based on fundamental principles in the Constitution and judicial opinions, as reviewed by the commenter, it is unlawful and unreasonable for the Commission to make voluntary standards mandatory without providing free access to the law.

(*Response 21*) The infant bath tub standard is authorized by Congress under section 104 of the CPSIA. This CPSIA provision directs the Commission to issue standards for durable infant or toddler products that are "substantially the same as," or more stringent than, applicable voluntary standards. Thus, unless the Commission determines that more stringent requirements are needed, the Commission's rule must be nearly the same as the voluntary standard. ASTM's voluntary standards are protected by copyright, which the Commission (and the federal government generally) must observe. The United States may be held liable for copyright infringement. 28 U.S.C. 1498. The Office of the Federal Register (OFR) has established procedures for incorporation by reference that seek to balance the interests of copyright protection and public accessibility of material. 1 CFR part 51. The CPSC complies with these requirements whenever incorporating material by reference. In addition, when the Commission proposes a section 104 rule, ASTM's copyrighted voluntary standards are available for free during the comment period.

The Commission's process for developing section 104 rules is open and transparent. CPSC staff works with stakeholders through the ASTM process, specifically the ASTM subcommittee responsible for each product type, to evaluate each voluntary standard and its ability to address the injuries found in CPSC's incident data. The ASTM subcommittee includes representatives from government, manufacturers, retailers, trade organizations, laboratories, and consumer advocacy groups, as well as consultants and members of the public. CPSC staff that participates in ASTM meetings are required to place such meetings on the Commission's public calendar, draft a meeting summary, and provide such

summary to the Commission's Office of the Secretary, pursuant to 16 CFR 1031.11(f) and 1012. Once rulemaking commences, staff also places meeting summaries on the rulemaking docket. As required, the Commission's section 104 rulemakings follow notice and comment procedures of the Administrative Procedure Act (APA) with an NPR and a final rule that explain the substance of the proposed and final requirements.

We disagree that the public is less safe because final rules under section 104 of the CPSIA are based on a voluntary standard. Voluntary standards generally can be updated more frequently than a traditionally enacted mandatory standard to respond to changing products and emerging hazards. Durable infant and toddler products, in particular, are subject to frequent product changes, including design modifications. Section 104 of the CPSIA also includes a mechanism allowing the CPSC to update the mandatory standard when voluntary standard modifications occur.

(*Comment 22*) A commenter objected to the process for promulgating rules related to durable infant and toddler products under section 104 of the CPSIA. More specifically, the commenter objected to the lack of availability and accessibility of the voluntary standard that the Commission proposes to incorporate by reference. The commenter stated that although ASTM made a copy of the voluntary standard that CPSC proposes to incorporate by reference into the rule available for viewing on ASTM's Web site:

- A redline of CPSC's modifications to the voluntary standard was not made available;
- the standard was "read only";
- the standard was displayed with a legal warning restricting use;
- the standard did not allow for copy and paste of the text in the standard; and
- the document is difficult for people with visual impairments to use.

(*Response 22*) The Freedom of Information Act requires that the text of the material being incorporated by reference be "reasonably available." 5 U.S.C. 552(a)(1)(E); 1 CFR part 51. As set forth in response to comment 21, the Commission complies with this requirement. Nothing in the law requires the specific enhancements to text of the proposed mandatory standard articulated by the commenter.

(*Comment 23*) A commenter suggested that a conflict of interest occurs when a government entity relies on a voluntary standards body, such as

ASTM, that profits from the sale of what essentially becomes the law. The commenter stated that many government agencies have joined ASTM as organizational members, and that 44 CPSC employees are members of ASTM. The commenter also noted that the ASTM standard for infant bath tubs is five pages long and that when CPSC's proposed edits to the standard are incorporated, the standard is six to seven pages long. The commenter asserted that based on this: "the government is clearly an author of this work."

(*Response 23*) CPSC staff did not author the voluntary standard on infant bath tubs. ASTM began working on the voluntary standard for infant bath tubs in 2006, well before the congressional mandate to issue mandatory standards based on the voluntary standards for durable infant and toddler products. CPSC staff contributed, as it always has, to the development of the voluntary standard to address incident data, along with all stakeholders who participate on the relevant subcommittee. Through the rulemaking process, the Commission assesses each voluntary standard for its ability to adequately address injuries found in CPSC's incident data. If the voluntary standard should be more stringent, the Commission proposes modifications for the mandatory rule. In the case of infant bath tubs, based on modifications made in the voluntary standard since issuance of the NPR, the Commission incorporates by reference the most recent voluntary standard, ASTM F2670-17, as the final rule for infant bath tubs, without modification.

(*Comment 24*) A commenter argued that CPSC's Voluntary Standards Coordinator, by serving on the board of ANSI, has been placed in the position of "serving two masters," as the person has a fiduciary responsibility to ANSI, as well as to his employer, the U.S. government. The commenter criticized the CPSC for not "clearly delineat[ing] the roles government employees will take when assuming fiduciary responsibilities for private organizations." The commenter stated that although CPSC's Voluntary Standards Coordinator served on the board of ANSI, the CPSC had no memorandum of understanding (MOU) with ANSI regarding this relationship; and instead, CPSC asserted its reliance on the Commission's regulation at 16 CFR part 1031. The commenter stated that the Office of Government Ethics (OGE) has provided the guidance on government employees serving on the boards of external nonprofits, and the OGE recommends an MOU among the agency, employee and the nonprofit

organization to avoid violation of 18 U.S.C. 208(a).

(Response 24) CPSC does not rely on a unique MOU among the agency, employee, and each voluntary standards organization. Because CPSC employees, based on job description, participate in different capacities with different organizations, the Commission has regulations (16 CFR part 1031) setting forth best practices and ethical responsibilities of employees involved in voluntary standards activities.

## VI. Incorporation by Reference

Section 1234.2(a) of the final rule provides that infant bath tubs must comply with ASTM F2670–17. The OFR has regulations concerning incorporation by reference. 1 CFR part 51. These regulations require that, for a final rule, agencies must discuss in the preamble to the rule the way in which materials that the agency incorporates by reference are reasonably available to interested persons, and how interested parties can obtain the materials. Additionally, the preamble to the rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, the discussion in section VII of this preamble summarizes the provisions of ASTM F2670–17. Interested persons may purchase a copy of ASTM F2670–17 from ASTM, either through ASTM's Web site, or by mail at the address provided in the rule. A copy of the standard may also be inspected at the CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, or at NARA, as discussed above. Note that the Commission and ASTM arranged for commenters to have "read only" access to ASTM F2670–13 during the NPR's comment period.

## VII. Description of the Final Rule

### A. Final Safety Standard for Infant Bath Tub

For the final rule for infant bath tubs, the Commission will incorporate by reference ASTM F2670–17, without modification. ASTM F2670–17 contains both general and product-specific requirements to address the hazards associated with infant bath tubs. ASTM F2670–17 includes the following key provisions: Scope, Terminology, General Requirements, Performance Requirements, Test Methods, Marking and Labeling, and Instructional Literature.

**Scope.** Section 1 of ASTM F2670–17 provides the scope of products covered by the standard, which: "establishes performance requirements, test methods, and labeling requirements to

promote the safe use of infant bath tubs." As stated in section II.A. of this preamble, ASTM F2670–17 defines an "infant bath tub" as a "tub, enclosure, or other similar product intended to hold water and be placed into an adult bath tub, sink, or on top of other surfaces to provide support or containment, or both, for an infant in a reclining, sitting, or standing position during bathing by a caregiver." This description includes "bucket style" tubs that support a child sitting upright, tubs with an inclined seat for infants too young to sit unsupported, inflatable tubs, folding tubs, and tubs with more elaborate designs including handheld shower attachments and even whirlpool settings. ASTM F2670–17 excludes from its scope "products commonly known as bath slings, typically made of fabric or mesh."

**Terminology.** Section 3 of ASTM F2670–17 provides definitions of terms specific to the infant bath tub standard.

**General Requirements.** Section 5 of ASTM F2670–17 sets forth general requirements for infant bath tubs, including:

- Sharp Edges or Points (referencing 16 CFR 1500.48 and 1500.49);
- Small Parts (referencing 16 CFR 1501);
- Lead in Paint and Surface Coatings (referencing 16 CFR 1303);
- Resistance to Collapse;
- Scissoring, Shearing, and Pinching;
- Openings;
- Protective Components;
- Requirements for Toys (incorporating ASTM F963); and
- Labeling.

**Performance Requirements and Test Methods.** Section 6 of ASTM F2670–17 contains performance requirements for restraint systems, static load, and suction cups. Section 7 of the standard sets forth test methods for the performance requirements set forth in sections 5 and 6 of the standard.

**Marking and Labeling.** Section 8 of ASTM F2670–17 contains requirements for marking products, including warnings that must be applied to the product and the product packaging. Section 8 sets forth the substance, format, and prominence requirements for warning information.

**Instructional Literature.** Section 9 of ASTM F2670–17 requires that instructions provided with infant bath tubs be easy to read and understand. Additionally, the section contains requirements for instructional literature contents and format, as well as prominence of certain language.

### B. Amendment to 16 CFR Part 1112 to Include NOR for Infant Bath Tub Standard

The final rule amends part 1112 to add a new § 1112.15(b)(41) that lists 16 CFR part 1234, *Safety Consumer Safety Specification for Infant Bath Tub*, as a children's product safety rule for which the Commission has issued an NOR. Section XIII of the preamble provides additional background information regarding certification of infant bath tubs and issuance of an NOR.

## VIII. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). CPSC generally considers 6 months to be sufficient time for suppliers of durable infant and toddler products to come into compliance with a new standard under section 104 of the CPSIA, and the Commission proposed a 6-month effective date in the NPR for infant bath tubs. We received no comments on the proposed effective date. Accordingly, the final rule will have a 6-month effective date. We note that two recent versions of the voluntary standard, ASTM F2670–16 and ASTM F2670–16a, both contain a majority of changes that align with the NPR, so manufacturers that comply with the voluntary standard will have had a year to prepare production to the new federal regulation.

## IX. Regulatory Flexibility Act

### A. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires that agencies review a proposed rule and a final rule for the rule's potential economic impact on small entities, including small businesses. Section 604 of the RFA generally 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 economic impact on a substantial number of small entities. As discussed in this analysis, adopting ASTM F2670–17 without modification would not be expected to have a significant impact on a substantial number of small entities.

For the final rule, the Commission is incorporating by reference the voluntary standard for infant bath tubs, ASTM F2670–17, without modification. As set forth in section IX.B below, six of the 10 small manufacturers and four of the five small importers are already believed to be in compliance with the requirements of the voluntary standard. Because the products are not complex, modifications

required to bring the remaining products into compliance should be minor. All firms will need to make changes to their product's warning labels and use different equipment in the static load test. CPSC expects the cost of these modifications to be low. Firms will incur additional costs associated with third party testing. However, CPSC does not expect the impact of third party testing to be economically significant for most firms. Accordingly, the Commission certifies that the final rule for infant bath tubs will not have a significant economic impact on a substantial number of small entities.

#### *B. Impact on Small Businesses*

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of infant bath tubs is small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 16 of the 22 domestic firms known to be supplying infant bath tubs to the U.S. market are small firms—10 manufacturers, five importers, and one firm with an unknown supply source.

##### 1. Small Domestic Manufacturers

The impact of the final rule on small manufacturers will differ, based on whether manufacturers' infant bath tubs are already compliant with F2670–16. Six domestic manufacturers are in compliance with ASTM F2670–16 and are likely to continue to comply with the new voluntary standard approved in January 2017, ASTM F2670–17. Firms in compliance with the voluntary standard will not need to make physical modifications to their products, but still will need to make some modifications to the warning labels on their products. However, the costs of modifying an existing label are usually small.

Four domestic manufacturers appear to be noncompliant with ASTM F2607–16 and will need to modify their products in order to meet ASTM F2607–17. The Commission expects product modifications to be minor because the products are not complex; the products are generally composed of one or two pieces of hard or soft plastic molded together. Modifications to meet the standard primarily involve adjusting the size of grooves or openings on the side of the product to avoid finger entrapment. All firms will need to modify their warning labels to meet the mandatory standard. Staff believes 6 months is sufficient time to make the necessary changes and the costs associated with doing so are low. Therefore, the impact of the final rule is

likely to be small for most producers who do not comply with ASTM F2607–16.

Under section 14 of the CPSA, infant bath tubs are also subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107). Third party testing will include physical and mechanical test requirements specified in the infant bath tub final rule; lead and phthalates testing is already required. Third party testing costs are in addition to the direct costs of meeting the infant bath tub standard.

Based on testing costs for similar juvenile products, staff estimates that testing to the ASTM voluntary standard could cost approximately \$500–\$600 per model sample. On average, each small domestic manufacturer supplies three different models of infant bath tubs to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$1,500–1,800 annually. Based on a review of firms' revenues and products, the impact of third party testing to ASTM F2670–17 would not exceed one percent of revenues. Thus, it seems unlikely that the impacts of the rule will be economically significant for most small producers.

##### 2. Small Domestic Importers

Most importers will not experience significant impacts as a result of the final rule. The Commission believes that four of the five small importers are compliant with the ASTM F2670–16 voluntary standard, and therefore only would need to assure that their suppliers make the label modifications to comply with the final rule. Complying with the final rule could be more difficult for the remaining importer because changes beyond simple modifications to the warning label are probably necessary. The remaining importer, who is likely not in compliance with the voluntary standard, might need to find an alternate source of infant bath tubs if their existing suppliers do not come into compliance with the requirements of the final rule. Alternatively, this firm may discontinue importing infant bath tubs altogether or perhaps substitute another product.

As is the case with manufacturers, all importers will be subject to third party

testing and certification requirements, and consequently, they will experience the associated costs, if their supplying foreign firm(s) does not perform third party testing. However, based on firms' revenues and on the number of samples that would be required, it is unlikely that there will be a significant economic impact due to the testing requirements.

As mentioned above, one small domestic firm has an unknown supply source. However, the firm has a diverse product line and claims compliance with various standards for several of its other infant products. It is possible that the firm's infant bath tub is compliant with the current bath tub standard and the firm would only need to modify existing warning labels. In any case, this firm should not experience large impacts because infant bath tubs are only one of many products it supplies. The labeling requirements also apply to importers. However, as described above, staff believes firms can easily meet this requirement.

#### **X. Environmental Considerations**

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, a rule that has "little or no potential for affecting the human environment," is categorically excluded from this requirement. 16 CFR 1021.5(c)(1). The final rule falls within the categorical exclusion.

#### **XI. Paperwork Reduction Act**

The final rule for infant bath tubs contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The preamble to the proposed rule (80 FR at 48776–77) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. OMB has assigned control number 3041–0171 to this information collection. We did not receive any comment regarding the information collection burden of the proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated manufacturers subject to the information collection burden is now estimated at 25 manufacturers rather than the 26 manufacturers initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

16 CFR Section	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total burden hours
1234 .....	25	3	75	1	75

Our estimate is based on the following:

Section 8.1 of ASTM F2670–17 requires that all infant bath tubs and their retail packaging be permanently marked or labeled as follows: The manufacturer, distributor, or seller name, place of business (city, state, mailing address, including zip code), and telephone number; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 25 firms that supply infant bath tubs in the U.S. market. For PRA purposes, we assume that all 25 firms use labels on their products and on their packaging already. All firms will need to make some modifications to their existing labels. We estimate that the time required to make these modifications is about 1 hour per model. Each of the 25 firms supplies an average of three different models of infant bath tubs. Therefore, we estimate the burden hours associated with labels to be 75 hours annually (1 hour × 25 firms × 3 models per firm = 75 hours annually).

We estimate the hourly compensation for the time required to create and update labels is \$33.30 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” September 2016, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, we estimate the annual cost to industry associated with the labeling requirements in the final rule to be approximately \$2,498 (\$33.30 per hour × 75 hours = \$2,497.5). This collection of information does not require operating, maintenance, or capital costs.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this final rule to the OMB.

**XII. Preemption**

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section

26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules.” Therefore, the preemption provision of section 26(a) of the CPSA applies to this final rule issued under section 104.

**XIII. Amendment to 16 CFR Part 1112 To Include a Notice of Requirement for the Infant Bath Tub Standard**

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other Act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children’s products subject to a children’s product safety rule be based on testing conducted by a CPSC-accepted, third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children’s product safety rule to which a children’s product is subject. The *Safety Standard for Infant Bath Tubs*, to be codified at 16 CFR part 1234, is a children’s product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third-Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as part 1112). Part 1112 became effective on June 10, 2013 and establishes requirements for accreditation of third-party conformity assessment bodies (or laboratories) to test for conformance with a children’s product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the standard for infant bath tubs, require the Commission to amend part 1112. Accordingly, the

Commission is now amending part 1112 to include the standard for infant bath tubs in the list of other children’s product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third-party conformity assessment body to test to the new standard for infant bath tubs would be required to meet the third-party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to Third-Party Conformity Assessment Bodies*. When a laboratory meets the requirements as a CPSC-accepted third-party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1234, *Safety Standard for Infant Bath Tubs*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

As required by the RFA, staff conducted a FRFA when the Commission issued the part 1112 rule (78 FR 15836, 15855–58). Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small test laboratories because no requirements were imposed on test laboratories that did not intend to provide third-party testing services. The only test laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision. Moreover, a test laboratory would only choose to provide such services if it anticipated receiving revenues sufficient to cover the costs of the requirements.

Based on similar reasoning, amending 16 CFR part 1112 to include the NOR for the infant bath tubs standard will not have a significant adverse impact on small test laboratories. Moreover, based upon the number of test laboratories in the United States that have applied for CPSC acceptance of accreditation to test for conformance to other mandatory juvenile product standards, we expect that only a few test laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant bath tub standard. Most of these test laboratories will have

already been accredited to test for conformity to other mandatory juvenile product standards, and the only costs to them would be the cost of adding the infant bath tubs standard to their scope of accreditation. For these reasons, the Commission certifies that the NOR amending 16 CFR part 1112 to include the infant bath tubs standard will not have a significant impact on a substantial number of small entities.

#### List of Subjects

##### 16 CFR Part 1112

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

##### 16 CFR Part 1234

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, bath tub, and Toys.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations as follows:

#### PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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

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

- 2. Amend § 1112.15 by adding paragraph (b)(41) to read as follows:

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

\* \* \* \* \*

(b) \* \* \*

(41) 16 CFR part 1234, Safety Standard for Infant Bath Tub.

\* \* \* \* \*

- 3. Add part 1234 to read as follows:

#### PART 1234—SAFETY STANDARD FOR INFANT BATH TUBS

Sec.

1234.1 Scope.

1234.2 Requirements for infant bath tubs.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

##### § 1234.1 Scope.

This part establishes a consumer product safety standard for infant bath tubs.

##### § 1234.2 Requirements for infant bath tubs.

Each infant bath tub must comply with all applicable provisions of ASTM F2670–17, Standard Consumer Safety Specification for Infant Bath Tubs, approved on January 1, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal-register/code-of-federal-regulations/ibr\\_locations.html](http://www.archives.gov/federal-register/code-of-federal-regulations/ibr_locations.html).

Dated: March 27, 2017.

**Todd A. Stevenson,**

Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–06270 Filed 3–29–17; 8:45 am]

BILLING CODE 6355–01–P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Part 1

[Docket No. FDA–2017–N–0011]

##### Requirements To Submit Prior Notice of Imported Food; Technical Amendments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendments.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the prior notice of imported food regulations to reflect a change in the electronic data interchange system and its expanded capabilities, to correct inaccurate number designations in section headings, and to reflect a change in an office's name. This action is ministerial or editorial in nature.

**DATES:** This rule is effective March 30, 2017.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Thomas, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2094.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(m)) requires that FDA establish regulations requiring that those persons importing articles of food or offering articles of food for import into the United States submit certain information about imported foods before the products' arrival in the United States. We have established the regulations at title 21, Code of Federal Regulations (CFR) part 1, subpart I (21 CFR 1.276 to 1.285). Section 801(m) of the FD&C Act also provides that an article of food imported or offered for import is subject to refusal of admission into the United States if adequate prior notice has not been provided to FDA. Our regulations in 21 CFR part 1, subpart I, include information on when to submit prior notice, how to submit prior notice, and what information is required in a prior notice.

##### II. Description of the Technical Amendments

We are making technical amendments in our prior notice regulations in part 1, subpart I (§§ 1.276 to 1.285), to:

- Reflect the change in an electronic data interchange system and its expanded capabilities;
- correct paragraph number designations in certain introductory text paragraphs; and
- revise the name of an FDA office receiving certain information.

The technical amendments are ministerial or editorial in nature and are not intended to modify any substantive requirements.

##### A. Revising an Electronic Data Interchange System and Recognizing Its Expanded Capabilities

Our current regulations, at §§ 1.279, 1.280, 1.281, and 1.282, refer to the “Automated Broker Interface/Automated Commercial System (ABI/ACS)” or “Automated Broker Interface of the Automated Commercial System (ABI/ACS).” We are amending these regulations to reflect the change of the electronic data interchange system from “Automated Broker Interface/Automated Commercial System (ABI/ACS)” or “Automated Broker Interface of the Automated Commercial System (ABI/ACS)” to “Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS).” In the **Federal Register** of May 16, 2016 (81 FR 30320), the Department of Homeland Security's U.S. Customs and Border Protection (CBP) issued a notice