



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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This document has been electronically
approved and signed.

DATE: March 15, 2017

BALLOT VOTE SHEET

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Patricia M. Pollitzer, Assistant General Counsel
Mary A. House, Attorney, OGC

SUBJECT: Final Rule: Safety Standard for Infant Bath Tubs

BALLOT VOTE DUE Tuesday, March 21, 2017

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the *Federal Register*. Pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), the draft final rule would incorporate by reference the voluntary standard, ASTM F2670-17, *Standard Consumer Safety Specification for Infant Bath Tubs*, without modification, as the mandatory federal safety standard for infant bath tubs. Additionally, the draft final rule amends the Commission's regulation 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.

Please indicate your vote on the following options:

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

(Signature)

(Date)

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

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

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Final Rule for Safety Standard for Infant Bath Tubs

Billing Code 6355-01-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 [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSTERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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; e-mail: *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).¹

¹ 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).

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 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.²

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.

² Staff made these determinations using information from Dun & Bradstreet and Reference USA Gov, as well as firm websites.

This total includes 45 new infant bath tub-related incidents reported since the NPR³ (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 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

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

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*⁴

Commission staff estimates a total of 2,300 injuries (sample size = 89, coefficient of variation=0.18) related to infant bath tubs occurred from 2004 to 2015, which were treated in U.S. hospital emergency departments.⁵ The injury estimates for individual years are not reportable because they fail to meet publication criteria.⁶

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:

⁴ 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.

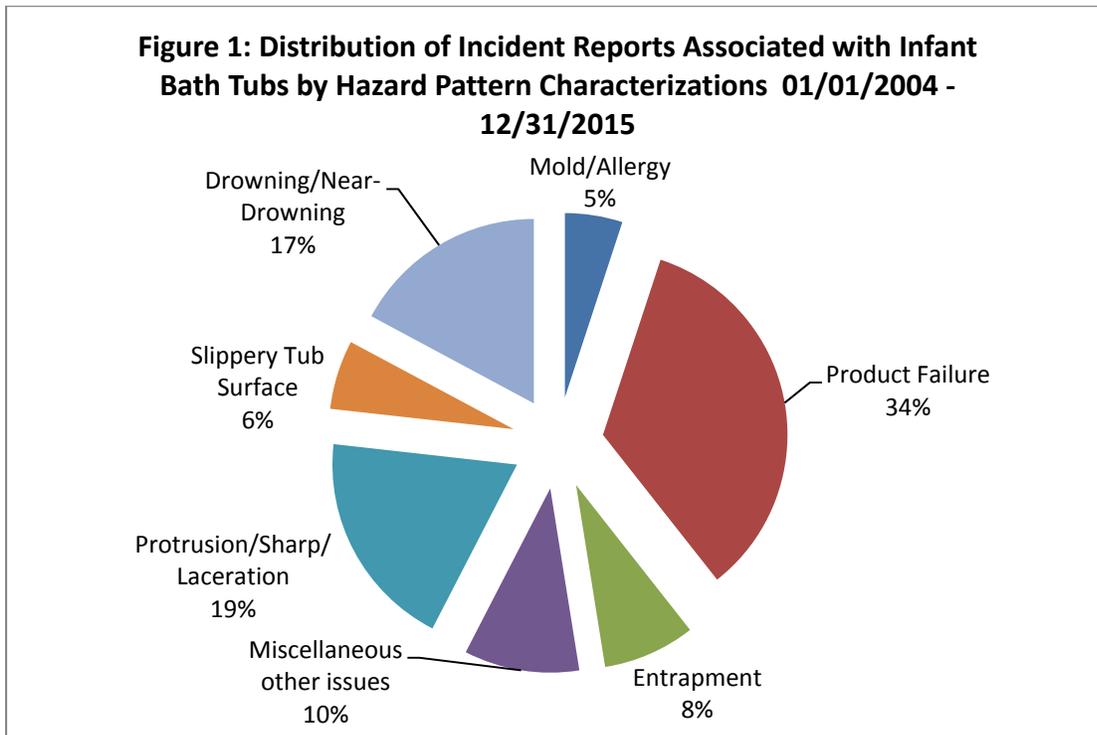
⁵ National injury estimates for 2004–2014 were presented in the NPR.

⁶ 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.

- 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.



Source: CPSC epidemiological databases IPII, 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 locations(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.⁷ 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

⁷ 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.

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,⁸ 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.⁹

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

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

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

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, 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 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 Pub. L. No. 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 C.F.R. § 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 website:

- 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 website, 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 Tubs

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 .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 Tubs Standard

The final rule amends part 1112 to add a new section 1112.15(b)(41) that lists 16 CFR part 1234, *Safety Consumer Safety Specification for Infant Bath Tubs*, 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 x 25 firms x 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 x 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 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.

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, 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 Tubs.

* * * * *

- 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.

(a) 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.

Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



**Staff's Draft Final Rule for Infant Bath Tubs under
the Danny Keysar Child Product Safety Notification
Act**

March 15, 2017

Table of Contents

Briefing Memorandum.....	iii
TAB A: Infant Bath Tubs-Related Deaths, Injuries and Potential Injuries, and NEISS Injury Estimates January, 2004 – December, 2015	16
TAB B: EPHA Staff’s Response to Public Comments to the NPR for Infant Bath Tubs	24
TAB C: Human Factors Staff Assessment of Warning Label Provisions and Response to Comments for Infant Bath Tubs Final Rule.....	28
TAB D: Infant Bath Tub Rulemaking: LSM Assessment of F2670 and Response to Comments	41
TAB E: Final Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Infant Bath Tubs and Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bath Tub Standard.....	50

Briefing Memorandum



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

This document has been electronically
approved and signed.

Memorandum

Date: March 15, 2017

TO: The Commission
Todd A. Stevenson, Secretary

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

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

Celestine T. Kish, Project Manager
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Staff's Draft Final Rule for Infant Bath Tubs under the Danny Keysar
Child Product Safety Notification Act

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act. This Act requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to: (1) examine and assess voluntary safety standards for certain infant or toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Although the list of products in section 104 does not include infant bath tubs, the Commission specifically identified "infant bath tubs" as a "durable infant or toddler product" in the Commission's product registration card rule under section 104(d).¹

¹74 Fed. Reg. 68,668 (Dec. 29, 2009) (16 C.F.R. § 1130.2(a)(16)).

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.” The infant bath tub category covers a variety of products, including bucket-style tubs, inflatable tubs, foldable tubs, and bath tubs with spa features, such as “whirlpool” settings and separate handheld showers. The majority of children who use all types of infant bath tubs are under age 5.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. This consultation process has been ongoing with staff’s participation in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.² This consultation process commenced in fall 2014, with staff participating in the subcommittee F15.20 – Infant Bath Tubs meeting.³

This briefing package provides:

- staff’s assessment of changes made to the voluntary standard for infant bath tubs, ASTM F2670 *Standard Consumer Safety Specification for Infant Bath Tubs*;
- staff’s response to comments received regarding the notice of proposed rulemaking (NPR), which was published on August 14, 2015, in the *Federal Register* (80 *Fed. Reg.* 48769); and
- staff’s recommendation regarding a draft final rule to address potential hazards in infant bath tubs.

II. BACKGROUND

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 in 2009, and then revised in 2010, twice in 2011, 2012, 2013, and twice in 2016. The NPR referenced ASTM F2670-13. In the time since the NPR was published, ASTM approved and published three more versions of the standard, with the most current version, ASTM F2670-17, approved and published on January 1, 2017.

An “infant bath tub” is defined in the ASTM voluntary standard 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.*

²ASTM International website: www.astm.org. About ASTM International.

³The meeting logs are available in the supporting documents folder at : <https://www.regulations.gov/docket?D=CPSC-2015-0019>.

III. DISCUSSION

A. Overview of Incident Data (Tab A)

CPSC staff is aware of a total of 247 incidents (31 fatal and 216 non-fatal) 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 NPR⁴ (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 Program." 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 more detailed discussion of incident data that follows does not include year 2016 incidents.

Fatalities

Of the 31 decedents in the fatal incidents, 29 of the victims were between the ages of 4 and 11 months old; the other 2 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.

Nonfatal Incidents

Thirty-two (32) 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. Near-drowning means a person almost died from not being able to breathe (suffocating) under water. 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, hit on head by toy accessory, and concussion from fall from a tub.

⁴ Data discussed in the NPR was collected from January 1, 2004 through May 20, 2015.

*National Injury Estimates*⁵

Staff estimates a total of 2,300 injuries (sample size = 89, coefficient of variation=0.18) related to infant bath tubs occurred from 2004 to 2015 that were treated in U.S. hospital emergency departments.⁶ The injury estimates for individual years are not reportable because they fail to meet publication criteria.⁷

One drowning death was reported through the NEISS and is included in the fatality counts in the prior section. About 93 percent of the estimated emergency department visits during the 12-year period involve 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 were: 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

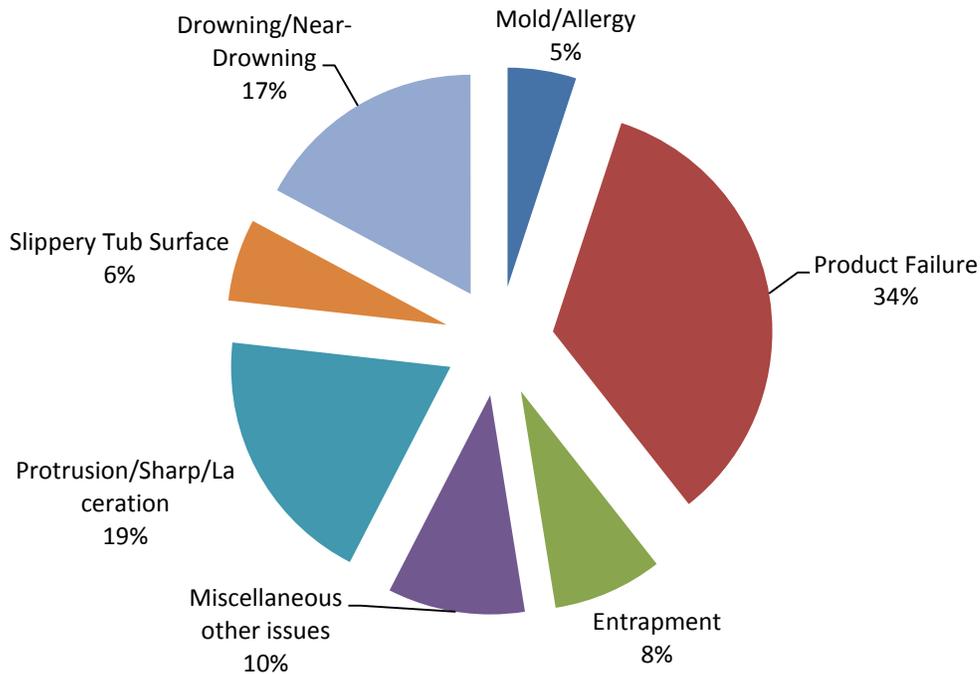
The section below summarizes the hazard pattern characterizations based on the incident data. Figure 1 shows the distribution of hazard patterns by frequency.

⁵ 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.

⁶ National injury estimates for 2004–2014 were presented in the NPR.

⁷ 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.

Figure 1: Distribution of Incident Reports Associated with Infant Bath Tubs by Hazard Pattern Characterizations 01/01/2004 - 12/31/2015



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

1. *Drowning/Near-Drowning* incidents 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, staff cannot determine a pattern in what led to the submersions. However, in 38 of 43 incidents, the parent or guardian was not present at the time the incident occurred. In the other five incidents in which the parent or guardian was present, four of the children survived. Frequently, the child was found floating. Only one reported fatality was not ruled a drowning; this incident is included in the miscellaneous category.

2. *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 include 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 “hammock/sling” attachment was involved in this type of protrusion incident. One incident required a hospital visit and the remaining 47 incidents involved either 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.

3. *Product Failures* account for 34 percent (85 of 247) of reported incidents. Fifty-nine incidents reported the “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 visited hospitals 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.
4. *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 injured body parts reportedly injured include 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.
5. *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.
6. *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 all over the 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.
7. *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 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 involved either an incident with no injury or a minor injury, including six battery-related complaints.

C. *Staff's Assessment of F2670 for Draft FR*

The NPR was based on the 2013 version of ASTM's voluntary standard, ASTM F2670-13 with the following modifications to the ASTM standard:

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, 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 addition, the NPR recommended ASTM consider including infant bath slings in the standard and remove the exclusion.

Revised latching or locking mechanism requirements

The NPR proposed allowing more time for the latching or locking mechanism testing to accommodate more complicated mechanisms.

7.1.2 Latching or Locking Mechanism Durability—The latching or locking mechanism(s) shall be cycled through its normal operation a total of 2000 cycles. Each cycle shall consist of opening and closing the mechanism and erecting/folding the product. Cycling shall be conducted at a rate of between 8 cycles to 12 cycles per minute.

Through the ASTM process, the wording and rationale for the latching or locking mechanism durability testing evolved into the language in the current standard, which staff supports.

Revised static load requirements

The NPR proposed changing the static load test apparatus to a shot bag as recommended by the ASTM subcommittee.

7.4.2 Place a load on the center of the seating surface using a 6 to 8 in. (150 to 200 mm) diameter bag filled with steel shot and which has a total weight of 50 lb (22.7 kg) or three times the maximum weight of the child recommended by the manufacturer whichever is greater, on the center of the product. And distribute it upon a 6 by 6 in. (150 by 150 mm) 3/4 in. (19 mm) thick block made of high density polyethylene (HDPE).

After the NPR was published, but before the ASTM language was balloted, the subcommittee chairman made editorial changes to the static load test language. This created two sets of similar

but not identical language: the NPR language and the new language in the ASTM proposal. Staff supports the new language in F2670-17.

Revised content of the warnings, markings, and instructions

The NPR proposed 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. In addition, the standard did not require a specific format for the warning labels. The Commission proposed in the NPR to separate the warnings to more clearly identify the drowning hazard and fall hazard and to provide guidance on how to avoid these hazards. In addition, the NPR proposed warning language that was more personal by use of the words “babies” as opposed to “infant” and “stay in arm’s reach of your baby” as opposed to “ALWAYS keep infant within adult’s reach.” The ASTM Subcommittee for Infant Bath Tubs discussed the warnings proposed in the NPR and accepted the Commission’s edits except for one. The ASTM Subcommittee decided that the drowning hazard statement “Keep drain open” needed to clarify that the drain in the adult tub should be kept open during bathing. The subcommittee balloted and approved “Keep drain open in adult tub or sink.” This revision and the Commission’s edits noted above are included in ASTM F2670-17. Staff agrees the added statement clarifies the directions to caregivers and recommends incorporating the revised warning in the draft final rule.

Warning label format

As stated above, F2670-13 did not require any specific formatting for the warnings. Human Factors staff regularly cites the ANSI Z535.4 *American National Standard for Product Safety Signs and Labels* as a baseline in developing warning materials. Commission-proposed changes on the formatting of warning labels in the NPR were consistent with the ANSI Z535.4 language.

Since the NPR was published, ASTM convened a task group, 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

voluntary standards. The Human Factors Division hazard communication subject matter expert,⁸ who also is the CPSC staff representative on the ANSI Z535 committee, represented CPSC staff in this task group. The Ad Hoc TG recommendations were published as a reference document entitled “Ad Hoc Wording – May 4, 2016” for F15 committee members. The reference document recommends wording very similar to the ANSI Z535.4, with modifications to make the Ad Hoc TG’s recommendations more stringent.

The ASTM F2670 committee also balloted and approved incorporation of the Ad Hoc Wording reference recommendations into ASTM F2670-17. Accordingly, staff believes that adopting the Ad Hoc Wording reference document recommendations provides noticeable and consistent warning labels on infant bath tubs and across juvenile products. Therefore, staff recommends incorporating by reference ASTM F2670-17 to clarify the warning label format requirements in the draft final rule.

Warning label font size

One modification in the NPR that was unique to Infant Bath Tubs, as opposed to the other durable infant and toddler products currently under rulemaking, was to increase the 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.⁹ The intent of the revision was to align the labeling information for bath tubs with that of infant bath seats (16 CFR 1216). The Ad Hoc Wording guidance document does not have this unique modification; rather, the guidance recommends the safety alert symbol, and the word “WARNING,” not be less than 0.2 in. (5 mm) high and the remainder of the text with upper case characters not be less than 0.1 in. (2.5 mm) high. Thus, the Ad Hoc language keeps the size requirements consistent with the standard referenced in the NPR (F2670-13) rather than the increased size recommended in the NPR.

Staff recognizes that increasing the size of the warnings was not the only change recommended in the NPR or through the Ad Hoc guidance to improve the formatting and, therefore, effectiveness of the warnings. ASTM F2670-17 contains all of the Ad Hoc Wording guidance document recommendations. As stated above, the specific formatting changes 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. Commission staff regularly uses ANSI Z535.4, American National Standard for Product Safety Signs and Labels — the primary U.S. voluntary consensus standard for the design, application, use, and placement of on-product warning labels—when developing or assessing the adequacy of warning labels. Experts in human factors and warnings literature regularly cite ANSI Z535.4 when discussing the design and evaluation of on-product warning labels, and identify it as the minimum set of requirements that products containing such labels that are sold in the U.S. should meet, (*e.g.*, Vredenburg & Zackowitz, 2005; Wogalter & Laughery, 2005). Hellier and Edworthy (2006) and Peckham (2006) report that this has been reaffirmed by the U.S. courts, who have accepted

⁸ Timothy P. Smith.

⁹ 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.

the ANSI Z535 series of standards, in general, and the ANSI Z535.4 standard, in particular, as the benchmark against which warning labels are evaluated for adequacy because these standards are seen as the state of the art (also see Laughery & Wogalter, 2006).

The warning label provisions in F2670-17 bring the formatting and language of the warning label in close alignment with the NPR proposal, except for the size requirements. However, staff believes all of the formatting and wording provisions in the current ASTM standard improve the labeling over the labeling in F2670-13, referenced in the NPR. CPSC staff cannot state definitively whether the formatting changes, along with the increased font size, will influence consumer's behavior more than the formatting changes alone. Therefore, staff recommends the draft final rule incorporate ASTM F2670-17 by reference without any modifications.

Infant Bath Slings

In October 2016, CPSC recalled the infant bath tub with a sling accessory that was involved in the majority of infant bath sling incidents.¹⁰ In addition, updated incident data demonstrates that 59 of the 85 “product failure” incidents involve the infant bath hammock or sling collapsing with no or minor injuries.

At this time, ASTM F2670-17 does not include provisions that will specifically address the incidents involving infant bath hammocks/slings. The ASTM subcommittee on bath tubs created two task groups to address this issue, but the task groups have not yet completed their work. CPSC staff will continue to work with ASTM to address the risks of infant bath slings. The first task group is developing performance requirements for infant bath slings that can only 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 covered in a new, separate standard. CPSC staff believes that new requirements for infant bath hammocks/slings that can be used with an infant bath tub will be added to the infant bath tub voluntary standard in the near future. The task group plans to present its recommendations to the larger subcommittee during the April 2017 meeting, and anticipates balloting of the new provisions shortly after the meeting. Staff recommends the Commission proceed with a final rule on infant bath tubs and urge the ASTM subcommittee to finalize the inclusion of infant bath hammock/sling requirements to the ASTM standard.

Should the Commission promulgate the final rule, then, once the voluntary standard for infant bath tubs is revised to include infant bath slings and the Commission is notified of the revised standard by ASTM, staff will assess the 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

¹⁰ <https://www.cpsc.gov/Recalls/2017/Summer-Infant-Recalls-Infant-Bath-Tubs> (viewed on website 11/22/2016.)

recommendation to the Commission whether to create a new mandatory durable infant and toddler standard under section 104 of the CPSIA for such products.

D. Staff Responses to NPR Comments

On August 14, 2015, the Commission published an NPR regarding options to address infant bath tub safety hazards. The NPR reviewed incident data related to the hazard patterns discussed above. The NPR solicited information and comments concerning all aspects of the proposed rule, and also 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. Staff received 12 comments; seven expressed general support of the NPR with additional comments. Five either requested more time for the ASTM standard to be updated or disagreed with some of the recommendations in the NPR. Comments and other supporting documentation are available on www.Regulations.gov by searching docket no. CPSC-2015-0019. CPSC technical directorate staff's responses can be found in Tabs B-E.¹¹

E. Potential Small Business Impact

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.

All firms will need to make modifications to their products' warning labels and use different equipment in the static load test. However, the cost of these modifications is expected to be low. Staff expects that the draft final rule would not have a significant impact on a substantial number of small firms.

F. Notice of Requirements

As explained in the briefing package for the NPR, section 14(a) of the CPSA requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. That certification must be based on testing by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to issue a notice of requirements (NOR) for the accreditation of third party testing laboratories to determine compliance with children's product safety rules, such as the bath tub rule. Accordingly, in the bath tub NPR the Commission proposed to amend the regulation that codifies the NORs (16 CFR part 1112) so that it would include an NOR for the bath tub standard. The draft final rule includes a provision to finalize the NOR.

¹¹ Tab B – EPHA Staff's Response to Public Comments to the NPR for Infant Bath Tubs
Tab C- Human Factors Staff Assessment of Warning Label Provisions and Response to Comments for Infant Bath Tubs Final Rule
Tab D – Infant Bath Tub Rulemaking: LSM Assessment of F2670 and Response to Comments
Tab E – Final Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Infant Bath Tubs and Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bath Tub Standard

G. *Effective Date of Final Rule*

The Administrative Procedure Act (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)). Staff agrees with the NPR's proposed 6-month effective date. ASTM standard F2670-16a, contained the majority of changes that align with the NPR, was published in September 2016 and therefore, manufacturers will have had almost a year to prepare production to the new standard and federal regulation.

IV. STAFF RECOMMENDATIONS

CPSC staff recommends incorporating ASTM F2670-17 without any modifications. CPSC staff believes ASTM F2670-17 will reduce the number of deaths and injuries to infants associated with infant bath tubs and recommends that the Commission adopt staff's draft final rule for infant bath tubs with an effective date of six months after publication for products manufactured or imported on or after that date.

TAB A: Infant Bath Tubs-Related Deaths, Injuries and Potential Injuries, and NEISS Injury Estimates January, 2004 – December, 2015

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

Memorandum

Date: April 6, 2016

TO : Celestine T. Kish
Infant Bath Tubs Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
Associate Executive Director, Epidemiology, EP
Directorate for Epidemiology

Stephen Hanway
Division Director, Hazard Analysis, EPHA
Directorate for Epidemiology

FROM : Adam Suchy
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Infant Bath Tubs-Related Deaths, Injuries and Potential Injuries, and NEISS
Injury Estimates January, 2004 – December, 2015

Introduction

This memorandum characterizes the number of deaths and injuries and the types of hazards related to products coded as infant bath tubs from January, 2004 through December, 2015.¹ These characterizations are based on reports received by CPSC staff.

An infant bath tub is defined in section 3.1.2 of the ASTM voluntary standard F2670-17 as a *“tub, enclosure, or other similar product intended to hold water and be placed into an adult bath*

¹ Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather to quantify the number of fatalities and injuries reported to CPSC staff and to provide estimates of emergency department-treated injuries.

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.” Infant bath tubs are tubs that hold water meant for bathing a child, and do not include bath seats or stand-alone bath slings. Due to the large number of injury reports received through the emergency departments during this timeframe, the estimates of emergency department-treated injuries associated with infant bath tubs are presented separately from the rest of the incident data.

Incident Data^{2,3}

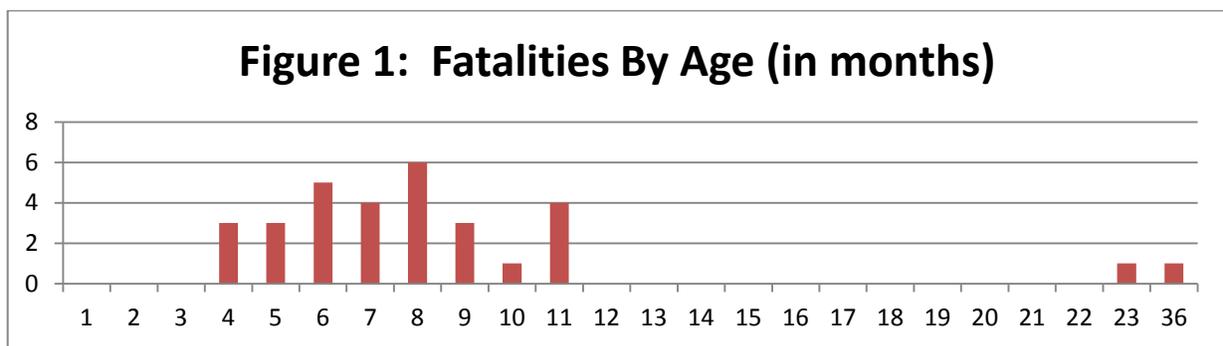
CPSC staff is aware of a total of 247 incidents (31 fatal and 216 non-fatal) related to infant bath tubs that were reported to have occurred from January, 2004 through December, 2015. Seventy-two (72) incident reports have the age as unknown. Of the remaining 175 incidents with known ages, only 5 victims were over 2 years of age, including one adult woman who had an allergic reaction. Most of the 72 incidents with unknown ages consist of either product malfunction, breakage or other injury concerns related to the product with no injury occurring, or the incident involved a baby of unknown age. Of the children where the gender of the child is known, 116 were male children, and 92 were female children. Thirty-nine (39) reports have an unknown gender. Just over half (146 out of 247 or 59 percent) of the reported incidents had a document submitted to CPSC by retailers and manufacturers through CPSC’S “Retailer Reporting System.” Of the 146 incidents with documents from manufacturers, 6 reports had additional documents in the CPSC databases of the same incident (all 6 incidents had investigation IDI documents). In addition, 101 incident reports were submitted to CPSC from various sources such as hotlines, internet reports, newspaper clippings, medical examiners, death certificates, NEISS (National Electronic Injury Surveillance System) investigations and other state/local authorities. After further investigation, one non-fatal incident that appeared in the May 2015 memorandum describing data for the NPR was later determined to involve an infant bather, rather than an infant bath tub, and has been omitted from the data reported in this memorandum describing data for a draft final rule.

² The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the National Electronic Injury Surveillance System (NEISS). Ten (10) NEISS investigations (IDIs) were completed by CPSC staff, including 1 fatality, in the incident data counts and also in the NEISS section. The reported deaths and incidents in the counts are neither a complete count of all that occurred during this time period nor a sample of known probability of selection. However, they provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to infant bath tubs.

³ Date of extraction for reported incident data was 02/17/16. All data coded under product codes 1544 (baby baths or “bathinettes”) and 1557 (baby bathtub seats or rings (not toys)) were extracted. A second search criterion was used to pull data under product codes: 609, 610, 611, 4030 and 638 along with many narrative keywords. Upon careful joint review with infant bath tub team members, some cases were considered out-of-scope for the purposes of this memorandum. With the exception of incidents occurring in U.S. military bases, all incidents that occurred outside of the U.S. have been excluded. To prevent any double-counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

Fatalities

Thirty-one (31) fatalities were reported to have been associated with an infant bath tub during the time period January 2004 to December 2015. Twenty-nine (29) of the victims were between the ages of 4 and 11 months old; the other 2 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. In those fatalities, the parent or guardian left the child alone for a variety of reasons for at least a short period of time, and then returned to find the child submerged. Drowning was the cause of death reported for 30 of the 31 fatalities (the other fatality involved a child with a ventricular septal defect and the coroner listed that the immediate cause of death was attributed to pneumonia). The distribution of the 31 fatalities described above, by age in months, is shown in Figure 1.



Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS.

Non-Fatal Incidents

A total of 216 non-fatal incidents associated with infant bath tubs were reported to CPSC staff that occurred from January, 2004 through December, 2015. The 216 reports included 32 reports of injuries requiring first aid, professional medical attention or hospitalization. Nine of the injury reports were of children requiring hospital admission. Eight of the nine hospitalizations were due to near-drowning, and one was due to a scalding water burn. Near-drowning means a person almost died from not being able to breathe (suffocating) under water. 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. Ten of the injury reports required emergency department treatment: five were due to near-drowning, one due to rashes, one was due to mold on the product, one was due to slipping when attempting to stand, one was due to a toy detaching and hitting the child in the head, and one child had a concussion from a fall from a tub that was located on a counter top when a collapsible leg folded up. Eight of the injury reports were of children requiring treatment by a medical professional, of which six were due to mold on the product, one to a rash, and one to a laceration. Five incidents required first aid by a non-medical professional, four due to finger, hand or foot entrapments, and one laceration by a sharp edge by the drain hole of the tub.

Hazard Pattern Identification

CPSC staff considered all 247 (31 fatal and 216 non-fatal) incidents to identify the hazard patterns associated with infant bath tub related incidents. The hazard patterns were grouped into the following categories in order of frequency of incident reports:

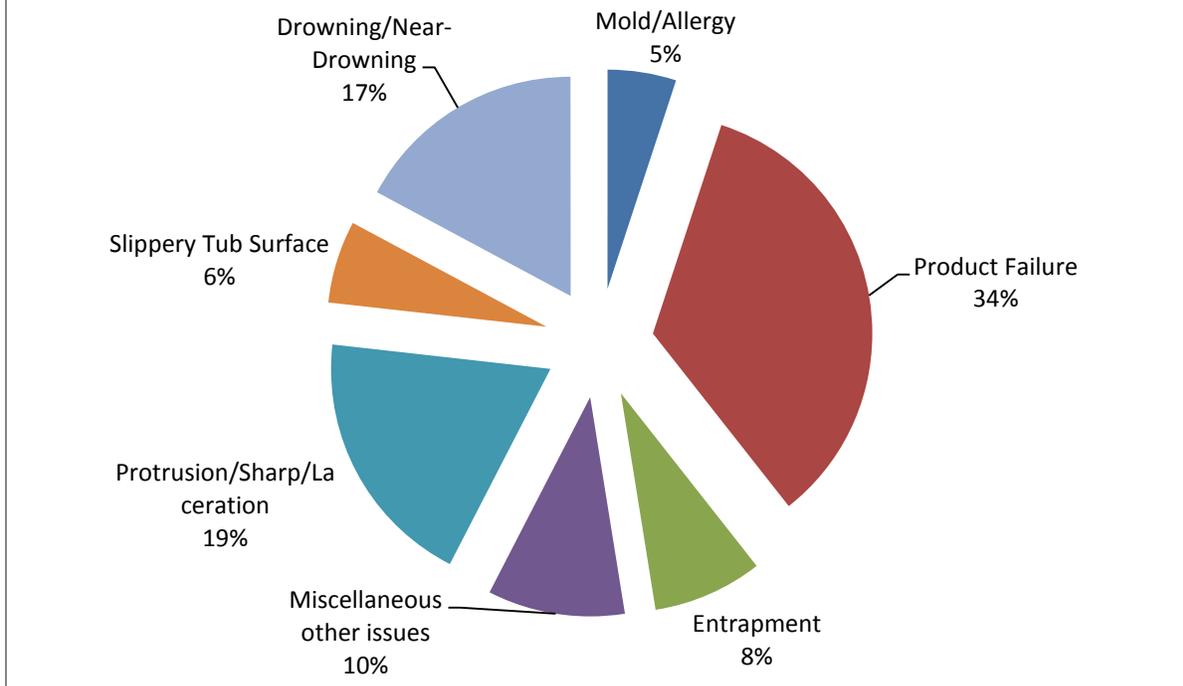
1. ***Drowning/Near-Drowning*** incidents account for 17% (43 out of 247) of reported incidents. Of the 43 drowning or near-drowning incidents, 30 were drowning fatalities and 13 were near-drowning incidents. In 38 of the 43 incidents, no parent or guardian was present at the time of the incident occurrence. In 4 of the other 5 incidents when the parent or guardian was present the child lived. Because most of the incidents involved no witness, staff cannot determine what led to the drowning. Generally, the child was found floating, but staff cannot determine a hazard scenario, such as whether the tub capsized, the child climbed out of the tub, the tub was slippery, there was too much water in the tub, or whether some other circumstances contributed to the incident. Only one fatality was not ruled a drowning by the coroner. This fatality is categorized in the *miscellaneous issues* category.
2. ***Protrusion/Sharp/Laceration issues*** account for 19% (48 out of 247) of reported incidents. This category commonly involves a part of the product that sticks out and a child rubbing against it in some way, causing red marks, cuts, or bruising. In most incidents, the protrusion is described as a 'bump' or 'hump' in the tub that the child rubs against causing the incident. In some reports, the 'hammock/sling' attachment is involved in this type of protrusion incident. The injured body parts reportedly involved toes, feet, bottom, genitalia, and back. The reported incidents in this category do not mention the infant sliding before being hurt on protruding parts in the tub, but this protrusion category can be confounded with the 'slippery tub surface' category. Both categories deal with contact with the surface of the tub, and both result in similar injury patterns. Of the 48 protrusion reports, one incident required attention from a medical professional, one incident required first aid, and the rest involved either an incident with no injury or a minor injury. The incident requiring a medical professional involved a scratch to the back of a child caused by a screw going through the tub during the tub assembly process. The incident requiring first aid involved a toe and foot being cut by a sharp edge near the drain area.
3. ***Product Failures*** account for 34% (85 out of 247) of reported incidents. Of the 85 reports, 2 required a trip to the hospital, and the rest involved either an incident with no injury or a minor injury. Two children who required hospital trips were both treated and released. One incident was due to a toy attached to the tub falling off the tub and causing a deep cut to the forehead; the second was due to a tub placed on a counter top that had a tub leg collapse, which caused the child to fall from the counter top to the floor, causing a concussion. Fifty-nine (59) incidents involved the 'hammock' or 'sling' attachment collapsing or breaking, and 8 incidents of the locking mechanism failing or breaking. The rest of the incidents involved various tub parts breaking.
4. ***Entrapment issues*** account for 8% (20 out of 247) of reported incidents. Entrapment incidents involve body parts getting caught or stuck in 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. Common places on the tub that body parts were being entrapped were in hinges, holes and the foot area inside the tub. Four injuries required first aid by a non-medical professional due to a finger, hand and foot

entrapment and swelling. Remaining reports were either an incident with no injury or a minor injury.

5. ***Slippery tub surface issues*** account for 6% (15 out of 247) of reported incidents. Common reported incidents and concerns include the body being scratched or hit by protrusions on the tub, or the potential for the head to become submerged. One emergency room visit involved pumping the stomach of a child that had slipped under water and swallowed some water, and the rest of the reports were either an incident with no injury or a minor injury.
6. ***Mold/Allergy issues*** account for 5% (12 out of 247) of reported incidents. Of the 12 incidents, 8 were attributed to mold, and 4 were allergy related. Reported issues included a variety of symptoms: itching, rashes, foul odor, respiratory issues, and a urinary tract infection. Eight incidents involved a single tub make and model, including 6 with mold and 2 with allergy incidents. Of the 12 incidents, there were 2 emergency room visits; one child may have developed an upper respiratory issue, and one child broke out in a rash all over the back. Seven children were seen by a medical professional, of which 4 had itching and rashes, one had a urinary tract infection, one had a severe cold with coughing, wheezing and fever, and one developed mold spores on the genitalia.
7. ***Miscellaneous issues*** accounted for the remaining 10% (24 out of 247) of the reported incidents. The incidents included reports of children falling out of the tub, unstable tubs, missing pieces, product component batteries leaking or overheating, rust, and scalding. Of the 24 miscellaneous issues, 7 were battery-related incidents. The miscellaneous category includes 1 fatality and 1 hospital admission. The fatality involved a child with a ventricular septal defect and the cause of death was attributed to pneumonia. The hospital visit was caused by scalding when 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. Remaining reports were either an incident with no injury or a minor injury.

Figure 2 shows the distribution of the 247 reported incidents by the hazard patterns described in categories 1 through 7 above.

Figure 2: Distribution of Incident Reports Associated with Infant Bath Tubs by Hazard Pattern Characterizations 01/01/2004 - 12/31/2015



Source: CPSC epidemiological databases IPIL, INDP, DTHS, and NEISS completed investigations (NEISS IDIs). Percentages do not sum to 100, due to rounding.

National Injury Estimates⁴

Staff estimates a total of 2,300 injuries (sample size = 89, coefficient of variation = 0.18) occurred over the twelve-year period from 2004 to 2015 related to infant bath tubs that were treated in U.S. hospital emergency departments. The weights for the 2016 data are not yet final so staff excluded these cases from injury estimates. The injury estimates for individual years are not reportable because they fail to meet publication criteria.⁵

⁴ The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS). NEISS injury data are gathered from emergency departments of hospitals selected as a probability sample of all the U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable the CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products. Staff extracted all data coded under product code 1544 (baby baths or “bathinettes”) and 1557 (baby bathtub seats or rings (not toys)). Staff used a second search criterion to pull data under product codes: 609, 610, 611, 4030 and 638 along with many narrative keywords. Staff did not use an age restriction in the search criteria. Staff reviewed incidents and removed records that were considered out-of-scope for the purposes of this memorandum. For example, staff excluded a child running into an infant bath tub or kicking an infant tub prior to deriving the statistical injury estimates.

⁵ 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% or smaller.

One drowning death was reported through the NEISS and is included in the fatality counts in the prior section. About 93 percent of the estimated emergency department visits were made by infants 12 months of age or younger and all but 3 cases involved children 2 years of age or younger. The cases involving children older than 2 years of age were: a 5-year-old receiving 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 fairly evenly among male and female children, with 52 percent female and 48 percent male 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 cases 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 (includes 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%).

**TAB B: EPHA Staff's Response to Public Comments to the
NPR for Infant Bath Tubs**

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

Memorandum

Date: January 31, 2017

TO : Celestine T. Kish
Infant Bath Tubs Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
Associate Executive Director, Epidemiology, EP
Directorate for Epidemiology

Stephen Hanway
Division Director, Hazard Analysis, EPHA
Directorate for Epidemiology

FROM : Adam Suchy
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : EPHA Staff's Response to Public Comments to the NPR for Infant Bath Tubs

This memorandum contains Directorate for Epidemiology, Division of Hazard Analysis (EP) staff's response to comments related to data referred to in the notice of proposed rulemaking (NPR) for Infant Bath Tubs (80 Federal Register 48769).

Comment regarding incident data:

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.

Staff Response:

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 regarding data trends:

One commenter stated that "...It can be observed from the current Incident Summary that incidents over the time period identified in the NPR have DECLINED over the years. Fatalities have significantly declined to 1 in 2013, 1 in 2014 and NONE in 2015. Non-fatalities have also significantly DECLINED, from a high of 21 in 2011 to 4 in 2015. The subcommittee's Incident Summary is included with here for reference. Based on the decline in incident data described above, I do not believe there is an urgency to promulgate a rule for Infant Bath Tubs immediately."

Staff Response:

The NPR data consists of incidents received by CPSC on or before May 20, 2015. Therefore, any comparison of the number of incidents reported to CPSC in 2015 to any past years is inappropriate because it does not represent the full year of 2015 data. In the NPR, of the overall

31 fatalities, there were four deaths reported in each of 2010 and 2011, two deaths reported in 2012 and one death in each of 2013 and 2014. In the most current infant bath tub Epidemiology memo, no deaths occurring in 2015 have been reported to CPSC as of February 17, 2016. CPSC generally *does not expect* completed reporting of fatal incidents for a particular year until 2 to 3 years later due to lag time in 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. As a result, 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.

The NPR included reported incidents received by CPSC on or before May 20, 2015, which do not include any incidents that occurred from May 20, 2015 through the rest of 2015. The NPR only included four reported incidents (all non-fatalities) that occurred in the year 2015. However, in the most recent infant bath tub data collection, with the inclusion of incidents reported to CPSC on or before February 17, 2016, the number of reported non-fatal reports received by CPSC has increased over the most recent years. There were 26, 31, and 44 reports received by CPSC for the years 2013, 2014 and 2015 respectively. There is a similar lag time period between the day a non-fatality incident or concern occurs and the date it is reported and received by CPSC.

There is no assurance that reporting to CPSC in any year is inclusive of all fatality, injury, or potential injury incidents that occurred in a given year, so CPSC considers reported anecdotal incidents to be a minimum. The degree to which reporting of an incident to CPSC for a given year would be inclusive is unknown and could change from year to year. Therefore, year to year changes in incident reporting should be done with extreme caution. The National Electronic Injury Surveillance System (NEISS) by contrast, provides a probabilistic estimation of injuries seen in emergency departments and thus allows for analysis of trends over time. No statistically significant trend (either increasing or decreasing) was identified for the 12-year time period from 2004 through 2015.

TAB C: Human Factors Staff Assessment of Warning Label Provisions and Response to Comments for Infant Bath Tubs Final Rule

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

Memorandum

DATE: January 31, 2017

TO: Infant Bath Tubs Briefing package

THROUGH: Joel Recht, Ph.D., Associate Executive Director
Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Division Director
Division of Human Factors
Directorate for Engineering Sciences

FROM: Celestine T. Kish, Senior Engineering Psychologist, and
Hope E J. Nesteruk, General Engineer, and
Timothy P. Smith, Senior Human Factors Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Staff Assessment of Warning Label Provisions and Response to
Comments for Infant Bath Tubs Final Rule

This memorandum discusses ASTM F2670-13 *Standard Consumer Safety Specification for Infant Bath Tubs* warning label provisions referenced in the notice of proposed rule (NPR) and provisions of the current F2670-17 recommended for inclusion in the final rule (FR) for infant bath tubs. Also included are responses to the major human factors issues and general issues raised in the comments submitted in response to the proposed rule for a safety standard for infant bath tubs in the *Federal Register* (80 *Fed. Reg.* 48769 (Aug. 14, 2015)) NPR, based on the voluntary standard, ASTM F2670-13.

BACKGROUND

The Commission issued the NPR for a safety standard for infant bath tubs in August 2015. The NPR was based on the 2013 version of ASTM's voluntary standard, ASTM F2670-13.

The NPR contained the following warning modifications to the ASTM standard:

1. Revised content of the warnings, markings, and instructions:
 - (a) changed the text in the drowning warnings to read:

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**; and

(b) added fall hazard warning:

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

- Place tub **only** [insert manufacturer’s intended locations(s) for safe use (*e.g.*, in adult tube, sink or on floor; in adult tub or on floor)].
 - **Never** lift or carry baby in tub.
2. Specified a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.
 3. 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.”

DISCUSSION

Revised content of the warnings, markings, and instructions

The NPR proposed 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 locations(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. In addition, the standard did not require a specific format for the warning labels. The Commission proposed in the NPR to separate the warnings to more clearly identify the drowning hazard and fall hazard and to provide guidance on how to avoid these hazards. In addition, some of the statements were made more personal by using the words “babies,” as opposed to “infant,” and “stay in arm’s reach of your baby,” as opposed to “ALWAYS keep infant within adult’s reach.” The ASTM Subcommittee for Infant Bath Tubs discussed the warnings proposed in the NPR and accepted the Commission’s edits except for one statement. The ASTM subcommittee decided that the drowning hazard statement “Keep drain open” needed to clarify that the drain in the adult tub should be kept open during bathing. The subcommittee balloted and approved “Keep drain open in adult tub or sink.” This revision, as well as the Commission edits noted above, is included in ASTM F2670-17. Staff agrees the added statement clarifies the directions to caregivers and recommends incorporating the revised warning in the draft final rule.

Warning label format

As stated above, F2670-13 did not require any specific formatting for the warnings. Human Factors staff regularly cites the ANSI Z535.4 *American National Standard for Product Safety Signs and Labels* as a baseline in developing warning materials. Commission-proposed changes on the formatting of warning labels in the NPR were consistent with the ANSI Z535.4 language.

Since the NPR was published, ASTM convened a task group, 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 voluntary standards. The Human Factors Division hazard communication subject matter expert,¹ who also is the CPSC staff representative on the ANSI Z535 committee, represented CPSC staff in this task group. Ad Hoc TG recommendations 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 reference document recommends wording very similar to the ANSI Z535.4, with modifications to make the Ad Hoc TG’s recommendations more stringent.

Subsequent to publication of the Ad Hoc Wording reference, the ASTM committee for F2670 balloted and approved incorporation of the Ad Hoc Wording reference recommendations into ASTM F2670-17. Accordingly, staff believes that adopting the Ad Hoc Wording reference document recommendations provides noticeable and consistent warning labels on infant bath tubs and across juvenile products. Therefore, staff recommends clarifying the warning label format requirements in the draft final rule by incorporating ASTM F2670-17.

Warning label font size

One modification proposed in the NPR that was unique to Infant Bath Tubs as opposed to the other durable infant and toddler products currently under rulemaking was to increase the safety alert symbol and the word “WARNING” text size 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.² The revision was proposed to align the labeling with ASTM F1967 *Standard Consumer Safety Specifications for Infant Bath Seats* which is already incorporated into a federal standard. The Ad Hoc Wording guidance document does not have this unique modification; rather, recommends the safety alert symbol, the word “WARNING”, and the statement of hazard text size 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. Thus, the Ad Hoc language keeps the size requirements consistent with the standard referenced in the NPR (F2670-13) as opposed to the increased size recommended in the NPR.

¹ Timothy P. Smith.

² 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.

Staff recognizes that increasing the size of the warnings was not the only change recommended in the NPR or through Ad Hoc guidance to improve the formatting and, therefore, effectiveness of the warnings. ASTM F2670-17 contains all of the Ad Hoc Wording guidance document recommendations. As stated above, the specific formatting changes 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 Commission staff regularly uses ANSI Z535.4, American National Standard for Product Safety Signs and Labels — the primary U.S. voluntary consensus standard for the design, application, use, and placement of on-product warning labels—when developing or assessing the adequacy of warning labels. Experts in human factors and warnings literature regularly cite ANSI Z535.4 when discussing the design and evaluation of on-product warning labels, and identify it as the minimum set of requirements that products containing such labels that are sold in the U.S. should meet (*e.g.*, Vredenburg & Zackowitz, 2005; Wogalter & Laughery, 2005). Hellier and Edworthy (2006) and Peckham (2006) report that this has been reaffirmed by the U.S. courts, who have accepted the ANSI Z535 series of standards, in general, and the ANSI Z535.4 standard, in particular, as the benchmark against which warning labels are evaluated for adequacy because these standards are seen as the state of the art (also see Laughery & Wogalter, 2006).

Two commenters urged the Commission to wait to publish the final rule until ASTM updated the standard incorporating the Ad Hoc warnings. The warning label changes in F2670-17 bring the formatting and language of the warning label in close alignment with the NPR proposal, except for the size requirements. However, staff believes all of the formatting and wording changes improve the labeling over the labeling in F2670-13, referenced in the NPR. CPSC staff cannot state definitively whether the formatting changes, along with the increased font size, will influence consumer's behavior more than the formatting changes alone. Therefore, staff recommends the Commission issue the draft final rule incorporating ASTM F2670-17 by reference without any modifications.

PUBLIC COMMENTS

This section of the memorandum responds to human factors issues raised in specific comments and general comments being addressed here as project manager.

Comment regarding use of a water line

Comment

Two commenters request that CPSC require a maximum water fill line on infant bath tubs. One commenter suggests that the “fill line demarcation be specified at depths of no greater than 2 inches.” The other comment suggests the manufacturer be responsible for providing a maximum fill line that is in a “suitable position.”

Staff Response

Commission staff is aware that similar comments regarding use of a water line were raised in comments to the infant bath seat NPR, but the water line was not included in the final rule. For the same reason as given for infant bath seats, staff continues to be concerned that a water 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 believes 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,” describes the risk associated with any level of water in a more accurate manner. At this time, CPSC staff does not believe a maximum water level requirement should be added to the standard. CPSC staff will continue to monitor this issue.

Use of icons/pictograms on labels

Comment

A commenter indicated that icons for key safety messages were clearer to consumers, but the commenter did not specifically recommend CPSC require use of icons/pictograms.

Staff Response

Staff acknowledges that icons/pictograms can be used to more effectively convey the hazard, especially for users with limited or no English literacy. However, the design of effective graphics can be difficult. Some seemingly obvious graphics are poorly understood and can give rise to interpretations that are opposite of the intended meaning (so-called “critical confusions”). Thus, although staff may recommend action in the future if we believe graphic symbols are needed to further reduce the risk of injury associated with infant bath tubs, at this time staff does not support mandating graphics for infant bath tubs.

Spanish labels

Comment

A commenter indicated that “any safety wording should be equally visible in Spanish as well as English.”

Staff Response

The NPR states that the warning label shall appear, at a minimum, in the English language. Staff does not dismiss the potential 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, staff’s prior analyses of the incident data associated with infant bath tubs have not revealed a pattern of incidents involving people who speak Spanish and not English. Thus, although the draft final rule does not prohibit manufacturers from providing the required warnings in languages other than English, the available information provides no basis for mandating that manufacturers to include warnings in Spanish.

Infant Bath Sling accessories

Comment

Two commenters urge CPSC to monitor ASTM’s work on including infant bath sling accessories to the infant bath tub standard.

Staff Response

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 commends the task group on the progress they have achieved to date and encourages the task group to finalize the recommendations so the ASTM subcommittee can discuss this progress and vote for inclusion of infant bath sling requirements into the infant bath tub standard.

Scope of standard

Comment

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

Staff Response

Section 104 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.” While infant bath tubs are considered durable infant or toddler products, no age requirement or 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. Staff does not recommend adding an age limit to this standard because safety requirements included in the ASTM standard benefit infants and toddlers across all intended ages of foreseeable users.

Warnings and Instructions

Comment

One commenter supports the “new wording as it is clearer,” and “new FALLING HAZARD is a good addition.” The commenter suggests adding an additional warning to “NOT USE ON RAISED SURFACES, SUCH AS TABLES OR WORKTOPS.”

Staff Response

Staff believes the fall warnings already included in ASTM F2670-17 adequately and succinctly convey the message of where the infant bath tub should be used safely based on the manufacturer’s intentions. Specifically, section 8.5.2.2 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 does not recommend further changes.

Comment

Two comments recommend 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.

Staff Response

As already discussed above, 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. Staff recommends incorporation of the new standard into the final rule.

Comment

One commenter stated that "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."

Staff Response

Proposed 16 C.F.R. § 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." After participating in the discussion with the ASTM task groups, staff agrees with the task groups' assessment that the requirement would be too subjective for testing laboratories to evaluate. Staff believes the specific changes made to the literature as a result of the changes made to the warning information will adequately convey the safe practices.

Miscellaneous issues

Comment

A commenter stated that while the commenter was appreciative of CPSC staff's work on the proposed rule, the commenter was concerned about CPSC staff's "ability to seemingly be able to arbitrarily change language or standards without any justification," stating further that "[i]t is the role of the Commission, **not professional staff** to dictate changes in policy." (Emphasis in comment).

Staff Response

CPSC staff 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 issuing the NPR the Commission expressed its policy decisions. Further, at ASTM meetings, CPSC staff is not speaking for the Commission but is expressing staff's views based on their 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. Staff's recommendation for the final rule is to incorporate F2670-17 without modification.

Comment

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

- 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.

Staff Response

The omission of Figure 1 from the NPR was purposeful. Figure 1 is referenced in paragraph 5.6 of ASTM F2670-13, and the Commission proposed to incorporate paragraph 5.6 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, staff agrees with the comment and references to figures are corrected in the final rule by incorporation of ASTM F2670-17 without modification.

Comment

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 which is subject to copyright restrictions. The commenter made several arguments in support of 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 into reference by 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 and 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.

Staff Response

The infant bath tub standard is authorized by Congress under section 104 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 C.F.R. 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 is 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 C.F.R. § 1031.11(f) and 1012. Once rulemaking commences, staff should also place 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.

The public is not less safe because final rules under section 104 of the CPSIA are based on a voluntary standard. Voluntary standards can generally 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

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 website:

- 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.

Staff Response

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 C.F.R. 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

A commenter suggested that a conflict of interest occurs when a government entity relies on a voluntary standards body, such as ASTM, which 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 6-7 pages long. The commenter asserted based on this that “the government is clearly an author of this work.”

Staff Response

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 that 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, staff recommends the Commission incorporate by reference the most recent voluntary standard, ASTM F2670-17, as the final rule for infant bath tubs without modification.

Comment

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 states 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 stated reliance on the Commission’s regulation at 16 CFR part 1031. The commenter stated that the Office of Government Ethics has provided the guidance on government employees serving on the board of external nonprofits which recommends an MOU between the agency, employee and the nonprofit organization to avoid violation of 18 U.S.C. § 208(a).

Staff Response

CPSC does not rely on a unique memorandum of understanding 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 C.F.R. part 1031) setting forth best practices and ethical responsibilities of employees involved in voluntary standards activities.

CONCLUSIONS

ESHF staff suggests incorporating ASTM F2670-17 into the final rule without any modifications.

REFERENCES

- American National Standards Institute. (2011). *ANSI Z535.4. American national standard: Product safety signs and labels*. Rosslyn, VA: National Electrical Manufacturers Association.
- Hellier, E., & Edworthy, J. (2006). Signal Words. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 407–417). Mahwah, NJ: Lawrence Erlbaum Associates.
- Laughery, Sr., K. R., & Wogalter, M. S. (2006). The Warning Expert in Civil Litigation. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 605–615). Mahwah, NJ: Lawrence Erlbaum Associates.
- Newens, S., Nesteruk H. E J, Smith, T. P. (2016). *Human Factors Assessment of ASTM 3118-15 Requirements for Infant Inclined Sleep Products (CPSIA Section 104)*. CPSC Memorandum to C. T. Kish, Infant Inclined Sleep Products Project Manager, U.S. Consumer Product Safety Commission, Bethesda MD.
- Peckham, G. M. (2006). An Overview of the ANSI Z535 Standards for Safety Signs, Labels, and Tags. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 437–443). Mahwah, NJ: Lawrence Erlbaum Associates.
- Smith, T. (2015). *Human Factors Assessment of ASTM F404 – 15 Requirements for High Chairs (CPSIA Section 104)*. CPSC Memorandum to S. Marques, High Chairs Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Vredenburg, A. G., & Zackowitz, I. B. (2005). Human Factors Issues to be Considered by Product Liability Experts. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 26). Boca Raton, FL: CRC Press.
- Wogalter, M. S., & Laughery, K. R. (2005). Effectiveness of Consumer Product Warnings: Design and Forensic Considerations. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 31). Boca Raton, FL: CRC Press.

TAB D: Infant Bath Tub Rulemaking: LSM Assessment of F2670 and Response to Comments

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

Memorandum

DATE: January 31, 2017

TO : Celestine T. Kish
Infant Bath Tubs Project Manager
Division of Human Factors
Directorate for Engineering Sciences

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

Michael Nelson
Division Director, Laboratory Sciences – Mechanical, LSM
Directorate for Laboratory Sciences

FROM : Ian B. Hall
Mechanical Engineer
Division of Laboratory Sciences – Mechanical, LSM

SUBJECT : Infant Bath Tub Rulemaking: LSM Assessment of F2670 and Response to
Comments

This memorandum contains Division of Laboratory Sciences – Mechanical (LSM) staff's responses to comments received regarding the notice of proposed rulemaking (NPR) for infant bath tubs. Staff's response follows each comment noted by commenter's designated number and direct quote.

I. Overview

This memorandum assesses the effectiveness of the current version of the standard, ASTM F2670-17, and includes CPSC staff's recommendation that the Commission publish a final rule (FR) that incorporates by reference the ASTM standard with no modifications.

As specified in the latest ASTM infant bath tub standard (F2670), an "infant bath tub" is defined as "a tub, enclosure, or other similar product intended to hold water...to provide support or containment, or both, for an infant in a reclining, sitting, or standing position during bathing by a

caregiver.”¹ An infant bath tub can be placed into an adult bath tub, sink, or on top of other surfaces. Infant bath tubs that can be inflated by air and infant bath tubs that use a removable mesh sling are included under the voluntary standard. However, the removable sling is specifically excluded from the scope of this standard, at this time. ASTM is working to include sling accessories in the standard in the near future.

II. Review of ASTM revisions, NPR, and FR

ASTM F2670 – 09:

The ASTM voluntary standard for Infant Bath Tubs, ASTM F2670, was originally published in March 2009.² In addition to the conventional general requirements contained in most of the other ASTM juvenile product standards, the 2009 standard defined three performance requirements: the restraint system components, static load-carrying capacity, and suction cup retention.

The restraint system requirement allowed passive crotch restraints, but expressly forbade other restraint systems that required caregiver action. According to the static load requirement, “the tub shall not break, become permanently damaged, or fail to comply with any other requirement” when subjected to 50 lb. or three times the maximum weight recommended by the manufacturer, whichever is greater. In the suction cup requirement, “Each suction cup shall remain attached to the product and shall not become damaged or broken after testing.” The standard specified two suction cup tests. In the first test, the suction cups are required to absorb a 25-lbf tensile load placed on each individual suction cup. In the second test, the suction cups are required to remain attached to the surface when the infant tub is installed and subjected to a 25 lbf tensile load a total of 2,000 times.

ASTM F2670 – 10:

The ASTM subcommittee approved a new version of the standard in March 2010 and published that version in April 2010. ASTM changed the F2670 – 10 standard in two distinct respects. First, the ASTM subcommittee added a definition of a *smooth test surface*, which is defined as “a rigid plastic, metal, or porcelain surface to which suction cups can attach.” The ASTM subcommittee referenced that new test surface definition in all of the suction cup retention test procedures, listed in section 7.5. In the second major change between the 2009 and the 2010 versions, ASTM updated the requirements for warnings on the product’s retail packaging. The 2010 language stated: “All warnings” must be distinctly separate from other wording or designs, while the 2009 version referenced only “Specified warnings.”

¹ Standard Consumer Safety Specification for Infant Bath Tubs (ASTM F2670-17). (2017). West Conshohocken, PA: ASTM International (ASTM).

² Standard Consumer Safety Specification for Infant Bath Tubs (ASTM F2670 - 09). (2009). West Conshohocken, PA: ASTM International (ASTM).

ASTM F2670–11:

In September 2011, the ASTM subcommittee published a new version, ASTM F2670-11, in which ASTM modified several warnings. In section 8.4.1, the subcommittee added a required safety alert symbol illustration and clarified the font height requirement for the “remainder text,” by specifying that the upper case letters must be at least 0.1 inches tall. Additionally, the subcommittee provided additional flexibility by changing the requirements for the drowning and adult supervision warning language. The old language specified that the warning must match the warning text in the standard, while the new language required that the warning text simply address the hazard. Thus, the standard allowed manufacturers to use their own wording on warning labels, as long as it addressed the hazard described in the standard.

ASTM F2670–11a:

The ASTM subcommittee published a revised version, ASTM F2670–11a, in December 2011. The subcommittee clarified the definition of an “infant bath tub” to allow the infant to recline, sit, or stand while being bathed by a caregiver.

ASTM F2670–12:

The F2670–12 version, published in December 2012, included two changes from F2670–11a. The first change was made to the label permanency tests, to allow the pre-conditioning ambient humidity to fluctuate within a range during the 24-hour drying period, before conducting the label permanency tests. The 2011 version specified a relative humidity of 50 percent, while the 2012 version allowed the relative humidity to vary between 20 percent and 70 percent. This change was made because testing laboratories could not condition the samples at exactly 50 percent relative humidity for 24 hours. The subcommittee determined that the original requirement was too severe and relaxing the range would not affect results.

The second change was to clarify the specific warnings required on the retail packaging’s principal display panel. The retail packaging’s principal display panel warning was changed to include the safety alert symbol, the hazard identification, and the drowning and adult supervision warnings; whereas in the prior F2670–11a version, only the safety alert symbol and the hazard identification warning had been required.

ASTM F2670–13:

There was one change and one clarification between the F2670 – 12 and F2670 – 13 versions. The change related to the warning language on the retail packaging’s principal display panel. The 2013 version, published in March 2013, allowed the removal of duplicate warnings on the retail packaging’s principal display panel, if the warning labels on the product were not concealed by the retail packaging, and the labels were visible in their entirety. The clarification also specified that packaging used exclusively for shipping shall not be considered retail packaging, and therefore, would be exempt from the label requirements.

Notice of Proposed Rulemaking (NPR):

For the NPR, CPSC mechanical engineering staff recommended two changes to the physical test methods in ASTM F2670-13. The first change was to the static load test, and the second related to the resistance to collapse test.

1. Static Load Test

The ASTM F2670-13 standard required that a sample absorb a static load, applied through a load distribution plate. ASTM F2670-13 Section 7.4.2 defined the load distribution plate as a “6 by 6-in. (150 by 150-mm) 3/4-in. (19-mm) thick block made of high density polyethylene (HDPE).” In particular, the standard did not specify a chamfer (*i.e.*, a shallow edge usually at an angle of 45 degrees to a corner) or radius on the bottom edge of the load distribution plate. Internal CPSC testing indicated that sharp corners on the load distribution plate could create stress concentrations and damage certain tub materials and geometries. Those stress concentrations and the resulting tub damage were not the intent of the standard and did not match real-world loading.

Therefore, at the fall 2014 ASTM subcommittee meeting, CPSC staff recommended that the ASTM subcommittee investigate altering the corner geometry on the load distribution plate by adding a 1/8th inch (3-mm) chamfer or radius on the load distribution plate, and CPSC staff proposed a change to the standard. The language recommended by CPSC is underlined, while a strike-through denotes a deletion.

7.4.2 Place a weight of 50 lb (13.6 kg) or three times the maximum weight recommended by the manufacturer, whichever is greater, on the center of the product and distribute it upon a 6 by 6-in. (150 by 150-mm) 3/4-in. (19-mm) thick block made of high density polyethylene (HDPE). The HDPE block shall have a 1/8-in. (3-mm) radius on all corners.

The ASTM subcommittee decided to modify the test method from a drop mass plus distribution plate to a shot bag.

7.4.2 Place a load on the center of the seating surface using a 6 to 8 in. (150 to 200 mm) diameter bag filled with steel shot and which has a total weight of 50 lb (22.7 kg) or three times the maximum weight of the child recommended by the manufacturer whichever is greater, on the center of the product. ~~And distribute it upon a 6 by 6 in. (150 by 150 mm) 3/4 in. (19 mm) thick block made of high density polyethylene (HDPE).~~

CPSC staff recommended using the exact wording that the subcommittee was proposing at the time of the NPR.

2. Resistance to Collapse

ASTM F2670 – 13 Section 5.4 *Resistance to Collapse* stated that a tub with two distinct operations shall not collapse when it is folded and unfolded 2,000 times. CPSC staff noted one potential issue with the test method in ASTM F2670-13 Section 7.1.2, *Latching or Locking Mechanism Durability*. The standard specified a rate of 12 cycles per minute, or roughly one cycle every five seconds. For more complicated latching or locking mechanisms, or for unlatching operations that cannot be automated easily, a rate of 12 cycles wasn't achievable by CPSC technical staff.

CPSC staff recommended during the fall 2014 ASTM subcommittee meeting that the ASTM subcommittee consider allowing the test frequency to vary between 12 and 8 cycles per minute. CPSC staff did not believe that increasing the average cycle time from 5 seconds to 7 seconds would have any measurable effect on the severity of the test, but it would allow the more complicated mechanisms to be tested according to the standard. The recommended additional language is underlined, while a strike-through denotes a deletion.

7.1.2 Latching or Locking Mechanism Durability—The latching or locking mechanism(s) shall be cycled through its normal operation a total of 2000 cycles. Each cycle shall consist of opening and closing the mechanism and erecting/folding the product. Cycling shall be conducted at a rate of between 8 cycles to 12 cycles per minute.

The ASTM subcommittee reworded CPSC staff's recommended language and, on the same ballot as the static load revision, balloted the following:

7.1.2 Latching or Locking Mechanism Durability—The latching or locking mechanism(s) shall be cycled through its normal operation a total of 2000 cycles. Each cycle shall consist of opening and closing the mechanism and erecting/folding the product. ~~Cycling shall be conducted at a rate of 12 cycles per minute.~~ Cycling shall be conducted on a continuous basis without any pause between cycles except for rest periods for the person (or the test equipment) conducting the cycling consisting of a one 3-minute rest after every 7 minutes of cycling.

The balloted wording received a few negative votes; and after discussion in the subcommittee meeting on May 5, 2015, the subcommittee agreed upon new wording, and the wording was balloted on June 11, 2015. The balloted wording was:

7.1.2 Latching or Locking Mechanism Durability—The latching or locking mechanism(s) shall be cycled through its normal operation a total of 2000 cycles. Each cycle shall consist of opening and closing the mechanism and erecting/folding the product. ~~Cycling shall be conducted at a rate of 12 cycles per minute.~~ Cycling shall be conducted on a continuous basis.

Add the following rationale to the non-mandatory Appendix of the standard
X1.2 Section 7.1.2 – The timing of the durability cycling was revised so as to accommodate latching or locking mechanisms on some products that may require longer

than 5 seconds to activate and deactivate. Continuous cycling is being prescribed to accommodate these potential longer activation/deactivation cycles.

LSM staff believed that the standard, as balloted, was overly broad and recommended that the standard update the Appendix to define more clearly the intent of the standard, relative to the latching mechanism test rate. The suggested new language is underlined below.

Add the following rationale to the non-mandatory Appendix of the standard

X1.2 Section 7.1.2 – The timing of the durability cycling was revised to accommodate those latching or locking mechanisms that may require longer than 5 seconds to either activate or deactivate, but the intent of the standard is to cycle the mechanism at a rate as close to 12 cycles per minute as can be reasonably achieved for the specific mechanism.

Staff recommended these changes to the Resistance to Collapse test be included in the NPR and ASTM standard.

ASTM F2670-16:

After the NPR but before the ASTM language was balloted, the subcommittee chairman made light editorial changes to the static load test language. This created two sets of similar but not identical language: the NPR language and the new language in the ASTM proposal. The modified ballot passed the ASTM approval process, and the changes were incorporated in ASTM F2670-16. A strike-through identifies language that was initially proposed by the ASTM subcommittee and that CPSC had included in the NPR but was deleted by the ASTM subcommittee chairman prior to the ballot.

7.4.2 Place a load on the center of the seating surface using a 6 to 8 in. (150 to 200 mm) diameter bag filled with steel shot ~~and~~ which has a total weight of 50 lb (22.7 kg) or three times the maximum weight of the child recommended by the manufacturer whichever is greater, ~~on the center of the product.~~

CPSC technical staff had no objections to the edits in ASTM F2670-16, specifically in Section 7.4.2. With the F2670-16 revision, ASTM addressed all the mechanical engineering issues identified by staff.

ASTM F2670-16a:

The revision, ASTM F2670-16a, did not include any changes to physical testing requirements or test methods. The updates focused on warnings and labels, which is discussed in the Human Factors memo.³

³ Memorandum from Celestine Kish, Hope Nesteruk, and Timothy Smith, January 31, 2017. Subject: Human Factors Staff Assessment of Warning Label Provisions and Response to Comments for Infant Bath Tubs Final Rule.

ASTM F2670-17:

The latest revision, ASTM F2670-17, did not include any changes to physical testing requirements or test methods. The update was a correction to the instructional literature requirements.

III. Response to comments

Comment: Latching or Locking Mechanism Durability

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

Staff Response

Revision ASTM F2670-16, included updates to the Latching or Locking Mechanism test methodology in Section 7.1. The latest revision, ASTM F2670-17, uses identical language in that section.

LSM staff agrees with the Locking Mechanism Durability test language in ASTM F2670-17 Section 7.1, and LSM staff recommends using that language in the Final Rule.

Comment: Latching or Locking Mechanism Durability rationale

Two commenters recommended including the revised latching or locking mechanism durability test language rationale (X1.1 Section 7.1.2) in the final rule.

Staff Response:

Revision ASTM F2670-16, included updates to Appendix Section X1.1 Subsection 7.1.2. The latest revision, ASTM F2670-17, uses identical language in that section.

LSM staff agrees with the language in ASTM F2670-17 Appendix Section X1.1 Subsection 7.1.2, and LSM staff recommends using that language in the Final Rule.

Comment: Static Load test protocol

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

Staff Response:

At the time of the NPR, LSM staff recommended using the exact wording that the ASTM sub-committee was proposing. Subsequent to the NPR, the ASTM sub-committee chairman made editorial changes to the proposal, which resulted in the slight differences between the NPR and ASTM F2670-16. The ASTM sub-committee released a new revision, ASTM F2670-17, but there were no modifications in Section 7.4.

LSM staff agrees with the editorial changes made to the static load test procedure and thus recommends using the static load test language listed in ASTM F2670-17 Section 7.4 *Static Load Test* for the Final Rule.

Comment: Bath Stands

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 concern about an influx of European designed products have matching stands coming into the U.S. market.

Staff Response:

Commenter stated that infant bath tub stands are not covered by the current standard, ASTM F2670-17 *Standard Consumer Safety Specification for Infant Bath Tubs*.

CPSC staff is not aware of any incident data involving bath tub stands. Staff will monitor incident data and the retail market for use of these products, but at this time staff does not recommend any changes to the final rule to include bath tub stands.

IV. Conclusion

CPSC LSM staff recommends that the Commission publish a final rule that incorporates by reference the ASTM voluntary standard F2670-17 with no modifications.

TAB E: Final Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Infant Bath Tubs and Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bath Tub Standard

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**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

Memorandum

Date: January 31, 2017

TO : Celestine Kish
Project Manager, Infant Bath Tubs

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

Robert Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Samantha Li
Economist
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis of Staff-Recommended Final Standard for Infant Bath Tubs and Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bath Tub Standard

Introduction

On August 14, 2015, the Commission published a notice of proposed rulemaking (NPR) in the *Federal Register* (80 *Fed. Reg.* 48,769). The NPR proposed to incorporate by reference the voluntary standard for infant bath tubs (F2670-13) with a few modifications. Since the NPR, ASTM has published F2670-16, which includes the latching and locking mechanisms and static load test methods proposed by the Commission, and has approved and published F2670-17, which includes the changes to the warning labels proposed by the Commission. Staff recommends incorporating by reference ASTM F2670-17 into a final rule.

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. An initial regulatory flexibility analysis (IFRA) was published with the proposed rule. Section 604 of the RFA requires a final regulatory flexibility analysis (FRFA) when an agency promulgates a final rule unless the agency certifies that the rule will not have significant economic impact on a substantial number of small businesses. 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 and the Commission could so certify.

The Product

As specified in the ASTM standard (F2670-17), an infant bath tub is a tub, enclosure, or other similar product intended to hold water for an infant in a reclining, sitting, or standing position during bathing. An infant bath tub can be placed into an adult bath tub, sink, or on top of other surfaces to provide support. Infant bath tubs that can be inflated by air are included under the voluntary standard.

The Market for Infant Bath Tubs

Typically, infant bath tubs are produced and/or marketed by juvenile 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.¹

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

During the 12 year period from 2004 through 2015, the Directorate for Epidemiology² estimates that 2,300 hospital emergency department-treated injuries involving children under age 2 years involved infant bath tubs, or about 192 injuries annually. Therefore, about 0.22 emergency department-treated injuries may occur annually for every 10,000 infant bath tubs *owned*, and about 0.44 emergency department-treated injuries annually for every 10,000 infant bath tubs *in use*.

Reason for Agency Action and Legal Basis for the Staff-Recommended Final Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. In the NPR, the Commission proposed adopting the voluntary standard, with some modifications, which CPSC staff believes were needed to make the standard more stringent. Since the publication of the NPR, ASTM has adopted F2670-16, which included the changes to the test procedures for durability of latching and locking mechanisms, and the static load test, which were all proposed by the Commission and subsequently approved and published by ASTM in F2670-17, including the warning label

¹ Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firms' websites.

² Memorandum from Adam Suchy, Directorate for Epidemiology, dated April 6, 2016, Subject: Infant Bath Tubs-Related Deaths, Injuries and Potential Injuries, and NEISS Injury Estimates January 2004 – December 2015.

statements proposed by the Commission. CPSC staff now recommends that the draft final rule incorporate the current voluntary standard, ASTM F2670-17, without any modifications.

Issues Raised by Public Comments

The Directorate for Economic Analysis responded to three public comments.

Comment

One commenter, a domestic manufacturer of inflatable infant bath tubs, asserted that it would be adversely affected by several provisions of the proposed rule. The proposed rule would require the manufacturer to provide consumers with prepaid product registration cards and to provide an option for consumers to register via the Internet. The commenter asserted that this would increase its costs by 1.5 to 2.0 percent on an ongoing basis.

Staff Response

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 proposed rule. In 16 C.F.R. part 1130, the Commission determined that infant bath tubs are durable infant or toddler products and 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 therefore, will be unaffected by the proposed rule.

Comment

The commenter also 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. The commenter also said that the company would likely “cease manufacturing inflatable bath tubs for sale in the U.S.,” if the standard is codified as currently written.

Staff Response

Staff believes that the commenter may have misunderstood some of the requirements of the proposed rule and 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. There is no requirement that establishes a minimum expected life of the product itself.

Comment

One commenter stated that the cost of the labelling is not as small as indicated. 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.

Staff Response

Although the commenter asserted that the labelling cost would be greater than indicated, the commenter did not provide any specific estimates of the commenter’s expected labelling costs, and staff has not identified any other information indicating that the costs would be significantly higher than suggested in the NPR. Therefore, staff does not have a basis for changing the conclusion regarding the labeling costs in the IRFA.

Compliance Requirements of the Staff-Recommended Final Rule

CPSC staff recommends incorporating by reference the voluntary standard for infant bath tubs, without any changes. Key components of the current ASTM standard for infant bath tubs (F2670-17) include:

- static load requirement – intended to prevent breakage during use;
- latching or locking requirement– ensures the durability of latching and locking mechanisms; and
- warning label statements and instructional literature requirements – intended to provide greater clarification of hazards associated with infant bath tubs.

The voluntary standard also includes: (1) requirements to prevent cuts (hazardous sharp edges or points, small parts, minimum and maximum opening sizes, and scissoring, shearing, and pinching); (2) requirements for lead in paints; (3) requirements for the permanency and adhesion of labels; (4) requirements for a passive crotch restraint system; (5) requirements for protective components; (6) requirements for toy accessories, if present; (7) requirements to ensure that suction cups adhere to the product and attached surface; and (8) warning labels and instructional literature, including language emphasizing that infants have drowned while using infant bath tubs.

The revised bath tub warning label and instructional literature statements elaborate on the potential fall and drowning hazards scenarios and simplify warning statements for comprehension. Requirements for labeling now include specifying the font size, format style, and color that may be used for marking and labeling.

Other Federal Rules

CPSC staff has not identified any federal or state rule that either overlaps or conflicts with the staff-recommended final rule.

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.

Small Domestic Manufacturers

The impact of the staff-recommended draft final rule on small manufacturers will differ, based on whether manufacturers' infant bath tubs are already compliant with F2670-16. Although ASTM approved a new standard (F2670-17) was approved and published in January 2017, firms that were in compliance with ASTM F2670-16 are likely to continue to comply with the new voluntary standard.

Staff believes that the impact of the draft final rule is unlikely to be significant for most small manufacturers. Based on information on firms' websites, six domestic manufacturers currently comply with F2607 – 16. This includes two infant bath tub manufacturers that are certified by the Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, as compliant with the voluntary standard. 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 F2607-17. Based upon past discussions with Mechanical Engineering staff, the modifications are expected 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 would 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 draft final rule is likely to be small for most producers who do not comply with 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.

Small Domestic Importers

Most importers would not experience significant impacts as a result of the staff-recommended draft final rule. Four of the five small importers are believed to be compliant with the F2670-16 voluntary standard, and therefore would only need to assure that their suppliers make the label modifications to comply with the draft proposed rule. Complying with the draft final rule could be more difficult for the remaining importer because changes beyond simple modifications to the warning label are probably necessary. The other importer, who CPSC staff does not believe to be 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 draft proposed 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 its infant bath tub is compliant with the current bath tub standard and the firm only would need to modify existing warning labels. In any case, this firm should not experience large impacts since 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.

Summary

Staff is recommending that the Commission adopt ASTM F2670-17, which covers infant bath tubs, without modification. 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 standard. Because the products are not complex, the modifications that would be 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. The cost of these modifications is expected to be low. Firms will incur additional costs associated with third

party testing. However, the impact is unlikely to be economically significant for most firms. Therefore, adopting ASTM F2670-17 without modification would not be expected to have a significant impact on a substantial number of small entities and the Commission could so certify.

The 1112 Rule and the Impact on Small Conformity Assessment Bodies

In accordance with section 14 of the CPSA, children's products that are subject to a children's product safety rule must be tested by one of the accredited conformity assessment bodies (*i.e.*, testing laboratories) for compliance with applicable product safety rules. These accreditation requirements have been codified for existing rules at 16 C.F.R. part 1112. Consequently, the Commission proposed an amendment to 16 C.F.R. part 1112 that would establish the accreditation requirements for the testing laboratories that want to test for compliance with the infant bath tub final rule.

A final regulatory flexibility analysis (FRFA) was conducted as part of the original 1112 rule (78 *Fed. Reg.* 15,836, 15,855-58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small testing laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only 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.

Based on similar reasoning and the fact that the cost to the few U.S. laboratories that are expected to seek acceptance of their accreditation to test for conformance to the infant bath tub standard would probably be limited to the cost of adding the standard to their scope of accreditation, the Commission certified that the Notice of Requirements (NOR) amending 16 CFR 1112 to include the NOR for the infant bath tub standard would not have a significant adverse impact on small laboratories. No public comments were received, nor is the staff aware of any new information, that would cause it to question the certification that the amendment to 16 CFR 1112 would not have a significant impact on a substantial number of small entities.