



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
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 BETHESDA, MD 20814

This document has been electronically
 approved and signed.

DATE: JULY 22, 2015

BALLOT VOTE SHEET:

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
 Patricia H. Adkins, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
 Ray M. Aragon, Special Attorney, OGC

SUBJECT: Proposed Rule: Safety Standard for Infant Bath Tubs

BALLOT VOTE DUE: July 28, 2015

The Office of the General Counsel is providing for Commission consideration the attached draft notice of proposed rulemaking for publication in the *Federal Register*. The proposed rule would establish a safety standard for infant bath tubs under the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008. Staff recommends that the Commission propose adoption of the voluntary standard with several modifications staff believes will augment the impact of the required warnings and instructions and improve the accuracy, consistency, and repeatability of durability and strength testing.

Please indicate your vote on the following options:

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

 (Signature)

 (Date)

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 Email: test@cirs-group.com

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: Proposed Rule to Establish a Safety Standard for Infant Bath Tubs

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1234

CPSC Docket No. 2015-[INSERT]

Safety Standard for Infant Bath Tubs

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

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,” “CPSC,” or “we”) 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 proposing a safety standard for infant bath tubs in response to the direction under Section 104(b) of the CPSIA. In addition, the Commission is proposing an amendment to 16 CFR part 1112 to include 16 CFR part 1234 in the list of notice of requirements (NORs) issued by the Commission.

DATES: Submit comments by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed mandatory standard for infant bath tubs should be directed to the Office of Information and Regulatory Affairs, the Office of

CIRS|C&K Testing
www.cirs-ck.com
hotline: 4006-721-723
Email: test@cirs-group.com

Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC 2015-[INSERT], may be submitted electronically or in writing:

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

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

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

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number CPSC-2015-[INSERT], into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Celestine T. Kish, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email: ckish@cpsc.gov; telephone: (301) 987-2547.

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 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 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 infant bath tubs 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 Fed. Reg. 68668, 68669 (Dec. 29, 2009); 16 C.F.R. § 1130.2(a)(16).

Pursuant to section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this notice of proposed rulemaking (“NPR”), largely through the standards development process of ASTM International (formerly the American Society for Testing and Materials) (“ASTM”). The proposed rule is based on the voluntary standard developed by ASTM, ASTM F2670-13, *Standard Consumer Safety Specification for Infant Bath Tubs* (“ASTM F2670-13”), with several modifications to strengthen the standard.

The testing and certification requirements of section 14(a) of the Consumer Product Safety Act (“CPSA”) apply to product safety standards promulgated under section 104 of the CPSIA. Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (test laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The infant bath tub standard, if issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR. To meet the requirement that the Commission issue an NOR for the infant bath tub standard, this NPR proposes to amend 16 CFR part 1112 to include 16 CFR part 1234, the CFR section where the infant bath tub standard will be codified if the standard becomes final.

II. Product Description

A. Definition of Infant Bath Tub

ASTM F2670-13 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.” ASTM F2670-13 § 3.1.2. Falling within this definition are products of various designs, including “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. The ASTM standard 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.” *Id.* § 6.1. ASTM F2670-13 excludes from its scope “products commonly known as bath slings, typically made of fabric or mesh.” *Id.* § 1.1.

B. Market Description

CPSC staff is aware of at least 26 firms that supply infant bath tubs to the U.S. market. Twenty-three of these firms are domestic, including 14 manufacturers, eight importers, and one with an unknown supply source. Three foreign companies export directly to the United States via Internet sales or to U.S. retailers.

III. Incident Data

CPSC staff has received detailed reports from various sources of 202 incidents related to infant bath tubs from January 1, 2004 through May 20, 2015. Thirty-one of these incidents (15%) were fatal. Of the 146 victims whose age could be determined, 141 (97%) were under 2 years of age. In the 168 incidents in which the sex of the child was reported, 54 percent of the victims were male, and 46 percent of the victims were female.

A. Fatalities

Thirty-one fatalities were reported to have been associated with infant bath tubs from January 1, 2004 through May 20, 2015. Drowning was the reported cause of death for 30 of the fatalities (97%); the remaining fatality involved a child with a heart defect, whose death was attributed to pneumonia. Twenty-nine of the fatality victims (94%) were between 4 months and

11 months of age; the remaining two fatality victims were 23 months and 3 years of age. In all but one of the drowning fatalities, a parent or caregiver left the victim alone in the infant bath tub, and returned to find the child submerged. Sixteen of the fatalities (52%) were male, while 15 (48%) were female.

B. Nonfatal Injuries

One hundred seventy-one nonfatal incidents associated with infant bath tubs were reported to have occurred from January 1, 2004 through May 20, 2015. The 171 reports included 30 reports of injuries requiring hospitalization (nine reports), emergency room treatment (nine reports), treatment by a medical professional (eight reports), or first aid (four reports). The nine incidents requiring hospitalization included eight near-drowning incidents in which a child almost died from suffocation under water, and one scalding water burn. All eight near-drowning incidents resulting in hospitalization occurred while the parent or caregiver was not present. The nine incidents requiring emergency room treatment consisted of five near-drowning incidents, a head injury caused by a bath toy detaching from a tub, a concussion from a fall from a tub located on a counter when a tub leg collapsed, one rash, and an injury caused by mold on a tub. The eight injury reports requiring a visit to a medical professional consisted of one laceration, one rash, and six injuries involving mold. The four incidents requiring home first aid resulted from finger, hand, and foot entrapments.

C. Hazard Pattern Identification

CPSC staff considered all 202 (31 fatal and 171 nonfatal) reported infant bath tub incidents to identify the hazard patterns associated with infant bath tub-related incidents. Staff grouped the hazard patterns into the following categories in order of frequency:

1. ***Drowning/Near Drowning*** incidents account for 43 out of 202 (21%) of the reported incidents. Thirty of these 43 incidents were drowning fatalities; the remaining 13 incidents involved near-drownings. In 38 of the 43 drowning or near-drowning incidents (88%), the parent or guardian was not present at the time the incident occurred. Because there were no witnesses to a majority of drowning or near-drowning incidents, determining exactly what happened is difficult. Generally, the child was found floating, but exactly what transpired was unclear. One incidental fatality was attributed to pneumonia rather than drowning; this incident is discussed in the “Miscellaneous Issues” category.

2. ***Protrusion/Sharp/Laceration issues*** accounted for 39 out of 202 (19%) of the reported incidents. In most of these incidents, the child made contact with a part that protrudes from the tub, causing red marks, cuts, or bruising. The body parts reportedly injured were toes, feet, bottom, genitalia, and back. In 29 of the 39 incidents, a protrusion described as a “bump” or “hump” caused a red mark or discomfort to the infant. In many of these protrusion incidents, a “hammock/sling” attachment was involved.

Only one of the 39 “protrusion” incident reports required a hospital visit; in that incident, a child’s back was scratched by a screw that penetrated the tub wall. The remaining 38 incidents in this category resulted in a minor injury or no injury.

3. ***Product failures*** accounted for 53 out of 202 (26%) of the reported incidents. In 28 incidents, the “hammock” or “sling” collapsed or broke, and in eight incidents the tub’s locking mechanism failed or broke. The remaining 17 “product failure” incidents involved various tub parts breaking. In two of the 53 “product failure” incidents a child was treated at a hospital and released; in the remaining incidents, there was either no injury or a minor injury. In one of the incidents requiring a hospital visit, a toy attached to a tub fell and caused a deep cut on

a child's forehead. In the second incident, the leg of a tub collapsed, causing a child to fall from the counter top supporting the tub onto the floor, resulting in a concussion.

4. ***Entrapment issues*** accounted for 20 out of 202 (10%) of the reported incidents. Entrapment incidents involved fingers, arms, feet, legs, or genitalia caught or stuck on parts of the tub, mostly in a pinching manner. Many of these injuries occurred in tubs that fold. Hinges, holes, and the foot area inside a tub were common areas of entrapment. These entrapment incidents resulted in no injury or minor injury; there were no reported hospitalizations.

5. ***Slippery tub surface issues*** accounted for 14 of 202 (7%) of the reported incidents. These incidents resulted in minor skin abrasions or scratches, and potential submersions. These incidents resulted in no injury or minor injury.

6. ***Mold/Allergy issues*** accounted for 12 of 202 (6%) of the reported incidents. Eight incidents were attributed to mold, and four were allergy related. The reported issues included itching, rashes, foul odor, respiratory issues, and a urinary tract infection. Eight of these incidents, six involving mold issues and two involving allergy issues, involved a single infant tub make and model. The 12 reported incidents included two emergency room visits, one for an upper respiratory issue, and one for a rash on the child's back. In seven additional incidents, children were seen by a medical professional for itching and rashes (four incidents), a urinary tract infection, a severe cold with fever, and the presence of mold spores on the genitalia.

7. ***Miscellaneous issues*** accounted for 21 out of 202 (10%) of the reported incidents. The issues included falling out of a tub, an unstable tub, missing pieces, batteries leaking or overheating, rust, and scalding. Miscellaneous issues resulted in one fatality and one hospital admission. The fatality involved a child with a ventricular septal defect whose death was attributed to pneumonia. The hospital visit was caused by scalding when a parent poured hot

water from a stove onto a tub's foam cushion and then placed the child in the tub. The rest of the reports involved no injury or a minor injury.

D. National Injury Estimates

CPSC also evaluates data reported through the National Electronic Injury Surveillance System (NEISS), which gathers summary injury data from hospital emergency departments selected as a probability sample of all the U.S. hospitals with emergency departments. This surveillance information enables CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products. Based on a review of emergency department visits related to infant bath tubs for the years 2004 to 2014, staff estimates that there were 2,200 injuries treated in U.S. hospital emergency rooms over that 11-year period associated with infant bath tubs (sample size = 82, coefficient of variation = 0.18).² The NEISS data included one infant death, which has been included in the fatality statistics reported above. Approximately 94 percent of the victims were 12 months of age or younger and only one of the 82 reported NEISS cases involved a child older than 24 months.

For the injuries reported through NEISS, the most prominent hazard was falling, which occurred in 33 percent of the incidents. Drowning or near-drowning occurred in 22 percent of the incidents. Head injuries were common (35%), as were body injuries (22%), and face injuries (18%). In more than 80 percent of the NEISS cases, the victim was treated at the emergency room and released, while 15 percent were admitted or transferred to a hospital.

² NEISS reports for infant bath tub incidents are summary in nature and provide limited detail for determining hazard scenarios. For that reason, NEISS incident data are not included in our analysis and discussion of overall hazard patterns, unless a NEISS incident report was supplemented by further investigation.

IV. The ASTM Infant Bath Tub Standard

A. History of ASTM 2670-13

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of “consumer groups, juvenile product manufacturers, and independent child product engineers and experts” to “examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products.” As a result of incidents arising from infant bath tubs, CPSC staff requested that ASTM develop voluntary requirements to address the hazard patterns related to their use. Through the ASTM process, CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public, and the infant bath tub standard was developed.

ASTM F2670 was first approved in 2009, and then revised in 2010, 2011, 2012, and 2013. The current version, ASTM F2670-13, was approved on February 15, 2013, and was published in March 2013.

B. Description of the Current ASTM Voluntary Standard-ASTM 2670-13

ASTM F2670-13 contains both general and performance requirements to address the hazards associated with infant bath tubs. ASTM F2670-13 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

Scope. This section states the scope of 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 F2670-13 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 F2670-13 excludes from its scope “products commonly known as bath slings, typically made of fabric or mesh.” *Id.* § 1.1.

Terminology. This section provides definitions of terms specific to this standard.

Requirements and Test Methods. These sections set both general and performance requirements to address several hazards, many of which are also found in the other ASTM juvenile product standards. These requirements and test methods address:

- Sharp edges or points (incorporating CPSC standards for sharp edges and sharp points³);
- Small parts (incorporating CPSC standards for small parts⁴);
- Lead in paint and surface coatings (incorporating CPSC lead and surface coating standards⁵);
- Passive restraints;
- Size and safety requirements for attached toys (incorporating CPSC toy standards⁶);
- Resistance to collapse or displacement in use;
- Durability and strength of locking components;

³ See 16 CFR section 1500.48 (sharp point standard) and 1500.49 (sharp edge standard).

⁴ See 16 CFR part 1501 (small part limitations).

⁵ See 16 CFR part 1303 (limitations on lead in paint and surface coatings).

⁶ See ASTM F963, *Standard Consumer Safety Specification for Toy Safety* (ASTM F963).

- Displacement of protective components;
- Adherence of suction cups;
- Permanence of labels and warnings;
- Protection from scissoring, shearing and pinching
- Limits on openings; and
- Labeling.

Marking and Labeling. This section contains various requirements related to warnings, labeling, and required markings for infant bath tubs. This section prescribes various substance, format, and prominence requirements for such information.

Instructional Literature. This section 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.

V. Assessment of Voluntary Standard ASTM F2670-13

Staff considered the fatalities, injuries, and non-injury incidents associated with infant bath tubs, and evaluated ASTM F2670-13 to determine whether the ASTM standard adequately addresses the incidents, or whether more stringent standards would further reduce the risk of injury associated with these products. We discuss the staff's assessment in this section.

A. Warnings and the Risk of Drowning Due to Inattention by Parent or Caregiver

From 2004 to 2014, 30 drowning fatalities and 13 near-drowning incidents have been associated with infant bath tubs. In 29 of the 30 drowning fatalities (97%), the caregiver left a child alone in an infant bath tub. In 38 of 43 total drowning or near-drowning incidents (88%), the child was left alone when the incident occurred.

From the perspective of setting product standards, the only way caregiver behavior, such as leaving an infant unattended in an infant bath tub, can be addressed is through warnings and instructions to caregivers. Staff reviewed the warnings and instructions required by ASTM F2670-13 to determine whether the ASTM standard's provisions are adequate or a more stringent standard would reduce the risk of drowning and near-drowning associated with these products. The currently required warnings include the phrases: "WARNING – DROWNING HAZARD," in bold capital letters, "Infants have DROWNED in infant bath tubs" (with the word "DROWNED" in bold capital letters), and "ALWAYS keep infant within adult's reach."

Staff determined that these current warning requirements allow for considerable variation in the conspicuity and format of the warnings presented to consumers. Staff's research suggests that the impact of these warnings would be improved by providing specific guidance for a more consistent and prominent presentation of hazard information. Staff's research also indicates that changes to the size, color, content, and format of required warnings and instructions could augment the impact of the warnings and instructions for infant bath tubs, resulting in a higher level of caregiver compliance.

Staff developed suggested wording and formatting changes for infant bath tubs that staff believed would improve the warning and instructions sections of the voluntary standard. Staff circulated these proposed wording and formatting changes to the ASTM subcommittee responsible for ASTM F2670-13, and discussed the proposed changes at a public ASTM meeting in May 2015. In response to feedback received from ASTM and stakeholders, staff made adjustments to staff's proposed warnings and instructions.

The Commission now proposes to adopt ASTM F2670-13 with modifications to some of the warnings and instructions for infant bath tubs. In particular, the Commission proposes the following modifications:

- Increasing the size of the text in the on-product warnings to make the warnings for infant bath tubs consistent with Commission requirements for warnings for a similar product, infant bath seats;
- Requiring the use of a “hazard color” in the on-product and retail package warnings;
- Revising the warning content to simplify and clarify the language and to add specific language to address the risk of falls; and
- Specifying the format of the warnings on the product, on the retail packaging, and in the accompanying instructions to increase the potential impact of the warnings and provide a more consistent presentation of hazard information.

Based on research relating to the efficacy of warnings and instructions, staff believes that these changes will help capture and maintain caregiver attention, personalize the tone of the warnings, be simpler to comprehend than the current warnings, and provide consistency with the warnings regarding baby bath seats, a similar product. These changes, plus the new required warning of the risk of falls, may result in increased caretaker comprehension of, and compliance with, product warnings and instructions. The Commission believes that these changes constitute more stringent warning and labeling requirements than the current standard, and will further reduce the risk of injury to infants and toddlers associated with infant bath tubs.

B. Hazards Related to Protrusion/Sharp/Laceration Issues

Protrusion issues were involved in 39 of 202 (19%) of the reported incidents. In one incident, a protruding screw scratched a child, resulting in a hospital visit; and other incidents involved red marks, cuts, or bruising from rough or protruding edges. However, staff found no trends in the incident data involving scrapes or cuts.

In most of the “protrusion” incidents, a “hump” or “bump” in the tub, designed to help older infants sit upright, caused a red mark or discomfort for the infant, typically when the infant bath tub was used with a hammock or sling attachment and the child made contact with the “hump.” As discussed in more detail in section IV.C. of this preamble, ASTM has formed two task groups to develop new infant sling performance requirements.

C. Hazards Related to “Bath Sling” Products

The current ASTM standard specifically excludes bath slings, which are net or mesh products that do not hold water, attached to an infant bath tub or a frame, and used for bathing newborn babies and young infants. Several infant bath tub models include bath slings as part of the tub, or as an accessory.

Staff is aware that 28 of the 53 “product failure” incidents involved bath hammocks or slings. Staff and ASTM are working to investigate how the observed risks of bath slings should be addressed. In addition, ASTM formed two task groups to address the risks of bath slings. One group is developing performance requirements for infant slings that can only be used with infant bath tubs, which will be addressed in the infant bath tub standard. A second group is developing requirements for bath slings that are used separately or as tub accessories, which will be addressed under a new, separate standard.

D. Latching or Locking Mechanism Testing

A number of incidents involved tub locking mechanisms that failed or broke. Staff believes the current standard for latch mechanism testing in ASTM F2670-13, Section 7.1.2., which requires that latches be tested more than 2,000 cycles, is appropriately stringent. However, staff also has observed that some complex locking and latching mechanisms are difficult to test within the required “cycle time” of 12 cycles per minute. Staff has worked with ASTM to find an alternate method of conducting this test to make testing results for infant bath tubs more accurate and consistent. Staff has determined that requiring the 2,000-cycle testing to be conducted on a “continuous basis” will allow more designs of infant bath tubs to be tested consistently and accurately to the standard of Section 7.1.2. Moreover, ASTM is currently considering adopting the change that staff suggested to ASTM, but has not yet done so.

In this NPR, the Commission proposes to modify Section 7.1.2 to improve the accuracy and consistency of the mandatory product testing. The Commission also proposes adding an Appendix regarding Section 7.1.2, to clarify that although the cadence of testing has changed to accommodate a broader variety of infant bath tub designs, the intent of the standard is to require continuous testing while maintaining a rate as close to 12 cycles per minute as can reasonably be achieved. The Commission believes these changes will augment product safety, by improving the accuracy, consistency, and repeatability of durability testing.

E. Static Load Testing.

The static load testing requirement and the testing for resistance to collapse in the infant bath tub standard is intended to address the issue of breaks. Infant bath tubs are required to support a load of 50 lbs. (22.7 kg.), or three times the maximum weight recommended by the manufacturer, whichever is greater, for 20 minutes. Staff believes that the current load testing

provides an appropriate level of protection from breakage. However, staff also has determined that the current testing standard, which mandates the use of a 6" x 6" block of high-density polyethylene to provide the required weight, may damage some infant bath tub designs, which could create additional risks. Staff recommended to ASTM that the required polyethylene block be rounded on the corners; but ASTM decided to replace the block with a bag of steel shot for static load testing. This matter was addressed at an ASTM public meeting, was balloted and approved by ASTM, and will be added to the next published edition of the ASTM standard. The Commission believes that including this modification in the NPR will augment product safety by improving the accuracy, consistency, and repeatability of static load testing.

F. Entrapment

Entrapments accounted for 20 of 202 reported incidents (10%). Most of the incidents involved body parts becoming stuck or caught in a tub, and most of those incidents involved pinching. Many of the incidents involved folding tubs. However, staff found no trends in this incident data. The Commission believes that the current infant bath tub standard's requirements for scissoring, shearing, and pinching (§ 5.5) and Openings (§ 5.6) are appropriate to protect the public.

G. Slippery Surfaces

Slippery tub surfaces accounted for 14 of the 202 reported incidents (7%), resulting in abrasions and submersions but no injuries. Most of these incidents contain little detail. Therefore, the Commission is not proposing any modifications to the ASTM infant bath tub standard regarding this issue. Staff will continue to monitor, collect, and study details on slip-related fall and submersion incidents in infant tubs. In addition, staff will work with ASTM, if warranted, to

develop appropriate performance requirements to address slip-related fall and submersion incidents.

H. Mold/Allergy Issues

The mold and allergy issues involved itching, rashes, foul odor, respiratory issues, and a urinary tract infection. This is a difficult issue to address through performance requirements because the issue arises from the consumer's inability to clean and dry the infant tub to prevent mold. Therefore, the Commission is not proposing any modifications to the ASTM infant bath tub standard regarding this issue. However, CPSC staff will continue to review the incident data. If warranted, staff will address this matter through the ASTM process to determine whether additional instructions or warnings would be effective in reducing this risk.

7. Miscellaneous Issues

Miscellaneous issues included falling out of the tub, unstable tubs, missing pieces, batteries leaking or overheating, rust and scalding. Incidents in this category included one fatality that was attributed to pneumonia and one hospitalization from scalding. The rest of the reports were incidents with no injury or a minor injury. Staff's review of these miscellaneous incidents did not result in any recommendations to change the infant bath tub standard.

VI. Proposed CPSC Standard for Infant Bath Tubs

The Commission is proposing to incorporate by reference ASTM F2670-13, with certain modifications to strengthen the standard. As discussed in the previous section, the Commission concludes that these modifications will further reduce the risk of injury associated with infant bath tubs.

Section 1234.1 would state the scope of the rule; infant bath tubs. The definition of "infant bath tub" is provided in ASTM F2670-13 § 3.1.2.

Section 1234.2(a) would incorporate by reference ASTM F2670-13, with the exception of certain provisions that the Commission proposes to modify.

Section 1234.2(b) would detail the changes and modifications to ASTM F2670-13 that the Commission has determined would further reduce the risk of injury from infant bath tubs. In particular:

- Section 7.1.2, *Latching or Locking Mechanism Durability*, would be changed to permit continuous testing of infant bath tub latches through 2,000 cycles. An Appendix regarding Section 7.1.2 would be added to clarify that the cadence of testing has been changed to accommodate tubs that could not be tested at the previous rate of 12 cycles per minute, but that testing is to be conducted continuously while maintaining a rate as close to the previous standard as possible.
- Section 7.4.2 would be changed to require that a 50 lb. (22.7 kg) bag of steel shot is to be used to test infant bath tubs in the required static load testing, rather than a block of high-density polyethylene, which might damage or puncture some tubs. Additionally, the text of this section would be changed to make the required weight equivalent, whether stated in pounds or kilograms.
- Section 8.4 would be changed to require warning statements on infant bath tubs and infant bath tub retail packaging to have prescribed warning language, and for the warning statements to be permanent, conspicuous, in contrasting color(s), bordered, and in type larger than currently required. Section 8.4 will also require additional warnings for infant bath tubs with suction cups. The changes would be accompanied by exemplar warnings.

- Section 9 would be changed to require that instructional literature for infant bath tubs contain new prescribed warnings regarding the risks of drowning or falling; explain the proper use of the product; and emphasize the safety practices stated in the warnings. The instructions must also address appropriate temperature ranges for bath water, and instruct users to discontinue use of infant bath tubs that become damaged, broken, or disassembled. The changes would be accompanied by an exemplar warning.

VII. Incorporation by Reference

Section 1234.2(a) of the proposed rule incorporates by reference ASTM F2670-13. The Office of the Federal Register (“OFR”) has regulations concerning incorporation by reference. 1 CFR part 51. The OFR recently revised these regulations to require that, for a proposed rule, agencies must discuss in the preamble to the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons, or explain how the agency worked to make the materials reasonably available. In addition, the preamble to the proposed rule must summarize the material. 1 CFR 51.5(a).

In accordance with the OFR’s requirements, section IV.B. of this preamble summarizes the provisions of ASTM F2670-13 that the Commission proposes to incorporate by reference. ASTM F2670-13 is copyrighted. By permission of ASTM, the standard can be viewed as a read-only document during the comment period on this NPR, at: <http://www.astm.org/cpsc.htm>. Interested persons may also purchase a copy of ASTM F2670-13 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org>. One may also inspect a copy at CPSC’s Office of the Secretary, U.S. Consumer Product Safety

Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923.

VIII. Amendment of 16 CFR Part 1112 to Include NOR for Infant Bath Tubs

The CPSA establishes certain requirements for product certification and testing. 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). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which a children's product is subject. *Id.* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1234, Safety Standard for Infant Bath Tubs, if issued as a final rule, would be a children's product safety rule requiring 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), codified at 16 CFR part 1112 (“part 1112”) and effective on June 10, 2013, establishing requirements for CPSC acceptance of third party conformity assessment bodies 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 all of the NORs previously issued by the Commission.

All new NORs for new children's product safety rules, such as the infant bath tub standard, require an amendment to part 1112. To meet the requirement that the Commission issue an NOR for the proposed infant bath tub standard, as part of this NPR, the Commission

proposes to amend the existing rule that codifies the list of all NORs issued by the Commission to add infant bath tubs to the list of children's product safety rules for which the CPSC has issued an NOR.

Test 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 part 1112. 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, *Standard Consumer Safety Specification for Infant Bath Tubs*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

IX. Effective Date

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). The Commission is proposing an effective date of 6 months after publication of the final rule in the Federal Register for products manufactured or imported on or after that date. The proposed rule does not require manufacturers to make design or manufacturing changes; rather, the proposed rule requires only that manufacturers create and print new labels. The two product testing recommendations require a simple change in equipment (replacing a block of high-density polyethylene with a 50-lb. shot bag), and a timing change in the cycle testing for latches or locking mechanisms. Similar equipment and testing methods are already used in child product testing, so the testing changes can be made without delay. The 6-month period will allow ample time for manufacturers and importers to arrange for third party testing, and this is consistent with the timeframe adopted in a number of other section 104 rules.

We also propose a 6-month effective date for the amendment to part 1112.

We ask for comments on the proposed 6-month effective date.

X. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (“RFA”) requires agencies to consider the impact of proposed rules on small entities, including small businesses. The RFA generally requires agencies to review proposed rules for their potential impact on small entities and prepare an initial regulatory flexibility analysis (“IRFA”) unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. §§ 603 and 605. Because staff was unable to estimate precisely all costs of the draft proposed rule, staff conducted such an analysis. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA must contain:

- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule; and

- a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and minimize the rule’s economic impact on small entities.

B. Market Description

CPSC staff is aware of at least 26 firms that supply infant bath tubs to the U.S. market. Twenty-three of these firms are domestic. Of the domestic firms, 14 are manufacturers, eight are importers, and one has an unknown supply source. Seventeen of the domestic firms qualify as “small firms” under the guidelines of the U.S. Small Business Administration (“SBA”). Three foreign companies export to the United States via Internet sales or to U.S. retailers.

C. Reason for Agency Action and Legal Basis for Proposed Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards that are substantially the same as or more stringent than, the voluntary standards for durable infant or toddler products. The proposed rule implements that congressional direction.

D. Other Federal Rules

Section 14(a)(2) of the CPSA requires every manufacturer and private labeler of a children’s product that is subject to a children’s product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory that the product complies with all applicable children’s product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards requiring children’s products to be tested periodically and when there has been a material change in the product, and safeguarding against any undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing these requirements, *Testing and Labeling Pertaining to Product Certification* (16

CFR part 1107) became effective on February 13, 2013 (the “1107 Rule”). If a final children's product safety rule for infant bath tubs is adopted by the Commission, infant bath tubs will be subject to the third party testing requirements, including record keeping, when the final rule becomes effective.

Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (*i.e.*, testing laboratories) for each children's product safety rule. The NORs for existing rules are set forth in 16 CFR part 1112. If the Commission adopts a final rule on infant bath tubs, publication of a NOR establishing requirements for the accreditation of testing laboratories will be required.

E. Impact of the New Standards and Testing Requirements on Small Businesses

Under SBA guidelines, a manufacturer of infant bath tubs is categorized as “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, 17 of the 23 domestic firms known to be supplying infant bath tubs to the U.S. market are small firms: 10 manufacturers, six importers, and one firm with an unknown supply source.

Small Domestic Manufacturers. The impact of the proposed rule is not likely to be significant for small manufacturers. Based on information on firms’ websites, staff believes six domestic manufacturers already comply with the current infant bath tub standard. 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 already in compliance with the infant bath tub standard will not need to make physical modifications to

their products, but will have to make modifications regarding the warnings and instructions with their products. The costs of modifying existing labeling are usually small.

The four domestic manufacturers who do not appear to be in compliance with the infant bath tub standard might need to modify their products. However, these modifications are likely to be minor because the products are not complex; infant bath tubs generally are 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. Therefore, the impact of the proposed rule is likely to be small for producers who do not yet comply with the infant bath tub standard.

Under section 14 of the CPSA, should the Commission adopt the infant bath tub standard as a final rule, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing and labeling rule (16 CFR part 1107). Third party testing will include any physical and mechanical test requirements specified in the final infant bath tub rule that may be issued; lead 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 infant bath tub 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, which were, on average, about \$29 million annually, it seems unlikely that the impacts of the rule will be economically significant for small producers.

Small Domestic Importers. Staff believes that four of the six small importers are compliant with the current infant bath tub standard, and would only need to assure that their suppliers make the label modifications to comply with the proposed rule. The two remaining importers 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 proposed rule. Alternatively, these firms may discontinue importing infant bath tubs altogether and perhaps substitute another product.

Importers of infant bath tubs will be subject to third party testing and certification requirements, and will experience the associated costs if their supplier(s) does not perform third party testing. Based upon review of the firms' revenues, which were, on average, about \$4.0 million annually, the impact of the testing requirements could exceed 1 percent of revenues if the firms needed to test more than one unit per model. Hence, staff cannot rule out a significant economic impact on small domestic importers 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 to be compliant with various standards for several of its other infant products. It is possible that its infant bath tub is already compliant with ASTM F2670-13, and thus, would only have to modify existing labels. Regardless, this firm should not experience large impacts because infant bath tubs are only one of many products this firm supplies.

In summary, staff concluded that the impact of the proposed rule is unlikely to be economically significant for most firms, but is unable to conclude that the proposed rule would not have a significant economic impact on small importers.

Alternatives. Under section 104 of the CPSIA, the Commission is required to promulgate a standard that is either substantially the same as the voluntary standard or more stringent. The

Commission could promulgate the existing voluntary standard without revision. However, the proposed warning labels and testing procedures are not expected to have a substantial impact on costs to small businesses. Another alternative that would reduce the impact on small entities is to set an effective date later than the proposed 6 months. This would allow manufacturers additional time to modify and/or develop compliant infant bath tubs, thus spreading the costs associated with compliance over a longer period of time.

F. Impact of Proposed 16 CFR Part 1112 Amendment on Small Businesses

As required by the RFA, staff conducted a Final Regulatory Flexibility Analysis (“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 testing 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.

Based on similar reasoning, amending 16 CFR part 1112 to include the NOR for the infant bath tub 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 conformance to other mandatory juvenile product standards, and the only costs to them would be the cost of adding the infant bath

tub standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR amending 16 CFR part 1112 to include the infant bath tub standard will not have a significant impact on a substantial number of small entities.

XI. Environmental Considerations

The Commission's regulations address whether we are 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 exempt from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

XII. Paperwork Reduction Act

This proposed rule 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 (“PRA”) (44 U.S.C. 3501-3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Infant Bath Tubs

Description: The proposed rule would require each infant bath tub to comply with ASTM F2670-13, with the changes proposed in this Notice, which contains requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import infant bath tubs.

Estimated Burden: We estimate the burden of this collection of information 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
1234.2	26	3	78	1	78

Our estimate is based on the following:

Section 8.1 of the infant bath tub standard requires that the name of the manufacturer, distributor, or seller, and either the place of business (city, state, and mailing address, including zip code) or telephone number, or both, to be marked clearly and legibly on each product and its retail package. Section 8.1.2 requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture. Section 8.4 describes required safety labeling.

There are 26 known entities supplying infant bath tubs to the U.S. market. All firms are assumed to use labels already on both their products and their packaging, but they may need to make some modifications to their existing labels. Based on an informal survey by staff, the estimated time required to make these modifications is about 1 hour per model. Each entity

supplies an average of three different models of infant bath tubs; therefore, the estimated burden associated with labels is 1 hour per model \times 26 entities \times 3 models per entity = 78 hours. We estimate the hourly compensation for the time required to create and update labels is \$30.19 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2015, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$2,354.82 ($\30.19 per hour \times 78 hours = \$2,354.82). No other operating, maintenance, or capital costs are associated with the collection.

Section 9.1 of the infant bath tub standard requires instructions to be supplied with the product. Infant bath tubs are products that generally require use and/or assembly instructions. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the “normal course of their activities” are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are “usual and customary.” We are unaware of infant bath tubs that generally require use instructions, but lack these instructions. Therefore, we tentatively estimate that there are no burden hours associated with section 9.1 of the infant bath tub standard, because any burden associated with supplying instructions with infant bath tubs would be “usual and customary” and not within the definition of “burden” under the OMB's regulations.

Based on this analysis, the proposed standard for infant bath tubs would impose a burden to industry of 78 hours at a cost of \$2,355 annually.

In compliance with the PRA (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to

submit comments regarding information collection by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

XIII. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where 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 would apply to a rule issued under section 104.

XIV. Request for Comments

This NPR begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for infant bath tubs, and to amend part 1112 to add infant bath tubs to the list of children's product safety rules for which the CPSC has issued an NOR. We invite all interested persons to submit comments on any aspect of the proposed mandatory safety standard for infant bath tubs and on the proposed amendment to part 1112. Specifically, the Commission requests comments on the costs of compliance with, and testing to, the proposed mandatory infant bath tub standard, the proposed 6-month effective date for the new mandatory infant bath tub standard, and the amendment to part 1112.

Comments should be submitted in accordance with the instructions in the ADDRESSES section at the beginning of this notice.

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, and Toys

For the reasons discussed in the preamble, the Commission proposes to amend 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, 15 U.S.C. 2063, Pub. L. No. 110-314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. No. 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) Except as provided in paragraph (b) of this section, each infant bath tub shall comply with all applicable provisions of ASTM F2670-13, *Standard Consumer Safety Specification for Infant Bath Tubs*, approved February 15, 2013. 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.

(b) Comply with ASTM F2670-13 with the following additions or exclusions:

(1) Instead of complying with section 7.1.2 of ASTM F2670-13, comply with the following:

(i) 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 on a continuous basis.

(ii) [Reserved]

(2) Add as an Appendix to ASTM F2670-13, the following:

(i) 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, but the intent of the standard is to cycle the latching or locking mechanisms at a rate as close to 12 cycles per minute as can be reasonably achieved for the specific mechanism.

(ii) [Reserved]

(3) Instead of complying with section 7.4.2 of ASTM F2670-13, comply with the following:

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

(ii) [Reserved]

(4) Instead of complying with section 8.4 of ASTM F2670-13, including all subsections of section 8.4, comply with the following:

(i) 8.4 Each product shall be labeled with warning statements. The warning statements shall be in contrasting color(s), permanent, conspicuous and in non-condensed sans serif typeface. All warning(s) shall be distinctively separated from any other wording or designs and shall appear in the English language at a minimum. The specified warning label may not be placed in a location that allows the warnings to be obscured or rendered inconspicuous when in the manufacturer's recommended use position.

(A) 8.4.1 Warning Label Format – The safety alert symbol (▲) and the word “WARNING,” shall be at least 0.4 in. (10 mm) 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. The safety alert symbol (▲) and signal word “WARNING” shall be delineated with a bold solid line black border. The background color behind the safety alert symbol (▲) and signal word “WARNING” shall be orange, red, or yellow, whichever provides best contrast against the product background. The remainder of the label text shall be black and in upper and lower case letters on a white background surrounded by a bold solid line black border. Text within the message panel shall be left-justified. Precautionary statements shall be indented from hazard statements and preceded by bullet points. Message panels within the label shall be delineated with solid black lines between sections addressing different hazards. If an outer border is used to surround the bold solid black lines of the label, the outer border shall be white and the corners may be radiused. An example label in the format described in this section is shown in Fig. 2.

(B) 8.4.2 The following warning statement shall be included exactly as stated below:

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

(C) 8.4.3 Additional warning statements shall address the following:

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

(D) 8.4.4 The following warning statement shall be included exactly as stated below:

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

(E) 8.4.5 Additional warning statements shall address the following:

- Use **only** [insert safe location(s), e.g., in adult tub, sink, or on floor; in adult tub or on floor)].
- **Never** lift or carry baby in tub.

(F) 8.4.6 The drowning hazard warning statements and the fall hazard warning statements in 8.4.2 through 8.4.5 may be displayed on separate labels. If the fall hazard warning statements are displayed on a separate label, the label shall comply with the requirements of 8.4.1 except that the safety alert symbol (▲) and the signal word “WARNING” shall be at least 0.2 in. (5 mm) in height and the remainder of the text shall be at least 0.1 in. (2.5 mm) in height. The fall hazard warning label shall not be displayed above or before the drowning hazard warning label.

(G) 8.4.7 Products utilizing suction cups as an attachment mechanism to the support surface, and which are not intended by the manufacturer to be used on any type of slip-resistant surface, shall also include a warning to this effect. In addition, if there are other types of surfaces that the manufacturer does not intend the product be used on, then additional warning(s) shall be given regarding such surface(s). Such warning(s) shall use the signal word WARNING preceded by the safety alert symbol, and shall meet the requirements described in 8.4.1.

(5) Instead of complying with section 8.5 of ASTM F2670-13, comply with the following:

(i) 8.5 Each product’s retail package shall be labeled on the principal display panel as specified in 8.4 except that the safety alert symbol (▲) and the word “WARNING” shall be at least 0.2 in. (5 mm) high and the remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm) high. The warnings and statements are not required on the retail

package if they are on the product and visible in their entirety and are not concealed by the retail package. Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(ii) [Reserved]

(6) Instead of complying with section 9 of ASTM F2670-13, including all subsections of section 9, comply with the following:

(i) **9. Instructional Literature**

(A) 9.1 All products shall have instructional literature enclosed that explains the proper use of the product and that shall be easy to read and understand. Such literature shall include instructions for assembly, maintenance, cleaning, inspections, and limitations of the product, as well as the manufacturer's recommended use position(s).

(B) 9.2 *Warning Statements in Instructional Literature:*

(1) 9.2.1 Instructional literature shall include the warnings specified in 8.4.2 through 8.4.7. The phrase "To prevent drowning" shall be added before the bulleted statements in 8.4.3 and the phrase "To prevent falls" shall be added before the bulleted statements in 8.4.5.

(2) 9.2.2 Warning statements in instructional literature shall also address the following:

- Babies can drown in as little as 1 inch of water. Use as little water as possible to bathe your baby.

- **Never** rely on a toddler or preschooler to help your baby or alert you to trouble.

Babies have drowned even with other children in or near bath tub.

(3) 9.2.3 Warning statements in instructional literature shall meet the requirements described in 8.4 except that the background and text in the signal word panel need not be in color, and the remaining text shall be in highly contrasting colors, (e.g., black text on white). An example label that meets the requirements is shown in Fig. 3.

(C) 9.3 In addition to the warnings, the instructional literature shall emphasize and reinforce the safe practices stated in the warnings.

(D) 9.4 Instructional literature shall also advise to test the temperature of the water in, or being put into, the infant bath tub prior to placing the infant into the product. Instructions shall also indicate that the typical water temperature for bathing a baby should be between 90 and 100°F (32.2 and 37.8°C).

(E) 9.5 Instructional literature shall instruct to discontinue the use of the product if it becomes damaged, broken, or disassembled.

(F) 9.6 Instructional literature shall include the information as specified in 8.3.

(G) 9.7 Warnings, statements, or graphic pictorials shall not indicate or imply that the infant may be left in the product without a caregiver in attendance.

(7) Add the following Figure 2 to ASTM F2670-13, as follows:

WARNING

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

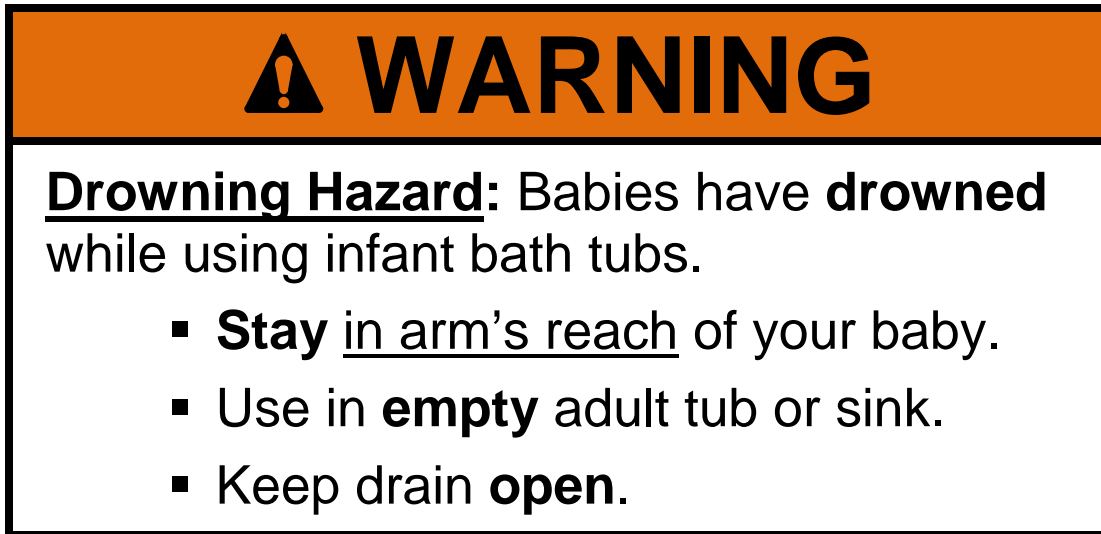
- **Stay** in arm's reach of your baby.
- Use in **empty** adult tub or sink.
- Keep drain **open**.

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.

Fig. 2 Example label that meets the requirements of Section 8 with the drowning and fall hazards combined in a single label.

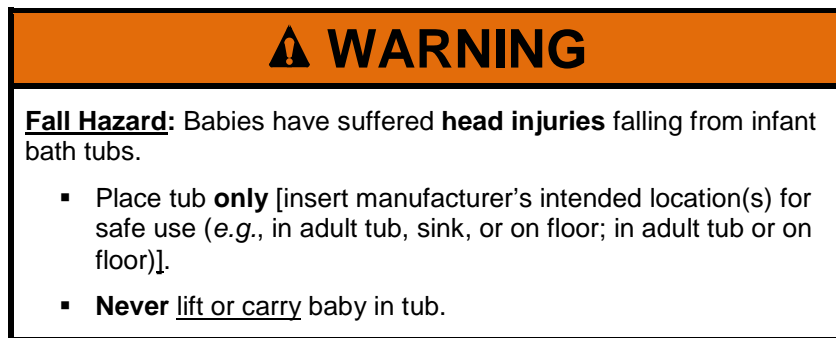
(8) Add the following Figure 3 to ASTM F2670-13, as follows:



⚠ WARNING

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**.



⚠ WARNING

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.

Fig. 3 Example labels that meet the requirements of Section 8 when the drowning hazard warning and fall hazard warning are presented in separate labels.

(9) Add the following Figure 4 to ASTM F2670-13, as follows:

WARNING

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

To prevent drowning: Stay in arm's reach of your baby.

- **Never** rely on a toddler or preschooler to help your baby or alert you to trouble. Babies have drowned even with other children in or near bath tub.
- Babies can drown in as little as **1 inch** of water. Use as little water as possible to bathe your baby.
- Use in an **empty** adult tub or sink.
- **Always** keep drain **open**.

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

To prevent falls:

- 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.

Fig. 4. Example label that meets the requirements of Section 9. Note: The fall hazard warning need not be presented in 0.2 in. text if it is displayed separately from the drowning hazard warning.

Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



Staff Briefing Package

Draft Notice of Proposed Rulemaking (NPR) for Infant Bath Tubs under the Danny Keysar Child Product Safety Notification Act

July 2015

Table of Contents

Briefing Memorandum iii

TAB A: Infant Bath Tub-Related Deaths, Injuries and Potential Injuries, and NEISS Injury Estimates
Reported Between January 1, 2004 and May 20, 201519

TAB B: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in Infant Bath Tubs.....19

TAB C: Staff Letter to ASTM Subcommittee Regarding ASTM F2670 Infant Bath Tubs41

TAB D: LSM Staff’s Recommendations for Infant Bath Tubs NPR49

TAB E: Staff Letter to ASTM Subcommittee Regarding Ballot F15 (15-04), Item 756

TAB F: Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Infant Bath tubs;
Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment
Bodies for Testing Conformance to the Infant Bath Tub Standard569

Briefing Memorandum

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

Memorandum

DATE: July 22, 2015

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel

Patricia H. Adkins, Executive Director

Robert J. Howell, 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: Notice of Proposed Rulemaking (“NPR”) for Infant Bath Tubs

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. 68668 (December 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 briefing package pertains to products that are included within the scope of the current voluntary standard, ASTM F2670 – 13, *Standard Consumer Safety Specification for Infant Bath Tubs*. The briefing package also reviews the relevant incident data and assesses the standard’s effectiveness. In addition, the briefing package discusses the potential impact of staff’s recommendations on small businesses, reviews recent recalls associated with infant bath tubs, and provides staff’s recommendations to the Commission. Additionally, the draft NPR includes a notice of requirements (“NOR”), which explains how test laboratories could become CPSC-accepted third party conformity assessment bodies to test infant bath tubs to the new safety standard.

II. BACKGROUND

A. Products

An “infant bath tub” is defined in ASTM F2670 – 13 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.” The voluntary standard states: “specifically excluded from the scope of this standard are products commonly known as bath slings, typically made of fabric or mesh.” The standard was developed in response to incident data supplied by CPSC staff to address drowning incidents and infant bath tubs that collapse.

B. ASTM Voluntary Standard Overview

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, 2011, 2012, and 2013. The current version, ASTM F2670 – 13, was approved on February 15, 2013, and

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

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published in March 2013.

The ASTM standard contains both general and performance requirements and references CPSC requirements for sharp edges or points, small parts, and lead in paint. There are also mechanical requirements for resistance to collapse, scissoring, shearing, and pinching. If infant bath tubs have restraint systems or suction cups, the restraint systems and suction cups are subject to specific performance requirements. The standard also addresses labeling for potential hazards, such as drowning.

The current version of the standard was published in 2013, and therefore, the subcommittee did not conduct any subcommittee meetings in fall 2013 or spring 2014. Upon the request of CPSC staff, the subcommittee convened meetings in fall 2014 and spring 2015 for CPSC staff to present and discuss staff's assessment of F2670 – 13 *Standard Consumer Safety Specification for Infant Bath Tubs*.

C. Juvenile Products Manufacturers Association Certification³

The Juvenile Products Manufacturers Association (“JPMA”) has a certification program for a variety of juvenile products, including infant bath tubs. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current ASTM voluntary standard. Currently, two manufacturers supply JPMA-certified infant bath tubs.

D. Incident Data

The memorandum from the Directorate for Epidemiology staff (Tab A) discusses 202 incidents (31 fatal and 171 nonfatal) related to infant bath tubs that were reported to have occurred from January 1, 2004 through May 20, 2015. Retailers and manufacturers submitted about half of the reports (102 of 202) through CPSC's “Retailer Reporting System.” Various sources, such as hotlines, Internet reports, newspaper clippings, medical examiners, and other state/local authorities submitted an additional 100 incident reports to CPSC. The data extracted include victims of all ages. In 56 incidents, the age was unknown. Of the remaining 146 incidents, all but five victims were under 2 years of age.

1. Fatalities

Thirty-one fatalities were reported to have been associated with an infant bath tub during the period January 1, 2004 through May 20, 2015. Twenty-nine of the victims were between the ages of 4 months old and 11 months old; the other two fatalities were a 23-month-old and a 3-year-old. With all but two of the fatalities, the parent or guardian left the child alone in the infant bath tub for a

³Certification JPMA. Juvenile Product Manufacturers Association. (n.d.). Retrieved June 5, 2015 from <http://jpma.org/content/certification/overview>.

variety of reasons and returned to find the child submerged. In one case, the parent was in the bathroom with the child, but was occupied on the toilet. Drowning was the cause of death reported for 30 of the 31 fatalities. The other fatality was incidental and involved a child with a ventricular septal defect, who was left alone in the tub. However, the death was attributed to pneumonia as opposed to submersion. The 31 fatalities included one drowning, reported through the National Electronic Injury Surveillance System (“NEISS”).

2. Nonfatal Injuries

One hundred seventy-one nonfatal incidents associated with infant bath tubs reported to CPSC staff occurred from January 1, 2004 through May 20, 2015. The 171 reports included 30 injuries requiring first aid, professional medical attention, or hospitalization. Nine of the injury reports involved children who required hospital admission: near-drowning incidents accounted for eight hospitalizations; and one incident resulted from a scalding water burn. “Near-drowning” means a person almost died from not being able to breathe under water (*i.e.*, suffocation). In all eight near-drowning hospitalizations, the parent or guardian left the child alone for at least a short period of time when the incident occurred. In nine additional injury reports, the victims required emergency department treatment. Five of the nine injuries involved near-drowning incidents. One injury resulted from a rash; one arose from mold on the product; one happened when a toy detached and hit the child in the head; and one resulted in a concussion to a child who fell from a bath tub atop a counter when a collapsible leg on the tub folded up. Another eight injury reports involved children who required medical treatment: six for mold on the product; one for a rash; and one for a laceration. The final four incidents required at-home first aid for finger, hand, or foot entrapments.

3. National Injury Estimates⁴

An estimated total of 2,200 injuries (sample size = 82, coefficient of variation = 0.18) related to infant bath tubs were treated in U.S. hospital emergency departments over the 11-year period from January 1, 2004 through December 31, 2014. The injury estimates for individual years are not reportable because they fail to meet publication criteria.⁵ Because the weights for the 2015 data are not yet final, staff excluded injury estimates for cases that occurred in 2015.

About 94 percent of the estimated emergency department visits during the 11-year period involve infants 12 months of age or younger, and all but one incident involved children 24 months of age or younger. The only case involving a child older than 2 years of age was a 5-year-old who received a laceration while playing with the infant bath tub.

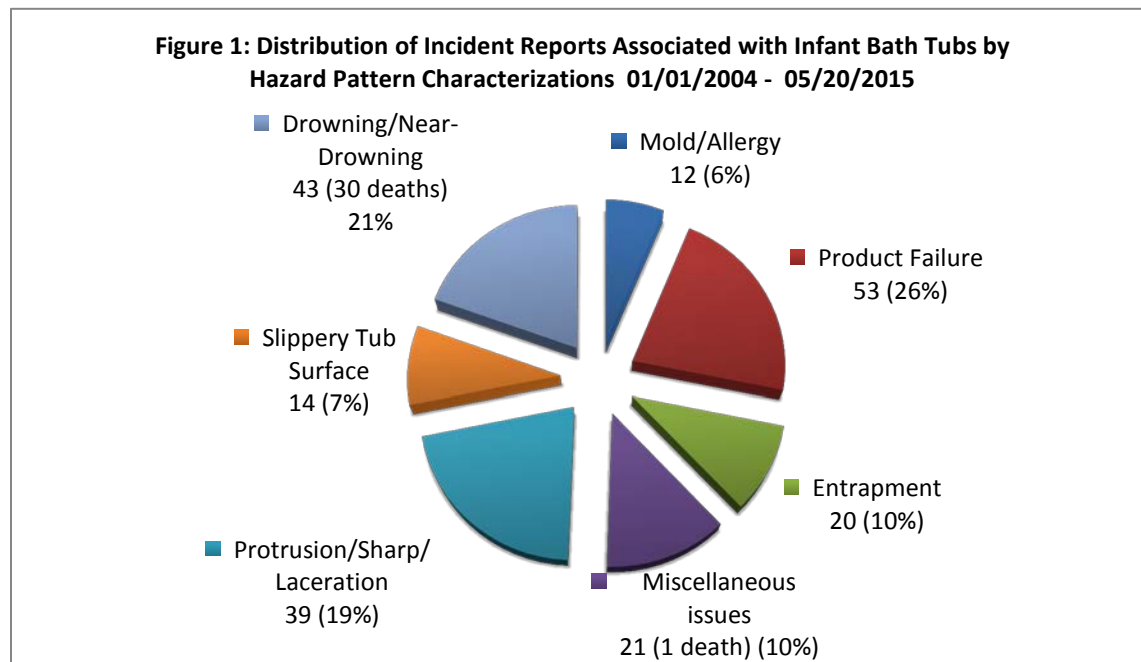
⁴The National Electronic Injury Surveillance System (“NEISS”) injury data are gathered from emergency departments of hospitals selected as a probability sample of all the U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable the CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products. All data coded under product codes 1544 and 1557 was extracted. A second search criterion was used to pull data under product codes 609, 610, 611, 4030 and 638 along with many narrative keywords. There was no age restriction in the search criteria. Staff reviewed data and excluded out-of-scope incidents. For example, a child running into an infant bath tub or kicking an infant tub were excluded prior to deriving the statistical injury estimates.

⁵According 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.

The estimated emergency department visits were split almost evenly among male (46%) and female (54%) children. More than 80 percent of the emergency department-treated victims were treated and released, and 33 percent of the reported causes of injury were reported as falls.

E. 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.



Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS completed investigations (NEISS IDIs).

1. *Drowning/Near-Drownings* account for 21 percent (43 of 202) of reported incidents. Of the 43 submersions or near-drowning incidents, there were 30 fatalities and 13 near-drowning incidents. Because no one witnessed most of the incidents, it is difficult to determine a trend in what led to the submersions. 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. However, the narratives were unclear regarding the cause of the incident. There was only one incidental fatality not ruled a drowning, and this incident is included in the miscellaneous category.
2. *Protrusion/Sharp/Laceration issues* account for 19 percent (39 of 202) 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 body parts reportedly injured were 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. There was one incident requiring a hospital visit and the remaining 38 incidents were either an incident with no injury, or a minor injury. The hospital visit was because of a scratch to the child’s back, caused by a screw that penetrated the tub wall.

3. *Product Failures* account for 26 percent (53 of 202) of reported incidents. There were 28 incidents of the “hammock/sling” attachment collapsing, and eight additional incidents of the locking mechanism failing or breaking. The remaining 17 incidents involved various tub parts breaking. Of the 53 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; the child fell from the counter top to the floor and suffered a concussion.
4. *Entrapment issues* account for 10 percent (20 of 202) 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. There were no hospital visits in any of the reported incidents. All of the reports involved either no injury or a minor injury.
5. *Slippery tub surface issues* account for 7 percent (14 out of 202) 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. All of the reports involved an incident with no injury or a minor injury.
6. *Mold/Allergy issues* account for 6 percent (12 of 202) of reported incidents. Of the 12 incidents, eight were due to mold, and four were due to allergy. The issues reported 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 that 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* accounted for the remaining 10 percent (21 of 202) of the reported incidents. The incidents included a fall from the tub, an unstable tub, missing pieces, leaking or overheating batteries, rust, and scalding. There was one incidental fatality and one hospital visit. 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 19 reports were either an incident with no injury or a minor injury, including six battery-related complaints.

III. DISCUSSION

A. Adequacy of F2670 Requirements

Based on the incident data discussed above, staff assessed the adequacy of ASTM F2670 – 13.

1. *Warnings and instructions* are the only way to address caregiver behavior (*i.e.*, leaving the infant unattended) to prevent drowning/near-drowning incidents. The requirements of the current voluntary standard allow for considerable variation in the conspicuity and format of the warnings presented to consumers regarding the use of the product. Research suggests that the potential impact of the warnings might improve by providing specific guidance for a more consistent presentation of hazard information. Before the May 2015 ASTM subcommittee meeting, staff presented ASTM with suggested wording and formatting changes to improve the warning and instructions sections of the voluntary standard (see Tab C, staff letter to ASTM). Feedback from ASTM during the subcommittee meeting, led staff to adjust the warnings and instructions recommendations; the NPR reflects these adjustments. Tab B discusses in detail why and how changes to the size, color, content, and format can all contribute to making the warnings and instructions more effective. Specifically, staff recommends: (1) increasing the text size in the on-product warning, consistent with federal requirements for warnings on infant bath seats (16 C.F.R. part 1215); (2) requiring the use of a hazard color in the on-product and retail package warning; (3) revising the warning content to simplify and clarify the language and address the fall hazard; and (4) specifying the format of the warning on the product, on the retail packaging, and in the accompanying instructions, to increase their potential impact and provide a more consistent presentation of hazard information.
2. *Protrusion/Sharp/Laceration* is addressed in Section 5.1 of ASTM F2670 – 13. Staff did not identify any trends in the few reported incidents of various scrapes or cuts from non-smooth edges and one screw coming through the tub material. The majority of the other incident reports related to protrusions indicated red marks on the infant’s back, or infant discomfort during bathing. Some tubs are designed for use by young infants who lie in a “hammock/sling” mounted on the tub over the “bump/hump” designed for support of older infants to prevent them from sliding forward. The infant’s weight causes the hammock/sling to stretch, resulting in the infant’s back resting on the bump/hump. ASTM has formed two task groups to develop infant sling performance requirements.
3. *The scope* of the current ASTM standard specifically excludes “bath sling” products. A bath sling is a fabric or mesh product that does not hold water, attaches either to a separate frame or to the infant bath tub, and typically is used for bathing newborn babies and young infants.

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Several models of infant bath tubs now include bath slings that attach to the infant bath tub or as an accessory with the infant bath tub. As an accessory, the sling can be used as a stand-alone product or with (*i.e.*, inside) the infant bath tub. As noted above, 28 of the 53 “product failures” involved the accessory “hammock/sling” separating from the frame.

During the September 2014 ASTM subcommittee meeting, CPSC staff discussed receiving reports of incidents involving infant slings and similar bathers that do not hold water, but are still used for bathing. Staff suggested addressing these products in the infant bath tub standard or through a new standard. The ASTM subcommittee established a task group to review data and make recommendations on how to address incidents involving infant slings and bathers. The task group developed two recommendations and presented them during the May 2015 ASTM subcommittee. First, the task group recommended that infant slings that can be used only with infant bath tubs should be addressed in the infant bath tub standard. Second, the task group recommended that infant slings and other bathers sold in conjunction with infant bath tubs and used as stand-alone product or as an accessory with the infant bath tub, should be addressed under a new and separate standard. The ASTM subcommittee agreed with these recommendations and formed two separate task groups to address these issues. CPSC staff will participate in the task group meetings to assist with the development of the requirements because none have been developed or balloted to date.

4. *Latching or locking mechanism durability* is a rigorous testing requirement in ASTM F2670 – 13, Section 7.1.2. However, Laboratory Sciences Mechanical staff (“LSM”) determined that more complicated latching and locking mechanisms are difficult to test within the specified time of 12 cycles per minute (see Tab D). Because of discussions in the September 2014 and May 2015 subcommittee meetings, ASTM has twice balloted language to allow for longer cyclic testing without lessening the stringent test requirements. Staff agrees with the latest balloted language (balloted June 11, 2015) that allows for continuous cycle testing, but staff commented on the ballot to reference the original 12 cycles per minute in the non-mandatory Appendix (see Tab E, staff comments to ballot) so that the intent of the test is not lost. Staff believes it is important to provide a timing reference point so testing laboratories and manufacturers are consistent in their testing. Staff believes these changes will augment product safety by improving the accuracy, consistency, and repeatability of durability testing.
5. *The static load testing device*, used during to address potential breaking issues, may unintentionally damage some inflatable infant bath tubs. Under the current standard, the edges of the 6 by 6-in. (150 by 150-mm) 3/4-in. (19-mm) thick block made of high density polyethylene (“HDPE”) are not required to be rounded; therefore, the edges could puncture the infant bath tub. In the September 2014 ASTM subcommittee meeting, staff recommended that ASTM consider adding a requirement to round the corners of the testing device. After discussion, the subcommittee decided to change the HDPE block to a shot bag and balloted that change. Staff agrees with the balloted and accepted change to use a

shot bag for static load testing. Staff recommends including this language in the Commission's NPR because staff believes these changes will augment product safety by improving the accuracy, consistency, and repeatability of static load testing.

6. *Pinching and entrapment incidents* are, in staff's view, adequately addressed through the performance requirements in Sections 5.5 *Scissoring, Shearing, and Pinching* and 5.6 *Openings*. Staff believes that because no trends were found in the data, the current requirements do not need any changes.
7. Most of the incidents involving *slippery tub surface* contain insufficient detail to determine the case of the product's slippery surface. Staff will continue to monitor and collect information on incidents involving slips, falls, and submersion in infant tubs. Staff is not recommending any modifications to slip resistance requirements at this time.
8. *Mold/allergy* is a difficult problem for manufacturers to address through a voluntary standard because mold results from the consumer's inability to fully clean and dry the infant bath tub. Staff will continue to monitor the incident data, but at this time, staff does not recommend any changes to the ASTM standard regarding mold/allergy issues.

Based on the incident data and review above, staff recommends incorporating by reference ASTM F2670 – 13 with changes to: (1) the test fixture used in the static load testing; (2) the latch or locking mechanism durability testing; and (3) the warnings and instructions.

Specifically, staff recommends:

- (1) accepting ASTM's balloted and accepted language to use a shot bag instead of the HDPE block as the static load testing device;
- (2) accepting ASTM's balloted language for continuous cycle testing but adding a reference to the 12-cycles-per-minute timing in the Appendix;
- (3) increasing the size of the text in the on-product warning consistent with federal requirements for warnings on infant bath seats (16 C.F.R. part 1215);
- (4) requiring the use of a hazard color in the on-product and retail package warning;
- (5) revising the warning content to simplify and clarify the language and address the fall hazard; and
- (6) specifying the format of the warning on the product, on the retail packaging, and in the accompanying instructions to increase their potential impact and provide a more consistent presentation of hazard information.

As noted in the discussions above, staff will continue to work with the ASTM subcommittee to develop language and performance requirements to include in the voluntary standard bath slings used on infant bath tubs. Staff will also participate in the development of a new standard for infant slings and bathers used with infant bath tubs or separately. Staff will continue to monitor incident data to assess whether additional requirements need to be included in the voluntary standard to

address slippery surfaces.

B. Potential Small Business Impact

As discussed in the memorandum from Directorate for Economic Analysis (Tab F), at least 26 firms supply infant bath tubs to the U.S. market. Twenty-three are domestic firms: 14 firms are manufacturers, eight are importers, and one firm has an unknown supply source. Based on U.S. Small Business Administration guidelines, 17 of the 23 domestic firms supplying infant bath tubs to the U.S. market are considered small firms.

All firms will need to make modifications to their product. However, the modifications are expected to be minor, ranging from changes to existing labeling and warning statements to adjustments to the size of grooves or openings on the side of the product. In addition to the requirements of the rule, there will be additional costs associated with third party testing. Based on examination of several firms' revenues, the impact is unlikely to be economically significant for most firms. However, we were unable to estimate precisely all costs of the draft proposed rule; and thus, staff conducted an Initial Regulatory Flexibility Analysis.

C. Compliance Recall Information

Since January 1, 2004, there have been no recalls associated with infant bath tubs.

IV. NOTICE OF REQUIREMENTS

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. The children's product certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements ("NOR") for the accreditation of third party test laboratories to determine compliance with a children's product safety rule to which a children's product is subject. A proposed rule for infant bath tubs, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*. 16 C.F.R. part 1112 (78 Fed. Reg. 15836 (March 12, 2013)) (referred to here as "part 1112"). This rule took effect on June 10, 2013. Part 1112 establishes the requirements for accreditation of third party testing laboratories to test for compliance with a children's product safety rule. The final rule also codifies all of the NORs that the CPSC has published, to date, for children's product safety rules. All new children's product safety rules, such as the proposed infant bath tub standard, would require an amendment to part 1112 to create an NOR. Therefore, staff recommends that the Commission propose to amend part 1112 to include infant bath tubs in the list

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of children's product safety rules for which the CPSC has issued NORs.

V. RECOMMENDED EFFECTIVE DATE

To allow time for infant bath tub manufacturers to bring their products into compliance after a final rule is issued, the staff recommends an effective date of 6 months after publication of a final rule for products manufactured or imported on or after that date. Although staff has recommended modifications to the ASTM warning labels and testing procedures, most firms should be able to comply within the 6-month timeframe. The two engineering technical recommendations do not require manufacturing changes to products, but rather, affect the testing equipment used for compliance and certification. Because these devices are currently used in other children's product testing, there should not be any delay required to acquire the new test equipment. The warning label and instruction changes do not affect the design and manufacturing of the infant bath tubs, but rather, require printing new labels. A 6-month effective date is consistent with the timeframe adopted in a number of other section 104 rules. The 6-month period will allow time for manufacturers and importers to arrange for third party testing.

IV. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission propose to incorporate by reference the voluntary standard, ASTM F2670 – 13, *Standard Consumer Safety Specification for Infant Bath Tubs*, with changes.

Specifically, staff recommends:

- (1) accepting ASTM's balloted and accepted language to use a shot bag instead of the HDPE block as the static load testing device;
- (2) accepting ASTM's balloted language for continuous cycle testing, but adding a reference to the 12-cycles-per-minute timing in the Appendix;
- (3) increasing the size of the text in the on-product warning, consistent with federal requirements for warnings on infant bath seats (16 C.F.R. part 1215);
- (4) requiring the use of a hazard color in the on-product and retail package warning;
- (5) revising the warning content to simplify and clarify the language and address the fall hazard; and
- (6) specifying the format of the warning on the product, on the retail packaging, and in the accompanying instructions, to increase their potential impact and provide a more consistent presentation of hazard information.

TAB A: Infant Bath Tub-Related Deaths, Injuries and Potential Injuries, and NEISS Injury Estimates Reported Between January 1, 2004 and May 20, 2015

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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BETHESDA, MARYLAND 20814

Memorandum

Date: May 27, 2015

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 Reported Between January 1, 2004 and May 20, 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 1, 2004 through May 20, 2015.⁶ These characterizations are based on reports received by CPSC staff.

An “infant bath tub” is defined in the ASTM voluntary standard F2670 – 13 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.*” Infant bath tubs hold water meant for bathing a

⁶ 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.

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^{7, 8}

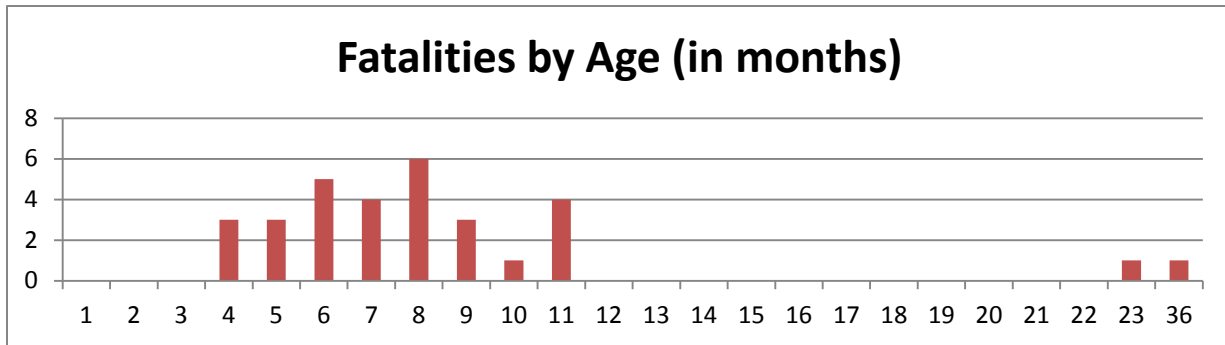
CPSC staff is aware of 202 incidents (31 fatal and 171 nonfatal) related to infant bath tubs that were reported to have occurred from January 1, 2004 through May 20, 2015. The data extracted include all ages. There were 56 incidents involving victims of unknown age. Of the remaining 146 incidents with known ages, all but five victims were under 2 years of age, including one adult woman who had an allergic reaction. Most of the 56 incidents with unknown ages consist of 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, there were 90 male children and 78 female children. There were 33 reports stating that the gender of the victim was unknown. About half of the reported incidents (102 of 202) had a document submitted to CPSC by retailers and manufacturers through CPSC's "Retailer Reporting System." Of the 102 incidents with documents from manufacturers, six had additional documents in the CPSC databases of the same incident; all six incidents had investigation IDI documents. In addition, there were 100 incident reports submitted to CPSC from various sources, such as hotlines, Internet reports, newspaper clippings, medical examiners, death certificates, National Electronic Injury Surveillance System ("NEISS") investigations and other state/local authorities.

Fatalities

There were 31 fatalities reported to have been associated with an infant bath tub during the time January 1, 2004 to May 20, 2015. Twenty-nine of the victims were between the ages of 4 and 11 months old, inclusive; the other two fatalities were a 23-month-old and a 3-year-old. The fatalities were split evenly between 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 the one fatality in which the parent was present, the parent was at the toilet next to the tub at the time of incident. With all but one of the fatalities in which the parent was not present, the parent or guardian left the child alone for a variety of reasons, for at least a short period, 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, in which the coroner attributed the immediate cause of death to pneumonia). The distribution of the 31 fatalities described above, by age in months, is shown in Figure 1.

⁷ 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"). There were 10 NEISS completed investigations ("IDIs"), 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 period, nor a sample of known probability of selection. However, they provide a minimum number of deaths and incidents occurring during this period and illustrate the circumstances involved in the incidents related to infant bath tubs.

⁸ Date of extraction for reported incident data was 05/20/15. 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.



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

Nonfatal Incidents

A total of 171 nonfatal incidents associated with infant bath tubs were reported to CPSC staff that occurred from January 1, 2004 through May 20, 2015. The 171 reports included 30 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 incidents, 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 left the child alone for at least a short period of time when the incident occurred. Nine injury reports noted emergency department treatment was required: five from near-drowning incidents; one for a rash; one from mold on the product; one because a toy detached and hit a child in the head; and one concussion after a child fell from a bath tub located on a counter after a collapsible leg on the tub folded. Eight of the injury reports were about children requiring treatment from a medical professional: six due to mold on the product; one for a rash; and one for a laceration. Four incidents required first-aid at home, all due to finger, hand, or foot entrapments.

Hazard Pattern Identification

CPSC staff considered all 202 (31 fatal and 171 nonfatal) incidents to identify the hazard patterns associated with infant bath tub-related incidents. Staff grouped the hazard patterns into the following categories in order of frequency of incident reports:

1. **Drowning/Near-Drowning** incidents account for 21 percent (43 out of 202) of reported incidents. Of the 43 drowning or near-drowning incidents, there were 30 drowning fatalities and 13 near-drowning incidents. In 38 of the 43 incidents, no parent or guardian was present at the time of the incident. In the other five incidents in which the parent or guardian was present, four of the children survived. Because there was no witness to what happened during most of these incidents, it is difficult to deduce what led to the drowning. Generally, the child is found floating, but it is not clear whether the tub capsized, the child climbed out of the tub, the tub was slippery, there was too much water in the tub, or some other circumstances contributed to the incident. There was only one fatality not ruled a drowning by the coroner, and it is included in the *miscellaneous issues* category.
2. **Protrusion/Sharp/Laceration issues** account for 19 percent (39 out of 202) of the reported incidents. Commonly a part of the product juts out and the child rubs against the protrusion, which causes red marks, cuts, or bruising. In most incidents, the report

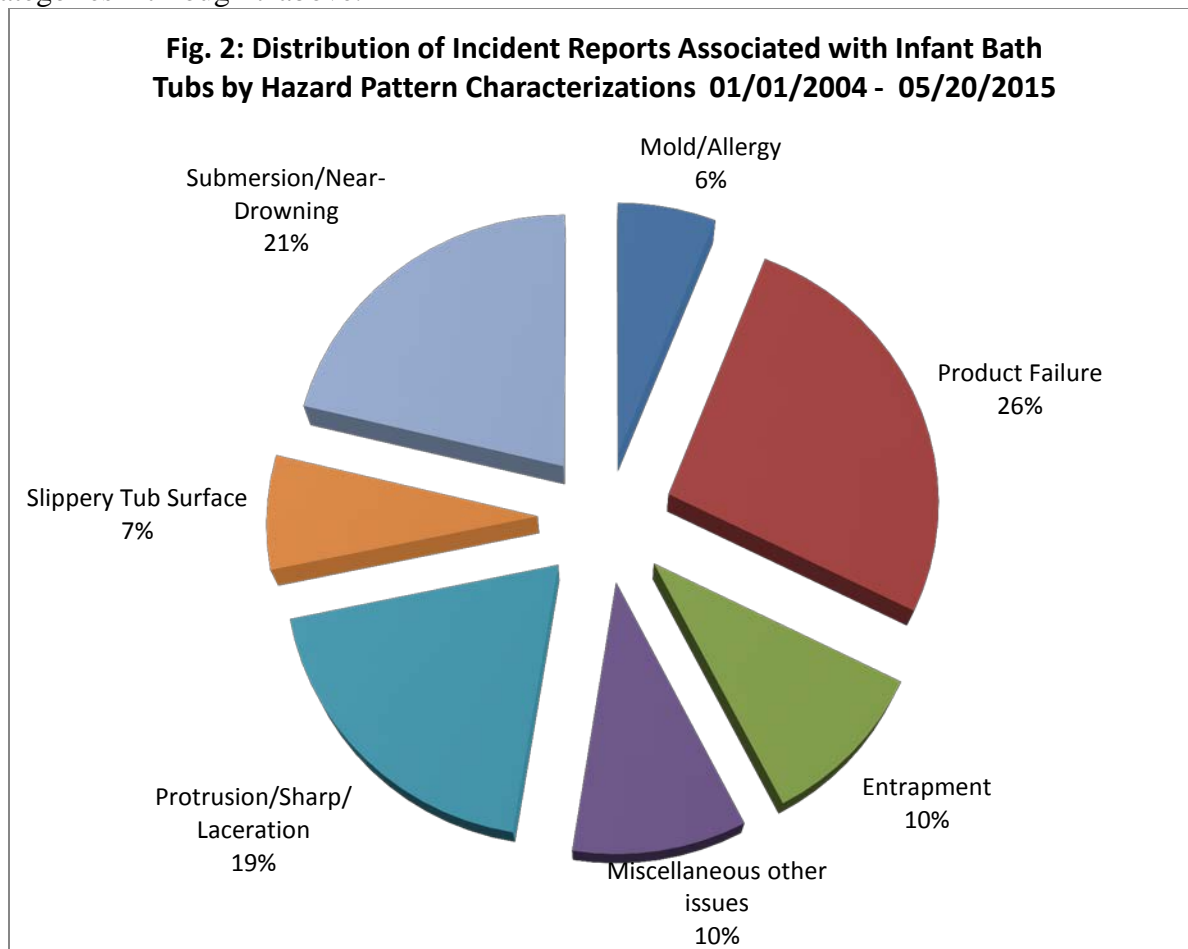
CPSC/C&K Testing
www.cpsc-ck.com
Hotline: 408-721-723
Email: test@cpsc-group.com

describes the protrusion 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 body parts reportedly injured are toes, feet, bottom, private parts, 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 39 protrusion reports, one incident required attention from a medical professional, and the rest were either an incident with no injury or a minor injury. The hospital visit was due to a scratch to the back of the child, caused by a screw penetrating through the tub wall.

3. **Product Failures** account for 26 percent (53 out of 202) of reported incidents. Of the 53 breakage reports, two injuries required a trip to the hospital, and the rest were either an incident with no injury or a minor injury. Two children who required hospital trips were both treated and released. One incident involved a toy attached to the tub falling off the tub and causing a deep cut to the forehead; the second resulted in a concussion when a tub, positioned atop counter, had a leg collapse, causing a child to fall to the floor. There were 28 incidents of a “hammock” or “sling” attachment collapsing or breaking, and eight incidents of the locking mechanism failing or breaking. The rest of the incidents involved various tub parts breaking.
4. **Entrapment issues** account for 10 percent (20 out of 202) of reported incidents. Entrapment incidents involve body parts caught or stuck in the tub, mostly in a pinching manner. The body parts reportedly injured were fingers, arms, feet, legs, and private parts. Many of these injuries occurred in tubs that fold. Common places on the tub that entrapped body parts include: hinges, holes, and the foot area inside the tub. Four injuries required first-aid at home for finger, hand, or foot entrapment and swelling. The rest of the reports were either an incident with no injury or a minor injury.
5. **Slippery tub surface issues** account for 7 percent (14 out of 202) of reported incidents. Common reported incidents and concerns included body scratches or hits from protrusions on the tub, or potential head submersions. All of the reports listed an incident with no injury or a minor injury.
6. **Mold/Allergy issues** account for 6 percent (12 out of 202) of reported incidents. Of the 12 incidents, eight were attributed to mold, and four were allergy related. The issues reported 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 six with mold and two with allergy incidents. Of the 12 incidents, there were two emergency room visits; one child may have developed an upper respiratory issue, and one child broke out in a rash all over their back. Seven additional children saw a medical professional, and four complained of 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 percent (21 out of 202) of the reported incidents. The issues included falling out of the tub; an unstable tub; missing pieces from a tub; product component batteries leaking or overheating; rust; and scalding.

Of the 21 miscellaneous issues, six involved battery incidents. One involved a fatality, and one required hospital admission. The fatality attributed to pneumonia occurred to a child with a ventricular septal defect. The hospital visit resulted from 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. The rest of the reports were either an incident with no injury or a minor injury.

Figure 2⁹ shows the distribution of the 202 reported incidents by the hazard patterns described in categories 1 through 7 above.



Source: CPSC epidemiological databases IPIL, INDP, DTHS, and NEISS completed investigations (NEISS IDIs).

⁹ Percentages do not sum to 100 due to rounding.

National Injury Estimates¹⁰

There was an estimated total of 2,200 injuries (sample size = 82, coefficient of variation = 0.18) related to infant bath tubs that were treated in U.S. hospital emergency departments over the eleven-year period 2004-2014. There were an additional 5 incidents found from January 1, 2015 through May 20, 2015, and none of these was investigated and none is included in the non-fatal incident section above. The weights for the 2015 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.¹¹

One drowning death was reported through the NEISS and is included in the fatality counts in the prior section. About 94 percent of the estimated emergency department visits were made by infants 12 months of age or younger, and all but one incident involved children 24 months of age or younger. The only case involving a child older than 2 years of age was a 5-year-old who received a laceration while playing with the infant bath tub. The estimated emergency department visits were split fairly evenly among male and female children, with 54 percent female and 46 percent male children. For the emergency department-treated injuries related to infant bath tubs, the following characteristics occurred most frequently:

- Hazard – falls (33%); a majority of the reports did not specify the manner or cause of fall.
- Injured body part – head (35%), all/over half of body (22%), and face (18%).
- Injury type – internal organ injury (28%), drowning or nearly drowning (22%), and contusions/abrasions (18%).
- Disposition – treated and released (82%) and admitted or transferred to a hospital (15%).

¹⁰ 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.

All data coded under product code 1544 (baby baths or “bathinettes”) and 1557 (baby bathtub seats or rings (not toys) was extracted. A second search criterion was used to pull data under product codes: 609, 610, 611, 4030 and 638 along with many narrative keywords. There was no 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, a child running into an infant bath tub or kicking an infant tub were excluded prior to deriving the statistical injury estimates.

¹¹ 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.

TAB B: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in Infant Bath Tubs

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

Memorandum

Date: June 5, 2015

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

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

Bonnie Novak, Director
Division of Human Factors
Directorate for Engineering Sciences

From: Catherine A. Sedney, Senior Engineering Psychologist
Division of Human Factors
Directorate for Engineering Sciences

Subject: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in
Infant Bath Tubs

BACKGROUND

This memorandum summarizes the Human Factors (“HF”) assessment of the hazard patterns associated with infant bath tubs, and the adequacy of the existing voluntary standard to mitigate those hazards, to support rulemaking mandated by Section 104 of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”).

The current voluntary standard, ASTM F2670 – 13, *Standard Consumer Safety Specification for Infant Bath Tubs*, establishes “performance requirements, test methods, and labeling requirements to promote the safe use of infant bath tubs.” As defined in section 3.1.2, an “infant bath tub” is 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.” The scope of the standard excludes “products commonly known as bath slings, typically made of fabric or mesh” (section 1.1).

Staff recommends that the Commission issue a proposed rule for infant bath tubs that incorporates by reference ASTM F2670 – 13, with modifications to specific provisions in the voluntary standard to make the proposed rule more stringent than the voluntary standard. Additionally, the data suggest that there are areas where further investigation is warranted; in these areas, including issues related to bath slings, bathers, and product slip-resistance, staff will continue to gather information and work with ASTM to develop solutions, as needed.

DISCUSSION

Products

Infant bath tub products that fall within the scope of the standard vary widely. Despite the term “infant” in the classification name, many products are intended for use into the toddler or even early pre-school years. Among the simplest are bucket-style tubs, said to mimic the womb, in which the child sits upright, and inflatable tubs that resemble small wading pools. Many brands have an inclined seat within the tub for infants too young to sit unsupported, and many are designed to adapt as the child grows, incorporating a removable “cradle” or hammock-style sling mounted on a frame or on the tub itself for the smallest infants. Some models fold for convenient storage, and the most elaborate include spa features, such as “whirlpool” settings and a separate handheld shower.

Incident Data

Staff from the Directorate for Epidemiology’s Division of Hazard Analysis (“EPA”) analyzed reports in the Commission’s non-NEISS databases and provided national estimates for infant bath tub-related emergency department visits from the CPSC’s National Electronic Injury Surveillance System (“NEISS”¹; Suchy, 2015). EPA staff reported 202 infant tub-related incidents, including 31 fatalities,² for the period January 1, 2004 through May 20, 2015. The data include 82 NEISS reports, which form the basis for EPA staff’s estimate that there were 2,200 emergency room visits for infant bath tub-related incidents from 2004 through 2014.³ Incident data from the two sources that are relevant to HF staff’s recommendations are discussed below.

¹ NEISS data refers to cases that resulted in visits to a representative sample of U.S. hospital emergency rooms. Non-NEISS refers to data reported in the In-Depth Investigation file (“INDP”), the Injury or Potential Injury file (“IPI”), and the Death Certificate file (“DTHS”).

² One reported death appears unrelated to the product (071108HCC1090). The child was left alone briefly by one caregiver, and was found unconscious, but not submerged, when a second caregiver resumed supervision. According to the Medical Examiner’s (“ME”) report, there were no fluids in the child’s lungs. The ME ruled the manner of death natural, and listed the cause of death as pneumonia.

³ Data reported for 2015 is incomplete and excluded from EPA staff’s analysis.

Non-NEISS (Reported) Incidents⁴

According to the EPHA analysis, for the 11-year period reviewed, there were 30 drowning deaths and 13 near-drownings that resulted in visits to emergency rooms associated with infant bath tubs reported to the CPSC. All but two of the children were 11 months of age and younger. In nine of the near-drowning incidents and all but one of the drowning deaths, caregivers acknowledged leaving the children alone, typically for brief periods, while they tended to another child, obtained needed items (*e.g.*, a towel, diaper, or clothing), answered the phone, or performed chores; children were hospitalized in eight of the near-drowning cases. In a few cases, the lapse in direct supervision was attributed to confusion regarding who in the household was responsible for the child at the time of the incident. In most cases, it is unclear whether the product played any role in the incidents beyond giving the caregiver an illusory sense of reassurance that the child was safe.

Caregivers reported 16 brief submersion incidents that occurred because the product's sling detached or the sling frame collapsed (10), some other part of the seat broke or collapsed (1), the product was slippery (4), or the product lacked head support (1). In an additional submersion incident, a consumer reported that her 5-month-old child stiffened when he fell backward into the inflatable tub and she had difficulty removing him from under the water. She attributed this to the design of the tub, which had a hard plastic rim that was smaller in diameter than the bottom of the tub. In 20 reports, caregivers described children slipping into the water, slipping and falling into the water, or expressed concern regarding submersion in one of these same categories (sling/sling frame, 5; slippery surface, 7; lack of head support, 2; broke or collapsed, 6).

One incident resulted in a fall from a height. The tub, with no water, was placed on a kitchen counter, and the caregiver was nearby preparing a bottle. One leg of the tub collapsed, and the 2-month-old occupant fell to the floor, sustaining a concussion.

NEISS Incidents

As noted above, EPHA staff searched the NEISS system and identified 82 emergency department visits related to infant bath tubs for the years 2004 through 2014.⁵ CPSC staff conducted telephone investigations for ten cases, all submersion incidents, which are included in the preceding section. Except for an incident that involved a 5-year-old, the children were 2 years old and younger. Included among the remaining 72 incidents were nine near-drownings. In two of these the parent reportedly leaned away or turned away, and turned back to find the child under water; in each, the child's disposition was reported as treated and released, or examined and released without treatment. Among the remaining children, five were hospitalized, one was treated and transferred, and one was admitted and held for observation. All submersion-related incidents involved children 13 months of age and younger.

⁴ Includes ten NEISS telephone IDIs comprising one submersion death and nine near-drowning incidents.

⁵ The NEISS incidents include one report of an injury that does not involve the product (80743482); the adult caregiver slipped while in the shower and landed on the child who was in the infant tub.

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www.cirs-ck.com
Hotline: 4006-721-723
Email: test@cirs-group.com

EPHA reports that falls were the most commonly reported pattern (33%), and correspondingly, that the head (35%) was the body part most frequently injured; facial injuries also were relatively common (18%). The details of the falls are sparse, as is typical of NEISS reports; however, where given, some indicate a particular issue or scenario. Seven incidents specify that the child slipped in the product, and ten cases specify that the child fell from a height other than a sink (*e.g.*, a counter, table, or stool).

Adequacy of the Current Voluntary Standard and Recommendations for Revisions

Staff presented the ASTM subcommittee for infant bath tubs several points on which the voluntary standard could be clarified or improved. Additionally, there are areas for which the staff did not suggest a specific change, but asked that the subcommittee examine the data and products to explore the need for additional changes. The sections below present HF staff's assessment of the voluntary standard, recommendations for changes as noted to make the proposed rule more stringent than the voluntary standard, and considerations for further review and possible future work.

Scope of the Voluntary Standard

The scope of the current standard specifically excludes bath slings and similar products that do not hold water. However, many infant bath tub products staff reviewed are sold with slings that are mounted either on the infant bath tub or on a frame that is intended to be placed within the tub for bathing newborns and young infants.⁶ Consumers have reported incidents of sling detachment and collapse leading to brief submersion. At the fall 2014 subcommittee meeting, staff requested that ASTM explore this issue and either expand the scope of the standard, or develop a new standard to address it. In response, the ASTM subcommittee formed a task group to review the data and consider the available options. The task group, in which CPSC staff participated, developed and presented two recommendations to the subcommittee: (a) expand the scope of ASTM F2670 to include these components when they are sold with the product as an accessory and cannot be used without the infant tub; and (b) develop a new voluntary standard for similar stand-alone products that are sold and used with or without infant tubs. The ASTM subcommittee accepted the task group recommendations and has formed two new task groups to address them. Because the changes are significant and require the development of new procedures and an additional standard, this work is expected to continue beyond the timeframe of the current 104 effort. Thus, the staff is not recommending that the Commission propose any modifications regarding bath slings at this time.

Slip-Resistance

Although some firms have marketed or currently market their products as having slip-resistant features,⁷ the existing voluntary standard for infant tubs has no provisions to prevent children

⁶ Referred to as bathers.

⁷ For example, see http://www.amazon.com/Fisher-Price-Precious-Planet-Whale-Tub/dp/B0018Z8CN8/ref=sr_1_1?ie=UTF8&qid=1434471084&sr=8-1&keywords=fisher-price+infant+bath+tub+nonslip#productDetails;

from slipping on product surfaces. LSM staff advises that there are no known test methods to measure the slip-resistance of materials intended to contact infants' skin; and additional information is needed about the products involved. The data include relatively few incidents in which complainants specifically attribute the cause to the slipperiness of the product surface, and most reports contain little detail. Staff will continue to monitor and collect details on slip-related fall and submersion incidents in infant tubs, and will work with ASTM, if warranted, to develop appropriate performance requirements to address them. Thus, staff is not recommending that the Commission propose any modifications regarding slip resistance at this time.

Warnings & Instructions

The main hazards associated with infant bath tubs are drowning and near-drowning, followed by falls. Fatal and near-fatal submersion incidents, and many fall incidents, are linked to caregiver behavior, and cannot be reduced effectively through product design changes. Thus, these hazards are addressable only through enhanced warnings and instructions.

The goal of the warnings is to influence behavior—to help establish safe behavior among new users of a product, and to change behavior among those who may use the product in unsafe ways. Research starting in the 1970s (*e.g.*, Dorris & Purswell, 1977), however, has demonstrated that warnings often have little or no effect, particularly in comparison to design approaches to injury prevention. Moreover, warnings are known to be weak with familiar products that consumers perceive to be safe. Well-designed warnings can influence consumer perceptions of injury likelihood and severity, which, in turn, can motivate compliance. As discussed below, for warnings to have an effect, consumers must notice, read, and comprehend them, find them credible and personally relevant, and be both able and motivated to comply with them on a consistent basis. It is important, therefore, when design and guarding options are not available, that warnings exploit attention-capturing and motivational potential, to the extent possible, to increase the likelihood of compliance.

The requirements of the current voluntary standard for infant bath tubs allow for considerable variation in the warnings presented to consumers regarding the use of these products. CPSC staff has asked ASTM to review the sections on warnings and instructions for possible revision. The potential impact of the warnings would be improved by more detailed guidance within the standard for a more conspicuous and consistent presentation of hazard information. Staff employs the American National Standard for Product Safety Signs and Labels (Z535.4; ANSI, 2011) and related standards as a baseline, in conjunction with relevant literature, in the development of warning materials. Specific issues are discussed below, and staff's recommended changes to the standard for the proposed rule are presented in ASTM ballot format in Appendix A.⁸

http://www.amazon.com/Munchkin-White-Hot-Inflatable-Duck/dp/B000066665/ref=sr_1_21?ie=UTF8&qid=1425851414&sr=8-21&keywords=baby+bath+tub+slip; and http://www.amazon.com/Karibu-Baby-Folding-Bath-White/dp/B0073WXL4A/ref=sr_1_15?ie=UTF8&qid=1425851502&sr=8-15&keywords=infant+bathtub+nonslip.

⁸ ASTM standards and ballots typically are presented in single-spaced, 10-point text. For ease of review only, Appendix A is presented in 12-point text and 1.15 line spacing.

Size

The first prerequisite for warning effectiveness is that the warning be noticed. Size attracts attention and is associated with importance; within reasonable limitations, therefore, bigger is generally better (Laughery & Wogalter, 2011; Laughery & Wogalter, 1997). As identified in team review of the voluntary standard,⁹ the minimum text size is half that specified in the federal requirements for warning labels on infant bath seats (16 C.F.R. part 1215), which are detailed in ASTM F1967 – 13, *Standard Consumer Safety Specification for Infant Bath Seats*.

To harmonize the labeling requirements for these two product categories, at the subcommittee meeting in September 2014, staff recommended that ASTM increase the minimum size of the safety alert symbol and the signal word “WARNING” on the product and package labels to 0.4 in. (10 mm) in height, with the remainder of the text to be not less than 0.2 in. (5 mm) in height. The ASTM subcommittee balloted this change in March 2015, and the subcommittee received negative votes that members deemed to be persuasive. One negative vote regarding the size change was primarily editorial; the voter intended to clarify that the size specifications applied to all text, including any warning statements added by the manufacturer. The other negative vote pertained to retail packaging, and the commenter made two points. First, the only packaging for many existing products is a small paper insert that fits inside the product and serves as a label. These inserts would need to be increased to accommodate the larger text. Second, the larger text size on the package is unlikely to impact tub use in the same manner that larger warnings on the product would because the package is thrown away after purchase. Staff concurs that the change to the retail packaging for infant bath tubs would have less impact on consumers. Thus, in this memorandum, staff proposes to limit the change in text size to the on-product warning labels, with exceptions as noted.

Staff suggested additional revisions to the warning and labeling sections of the voluntary standard in a letter to ASTM in March 2015 (see Tab C, staff letter to ASTM). In response, during the May 2015 subcommittee meeting, ASTM formed a task group, which included HF staff, to review the additional warning and labeling changes submitted by CPSC. The task group has not met since forming; however, staff received feedback on wording and the use of multiple labels versus a single label that combines drowning and fall hazards from subcommittee members attending the May 2015 meeting. Staff addressed subcommittee members’ feedback in the recommended revisions to the standard for the proposed rule discussed in the following sections.

⁹ I. Hall, Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM); personal communication, 8/6/13.

Color

The current voluntary standard for infant bath tubs allows all elements of the warning to be in any colors, provided the colors are contrasting. Staff noted during review of infant bath tub samples, as well as other juvenile products, that some firms take advantage of this flexibility to present warnings in colors that complement their products. Color is a salient stimulus that sends the viewer a message about the importance of the information associated with it.

Warnings are intended to convey risk. Printing them in a color that matches a baby product instead of a color that is associated with hazard weakens the effect of the warnings. For example, the table below shows the results of subject rankings of 12 ANSI-formatted¹⁰ warnings (*i.e.*, with a header panel displaying the safety alert symbol “▲” and signal word), and demonstrates the predominance of color over signal word. Subjects ranked warnings with a white header panel background as the least forceful, the weakest, and the least emphatic (Chapanis, 1994). In effect, pairing the signal words “Danger,” “Warning,” and “Caution” with a white background reduced their impact. The use of a hazard-related color (*i.e.*, red, orange, and yellow) showed the opposite effect, as indicated by the higher rankings for the warnings when the signal words in the header panel were paired with these colors.

Table 1. Mean rankings of the hazards associated with combinations of signal words and colours.

	Caution	Warning	Danger	Mean
Red	8.1	8.4	11.1	9.2
Orange	6.1	6.7	9.3	7.4
Yellow	4.2	6.6	9.1	6.6
White	1.4	2.5	4.6	2.8
Mean	4.9	6.1	8.5	

Note. Reproduced from “Hazards associated with three signal words and four colours on warning signs,” by A. Chapanis, 1994, *Ergonomics*. 37(2), 265-275.

Consistent with these findings, staff recommends that the proposed rule include a revision to the standard that requires a hazard color as part of the warning presentation for infant tubs. Although general practice is the use of an orange background with the safety alert symbol and signal word “WARNING” in black for hazards that may lead to serious injury or death, red or yellow, whichever contrasts best, may be used if the product is predominantly orange.

¹⁰ “ANSI” is the American National Standards Institute, Inc. ANSI Z535.4-1991 *Standard for Product Safety Signs and Labels* was the edition of the standard that was current at the time the research was conducted.

Content

The text of the current voluntary standard's warning content is presented below.

“8.4.2 The following warning statement shall be included exactly as stated below:

WARNING - DROWNING HAZARD

8.4.3 Additional warning statements shall address the following:

Infants have **DROWNED** in infant bath tubs.

ALWAYS keep infant within adult's reach.

NEVER lift this product with infant in it.

NEVER place this product in water in an adult bath tub or sink.

ALWAYS keep the drain open in the adult bath tub or sink.”

The content of the warnings can be improved on several points. Staff recommends that the Commission propose a rule that would include several modifications to the ASTM standard's warning content requirements. First, as the NEISS data indicate, infant tubs pose a significant risk of falls. However, someone lifting or carrying a child in the tub—a fall scenario that does not appear prominently in the data—is the only fall scenario included in the warning statements. Incongruously, this warning statement is presented before statements related to submersion scenarios that are likely to result in death. The warnings and instructions regarding placement of the product that relate to falls are inconsistent among the different brands of infant bath tubs. Some brands are clear that the product is designed to be used in a bathtub or sink, and not on elevated surfaces. Other products bear warnings that are ambiguous, and merely instruct consumers to place the product on a flat surface. Staff recommends treating falls as a separate topic on the label and that ASTM develop a more consistent message to address fall hazards. Staff's recommendations, presented at the end of this section, are flexible, however, and allow firms to specify how their products are to be used, if the products are designed to be used in different locations.

Second, the words “ALWAYS” or “NEVER” precede each of the warning statements. Although occasional use of words in all upper case letters provides emphasis in a warning, it is unnecessary to convey meaning, and especially when overused, can give the unwelcome effect of “yelling” at the reader. Note that in the lower example in Figure 1, these words tend to overpower the other text, and thus, may draw the user's attention from the rest of the sentence. Staff recommends revising the text of the warning to limit the use of this type of emphasis and vary the content to avoid the distracting effect of repetition.

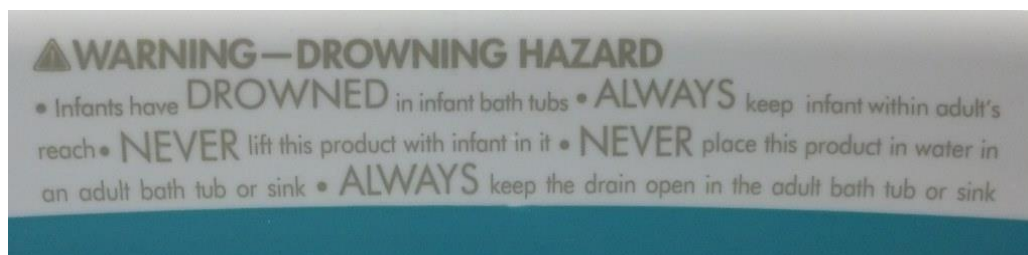


Figure 1. Note that the overuse of words in all uppercase letters may distract from the content.

Third, staff recommends the wording revisions discussed below to improve, simplify, and clarify the warning statements for the proposed rule:

- The current warning statements use the terms “infants” and “infant,” as did the original text for infant bath seats. The Rationale presented in F1967 – 13 (ASTM International, 2013) states that the bath seat subcommittee contracted a focus group comparison of bath seat warning labels to obtain consumer impressions of two alternative warnings. A discussion of the focus group participants’ responses to warnings regarding infant bath seats briefly mentions that “[u]sing the term, [*sic*] ‘babies’ was supported, because this word seems to have emotional implications and therefore seems more likely to get consumers’ attention...” The participants’ response to “babies” versus “infants” is consistent with research findings that the emotional and social salience of stimuli are important factors in the allocation of attention (*e.g.*, Fenske & Raymond, 2006; Raymond, 2009; Anderson, 2013), which is a critical prerequisite to warning effectiveness. “Infants,” although accurate, is an impersonal, clinical term that people do not use when referring to children in general, and their own children, in particular. Its use within warnings thus serves to distance the reader from the subject at risk. Therefore, with the exception of the product identification (*i.e.*, “infant bath tub”), staff recommends that the terms “baby” and “babies” be used in the product warnings.
- The statement in the current voluntary standard, “always keep infant within adult’s reach” seems to emphasize where one should “keep” the child relative to the adult, when in fact, the position of the adult is the variable of interest. The focus group discussion referred to above explains that this phrasing was chosen to convey “the need to avoid reliance on children as supervisors” (ASTM International, 2013). Staff’s recommendation regarding this statement departs somewhat from the reported suggestions of the bath seat focus group.¹¹ The primary behavioral objective of the warning is to persuade the caregiver to *stay* with the child, which obviates the need to rely on other children. Staff’s recommended wording is thus, “Stay in arm’s reach...” Staff also recommends personalizing the directive by adding the pronoun “your,” so that the full statement would read, “Stay in arm’s reach of *your* baby”[emphasis added]. As discussed by Vredenburg and Zackowitz (2006), people must find warning information relevant in order to attend to it; personalizing the risk associated with the hazard situation increases the likelihood that users of the product will perceive the warning to be relevant. Just as the term “babies” carries more emotional weight than “infants,” “your baby” has the potential to evoke mental images of the consequences for this particular child, along with a corresponding emotional response, should a caregiver fail to comply with the warning. Based on their review, Kalsher and Williams (2006) advise that compliance is likely to increase if a warning can cause the user to imagine how she might feel (*e.g.*, guilty) if the caregiver, or in this case, her child, were injured because of her failure to comply. Although the person bathing the child will not always be a parent, parents still are the primary caregivers. For the exceptions, the phrase may help focus attention on the specific child who is “your” responsibility at the moment, regardless of the relationship.

¹¹ Staff did not have access to the report discussed in the bath seats standard at the time of this writing. The Rationale explains that the phrase “keep infant within adult’s reach” addressed the inadequacy of child supervisors. Although focus group data is a valuable resource, user opinion is but one source of input for the development of warnings.

- In an informal review, staff asked a small number of people to read the warnings in the current version of the voluntary standard. The directive to “NEVER place this product in water in an adult bath tub or sink” tended to be confusing and comprehension required re-reading.¹² Some missed the phrase “in water,” and initially wondered where the product was supposed to be used if not in a tub or sink. One was confused because the tub obviously would float if the larger tub was filled, and thought she had misunderstood. In actual use, consumers often skip messages that are difficult to read, and dismiss warnings that “don’t make sense.” Rephrasing and shortening the statement to, “Use in **empty** adult tub or sink” makes it easy to read, and emphasis on the word “empty” helps create the appropriate mental image to clarify the correct use of the product.

For staff’s recommended revisions to the voluntary standard for the proposed rule, the remaining statements were reworded similarly, and a separate fall hazard warning was added to the label. During the May 2015 meeting with ASTM, participants discussed, but did not resolve, issues related to (1) the specific wording of the warning; (2) whether the fall hazard warning should necessarily be combined with the drowning hazard warning; and (3) whether the fall hazard warning must be the same size as the drowning hazard warning. Staff reviewed options for the presentation of the hazard information and recommends that two labels be an option. Staff recommends that the proposed rule specify that the text be of uniform size (*i.e.*, that the text of both the drowning hazard and the fall hazard warnings be 0.20 in) if the warnings are displayed on the same label below the signal word panel. If the fall hazard label is displayed separately, staff recommends the following: (1) that safety alert symbol (▲) and the signal word “WARNING” be at least 0.2 in. (5 mm) in height and be the same size; (2) that the remainder of the text be at least 0.1 in. (2.5 mm) in height; and (3) that the label not be displayed above or before the drowning hazard label.

Staff’s recommendations for revised warning statements in Section 8 for the proposed rule are presented below.

8.4.2 The following warning statement shall be included exactly as stated below:

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

8.4.3 The following warning statement shall be included exactly as stated below:

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

8.4.4 The following warning statement shall be included exactly as stated below:

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

8.4.5 Additional warning statements shall address the following:

- Place **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.

Staff recommends that the proposed rule include content changes to the provisions concerning the instruction manual, addressed in Section 9 of the voluntary standard, that parallel those for the on-product warnings (see Appendix A). Because the instruction manual provides space for additional

¹² This is likely due to the sequence of prepositional phrases.

content, the voluntary standard includes advice on other drowning-related topics, which includes the statement, “NEVER allow other children to substitute for adult supervision.” Including a statement regarding children as monitors is important because the data indicate that approximately one-quarter of the submersion deaths and near-drowning incidents occurred while siblings were present. However, the term “other children” is so broad as to be unrealistic because at some point “other children” are old enough to begin watching their younger siblings. The term may thus reduce the credibility of the warnings and other information provided. Staff recommends (1) that the guidance be specific to a child in the age group with whom young infants typically are left (in this dataset reported age ranged from 1¹³ to 4 years); and (2) that the message focus on the caregiver’s expectations of the sibling:

- **Never** rely on a toddler or preschooler to help your baby or alert you to trouble. Babies have drowned even with other children in or near bathtub.

Format

Current requirements for warnings in the voluntary standard do not address format, and no examples of either the on-product warnings or the warnings in the instructional materials are presented in the voluntary standard as guidance to firms. Consequently, the warnings on products and in manuals vary widely in conspicuity and readability across manufacturers, as staff noted during review of product samples for this effort and related work. Poor cases that meet the current infant tub standard in terms of format combine features such as a condensed sans serif font and a paragraph presentation style with text and background colors that, although contrasting, complement the product material. Two examples of on-product labels that comply with the current standard in terms of format are shown in Figure 2.



Figure 2. Examples of on-product warnings. Top, copied from IDI 050223CBB1512. Bottom, photograph of sample. Note paragraph-style format, lack of hazard-associated color, and particularly in bottom example, low text-to-background contrast.

¹³ Police records indicate that the child was 17 months of age (IDI 131017HCC1007).

Good formatting helps attract and maintain attention; it also can make text easier to read and comprehend. Text presented in bulleted lists is superior to prose for legibility and comprehension (e.g., Wogalter, Shaver, & Chan, 2002). In summarizing research on this topic, Wogalter and Vigilante (2006; p. 255-256) noted that the use of a bulleted list entails greater use of white space, which can be used to organize material into concepts, thereby making information acquisition easier. Findings cited in this area include faster reading speeds, better comprehension, superior content recall, greater preference, and better task performance (citing Desaulniers, 1987; Morrow, Leirer, Andrassy, Hier, & Menard, 1998; Wogalter & Post, 1989; Shaver & Wogalter, 2003). The benefits of a structured format are supported by research demonstrating that information is processed more quickly and easily when it is organized into brief chunks (Miller, 1994; Shiffrin, & Nosofsky, 1994; Chandler & Sweller, 1991; *see also* Young, Frantz, Rhoades, & Wisniewski, 2006). The U.S. Food and Drug Administration (“FDA”) included these principles in developing the label format requirements for nutrition and over-the-counter medications. Studies comparing the latter to then-existing labels confirmed that the new format (table structure organized by content, bold headings, bulleted lists, *etc.*) took less time to read, was easier to read and understand, and resulted in more correct product use decisions (FDA, 1999). Guides to good communication also typically recommend brief chunks of material with subheadings, highlighting, and generous use of white space to improve readability (e.g., Fischhoff, Brewer, & Downs, 2011). Singer and colleagues also recommend the use of highlighting techniques, (e.g., boldface, underlining, all uppercase letters) to emphasize key information (October, 2003).

Based on these findings, staff recommends that to increase conspicuity, legibility, and comprehension across products, the format for the warnings be specified in the proposed rule to include black, non-condensed, sans serif text on a white background; brief, bulleted statements organized in table form by hazard; and surrounded by a black border. Additionally, staff recommends that the proposed rule include formatted labels as figures to provide examples that meet the provisions of the standard.

CONCLUSIONS

Staff recommends that the Commission issue a proposed rule for infant bath tubs that incorporates by reference ASTM F2670 – 13, with modifications to specific provisions in the voluntary standard to improve and strengthen the proposed rule. These modifications, presented in detail in Appendix A, include revision of the warning and instructions requirements of the voluntary standard to: (a) increase the size of the text in the on-product warning consistent with federal requirements for warnings on infant bath seats (16 C.F.R. part 1215); (b) require the use of a hazard color in the on-product warning; (c) revise the warning content to simplify and clarify the language and address the fall hazard; and (d) specify the format of the warning on the product and in the accompanying instructions to increase their potential impact and provide a more consistent presentation of hazard information.

In addition, staff has identified certain issues that staff intends to continue working with ASTM to resolve. Staff recommends that ASTM: (1) expand the scope of the ASTM F2670 – 13 to address combination products that include slings that are mounted on the infant bath tub for bathing newborns and young infants; (2) develop a new voluntary standard to address

infant bathers that are designed to be used in sinks, infant tubs, or adult tubs, whether they are sold separately or with an infant tub; and (3) monitor and collect details of slip-related fall and submersion incidents to determine if the addition of slip-resistance provisions to the voluntary standard are warranted.

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Note: Consistent with ASTM practice, additions based on staff's recommendations are shown as underlined text, and deletions are shown as ~~strike-throughs~~. Double-underlines indicate text that is intended to be highlighted in the usual manner by underlining it with a single line. Due to a characteristic of the word-processing software, words in bold text that are preceded by bullets and followed by additions to the text that have double-underlines appear with a bold underline (see for example, the word "Stay" in 8.4.3). This is not intended to designate that the word is to be underlined. The intended format is shown in the example labels, in which the underline/strike-through convention is not employed.

8. Marking and Labeling

8.1 Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

8.1.1 The name of the manufacturer, distributor, or seller, and either the place of business (city, state, and mailing address, including zip code), or telephone number, or both.

8.1.2 A code mark or other means that identifies the model number and the date (month and year at a minimum) of manufacture.

8.2 Any upholstery label required by law shall not be used to meet the requirements in 8.1.

8.3 Each product's retail package shall address the recommended age, developmental stage, or size of the user.

8.4 Each product shall be labeled with warning statements. The warning statements shall be in contrasting color(s), permanent, conspicuous and in non-condensed sans serif typeface. All warning(s) shall be distinctively separated from any other wording or designs and shall appear in the English language at a minimum. The specified warning label may not be placed in a location that allows the warnings to be obscured or rendered inconspicuous when in the manufacturer's recommended use position.

8.4.1 Warning Label Format – The safety alert symbol (▲) and the word "WARNING," ~~and the statement of hazard~~ shall be at least 0.2 0.4 in. (510 mm) 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 0.10.2 in. (2.5 mm) high unless stated otherwise. The safety alert symbol (▲) and signal word "WARNING" shall be delineated with a bold solid line black border. The background color behind the safety alert symbol (▲) and signal word "WARNING" shall be orange, red, or yellow, whichever provides best contrast against the product background. The remainder of the label text shall be black and in upper and lower case letters on a white background surrounded by a bold solid line black border. Text within the message panel shall be left-justified. Precautionary statements shall be indented from hazard statements and preceded by bullet points. Message panels within the label shall be delineated with solid black lines between sections addressing different hazards. If an outer border is used to surround the bold solid black lines of the label, the outer border shall be white and the corners may be radiused. An example label in the format described in this section is shown in Fig. X1.

8.4.2 The following warning statement shall be included exactly as stated below:

~~WARNING – DROWNING HAZARD~~ Drowning Hazard: Babies have drowned while using infant bath tubs.

8.4.3 Additional warning statements shall address the following:

~~Infants have DROWNED in infant bath tubs.~~

~~ALWAYS keep infant within adult's reach.~~

~~NEVER lift this product with infant in it.~~

~~NEVER place this product in water in an adult bath tub or sink.~~

~~ALWAYS keep the drain open in the adult bath tub or sink.~~

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

8.4.4 The following warning statement shall be included exactly as stated below:

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

8.4.5 Additional warning statements shall address the following:

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

8.4.6 The drowning hazard warning statements and the fall hazard warning statements in 8.4.2 through 8.4.5 may be displayed on separate labels. If the fall hazard warning statements are displayed on a separate label, the label shall comply with the requirements of 8.4.1 except that the safety alert symbol (▲) and the signal word "WARNING" shall be at least 0.2 in. (5 mm) in height and the remainder of the text shall be at least 0.1 in. (2.5 mm) in height. The fall hazard warning label shall not be displayed above or before the drowning hazard warning label.

8.4.47 Products utilizing suction cups as an attachment mechanism to the support surface, and which are not ~~recommended~~ intended by the manufacturer to be used on any type of slip-resistant surface, shall also include a warning to this effect. In addition, if there are other types of surfaces that the manufacturer does not ~~recommend~~ intend the product be used on, then additional warning(s) shall be given regarding such surface(s). Such warning(s) shall use the signal word WARNING preceded by the safety alert symbol, and shall meet the requirements described in 8.4.1.

8.5 Each product's retail package shall be labeled on the principal display panel as specified in 8.4 except that the safety alert symbol (▲) and the word "WARNING" shall be at least 0.2 in. (5 mm) high and the remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm) high. ~~with the safety alert symbol, signal word, and hazard identification required in 8.4.2 and the first two warning statements required in 8.4.3 according to the requirements in 8.4.1 and 8.4.2.~~ The warnings and statements are not required on the retail package if they are on the product and visible in their entirety and are not concealed by the retail package. Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

8.6 Warnings, statements, or graphic pictorials on the product and package shall not indicate or imply that the infant may be left in the product without a caregiver in attendance.

9. Instructional Literature

9.1 All products shall have instructional literature enclosed ~~which~~ that explains the proper use of the product and that shall be easy to read and understand. Such literature shall include instructions for assembly, maintenance, cleaning, inspections, and limitations of the product, as well as the manufacturer's recommended use position(s).

9.2 *Warning Statements in Instructional Literature:*

9.2.1 Instructional literature shall include the warnings specified in 8.4.2 through 8.4.7, 8.4.3, and 8.4.4. The phrase "To prevent drowning" shall be added before the bulleted statements in 8.4.3 and the phrase "To prevent falls" shall be added before the bulleted statements in 8.4.5.

9.2.2 Warning statements in instructional literature shall also address the following:

- Infants Babies can drown in as little as 1 inch of water. Use as little water as possible to bathe your baby.

~~ALWAYS bathe your infant using as little water as necessary.~~

- Never rely on a toddler or preschooler to help your baby or alert you to trouble. Babies have drowned even with other children in or near bathtub. ~~NEVER allow other children to substitute for adult supervision.~~

9.2.3 Warning statements in instructional literature shall meet the requirements described in 8.4 ~~for letter height, contrasting color(s), and sans serif type face, and shall appear in the English language at a minimum~~ except that the background and text in the signal word panel need not be in color, and the remaining text shall be in highly contrasting colors, (e.g., black text on white). An example label that meets the requirements is shown in Fig. X2.

9.3 In addition to the warnings, the instructional literature shall emphasize and reinforce the safe practices stated in the warnings.

9.34 Instructional literature shall also advise to test the temperature of the water in, or being put into, the infant bath tub prior to placing the infant into the product. Instructions shall also indicate that the typical water temperature for bathing a baby should be between 90 and 100°F (32.2 and 37.8°C).

9.45 Instructional literature shall instruct to discontinue the use of the product if it becomes damaged, broken, or disassembled.

9.56 Instructional literature shall include the information as specified in 8.3.

9.67 Warnings, statements, or graphic pictorials shall not indicate or imply that the infant may be left in the product without a caregiver in attendance.

WARNING

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.

Fig. X1 Example label that meets the requirements of Section 8 with the drowning and fall hazards combined in a single label.

WARNING

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**.

WARNING

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.

Fig. X2 Example labels that meet the requirements of Section 8 when the drowning hazard warning and fall hazard warning are presented in separate labels.

WARNING

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

To prevent drowning: Stay in arm's reach of your baby.

- **Never** rely on a toddler or preschooler to help your baby or alert you to trouble. Babies have drowned even with other children in or near bath tub.
- Babies can drown in as little as **1 inch** of water. Use as little water as possible to bathe your baby.
- Use in an **empty** adult tub or sink.
- **Always** keep drain **open**.

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

To prevent falls:

- 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.

Fig. X3. Example label that meets the requirements of Section 9. Note: The fall hazard warning need not be presented in 0.2 in. text if it is displayed separately from the drowning hazard warning.

**TAB C: Staff Letter to ASTM Subcommittee Regarding
ASTM F2670 Infant Bath Tubs**

**T
A
B
C**

CIRS|C&K Testing
www.cirs-ck.com
Hotline: 4006-721-723
Email: test@cirs-group.com



U.S. CONSUMER PRODUCT SAFETY COMMISSION
5 Research Place, Rockville MD 20850

March 31, 2015

TRANSMITTED VIA EMAIL

Mr. Paul Ware
Subcommittee Chairman for ASTM Infant Bath Tubs
ASTM
100 Barr Harbor Dr.
West Conshohocken, PA 19428-2959

Re: ASTM F2670 Infant Bath Tubs

Dear Mr. Ware,

U.S. Consumer Product Safety Commission (CPSC, Commission) staff²⁵ is preparing a notice of proposed rulemaking (NPR) for infant bath tubs under section 104 of the Consumer Product Safety Improvement Act (CPSIA), which requires the Commission to promulgate standards for durable infant or toddler products. As required by the CPSIA, staff is to consult with various stakeholders and experts to assess the effectiveness of the relevant voluntary standards, and I appreciate your leadership and the subcommittee's efforts in assessing F2670 – 13, *Standard Consumer Safety Specifications for Infant Bath Tubs*.

As of this date, CPSC staff is aware of the following items balloted to address changes for two test procedures and the size of the warning label symbol and text. Staff agrees with these changes and highlighted a weight conversion error in 7.4.2; one clarification to the warning label; and added the missing safety triangle. The balloted items are shown below exactly as balloted with changes shown by ~~strikeout~~ and underline, where strikeout represents removed text, and underline represents added text:

7.1 Latching or Locking Mechanism:

7.1.1 Single Action Release Mechanism—With the product in each manufacturer's recommended use position, gradually apply a 10-lbf (45-N) force to the locking or latching mechanism(s) in the direction tending to release it.

²⁵ The views or opinions expressed in this letter are solely those of the staff, and these views and opinions do not necessarily represent those of the Commission.

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 one 3-minute rest after every 7 minutes of cycling.

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. Continuous cycling is prescribed, but with specified rest periods.

7.4 *Static Load Test:*

7.4.1 Install the product according to the manufacturer’s instructions onto a smooth test surface. In the case where the product must be supported on or near its ends, use an appropriate support structure to simulate this support.

7.4.2 Place a weight of 50 lb (~~13.6 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).~~ Apply the load on the center of the seating surface using a 6 to 8 in. (150 to 200 mm) diameter bag filled with steel shot.

7.4.3 Remove the weight after a time period of 20 min.

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

X1.1 Section 7.4.2 – The configuration of the static load was revised to allow for application of the load to soft or pliable seating surfaces without damaging the surface.

8.4.1 The safety alert symbol (~~A~~), the word “WARNING,” and the statement of hazard shall not be less than ~~0.2 in. (5 mm)~~ 0.4 in. (10 mm) high and ~~shall be~~ in bold capital letters. The remainder of the text shall be characters whose upper case shall not be less than ~~0.1 in. (2.5 mm)~~ 0.2 in. (5 mm) high.

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

X 1.3 Section 8.4.1 – Revision was made to specify the same size lettering for the warning header as is specified in Bath Seat ASTM standard F1967.

Additional CPSC staff recommended changes to the standard’s marking and labeling and instructional literature sections

Based on additional internal review of the incident data associated with infant bath tubs, staff identified submersions and falls as risks that could be more fully addressed in the voluntary standard to reduce the risk of injury. Staff recognizes that these hazards cannot be eliminated by designing them out or guarding against them; therefore, enhanced warnings and instructions appear to be the only options available to further reduce the risk of injury. Using published research and reviews as guidance (*e.g.*, Laughery, & Wogalter, 2011; Wogalter, & Vigilante, 2006; Frascara, 2006; FDA, 1999; Chapanis, 1994), staff has reevaluated the relevant content of the voluntary standard, and developed a number of changes to the existing F2670 – 13 sections on marking and labeling and instructional literature. Staff believes these changes, if implemented, would likely further reduce the risk of injury. Therefore, staff is requesting that

you ballot for inclusion in a revision to F2670 – 13 the following additional changes as shown by ~~strikeout~~ and underline, where strikeout represents removed text, and underline represents added text:

8. Marking and Labeling

8.1 Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

8.1.1 The name of the manufacturer, distributor, or seller, and either the place of business (city, state, and mailing address, including zip code), or telephone number, or both.

8.1.2 A code mark or other means that identifies the model number and the date (month and year at a minimum) of manufacture.

8.2 Any upholstery label required by law shall not be used to meet the requirements in 8.1.

8.3 Each product's retail package shall address the recommended age, developmental stage, or size of the user.

8.4 Each product shall be labeled with warning statements. The warning statements shall be in contrasting color(s), permanent, conspicuous and in non-condensed sans serif typeface. All warning(s) shall be distinctively separated from any other wording or designs and shall appear in the English language at a minimum. The specified warning label may not be placed in a location that allows the warnings to be obscured or rendered inconspicuous when in the manufacturer's recommended use position.

8.4.1 Warning Label Format – The safety alert symbol (▲) and the word “WARNING,” ~~and the statement of hazard~~ shall not be less than ~~0.2~~ 0.4 in. (~~5~~ 10 mm) high and shall be in bold capital letters. The remainder of the text shall be characters whose upper case shall not be less than ~~0.1~~ 0.2 in. (~~2.5~~ mm) high. The safety alert symbol (▲) and signal word “WARNING” shall be delineated with a bold solid line black border. The background color behind the safety alert symbol (▲) and signal word “WARNING” shall be orange, red, or yellow, whichever provides best contrast against the product background. The remainder of the label text shall be black and in upper and lower case letters on a white background surrounded by a bold solid line black border. Precautionary statements shall be indented from hazard statements and preceded by bullet points. Message panels within the label shall be delineated with solid black lines between sections addressing different hazards. If an outer border is used to surround the bold solid black lines of the label, the outer border shall be white and the corners may be radiused. An example label in the format described in this section is shown in Fig. X1.

8.4.2 The following warning statement shall be included exactly as stated below:

~~WARNING—DROWNING HAZARD~~ Drowning Hazard: Babies have drowned while using infant bath tubs.

8.4.3 Additional warning statements shall address the following:

~~Infants have DROWNED in infant bath tubs.~~

~~ALWAYS keep infant within adult's reach.~~

~~NEVER lift this product with infant in it.~~

~~NEVER place this product in water in an adult bath tub or sink.~~

~~ALWAYS keep the drain open in the adult bath tub or sink.~~

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

8.4.4 The following warning statement shall be included exactly as stated below:

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

8.4.5 Additional warning statements shall address the following:

- Use only [insert safe location(s), e.g., in adult tub, sink, or on floor; in adult tub or on floor].
- Never lift or carry baby in bath tub.

8.4.46 Products utilizing suction cups as an attachment mechanism to the support surface, and which are not ~~recommended~~ intended by the manufacturer to be used on any type of slip-resistant surface, shall also include a warning to this effect. In addition, if there are other types of surfaces that the manufacturer does not recommend the product be used on, then additional warning(s) shall be given regarding such surface(s). Such warning(s) shall use the signal word WARNING preceded by the safety alert symbol, and shall meet the requirements described in 8.4.1.

8.5 Each product's retail package shall be labeled on the principal display panel as specified in 8.4. ~~with the safety alert symbol, signal word, and hazard identification required in 8.4.2 and the first two warning statements~~

~~required in 8.4.3 according to the requirements in 8.4.1 and 8.4.2.~~ The warnings and statements are not required on the retail package if they are on the product and visible in their entirety and are not concealed by the retail package. Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

8.6 Warnings, statements, or graphic pictorials on the product and package shall not indicate or imply that the infant may be left in the product without a caregiver in attendance.

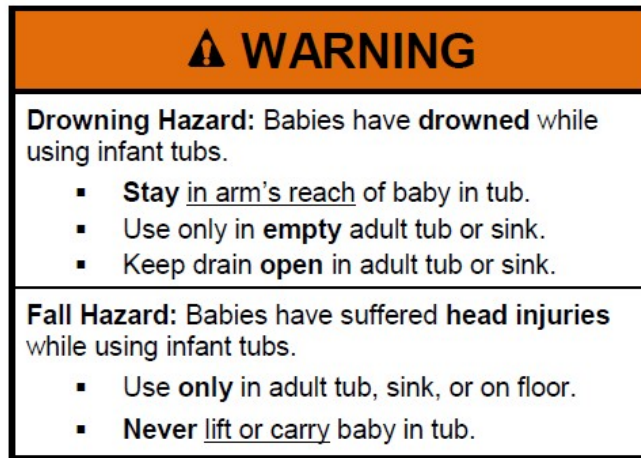


Fig. X1 Example label that meets the requirements of Section 8 except for size.

9. Instructional Literature

9.1 All products shall have instructional literature enclosed ~~which that~~ explains the proper use of the product and that shall be easy to read and understand. Such literature shall include instructions for assembly, maintenance, cleaning, inspections, and limitations of the product, as well as the manufacturer's recommended use position(s).

9.2 *Warning Statements in Instructional Literature:*

9.2.1 Instructional literature shall include the warnings specified in 8.4.2 through 8.4.6, 8.4.3, and 8.4.4. The phrase "Prevent drowning" shall be added before the bulleted statements in 8.4.3 and the phrase "Prevent falls" shall be added before the bulleted statements in 8.4.5.

9.2.2 Warning statements in instructional literature shall also address the following:

- Infants Babies can drown in as little as 1 inch of water. Use as little water as needed to bathe your baby. ~~ALWAYS bathe your infant using as little water as necessary.~~
- Babies have drowned even with other children in or near bathtub. Never rely on other children to watch baby. ~~NEVER allow other children to substitute for adult supervision.~~

9.2.3 Warning statements in instructional literature shall meet the requirements described in 8.4 ~~for letter height, contrasting color(s), and sans serif type face, and shall appear in the English language at a minimum~~ except that the background and text shall be in highly contrasting colors, (e.g., black text on white). An example label that meets the requirements is shown in Fig. X2.

9.3 In addition to the warnings, the instructional literature shall emphasize and reinforce the safe practices stated in the warnings.

9.34 Instructional literature shall also advise to test the temperature of the water in, or being put into, the infant bath tub prior to placing the infant into the product. Instructions shall also indicate that the typical water temperature for bathing a baby should be between 90 and 100°F (32.2 and 37.8°C).

9.45 Instructional literature shall instruct to discontinue the use of the product if it becomes damaged, broken, or disassembled.

9.56 Instructional literature shall include the information as specified in 8.3.

9.67 Warnings, statements, or graphic pictorials shall not indicate or imply that the infant may be left in the product without a caregiver in attendance.

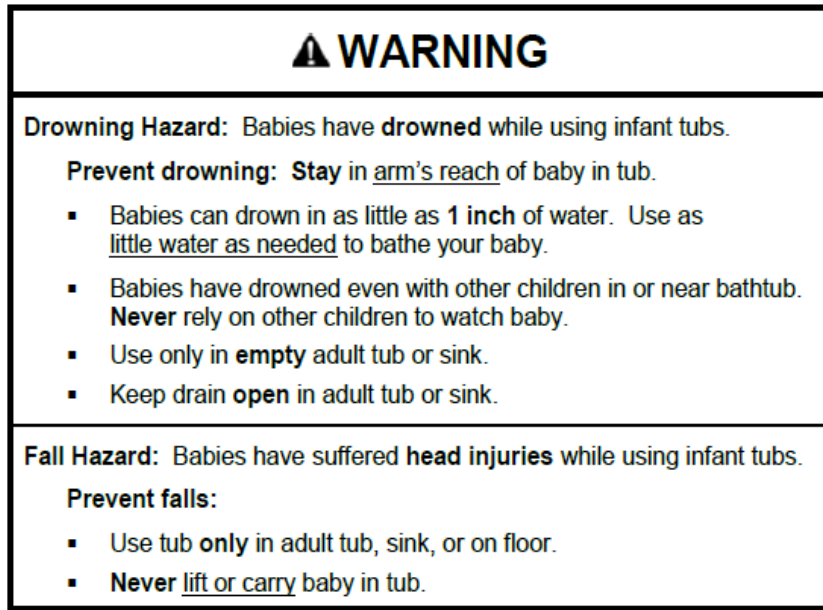


Fig. X2 Example label that meets the requirements of Section 9 except for size

As previously mentioned, the Commission has directed staff to prepare for their consideration in Fiscal Year 2015 a notice of proposed rulemaking (NPR) for infant bath tubs under Section 104 of CPSIA, the Danny Keysar Child Product Safety Notification Act. Staff intends to develop an NPR using the requirements in F2670 – 13, *Standard Consumer Safety Specifications for Infant Bath Tubs*. However, staff will also be evaluating requirements beyond those already found in the published voluntary standard, including the specific marking and labeling requirements discussed in this letter that may be necessary to reduce the risk of injury. Please note that based on the statutory language in CPSIA, if the Commission determines that a standard that is more stringent than the voluntary standard would further reduce the risk of injury, the more stringent standard must be adopted.

Thank you for your consideration of these comments.

Sincerely,

Celestine T. Kish

Celestine T. Kish
Project Manager, Infant Bath Tubs
CPSIA Section 104 Rulemaking

cc: Len Morrissey, ASTM F15 Staff Manager
100 Barr Harbor Dr.
West Conshohocken, PA 19428-2959

Colin Church, CPSC Voluntary Standards Coordinator

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TAB D: LSM Staff's Recommendations for Infant Bath Tubs NPR

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

Memorandum

DATE: June 16, 2015

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

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

Gregory K. Rea, Division Director
Mechanical Engineering Division
Directorate for Laboratory Sciences

FROM: Ian B. Hall, Mechanical Engineer
Mechanical Engineering Division
Directorate for Laboratory Sciences

SUBJECT: LSM Staff's Recommendations for Infant Bath Tubs NPR

I. OVERVIEW

This memorandum assesses the effectiveness of the current version of the standard, ASTM F2670 – 13, and includes CPSC staff's recommendation that the Commission publish a notice of proposed rule ("NPR") that incorporates by reference the ASTM standard, with certain modifications.

Laboratory Sciences Mechanical ("LSM") staff tested various physical tubs and reviewed the latest ASTM International ("ASTM") infant bath tub standard (F2670 – 13) in preparation for a mandatory infant bath tub rule.

As specified in the latest ASTM infant bath tub standard (F2670 – 13), 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.

¹ Standard Consumer Safety Specification for Infant Bath Tubs (ASTM F2670 - 13). (2013). West Conshohocken, PA.

CIRS|C&K Testing
www.cirs-ck.com
Hotline: 4006-721-723
Email: test@cirs-group.com

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.

Review of ASTM Standard:

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 to be “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.”

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

ASTM International (ASTM).

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

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toll-free: 4006-721-723
Email: test@cirs-group.com

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.

II. Adequacy of ASTM F2670 – 13

The current version of ASTM F2670 – 13 has two mechanical issues that CPSC staff recommends be modified and then adopted by the Commission. LSM staff further notes one additional area that requires further monitoring.

1. Static Load Test

The ASTM standard requires that a sample absorb a static load, which is applied through a load distribution plate. ASTM F2670 – 13 Section 7.4.2 defines 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 does 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 can create stress concentrations and damage certain tub materials and geometries. Those stress concentrations and the resulting tub damage are not the intent of the standard and do not match real world loading.

Therefore, in 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 recommended additional language 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 change the distribution plate to a shot bag. The following change was balloted by the ASTM subcommittee on March 27, 2015. This change was accepted through the balloting process, with some editorial changes. The accepted language is below:

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).~~

Staff believes these changes will augment product safety by improving the accuracy, consistency, and repeatability of static load testing. Therefore, staff recommends that the Commission include this language as a modification in the NPR.

2. Resistance to Collapse

ASTM F2670 – 13 Section 5.4 *Resistance to Collapse* states 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 currently specifies 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 are not automated easily, a rate of 12 cycles per minute may not be possible.

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 does not believe that increasing the average cycle time from 5 seconds to 7 seconds will 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, new wording was agreed upon, and was sent out to ballot on June 11, 2015. The balloted wording is:

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 believes these changes will augment product safety by improving the accuracy, consistency, and repeatability of durability testing. Therefore, staff recommends that the Commission include this language as a modification in the NPR.

3. Slip-Resistant Surfacing

CPSC Epidemiology staff identified 7 percent (14 out of 202) of incidents involving victims slipping on tub surfaces. One incident involved a child standing up in the tub and falling; and all other incidents were minor incidents or complaints without injuries. LSM staff was unable to find a directly applicable test method to measure the slip-resistant characteristics of infant tubs. There is an ASTM test method, ASTM F462-2007, "*Standard Consumer Safety Specification for Slip-Resistant Bathing Facilities*," which is designed to measure the frictional characteristics of adult bath tubs and showers. However, the test equipment specified in the standard may not fit within the confines of smaller infant tubs.

LSM staff recommends monitoring epidemiological data, and should the epidemiological data show a significant number of severe injuries, LSM staff would recommend developing an appropriate test method and associated performance requirement in conjunction with ASTM.

III CONCLUSION

CPSC LSM staff recommends that the Commission publish a notice of proposed rulemaking that incorporates by reference the ASTM voluntary standard with certain modifications, including two mechanical recommendations related to the static load test fixture and the latching or locking mechanism durability test. LSM staff further recommends continuing monitoring slip-related injuries.

**TAB E: Staff Letter to ASTM Subcommittee Regarding Ballot F15
(15-04), Item 7**

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U.S. CONSUMER PRODUCT SAFETY COMMISSION
5 RESEARCH PLACE
ROCKVILLE, MARYLAND 20850

Celestine T. Kish
Sr. Engineering Psychologist
Division of Human Factors
ckish@cpsc.gov

June 30, 2015

TRANSMITTED VIA EMAIL

Mr. Paul Ware
Infant Bath Tubs Subcommittee Chair
100 Barr Harbor Drive
PO Box C700
West Conshohocken, PA 19428-2959

Dear Mr. Ware:

U.S. Consumer Product Safety Commission (CPSC) staff³ would like to offer a comment on the proposed change to ASTM F2670 - 13, *Standard Consumer Safety Performance Specification for Infant Bath Tubs* in ballot F15 (15-04), Item 7.

In the current standard, Section 7.1.2 *Latching or Locking Mechanism Durability*, states: "Cycling shall be conducted at a rate of 12 cycles per minute." In ballot Item 7, the proposed language deletes the reference to a specific number of cycles per minute to a more general "continuous basis." While staff agrees with this broader more general requirement to allow more time to properly test more complicated latching or locking mechanisms, staff believes it is important to not lose the original intent of the timing of the cycle testing. Therefore, staff proposes adding to the proposed language in the non-mandatory Appendix of the standard a reference back to the 12 cycles per minute.

Specifically, CPSC staff proposes adding the following language:

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, but the intent of the standard is to cycle the mechanism at a rate of 12 cycles per minute.

³ The views in this letter are those of the staff and have not been reviewed or approved by, and may not reflect the views of, the Commission.

We hope this comment on the ballot item is useful. Thank you for your consideration.

Sincerely,

Celestine T. Kish

Cc: Len Morrissey, ASTM
Colin Church, CPSC

TAB F: Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Infant Bath Tubs; 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
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

Date: June 5, 2015

TO : Celestine T. Kish
Project Manager, Infant Bath Tubs

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

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Samantha Li
Economist
Directorate for Economic Analysis

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

Introduction

In accordance with section 104 of the Consumer Product Safety Improvement Act (“CPSIA”), staff recommends that the Commission issue a proposed rule for infant bath tubs, as described in the briefing memorandum. This memorandum examines the impact of the draft proposed rule on small businesses.

The Regulatory Flexibility Act requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the Regulatory Flexibility Act requires that agencies prepare an initial regulatory flexibility analysis and make it available to the public for comment when a general notice of proposed rulemaking is required. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any significant alternatives that

accomplish the stated objectives and minimize any significant economic impact on small entities. Specifically, the initial regulatory flexibility analysis must contain:

- (1) a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- (2) a description of the reasons why action by the agency is being considered;
- (3) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- (4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
- (5) identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- (6) a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimizes the rule's economic impact on small entities.

The Product

As specified in the ASTM standard (F2670 – 13), “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, there are at least 26 manufacturers and importers supplying infant bath tubs to the U.S. market. Staff identified 23 domestic firms: 14 are domestic manufacturers, eight are domestic importers, and one firm has an unknown supply source. In addition, staff identified three foreign companies that export directly to the United States via Internet sales or to U.S. retailers.²⁹

According to data collected with the CPSC's 2013 Durable Nursery Products Exposure Survey (“DNPEs”), households with children under 6 years old 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.

According to estimates derived from the National Electronic Injury Surveillance System (“NEISS”) by Directorate for Epidemiology staff, there were approximately 2,200 emergency-department treated injuries from 2004 to 2014 related to infant bath tubs, about 200 annually. Combining the estimated annual average for emergency-department

²⁹ Staff made these determinations using information from Dun & Bradstreet and Reference USA Gov, as well as firms' websites.

treated injuries with the DNPES data yields an injury rate of about 0.45 emergency department-treated injuries annually for every 10,000 infant bath tubs in use (200 injuries ÷ 4.4 million infant bath tubs in use x 10,000).³⁰

Reason for Agency Action and Legal Basis for the Draft Proposed 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. CPSC staff recommends that the Commission propose adopting the voluntary standard with a few modifications.

Compliance Requirements of the Draft Proposed Rule

CPSC staff recommends incorporating by reference the voluntary standard for infant bath tubs with a few modifications. Key components of the current ASTM standard for infant bath tubs (F2670-13) include:

- stability requirements – ensures the infant bath tub will not collapse during use; and
- static load requirement – intended to prevent breakage during use.

CPSC staff recommends adding to the existing ASTM standard the following requirements:

- A requirement that revises test procedure for durability of latching or locking mechanisms.
- A requirement that revises the test procedure for static load test.
- A requirement that revises warning label statements and instructional literature 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 the permanency and adhesion of labels; (3) requirements for a passive crotch restraint system; (4) requirements for protective components; (5) requirements for toy accessories; (6) requirements to ensure suction cups adhere to the product and attached surface; and (7) warning labels and instructional literature including language emphasizing that infants have drowned while using infant bath tubs.

The staff-recommended requirements represent minor modifications to existing tests. Staff recommends modifying the latching and locking mechanism test procedures to allow

³⁰ Memorandum from Adam Suchy, Directorate for Epidemiology, dated May 27, 2015, Subject: Infant Bath Tub-Related Deaths, Injuries and Potential Injuries, and NEISS Injury Estimates Reported between January 1, 2004 and May 20, 2015.

continuous cycling with a different test rate using the same test equipment specified in the current voluntary standard. Similarly, staff recommends using a round weight in the static load test that will not damage the infant bath tub when the product is tested to support the maximum recommended weight.³¹

The staff-recommended infant bath tub warning label and instructional literature statements elaborate on the potential fall and drowning hazards scenarios and simplify warning statements for comprehension. Changes to labeling include specifying the font size and format style and color that may be used for marking and labeling.³²

Other Federal Rules

Section 14(a)(2) of the Consumer Product Safety Act (“CPSA”) requires every manufacturer and private labeler of a children’s product that is subject to a children’s product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory that the product complies with all applicable children’s product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards by rule for, among other things, ensuring that a children’s product is tested periodically, and when there has been a material change in the product, and safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107), became effective on February 13, 2013 (the 1107 rule). Infant bath tubs will be subject to a mandatory children’s product safety rule, so they will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule.

In addition, section 14 of the CPSA and the 1107 rule require the third party testing of children’s products to be conducted by CPSC-accredited laboratories. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (“NOR”) for the accreditation of third party conformance assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children’s product safety rule. The NORs for existing rules are set forth in 16 C.F.R. part 1112. Consequently, staff recommends that the Commission propose an amendment to 16 C.F.R. part 1112 that would establish the requirements for the accreditation of testing laboratories to test for compliance with an infant bath tub final rule.

Impact on Small Businesses

Under U.S. Small Business Administration guidelines, a manufacturer of infant bath tubs is small if it has 500 or fewer employees, and importers and wholesalers are considered small

³¹ ASTM balloted and approved similar language in static load test procedure for inclusion in the next version of the standard. ASTM also balloted language for the latching and locking durability. Memorandum from Ian B. Hall, Mechanical Engineering Division, dated June 16, 2015, Subject: LSM Staff’s Recommendation for Infant Bath Tubs NPR.

³² Memorandum from Catherine A. Sedney, Division of Human Factors, dated June 5, 2015, Subject: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in Infant Bath Tubs.

if they have 100 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 17 of the 23 domestic firms known to be supplying infant bath tubs to the U.S. market are small firms-10 manufacturers, six importers, and one firm with an unknown supply source.

Small Domestic Manufacturers

Based on information on firms' websites, six domestic manufacturers currently comply with F2607-13. This includes two infant bath tub manufacturers that are certified by the Juvenile Products Manufacturers Association, the major U.S. trade association that represents juvenile product manufacturers and importers, as compliant with the voluntary standard. The other four firms state on their websites that their products are compliant. 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 F2607-13 and will need to modify their products. Based upon 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.

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 testing to the new requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107). Third party testing will include physical and mechanical test requirements specified in the infant bath tub final rule; lead 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, which were on average about \$29 million annually, it seems unlikely that the impacts of the rule due to the third party testing requirement will be economically significant for small producers.³³

³³For example, testing costs would constitute less than 0.2 percent of firms' revenues if 10 samples were required for testing. If 50 samples were required, testing costs would amount to less than one percent of sales revenue. While we are unsure of the number of samples that will be required to meet the third party testing requirement, the number is probably well below 50 and quite possibly below 10. Thus, it seems safe to conclude that testing costs are very small relative to revenue and unlikely to create significant economic impacts.

Small Domestic Importers

Four of the six small importers are believed to be compliant with the current 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 proposed rule could be more difficult for the remaining two importers because changes beyond simple modifications to the warning label are probably necessary. The two importers not believed 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, these firms may discontinue importing infant bath tubs altogether and 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. Based upon review of the firms' revenues, which were on average about \$4.0 million annually, the impact of the testing requirements could exceed one percent of revenues if the firms needed to test more than one unit per model. Hence, we cannot rule out 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 would only 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.

Alternatives

Under section 104 of the CPSIA, the Commission is required to promulgate a standard that is either substantially the same as the voluntary standard or more stringent. The Commission could, therefore promulgate the existing voluntary standard without any revisions. However, the staff recommended alternatives to warning labels and testing procedures are not expected to have a substantial impact on costs to small businesses. Another alternative that would reduce the impact on small entities is to set an effective date later than the staff-recommended 6 months. This would allow manufacturers additional time to modify and/or develop compliant infant bath tubs, thereby spreading the associated costs over a longer period of time.

The 1112 Rule and the Impact on Small Conformity Assessment Bodies

In accordance with section 104 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, staff recommends that the Commission propose 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. This section assesses the impact of the amendment on small laboratories.

A final regulatory flexibility analysis (“FRFA”) was conducted as part of the original 1112 rule (78 FR 15836, 15855-58), as required by the Regulatory Flexibility Act. 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, amending the rule to include the NOR for infant bath tub standard would not have a significant adverse impact on small 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 chairs standard to their scope of accreditation. Consequently, the Commission could certify that the NOR for the infant bath tub standard will not have a significant impact on a substantial number of small entities.