



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

BP - Infant Bath Seats - Final Rule
 The contents of this document will be
 discussed at the Open Commission Meeting
 on Wednesday, May 5, 2010

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISION MEETING FOR THIS MATTER IS SCHEDULED ON: May 12, 2010

Date: **APR 28 2010**

TO : The Commission
 Todd Stevenson, Secretary

THROUGH: Maruta Budetti, Executive Director *MB*

FROM : Cheryl A. Falvey, General Counsel *CAF*
 Philip L. Chao, Assistant General Counsel, RAD *PLC*
 Patricia M. Pollitzer, Attorney *PMF*

SUBJECT : Final Rule for Bath Seats under Section 104(b) of the Consumer Product Safety Improvement Act

Section 104(b) of the Consumer Product Safety Improvement Act ("CPSIA") directs the Commission to issue safety standards for durable infant or toddler products. Attached is a staff briefing memorandum recommending that the Commission issue a final rule under section 104(b) of the CPSIA for infant bath seats that is substantially the same as the applicable voluntary standard, ASTM F 1967-08a, with certain modifications. A draft final rule is provided at Tab E of the briefing package for your consideration.

Please indicate your vote on the following options.

- I. Approve publication in the *Federal Register* of the draft final rule for bath seats without change.

 Signature

 Date

RH 4/28/2010
 CLEARED FOR PUBLIC RELEASE
 UNDER CPSA 6(b)(1)

II. Approve publication in the *Federal Register* of the draft final rule for bath seats with changes (please specify changes):

Signature

Date

III. Do not approve publication in the *Federal Register* of the draft final rule for bath seats.

Signature

Date

IV. Take other action (please specify):

Signature

Date



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

This document has been
electronically approved and signed.

Date: April 28, 2010

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Maruta Z. Budetti, Executive Director

FROM : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification
and Reduction
Patricia Edwards, Division of Mechanical Engineering, Directorate for
Engineering Sciences

SUBJECT : Final Rule for Consumer Product Safety Improvement Act of 2008 (CPSIA),
Safety Standard for Baby Bath Seats

A) Introduction

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC, or Commission) to study and develop safety standards for certain infant and toddler products. The list of products in section 104 includes: full-size and non-full-size cribs; toddler beds; high chairs, booster chairs, and hook-on chairs; bath seats; gates and other enclosures for confining a child; play yards; stationary activity centers; infant carriers; strollers; walkers; swings; and bassinets and cradles. The Commission is charged with examining and assessing the effectiveness of any voluntary consumer product safety standards and for promulgating mandatory consumer product safety standards for these products.

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 voluntary standards. This consultation process commenced in October 2008 during the ASTM International (formerly known as the American Society of Testing and Materials) subcommittee meeting regarding the ASTM bath seat voluntary standard, in which CPSC staff participated. Consultations with members of the ASTM subcommittee are ongoing.

The Commission issued a Notice of Proposed Rulemaking (NPR) in 74 *Federal Register* 30983 dated September 3, 2009 (Tab A). The proposed rule (16 CFR part 1215) incorporated by reference the requirements for bath seats as outlined in the voluntary standard, ASTM F 1967-08a, "*Standard Consumer Safety Specification for Infant Bath Seats*," with certain changes to specific provisions in the voluntary standard in order to strengthen the proposed rule. This

briefing package updates the bath seat incident data, presents a final regulatory flexibility analysis to evaluate the possible economic impact of the draft final rule on small businesses, and provides staff's responses to the comments on the NPR as well as staff's recommendations regarding the draft final rule.

B) Incident Data Update (Tab B)

Tab B contains an update to the Hazard Analysis memorandum that was prepared by the Directorate for Epidemiology (EPI) for the NPR. The previous EPI memorandum analyzed incidents that occurred between 1983 – 2008¹ and that were extracted as of February 2009. The updated analysis in Tab B of this briefing package includes incident reports through November 2009. Five new fatalities and five new non-fatal incidents, all of which occurred in 2009 were identified. Three of the deaths and three of the additional non-fatal incidents involved bath seats that met the stability requirements of either F 1967-04 or F 1967-07. One death involved an earlier, pre-2004 bath seat product and the remaining death involved a combination infant bath tub-bath seat product that was certified to the 2004 edition of the bath seat and bath ring standard (F 1967-04) but is no longer being produced². This fatality is not included in the frequency statistics. This update also located additional information enabling staff to identify two 2005 fatality reports, previously considered to be independent, as being a single incident. Updated incident counts and synopses of reported fatal incidents that involved bath seats that met the stability requirements of ASTM F 1967-04 or F 1967-07 are provided in Tab B. In summary, from 1983 through November 30, 2009, bath seats or bath rings were associated with 174 reported fatalities, all of which were submersions, and 300 non-fatal incidents of which approximately 40% were submersion incidents.

C) Final Regulatory Flexibility Analysis (Tab C)

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis and make it available to the public for comment when the final rule is published. The final regulatory flexibility analysis must describe the impact of the final rule on small entities and identify any alternatives that may reduce the impact.

There are three firms currently marketing baby bath seats in the United States. One is a large domestic manufacturer and another is a small foreign manufacturer. The remaining firm is a small importer. All three firms are expected to require modifications to meet the proposed standard.

One alternative under section 104 of the CPSIA that could potentially reduce the impact on small entities would be to make the voluntary standard mandatory with no modifications. However, CPSC staff does not believe that this alternative would adequately address all of the known hazard patterns. Additionally, while this alternative would reduce the impact on the one large

¹ Incident reporting for 2006-2008 is still ongoing.

² Combination bath tub-bath seat products are no longer covered by F 1967 and are covered by a new, separate infant bath tub-specific standard, ASTM F 2670-09 "*Standard Consumer Safety Specification for Infant Bath Tubs*".

(and currently ASTM-compliant) domestic manufacturer, it is unlikely to substantially reduce the impact on the remaining small business.

Because the bath seats imported by the small domestic importer are not currently in compliance with the voluntary standard, they would require modification under either the proposed standard or the voluntary standard, if it were made mandatory without modification. Since the proposed modifications to the voluntary standard are not expected to have a substantial impact on costs, it is unlikely that making the voluntary standard mandatory without any modifications will substantially reduce the impact on this small firm.

D) Public Comments (Tab D)

Staff received seven comments on the NPR, four of which were from individual consumers who expressed their support for a mandatory safety standard for infant bath seats. In addition, staff received three specific comments on various aspects of the NPR. These three comments were from IISG (an international testing laboratory); the Juvenile Products Manufacturers Association (JPMA); and one comment from various consumer groups (Consumers Union, Kids In Distressed Situations, and Consumer Federation of America). Staff responses to these comments are provided in Tab D.

E) Recommended Changes to the Proposed Rule

Based on the comments received and a further review of the standard, staff recommends making two changes to the proposed rule as discussed below.

1) *Clarify Stability Test Procedure*

In the NPR, staff proposed a change to the stability test procedure [1215.2(b)(5)] to help better measure the level of water to be used for the test. For the final rule, staff is recommending adding an additional sentence to that stability test procedure for clarification purposes as seen in bold print below:

“For the purpose of measuring the water level, the product’s seating surface can be temporarily weighed down to prevent the seat from floating. The weight shall be removed following the measurement of the water level and prior to conducting the test.”

Staff believes that clarifying the stability test procedure makes the standard more stringent and will further reduce the risk of injury associated with infant bath seats as the stability of the bath seat relates directly to the submersion hazard addressed in the standard,

2) *Remove Redundant Wording*

Section 6.1 of ASTM F 1967-08a starts with a description of the definition of a specific bath seat. Because the proposed rule includes a new definition for bath seats, this wording is redundant and staff is recommending it be removed from the draft final rule. The removed words are indicated by ~~strikeouts~~ below:

Stability – ~~“For bath seats which provide support for an occupant’s back and support for the sides or front of the occupant, or both, †The geometry and construction of the product shall not allow for any parts of the product to become separated from it, shall not sustain permanent damage, and shall not allow the product to tip over after being tested in accordance with 7.4.”~~

F) Overall Summary of Recommended Changes to Voluntary Standard

In summary, staff is recommending that the new rule for baby bath seats be substantially the same as ASTM F1967-08a, “*Standard Consumer Safety Specification for Infant Bath Seats,*” with the following modifications (*the two recommended changes to the NPR discussed above are in italics*):

- Changing the definition of a bath seat to match what was presented in the 2003 bath seat NPR. *Remove redundant wording in section 6.1 of the standard that also defines a bath seat.* This change clarifies what is considered a bath seat.
- Changing “the most adverse position” as found in the leg opening requirement to read “in all orientations” to eliminate possible ambiguity.
- Changing the dimensions of the torso probe used in the leg opening requirement to match Figure 2 in Tab C. This change results in a more stringent leg opening requirement to address torso entrapment incidents recently reported to CPSC staff.
- Changing the stability requirements to address products that neither tip over nor return to a manufacturer’s recommended use position. This change would clarify the pass/fail criteria by failing any product that has shifted 12 degrees or more as a result of the test. This change results in a more stringent test to address incidents where children in bath seats may tilt the seat enough to be hazardous.
- Changing the procedure in the stability requirements for measuring the water level to account for bath seats that tend to float by adding a weight to the seat during the measurement. *Include a clarification that the added weight be removed after the water level is measured.*
- Changing the preparation of the test platform for the stability requirements to be more stringent by spraying the soap solution on all contact points. This change will address incidents where water may be present on the outside of the tub.
- Clarifying the order of the steps involved in preparing the test platform.

Staff believes that these changes will reduce the risk of injury associated with infant bath seats,

G) Effective Date of Final Rule

As already recommended in the NPR briefing package, CPSC staff believes that six months from publication of the final rule is reasonable and adequate for implementation of the rule. On its own initiative, staff will be adding some additional discussion in the preamble of the final rule regarding the testing certification requirements applicable to the products covered under the definition of bath seat once the final rule becomes effective. The staff hopes that this language

will provide manufacturers with guidance as to their regulatory obligations once the rule becomes effective.

TAB A

<http://www.cpsc.gov/businfo/frnotices/fr09/infantbath.pdf>

TAB B

Update to Hazard Analysis Memorandum for Bath Seat Final Rule Briefing Package



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: January 29, 2010

TO : Patricia Edwards, Project Manager
Division of Mechanical Engineering

THROUGH: Russell Roegner, Ph. D.
Associate Executive Director
Directorate for Epidemiology

Kathleen Stralka
Director
Division of Hazard Analysis

FROM : Kevin Gipson
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Update to Hazard Analysis Memorandum for Bath Seat Final Rule
Briefing Package

This memorandum updates the number of fatal and non-fatal incidents¹ (1983 – *November 30, 2009*²) related to bath seats and bath rings reported to CPSC staff as of December 2009. The previous memorandum covered the years 1983 – 2008 and was extracted as of February 2009. The updated data analysis identified five new fatalities and five new non-fatal incidents, all of which occurred in 2009. Three deaths and three additional non-fatal incidents involved bath seat products (not combination products) meeting the stability requirements of either ASTM International (ASTM) F1967-04 or F1967-07, Consumer Safety Specification for Infant Bath Seats. One death involved an earlier pre-2004 bath seat product and the remaining death involved a combination infant bath tub-bath seat product that was certified to the 2004 edition of the bath seat and bath ring standard (F1967-04) but is no longer being produced³. The combination infant bath tub-bath seat fatality is not included in the frequency statistics. The data update also located additional information enabling staff to identify two 2005 fatality incidents, previously considered to be independent, as being a single incident. A revised listing of incident synopses and updated tables are provided in this memorandum.

¹ Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather to update fatalities and non-fatal incidents reported to CPSC staff.

² Italics indicate years for which reporting is ongoing (2006, 2007, 2008, and 2009).

³ Combination bath tub-bath seat products are no longer covered by ASTM F1967 and will be covered by ASTM F2670-09, Consumer Safety Specification for Infant Bath Tubs.

In summary, for the years 1983 – *November 30, 2009*, bath seats or bath rings were associated with:

- 174 reported fatalities, all of which were submersions; and
- 300 non-fatal incidents of which approximately 40% were actual submersion incidents.

With respect to the 2004⁴ revision of the ASTM F1967 standard, for the years 2004 – *November 30, 2009*, there were:

- 47 reported fatalities and 72 non-fatal incidents associated with bath seats or bath rings. Of these 119 incidents, bath seats met the stability requirement of the 2004 standard for 77 incidents (23 fatalities and 54 non-fatal incidents);
- 21 incidents (3 fatalities and 18 non-fatal incidents) for which the bath seat arm disengaged from the tub side or broke; and
- 22 non-fatal entrapment incidents; 2 that presented a potential submersion hazard, 13 that did not present an apparent submersion hazard, and 7 where the reports had insufficient detail to allow staff to assess whether a potential submersion hazard was involved.

With respect to the 2007 revision of the ASTM F1967 standard, for the years 2007 – *November 30, 2009*, there were:

- no reported fatalities and 4 non-fatal incidents (2 were entrapments and 2 were scratches or cuts) associated with bath seats certified to the 2007 standard.

⁴ Incidents that met the stability requirements of this 2004 standard but may not have met the labeling requirements are counted as meeting the 2004 standard for the purposes of this memorandum.

Reported Fatalities

For 1983 – November 30, 2009, the CPSC staff has reports of 174 fatal incidents related to bath seats or bath rings. All of these fatalities were the result of submersion. Table 1 provides a chronology of these fatalities showing the total number of reports received by CPSC staff by year.

Table 1
Fatalities Reported to CPSC Staff
Involving Bath Seats or Bath Rings by Year
1983 – November 30, 2009

Year	Bath Seats or Bath Rings
<i>January 1, 2009 – November 30, 2009</i>	4
<i>2008</i>	3
<i>2007</i>	9
<i>2006</i>	11
2005	10 ⁵
2004	10
2003	16
2002	5
2001	15
2000	14
1999 ⁶	7
1998	8
1997	10
1996	10
1995	13
1994	9
1993	3
1992	5
1991	6
1990	1
1989	1
1988	0
1987	0
1986	1
1985	2
1984	0
1983	1
Total	174

Source: CPSC databases including NEISS (National Electronic Injury Surveillance System), IPII (Injury and Potential Injury Incidents), DTHS (Deaths), and INDP (In Depth Investigations). Italics indicate years for which fatality reporting is ongoing (2006, 2007, 2008, and 2009).

⁵ The count was reduced by one due to two reports being identified as reporting the same incident.

⁶ Beginning in 1999, death certificates were coded under the Tenth Revision of the International Classification of Diseases (ICD –10). Fatality data for years prior to 1999 are not directly comparable.

Reported Non-Fatal Incidents

For 1983 – November 30, 2009, the CPSC staff has reports of 300 non-fatal incidents related to bath seats or bath rings. A submersion hazard was identified in 154 of these non-fatal incidents, of which 117 involved the actual submersion of victims. The remaining 146 reports were non-submersion hazards such as entrapments, pinches, cuts and scratches. Table 2 shows the total number of reports received by CPSC staff by year and provides a breakdown of the reported incidents by “injury”, “no injury”, and “unknown”.

Table 2
Non-Fatal Incidents Reported to CPSC Staff
Involving Bath Seats or Bath Rings by Year
1983 – November 30, 2009

Year	Injury	No Injury	Unknown	Year Total
<i>Jan 1, 2009 – Nov 30, 2009</i>	1	4	0	5
<i>2008</i>	5	0	0	5
<i>2007</i>	11	2	0	13
<i>2006</i>	8	4	0	12
2005	12	2	2	16
2004	3	17	1	21
2003	4	8	0	12
2002	10	9	0	19
2001	8	15	0	23
2000	10	15	2	27
1999	16	9	1	26
1998	6	3	1	10
1997	3	4	1	8
1996	3	1	0	4
1995	6	3	1	10
1994	4	1	2	7
1993	3	1	3	7
1992	3	1	6	10
1991	6	2	16	24
1990	3	1	6	10
1989	1	1	5	7
1988	1	1	3	5
1987	2	2	1	5
1986	0	0	5	5
1985	1	0	3	4
1984	1	2	0	3
1983	1	0	1	2
Total	132	108	60	300

Source: CPSC databases including NEISS (National Electronic Injury Surveillance System), IPII (Injury and Potential Injury Incidents), and INDP (In Depth Investigations). Italics indicate years for which reporting is ongoing (2006, 2007, 2008, and 2009).

Hazard Patterns Reported Since 2004 ASTM Voluntary Standard

Table 3 shows bath seat or bath ring incidents reported to CPSC staff for the January 1, 2004 – November 30, 2009 time period and indicates their certification status.

Table 3
Reported Fatalities and Non-Fatal Incidents
Involving Infant Bath Seats or Bath Rings Indicating 2004 Certification
for Period January 1, 2004 – November 30, 2009

	Fatalities	Non-Fatal Incidents
Pre-2004 Standard	20	12
Certified to 2004 Standard or Met 2004 Stability Requirements	23	54
Unknown	4	6
Total	47	72

Source: CPSC databases including NEISS (National Electronic Injury Surveillance System), IPII (Injury and Potential Injury Incidents), DTHS (Deaths), and INDP (In Depth Investigations). Reporting is ongoing for 2006, 2007, 2008, and 2009.

Table 4 presents the frequency of bath seat incidents reported to CPSC staff by hazard scenario for those incidents that involved products certified to the 2004 edition of ASTM F1967.

Table 4
Hazard Scenarios for Reported Fatalities and Non-Fatal Incidents
Involving Infant Bath Seat Products⁷ Which were Confirmed as Meeting the
Stability Requirements of ASTM F1967-04 (2004 Standard)
January 1, 2004 – November 30, 2009

Hazard Scenario	Fatalities ⁸	Non-Fatal Incidents and Complaints	Total Number of Incidents
Product Loss of Integrity, Breakage	0	17	17
Plastic Arm Breakage	0	15	15
Other Plastic Part Breakage	0	2	2
Functional Failure, No Breakage	3	3	6
Arm Disengaged from Tub Side	3	3	6
Potential Product Design Issues	0	33	33
Entrapment/Potential Submersion (body)	0	2	2
Entrapment/No Potential Submersion (limb)	0	13	13
Entrapment/Unknown Potential Submersion	0	7	7
Pinching	0	4	4
Scratch or Cut	0	6	6
Other	0	1	1
No Obvious Failure or No Obvious Design Issue	19	1	20
Overflow	2	0	2
Not Properly Attached	4	0	4
Victim Found in Water	9	1	10
Victim Slumped Over in Water, Partially Out of Seat	4	0	4
Unknown	1	0	1
Total Incidents	23	54	77

Source: CPSC databases including NEISS (National Electronic Injury Surveillance System), IPII (Injury and Potential Injury Incidents), DTHS (Deaths), and INDP (In Depth Investigations). Reporting is ongoing for 2006, 2007, 2008, and 2009.

⁷ There were no bath ring products certified to the 2004 standard.

⁸ Appendix A gives more details about the 23 fatalities.

Appendix A: Summary Details of Fatal Incidents Involving Products Meeting ASTM F1967-04 Stability Requirements

IDI No.	Victims				Scenario					Bath Tub				
	Age (m)	Sex	Height (in)	Weight (lbs)	Hazard Scenario	Time Left Unattended Per Caregiver Estimate (mins)	Seat Condition (based on photos, report), and Position	Child Position	Child Still In Seat	Bathtub Characteristics (per IDI report)	Tap Left On	Water at Bathtub Overflow	Water Level (in)	Other Child In Bath
040524HCN0631	10	M	27.5	18.5	arm disengaged from tub side	5 to 10	intact, detached from tub side, overturned in tub	floating in tub, face down	unclear	standard shape - material not stated, smooth surface, no appliques	no	no	6.5	no
060203CNE0468	9	F	not stated	not stated	arm disengaged from tub side	2	intact, detached from tub side, overturned in tub	floating in tub	no	standard shape - material not stated	yes	possibly	unclear	no
091214HCC2226	10	F	25.98	16.5	arm disengaged from tub side	about 2 (maybe more)	detached from tub side, overturned in tub	partially under chair, face down	unclear	standard shape - material not stated	unclear, leaky faucet	no	halfway to top (of tub)	yes, 2 year old
060829HCC3832	8	F	28	24	overflow	15	intact- position not clear	floating in tub, face up	no	standard shape - material not stated	yes	yes	over-flowing	no
060306HWE5171	7	F	19.5	13	overflow	up to 60 (knocked out by fall)	intact, detached from tub side, overturned in tub	submerged, face up in tub	no	standard - porcelain coated - smooth	yes	yes	over-flowing	no
051110CCC3098	6.5	F	26	23	not properly attached	2	modified seat (arm removed to fit tub), overturned in tub	in tipped seat, sideways with face in water	yes (modified seat)	oval tub, material not stated	no	no	7	no
060502HWE5320	6	F	26	18	not properly attached	20	intact, detached from tub side, overturned in tub	submerged, lying on right side in tub	no	oval tub, arm not hooked over tub side	no	no	7.5	no
071004HCC3029	6	F	not stated	not stated	not properly attached	few minutes to change diaper	not stated	in water - position not specified	not stated	utility tub	no	no	6	no
081217HCC3201	8	M	29.5	23	not properly attached	3 to 4	intact, detached from tub side, overturned in tub	in flipped seat in tub, partially submerged	yes	arm not properly attached, standard shape - material not stated	yes	not stated	8.5	no
051110CCC1097	9.5	M	27.25	24	victim found in water	5	intact, position not stated	floating in tub, face down	no	not stated	yes	possibly	not stated	no
060403HNE0769	11	F	29	20	victim found in water	1 to 3	intact, attached to tub side	floating in tub, face up	no	standard shape, acrylic, smooth	no	no	11.5 to 12.0	no

IDI No.	Age (m)	Sex	Height (in)	Weight (lbs)	Hazard Scenario	Time Left Unattended Per Caregiver Estimate (mins)	Seat Condition (based on photos, report), and Position	Child Position	Child Still In Seat	Bathtub Characteristics (per IDI report)	Tap Left On	Water at Bathtub Overflow	Water Level (in)	Other Child Present In Bath
061024HCC3037	11	F	28.5	16	victim found in water	10	intact, attached to tub side	floating in tub, face down	no	standard shape - material not stated	no	no	5 to 6	possibly 22 month old
070705HCC3549	8	F	26	17	victim found in water	3 to 4	intact - position not stated	face down - not stated if floating or submerged	not stated	not stated	no	no	just over top ring of bathseat	no
071001HCC2001	10	F	31.1	21.6	victim found in water	counted to 100 (1-2 min maybe)	unknown - seat Intact - child not in it	face down - not stated if floating or submerged	no	not stated	no	no	8 to 9	yes, 2 year old
071003HCC3005	8	M	28.5	30	victim found in water	not stated	likely Intact, attached to tub side	submerged, face down in tub	no	not stated	no	no	8	no
080903HCC3824	9	M	29	30	victim found in water	2 to 3	intact, attached to tub side	floating in tub, face up	no	standard shape, material not stated	yes	not stated	8 to 9	no
090610HCC3652	9	F	27	24	victim found in water	1 to 2 (to answer phone)	intact, unclear If clamp attached to tub side	floating in tub face down	no	oval garden tub (not corner) slip resistant material not stated	no	no	7.5 to 8	no
090720HBB3793	12.5	F	29.9	27	victim found in water	1 to 3 (to get soap)	Intact, attached to tub side (*armrest base and top separating?)	floating in tub, face down, two older siblings pressing on back	no	standard shape, ceramic	no	no	4^	yes, 2 and 3 year old
050927HCN0916	7.5	F	not stated	not stated	victim slumped over in water or partially out of seat	5	intact, attached to tub side	slumped forward over front edge of seat, face submerged, body leaning forward, partially out of seat but legs still in holes	yes- but moved forward - slumped over	standard shape, fiberglass	no	yes	6	no
070222HNE1976	8	F	28	23	victim slumped over in water or partially out of seat	5	intact, attached to tub side	slumped forward over front edge of seat, face submerged, body leaning forward	yes	standard shape - material not stated	no	no	9	no
080215HWE7194	9	F	not stated	not stated	victim slumped over in water or partially out of seat	did not leave; sitting on floor writing journal	intact, attached to tub side	slumped forward over front edge of seat, face submerged, body leaning forward	yes (most likely)	standard shape - material not stated	yes	not stated	about 3 inches from top of bath tub	no
070117HCC1253	24*	F	32.5	not stated	victim slumped over in water or partially out of seat	1 to 2	intact, attached to tub side	slumped forward over front edge of seat, face submerged, body leaning forward	yes	standard shape, fiberglass	no	not stated	6 to 8	No
070523HCC2511	10	M	29	23	unknown	not stated	unknown - seat intact	submerged, not stated if in seat or not	not stated	standard shape with whirlpool jets - material not stated	not stated	not stated	not stated	possibly 2.5 year old

* Victim had a disability

^ Note measurement taken post incident, multiple children in tub at time of incident

TAB C

Final Regulatory Flexibility Analysis to Evaluate the Possible Economic Impact of the Staff-Recommended Final Standard for Baby Bath Seats on Small Businesses



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207**

Memorandum

Date: January 13, 2010

TO : Patricia Edwards
Project Manager for Baby Bath Seats

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 : Jill L. Jenkins, Ph.D., Economist
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis to Evaluate the Possible Economic Impact
of the Staff-Recommended Final Standard for Baby Bath Seats on Small
Businesses

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104 requires that the Consumer Product Safety Commission (CPSC) evaluate the currently existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. Bath seats are among the durable products specifically named in section 104.

Upon review, CPSC proposed adopting the voluntary ASTM standard for bath seats (F 1967 – 08a) with a few modifications. The staff now recommends that the Commission make the proposed rule final with one minor change.¹¹ The main provisions of the staff-recommended final standard include: 1) stability requirements, which would be updated to eliminate any possible misinterpretation of the pass/fail criteria; 2) requirements for restraint systems, depending upon whether they provide back restraint only or additional side and/or front support; 3) requirements that any suction cups remain attached to both the seat and the surface during use; 4) leg opening requirements intended to prevent children from slipping through them, which would be updated to use a modified torso probe that is more analogous to a human infant in a bathing environment; and 5) label requirements which specifically state that children have drowned in bath seats. The standard also includes various general requirements, including bans on hazardous sharp points or edges and the liberation of any small parts both before and after testing, among other things. CPSC staff also recommends modifying the ASTM section on *Surface Preparation and Product Installation* (7.4.1) to clarify the correct order of events for test installation, extending the portions of the test platform that must be saturated with the test

¹¹ CPSC staff has clarified that the weight used to measure the water level while flooding the test platform must be removed prior to testing.

solution mixture, and allowing for temporarily weighting the product to determine water level. Additionally, CPSC staff recommends clarifying the scope of the voluntary standard to further define the type of support that defines a bath seat.¹² These requirements apply to bath rings as well as infant bath seats.

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis and make it available to the public for comment when the final rule is published. The final regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. a succinct statement of the objectives of, and legal basis for, the rule;
2. a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. a description of and, where feasible, an estimate of the number of small entities to which the rule will apply;
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 type of professional skills necessary for the preparation of reports or records; and
5. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

The Product

Infant bath seats and bath rings are marketed as an aid in bathing infants from the time they can sit up unassisted (around 5 months) to the time they begin pulling themselves into a standing position (around 10 months). The ages are only approximate; the behaviors are the guide to appropriate use. According to the Juvenile Products Manufacturers Association (JPMA), bath seat use is generally discontinued once children are able to stand up or escape from the product.¹³ Bath seats are generally used in adult bathtubs and allow the child to be held in a seated position, thus freeing the caregiver from holding onto the child during bathing.

The Market for Bath Seats

¹² Removing an identical description later in the standard.

¹³ "Initial Comments in Opposition by the Juvenile Products Manufacturers Association" in response to Petition HP00-4, October 23, 2000.

Baby bath seats and bath rings are produced and/or marketed by juvenile product manufacturers and distributors. There are currently two manufacturers¹⁴ and one importer of baby bath seats known to be active in the U.S. market. All are members of the Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers. Bath seats are available in many countries besides the U.S., including Canada, Australia, the U.K., Italy, and Taiwan.¹⁵ Although there are currently only three firms supplying bath seats to the U.S. market, any foreign manufacturer is a potential supplier. Of the three firms currently selling bath seats in the U.S. market, all but one qualifies as a small business according to standards set by the U.S. Small Business Administration (SBA). Each produces a variety of children's products, of which bath seats are only a small proportion.

In a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*),¹⁶ 42 percent of new mothers¹⁷ indicated that they owned a baby bath seat or ring. Of these, 15 percent were handed down or purchased second-hand. This suggests that about 85 percent of the bath seats were acquired new, indicating annual sales of about 1.5 million (.85 x .42 x 4.3 million births per year).¹⁸ JPMA's estimate of annual sales, provided in 2000, was lower, about one million.¹⁹

In 2000, the JPMA also estimated that there may be up to two million baby bath seats in use.²⁰ This is somewhat higher than an estimate that can be derived from the most recent *Baby Products Tracking Study*. Since, in 2005, about 42 percent of new mothers said they owned baby bath seats or rings and there are about 4.3 million births per year, about 1.8 million bath seats were available for use for infants under the age of one year. From incident reports, we know that some baby bath seats are used with babies older than 1.²¹ Consequently, if we apply the ownership rates from the *2006 Baby Products Tracking Study* to the population of children up to 18 months old, the total number of bath seats available for use in 2007 could be as high as about 2.7 million.²²

Reason for Agency Action and Legal Basis for the Draft Final Rule

¹⁴ One small manufacturer has dropped out of the infant bath seat market since the initial regulatory flexibility analysis was performed.

¹⁵ Health Canada is currently considering banning baby bath seats.

¹⁶ The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, since the most recent survey was performed in 2005, it may not reflect changes in the bath seat market that have occurred since the modifications to the voluntary standard in 2004.

¹⁷ New mothers represent those who have recently given birth, as opposed to expectant mothers. Therefore, the application to annual births is appropriate.

¹⁸ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Preliminary Data for 2007," National Vital Statistics Reports Volume 57, Number 12 (March 18, 2009): 6 (Table 1). Number of live births in 2007 is rounded from 4,317,119. All other decimals are rounded as well.

¹⁹ "Initial Comments in Opposition by the Juvenile Products Manufacturers Association" in response to Petition HP00-4, October 23, 2000.

²⁰ Ibid.

²¹ Memorandum from Kevin Gipson, Directorate for Epidemiology dated December 31, 2009, Subject: Update to Hazard Analysis Memorandum for Bath Seat Final Rule Briefing Package.

²² Including the entire population up to age 2 would likely cause an over-estimate of the units in use, since most children probably stop using bath seats when they can easily get out of them.

Section 104 of the CPSIA requires CPSC to promulgate a mandatory standard for baby bath seats that is substantially the same as, or more stringent than, the voluntary standard. Based on the pattern of injuries under the current voluntary standard, CPSC staff is recommending a few modifications to the current ASTM standard because it has concluded that a more stringent standard would further reduce the risk of injury associated with infant bath seats.

Compliance Requirements of the Draft Final Rule

In order to meet the requirements of the Consumer Product Safety Improvement Act (CPSIA), CPSC staff recommends adopting the voluntary ASTM standard for bath seats with three modifications. Key components of the current ASTM infant bath seats standard (F 1967 – 08a) include:²³

- Torque/tension test for graspable components – ensures that component pieces such as those intended to protect children from sharp edges, points, or entrapment of fingers and toes cannot be removed by them.
- Accessible holes and openings tested for entrapment hazards – ensures that existing openings are large enough not to trap children’s fingers and toes.
- Stability test for preventing tip-over – ensures that bath seats will not tip over in “worst case scenario” situations, including on tubs with safety tread strips to prevent slipping.
- Tests on restraint system (where required) – except for seats that provide only back support, sets requirements for passive crotch restraints to prevent children from sliding through the front or sides of the seat; also bars additional restraint systems from being used in conjunction with passive restraints to prevent a false sense of security on the caretaker’s part.
- Scissoring, shearing, and pinching – ensures axes and fastening points are designed to prevent these types of injuries to children.
- Static load test to seat – intended to prevent incidents of product breakage.

The voluntary standard also requires that any suction cups used adhere both to the product and the attached surface. Additionally, the voluntary standard includes warning label language emphasizing that children have drowned while using bath seats.

The three ASTM infant bath seat requirements that CPSC staff recommends modifying are:

1. Leg openings

- Change the shape of the torso probe to make it more analogous to a wet and slippery human infant. Specifically, decrease the length of the vertical and horizontal axes of the current probe by 5% and round the corners with a 1.45” radius rather than the current 1” radius to account for the pliability of child torsos.²⁴

²³ JPMA, *ASTM Standards listed in JPMA Directory*, http://www.jpma.org/pdfs/JPMA_Directory_Final2008.pdf.

²⁴ Memorandum from Jonathan D. Midgett, Division of Human Factors, Directorate for Engineering Sciences dated July 14, 2009, Subject: Leg Opening Requirements in Bath Seats.

- Specify that the probe needs to be inserted in all orientations, rather than in only the most adverse orientation for each opening.²⁵
2. Stability requirements
 - Add an additional requirement that addresses units that may tilt, but neither tip-over nor return to the “intended use position” after the specified force has been applied. The new requirement would state: “If anytime during the application of force, the bath seat is no longer in the initial ‘intended use position’ and is tilted at an angle of 12-degrees or more from its initial starting position, it shall be considered a failure.” This would clear up any possible misinterpretation of the pass/fail criteria.²⁶
 3. Surface preparation and product installation
 - Clarify the correct order of events for test installation (i.e., prepare the test platform, install the product, and then flood the test platform to the specified level). The product would be weighted to determine the correct water level for products that float, but the weight would be removed for the actual testing.²⁷

Additionally, CPSC staff recommends clarifying the scope of the voluntary standard to specifically state what constitutes “support” on a bath seat. The draft final standard would require that bath seats entering commerce meet the new requirements within six months of publication of the final rule. It would not be retroactive.

The majority of older bath seat designs that relied on suction cups for stability cannot meet this standard. When ASTM’s performance requirements were modified in 2004 (F 1967 – 04), two major bath seat manufacturers (Safety 1st and The First Years) developed alternative seats that fasten to the sides of bathtubs for stability. Both were certified by JPMA as meeting the ASTM voluntary standard. The key change to the voluntary standard in 2004 was to require testing in an actual bathtub with both a smooth and non-slip surface. Another change to the 2004 standard was the warning label specifically tying drowning hazards to bath seats.

In response to additional safety concerns, the voluntary standard was further modified in 2007 to require that a soapy water solution be used during testing on any internal surface of the tub well or tub bottom that the bath seat is designed to contact. Safety 1st made the necessary modifications to comply with this new requirement and is currently the only manufacturer with an ASTM-compliant bath seat. Further enhancement of the warning label was also made in the 2007 version of the standard.

Issues Raised by Public Comments

There were no issues raised by public comments in response to the initial regulatory flexibility analysis. One comment received in response to the Notice of Proposed Rulemaking

²⁵ Memorandum from Troy Whitfield, Division of Mechanical Engineering, Directorate for Engineering Sciences dated July 10, 2009, Subject: Voluntary Standard for Infant Bath Seats.

²⁶ Ibid.

²⁷ Ibid.

(NPR) effected a change to the final draft standard that is reflected in the final regulatory flexibility analysis. Namely, CPSC staff agreed to include a statement requiring the removal of the weight used to prevent bath seat floating while flooding the test platform prior to testing to prevent the potential for a counterweight. However, this modification did not affect the regulatory flexibility analysis.

Other Federal Rules

CPSC staff has not identified any Federal or state rule that either overlaps or conflicts with the staff's draft final rule.

Impact on Small Businesses

There are three firms currently marketing baby bath seats in the United States. One is a large domestic manufacturer and another is a small foreign manufacturer. The impact on the remaining firm—a small domestic importer—is the focus of this analysis. The bath seats supplied by this small firm are expected to require modifications to meet the draft final standard.

Since importers do not manufacture bath seats, the effect of the regulation would be felt indirectly. Importers would need to change suppliers, rather than redesign their product and reequip their factories for production.²⁸ For this reason, the impact on the small domestic importer, with annual sales of approximately \$1 million,²⁹ is expected to be small. They would most likely respond by discontinuing the import of their non-complying bath seat, either replacing them with a complying product or another juvenile product. The option to import an alternative product is a reasonable and realistic alternative to offset the loss of revenue from bath seat sales. The firm is currently importing approximately 165 juvenile products of which 3 are substitutes for their imported bath seat.

Hence, even if the cost of developing a compliant product proves to be a barrier for individual small firms, the loss of bath seats as a product category is expected to be minor and would likely be mitigated by increased sales of competing products, such as multi-stage infant bathtubs, or entirely different juvenile products.

Alternatives

The final regulatory flexibility analysis must contain a description of any significant alternatives which accomplish the stated objectives of the final rule while minimizing the economic impact on small entities. It must also include a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

CPSC staff identified one alternative under section 104 of the CPSIA that would reduce the impact on small entities. That alternative is to make the voluntary standard mandatory with no

²⁸ Or, alternatively, discontinue production.

²⁹ ReferenceUSAGov.

modifications. Based on the pattern of injuries, CPSC staff does not feel that this is an appropriate alternative. Additionally, while this alternative would reduce the impact on the one large (and currently ASTM-compliant) domestic manufacturer, it is unlikely to substantially reduce the impact on the remaining small business.

Because the bath seats imported by this small firm are not currently in compliance with the voluntary standard, they would require modification under either the proposed standard or the voluntary standard, if it were made mandatory without modification. Since it is not believed that the three additional modifications to the voluntary standard would have a substantial impact on costs, it is unlikely that making the voluntary standard mandatory without any modifications will substantially reduce the impact on this small firm.

TAB D

Staff Response to Comments on the Infant Bath Seat Notice of Proposed Rulemaking, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207**

Memorandum

Date: January 26, 2010

TO : Briefing Package

THROUGH: Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction
Linda Edwards, Acting AED, Directorate for Engineering Sciences
Mark Kumagai, Director, Division of Mechanical Engineering

FROM : Patricia L. Edwards, Project Manager for Baby Bath Seats
Directorate for Engineering Sciences
Patricia M. Pollitzer, Attorney, Regulatory Affairs Division, Office of the General Counsel

SUBJECT : Staff Response to Comments on the Infant Bath Seat Notice of Proposed Rulemaking, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)

Introduction

This memorandum provides the Consumer Product Safety Commission (CPSC) staff response to comments on the Notice of Proposed Rulemaking (NPR), published in the Federal Register, Vol. 74, No. 170 on Thursday, September 3, 2009. The NPR is in regard to a safety standard on infant bath seats, under Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).

Comments

Staff received seven comments on the NPR, four of which were from individual consumers who expressed their support for a mandatory safety standard for infant bath seats. In addition, staff received three specific comments on various aspects of the NPR. These three comments were from IISG (an international testing laboratory); the Juvenile Products Manufacturers Association (JPMA); and one comment from various consumer groups (Consumers Union, Kids In Distressed Situations, and Consumer Federation of America). These three comments will be discussed separately below. Please note that excerpts of exact language were taken from the comments and provided in this memorandum.

1) *IISG Comments*

a) Leg Opening Test – Torso Probe Orientation

It should be clarified that the torso probe shall be inserted in a straight direction and it is not allowed to insert it partially and then rotate it along some minor axis to make it pass through the hole.

CPSC Staff Response

In the NPR, staff recommended a change to the voluntary standard that called for the torso probe to be inserted in all orientations of the leg openings to determine if any position can create a slip through and/or entrapment hazard. This change was recommended over the current language which stated that the probe should be inserted in the most adverse orientation. Staff recommended this change because it felt the original language was left open to interpretation by the person performing the test. The proposed language of IISG would actually make the requirement less restrictive than what is already in the voluntary standard. For this reasons, staff is not in agreement with the recommendation.

2) ***JPMA Comments***

a) CPSIA Process

CPSC should not modify existing effective standards unless it can clearly substantiate on the record before it that such changes will provide a demonstrable reduction of injury. Hypothetical improvements are insufficient on the record to justify the imposition of additional requirements. The ASTM standard was originally published in 1999 and has undergone several revisions since then. Requirements and test protocols have been refined through the ASTM subcommittee and task group process that has included CPSC participation and concurrence with the requirements of the current standard version published in 2008. Without adequate justification and rationale, there is little value in revising the current requirements in this standard by using the NPR regulatory process. We are concerned that the imposition of additional requirements without demonstrable evidence that they will both enhance bath safety and not create unintended entrapment related hazards, will restrict the availability of potentially lifesaving products. It is not clear that such an exclusion of these products is necessary or justified.

CPSC Staff Response

Section 104(b) of the CPSIA requires the Commission to use the notice and comment rulemaking process under the Administrative Procedure Act to promulgate consumer product safety standards for durable infant or toddler products. The CPSIA directs the Commission to issue a rule that is “substantially the same as” the applicable voluntary standard or “more stringent than” the voluntary standard if the more stringent standard “would further reduce the risk of injury associated with the product.” The statute does not require that the Commission “clearly substantiate on the record before it that such change will provide a demonstrable reduction in injury.” Section 104 takes durable infant or toddler products out of the Commission’s usual rulemaking procedure and all of the findings that would be required under

sections 7 and 9 of the CPSA. For these products, Congress wanted “the highest level of safety for such products that is feasible.” The staff recognizes that the ASTM standard has been in place for numerous years and has been refined through ASTM’s standard setting process. Nevertheless, incidents continue to occur. Under the mandate of section 104, the Commission is promulgating more stringent requirements where necessary to address certain design features that staff believes contribute to some of these continuing deaths and torso entrapments. The staff has conducted testing and performed analyses to support the requirements that are different from the ASTM requirements and that it believes would further reduce the risk of injury associated with infant bath seats.

b) Adopt the ASTM Standard

We believe the most streamlined approach to following the primary congressional mandate that standards required to be developed are to be “substantially the same as” applicable voluntary standards, would be to adopt a regulation that wholly adopts the existing ASTM standard, with the ability to subject it to the ASTM update and review process. CPSC can assure itself veto authority as part of an implementing regulation, which provides it with the ability to restrict diminution of effective ASTM standard provisions, similar to the authority applicable under CPSIA Section 106, as a check to changes that reduce stringent protections. We suggest that the CPSC staff consider by rule adopting ASTM F 1967-08a as a consumer product safety standard issued by the Commission under section 9 of the Consumer Product Safety Act (“CPSA”; 15 U.S.C. 2058). To the extent additional changes to the pending ASTM standard are sought we recommend that they be submitted to the ASTM standard setting process. This process could also incorporate a provision by rule that a reservation of right to the CPSC to object to any subsequent revisions to the ASTM Standard, similar to that afforded under CPSIA Section 106(g). This would provide the Commission with the ability to object to a revision, within 90 days after receiving notice of it, if the Commission notifies ASTM International that it has determined that the proposed revision does not improve the safety of the consumer product covered by the standard. Upon such objection, the existing standard can continue to be considered to be a consumer product safety rule without regard to the proposed revision. By proceeding in this manner the CPSC could 1) expediently assure adoption of admittedly effective ASTM juvenile standards as mandatory standards and carry out the intent of Congress as required under the statutory language of Section 104(b); 2) Continue to embrace the standard revision’s process applied by ASTM F1967-08a by more quickly developing or revising consensus standards based upon hazard data, expertise and analysis (which has traditionally been achieved more quickly than by CPSC rulemaking); and 3) reserve unto itself the ability to restrict diminution of such Standard with a veto ability to proposed changes to it.

CPSC Staff Response

The standard the Commission proposed for bath seats incorporates by reference most of ASTM F 1967-08a with a few modifications to strengthen the standard. Section 104(b) of the CPSIA sets forth the procedure for these standards for durable infant or toddler products, and it is different from what Congress provided in section 106 of the CPSIA. It is doubtful that a Commission rule could change the procedure Congress provided for section 104 rules to the one it provided for section 106 rules.

c) Stability Test Pass/Fail Criteria

The pass/fail criteria as represented in the standard was specifically created to require that both the attachment disengage the test platform and that the product fails to return to its manufacturer's intended use position after being tested. Both conditions must be present in order to constitute a failure. The CPSC staff's recommended stipulation that "If anytime during the application of force the bath seat is no longer in the initial 'intended use position' and is tilted at an angle of 12-degrees or more from its initial starting position, it shall be considered a failure." is not indicative of an unsafe condition, is a departure from the primary intent of the requirement which is to determine if the bath seat tips.

CPSC Staff Response

CPSC staff disagrees with JPMA's characterization of the intent of the pass/fail criteria. The first part of the current ASTM pass/fail criteria ("shall not allow the product to tip over") was part of the 2004 version of the standard. The second part of the pass/fail criteria ["In addition, if any attachment point disengages from (is no longer in contact with) the test platform and then fails to return to its manufacturer's intended use position after being tested in accordance with 7.4, it fails the requirement"] was added in the 2007 version of the standard. They were not considered at the same time, nor is there any language to suggest that both conditions must be met in order to constitute a failure. If that were the intent, then there would be no need to add the second pass/fail criteria because if the bath seat disengaged from the test platform (condition #1), then obviously it wouldn't return to the manufacturers intended use position (condition #2). This second condition was added in the 2007 standard to address those situations where a bath seat started tipping, to a degree that could be hazardous, but did not fully disengage from the tub. In the NPR, staff is clarifying the intent, as well as ensuring that a bath seat which significantly tips during the stability test but returns to a fully upright condition is not found to be in compliance with the requirement.

d) Risk of Submersion

These stipulations are consequently unrelated to submersion risk and would not reduce the risk of injury and submersion incidences identified in the incident data. The risk of submersion presents itself when the position of the product indicates that the child's head area would be in a compromising position.

CPSC Staff Response

CPSC staff agrees with the last statement presented above which is why the staff is recommending a clearer definition of the pass/fail criteria. It is clear that, if the bath seat is tilted, children can slump over, lean over, and expose their faces to the water more easily than if not tilted.

e) Stability Test Specified Force

The location of the force application is calculated using an equation in the standard to determine the theoretical location of the child's head, while the magnitude of the force equates to the total weight of the oldest user. The requirement, as presently represented in the standard, assumes that the child has the capability of applying a force equal to their mass when in seated position.

CPSC Staff Response

Staff believes that JPMA is incorrect in its characterization of the basis for the 17 lb force used for stability testing as equating to the total body weight of the oldest user. The rationale in the ASTM standard (Appendix, part X1.17) indicates the original basis for the 17 lb force is that it represents 60% of the 95th percentile (27.8 lb) body weight for oldest users (which was for 12-15 month old children at the time the requirement was developed). A review of the incident data shows that fatal incidents that occurred in the newer style bath seats (which are designed for children who cannot yet pull to a stand) involved babies whose weights ranged from 15 to 30 pounds, with at least two of the victims (ages 8 and 9 months) being 30 pounds at the time of their deaths. Thus, it is foreseeable that a child of this size may use the product and, therefore, it is staff's position that the 17 lb force is still valid.

f) Stability Test Force Rationale

Because gravity acts on the human body equally, the ability of the child to exert her total mass at the head location is improbable. The dynamic motion in combination with gravity would most certainly result in a downward, horizontal and consequently a resultant force. Therefore a more reasonable assumption is that the child would exert a percentage of her total weight in the horizontal plane, parallel to the products resting surface.

CPSC Staff Response

CPSC staff agrees with JPMA that it is a more reasonable assumption that a child's head would exert only a percentage of his/her total weight (not the full body weight) and has provided the justification of the 17 lb force above.

g) Recommended Stability Pass/Fail Criteria

Furthermore, inclusion of these stipulations to the failure definition would prohibit even infinitesimal movements with little to no bearing or conclusion on the safe condition or position of the product both during and after testing.

CPSC Staff Response

CPSC staff disagrees that this additional requirement would prohibit infinitesimal movement. As the standard stands now, the pass/fail requirement could be interpreted very strictly as to not allow any movement or tilt of the bath seat from the original position. By adding the 12 degree tilt limit, the stability test allows bath seats some controlled flexibility.

h) 12 Degree Limit Rationale

The 12 degree tilt angle is random at best, with no rationale as to how exceeding this angle results in a compromising unsafe condition.

CPSC Staff Response

In our development of this requirement, CPSC staff conducted an analysis looking at various water levels and possible head positions of occupants vs. angles of bath seats to determine what level of tilt was potentially hazardous. In addition, CPSC staff looked at other ASTM standards such as those for infant bouncer seats and toys which use a 10 degree table or tilt when testing for stability. Lastly, staff acknowledged that the requirement must allow for the ductility of the aluminum rod test fixture combined with some expected ductility or flexing of the bath seat itself, therefore, testing was performed to determine the maximum level of tilt that might be expected solely due to the flexibility of the bath seat and the test rig. As a result of this work, staff selected a tilt angle of 12 degrees as the pass/fail criteria to insure passing products will remain in the manufacturer's intended use position.

Thus, the 12 degree angle will allow for some inherent flexibility in the system (the product and the test rig) as a whole, but would fail a bath seat that 1) stayed firmly clamped to the bath tub but the bath seat itself experienced significant ductility or flexibility (12 degrees or more) during the testing or 2) had a clamping mechanism that lost firm contact with the bath tub and allowed the bath seat to tilt 12 degrees or more during the test.

i) Position of the Product During Testing

With the intent of replicating real behavior as well as anthropometric weight data, the condition of the product during the test has no bearing on the outcome of the result. In other words if a child can exhibit this sort of force and that force is applied to the product and the product returns to an original state then the end result upon conclusion of the test is the distinguishing factor as to whether or not the product complies. What if the product reaches a 15 degree angle? How does this angle result in an unsafe condition if the product remains attached? If the product moves from its original position, how does this result in an unsafe condition if it doesn't detach from the tub? Again the best measure of conformance is if the product actually tips, because we know at that point the child has the potential to become submerged.

CPSC Staff Response

CPSC staff disagrees with JPMA's assertion that the condition of the product during the test has no bearing on the outcome of the result. In the test, a 17 lb load is applied and then released. In real life, if a child leans over a bath seat railing, that might result in him/her not being able to sit back upright. The users are young infants who do not have a good sense of balance; and the more the bath seat allows them to tilt forward, the less likely they will be able to return to an upright position. If a child's body remains tilted forward, this could result in his/her face submerged in the water. And once an infant's face is submerged, he/she may not pull their face out of the water. Infants may be physically capable of lifting their heads, but they won't because they do not know better or because they breathe in a lungful of water before trying to lift their head. Bath seats should never allow an infant's face to be submerged under water. In addition, another argument against allowing any significant tilt during the test is that the more the seat tilts forward, the higher the likelihood for a child to crawl out of the seat. When the seat is far enough forward, even if it has not tipped over, the child can stand (hunched over) on his/her feet with legs still through the leg holes. That would also make a tilted seat hazardous.

j) Changes to Test Platform Preparation

CPSC staff recommends strengthening the stability requirements so that the soap solution is applied to all test platform surfaces above the water line where the product makes contact or could possibly make contact. As children play and splash about, the adult bathtub can become wet both in and out. While we agree with the application of the soap solution inside and outside of the tub, we also believe that this application should be applied once the product has been installed, if manufacturers present this as a prerequisite to use in instructional literature. Clamping mechanisms rely on a clean tub side surface for effectiveness. These conditions are unlike other products which rely on proper assembly and adherence to instruction in order to render them as safe and ready for use.

CPSC Staff Response

Staff believes that regardless of instructional literature or warnings, it is foreseeable that caregivers will install the bath seat on a wet and soapy tub; therefore, they should be tested under such conditions in order to reduce the risk of injury associated with the products during foreseeable conditions of use.

k) Weighing the Seat Down

To address testing of products that can "float" in the water when not occupied, staff suggests the following wording be added when flooding the test platform to the designated depth: "For the purpose of measuring the water level, the product's seating surface can be temporarily weighed down to prevent the seat from floating." While we agree that this requirement mitigates the "floating" potential, we recommend a provisional statement requiring removal of the weight once the seat is flooded to eliminate the potential for a counterweight to be included during the test.

CPSC Staff Response

CPSC staff has no objection to this recommended statement and have added it to the draft final rule.

l) Leg Opening Changes

Moreover, in both cases the proposed reduction in leg openings would not have prevented these or future similar incidents from occurring. The opportunity for a child to incorporate both feet into one leg opening remains with both the existing and proposed probe sizes. The proposed probe reduction would only limit the distance of travel through any one leg opening. In other words, the child may get caught before reaching the torso area, but ultimately would still get caught and result in an entrapped condition. We believe this condition is mitigated through adult supervision and when not available creates a fail stop to the more severe and life threatening submersion condition. Arguably the reduction in leg opening may exacerbate entrapment and ingress and egress conditions as a greater population would have the potential to become now entrapped in a smaller leg opening size. Based on the lack of data that the more stringent leg probe would reduce the risk of injury associated with the product and the concern that this change would actually increase entrapments in bath seats, we believe the standard presently has optimized this probe size and is consistent with other standards that provide similar submarining protection. We therefore recommend that the standard, in present form, be adopted with regard to leg openings.

CPSC Staff Response

Although it is true that the victims in the subject incidents became entrapped in the leg holes, staff is more concerned by the fact that in the two incidents cited in the NPR briefing package, the victim's pelvis and torso were able to penetrate the leg openings. Once the pelvis goes through the leg hole, the victim is in serious danger of submersion because the waist and upper torso are more malleable and therefore more capable of squeezing through the leg holes. Therefore, the leg holes failed to prevent a potential submersion condition, contrary to the JPMA's characterization of the incidents. They were not endangered by the entrapment as much as they were endangered by their position during their entrapment. These incidents show a failure in the design of the torso probe and the leg opening test which was developed to prevent the manufacture of leg holes that allow a pelvis to fit through them. Figure 1 shows a photograph taken of the actual victim from one of the incidents and clearly shows the pelvis has fit through the leg opening.

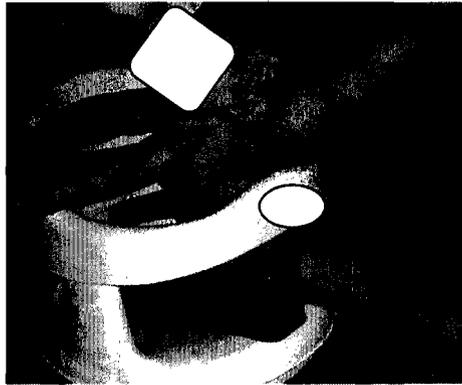


Fig 1: Torso Entrapment

The current bath seat torso probe used to test the leg openings was based on probes from other juvenile products that do not normally entail use with wet, naked babies. The data associated with these two subject incidents suggest that the unique use of a bath seat in a watery, soapy environment requires a smaller probe. Staff believes that reducing the size of leg openings by making the torso probe more rounded at the corners and slightly smaller will prevent future submersion incidents.

The issue of entrapment during ingress and egress is irrelevant to the leg hole opening test method. Staff is aware that consumers have encountered difficulties with ingress and egress with some models of bath seats currently sold in the U.S.; however, the size and shape of the leg hole opening is only one factor in the overall design of a bath seat's occupant retention space. Such features as the shape of the seat, the slope of the supports, and the thickness and the type of materials used to make the bath seat are not determined by the performance requirements of the standard. The leg hole opening test does not dictate any other dimensional or design requirements for bath seats, leaving the designer ample freedom to design a bath seat that allows easy ingress and egress while reducing the risk of injury from the product.

3) Consumer Group Comments

a) Stability/12 Degree Tilt Limitation

We agree with the Commission staff that the pass/fail criteria specified in the stability requirements ASTM F 1967-08a needs clarification so that laboratories conducting compliance testing will not misinterpret results. However, we do not agree that setting the maximum rotation at a somewhat arbitrary angle of 12 degrees provides the level of confidence required to know that a seat will not slip out of position and endanger an infant. Instead, we recommend that the Commission consider any movement from its originally fixed position to be a failure.

CPSC Staff Response

There are three ways that a bath seat can fail the stability requirement as proposed in the NPR: 1) if the bath seat tips over (and remains tipped over after the test), 2) if any attachment point disengages from (is no longer in contact with) the test platform (bath tub) and the bath seat fails to return to the manufacturer's recommended use position after the test, and 3) if the measured tilt angle during the test ever exceeds 12 degrees.

The first two pass/fail criteria above were already required under the voluntary standard and the third one was recommended by CPSC as a new additional requirement for the NPR, and also for the final rule. With regard to the third criteria, there are two different ways in which a bath seat can tilt during stability testing. The first is the tilt that might occur when the bath seat attachment slips or moves from its original fixed position. The second is the tilt that can occur due to the flexibility between all the parts of the bath seat and the bath seat test fixture (the aluminum rod and clamping devices). Depending on the product, it is possible to have both of these factors contribute to the tilt, or just the second one.

There is no way to eliminate the flexibility of the system (the bath seat and the test fixture) entirely. The flexibility of the aluminum rod itself can result in a 2 degree tilt. When the clamping fixtures and then the expected flexibility of the plastic used in the product are added, there is inherent flexibility in the system that cannot be totally eliminated. A tilt test must allow for this flexibility among all the components of the system. Twelve degrees allows for some practical amount of flexibility that is inherent in a bath seat and the test rig, but was still not a significant tilt angle that might compromise the safety of the occupant.

b) Maximum Water Level

We support the Commission staff's recommendation regarding water levels to weight the seat down in order to obtain an accurate water level reading. We recommend that all bath seats be clearly labeled with a maximum water level to be used. Since 96% of all deaths, injuries, and other incidents involve bath seats used in water depths greater than 1 or 2 inches, we recommend that the fill line demarcation be specified at depths of no greater than 2 inches.

CPSC Staff Response

Staff is concerned that a water line could imply a safe water level when, in reality, children can drown in very little water. In addition, because of various bath seat designs, 2 inches of water in the tub can correspond to a water level insufficient to cover the occupant's legs. Thus, the maximum water level recommended would change based on the design of the bath seat, and wouldn't necessarily reflect a safe level. Staff believes that the ASTM wording required in the user instruction, "Babies can drown in as little as 1 inch of water. ALWAYS bathe your infant using as little water as necessary," describes the risk associated with any level of water in a more accurate manner. If there was a water line indicator that could visually express the increasing risk with increasing water depth without implying that a shallow level was "safe," then staff may agree with the suggestion. At this time, staff does not believe a maximum water level requirement should be added to the standard, but we do believe it is something that manufacturers could consider for their products. Staff will continue to monitor this issue and could add such a requirement in the future if it is feasible.

c) Leg Opening Change

We agree that a smaller torso probe should be used to gauge whether an infant can slip through leg openings. Incident data indicate that leg openings on models that currently meet the ASTM

standard may still pose this hazard. A new torso probe that represents a smaller infant is required and tests should be conducted in all orientations to determine if any position can create a slip-through or entrapment hazard.

CPSC Staff Response

Staff concurs.

d) Incident Data

Furthermore, the numbers of fatalities published in the Federal Register do not reflect the increased fatality rate of recent years. The CPSC reported in the Federal Register that there have been 171 reported fatalities involving bath seats from 1983 through 2008. That represents an average of 6.6 reported deaths per year over the 26 year period. But an analysis of the most recent years for which there is complete data, specifically 1998 through 2007, shows an average of 9.7 reported deaths per year – nearly 50 percent more than stated. In comparison, baby bath tubs (a popular alternative) showed an average fatality rate of only 1.7 deaths per year during this same time period.

CPSC Staff Response

A more detailed memorandum concerning the incident data was included in Tab A of the NPR briefing package and is available on the CPSC website. This memorandum does indicate more fatalities in recent years, but some of these incidents were in older products. Caution should be used in any analysis since this product, its standards, and markets have changed significantly over the years. Comparisons between bath seats and infant bath tubs are not straightforward due to differences in the product and target population. Also, incidents are voluntarily reported and represent a minimum for counts. An updated memorandum of incident data is provided as part of this briefing package for the final rule.

e) Relative Risk Analysis

This analysis of risks relating to bath seats when compared to risks relating to baby tubs supports two conclusions: First, the ASTM F 1967 standard, which was first published in 1999, has not been effective in reducing infant deaths in bath seats. Second, bath seats are inherently more dangerous than infant bath tubs. These conclusions are based on the premise that the market share for both bath seats and bath tubs are about equal and have remained unchanged over the years. In doing this type of analysis one must be mindful that the utility of a bath seat lasts for only about 5 months of an infant's life where an infant bath tub is likely to be used for up to 24 months. Therefore the exposure in infant bath tubs is much greater --making the dichotomy in drowning incidents between bath seats and bath tubs even more glaring.

CPSC Staff Response

Risk analysis is very difficult to perform due to changes in the market, standards, and product. Without accurate usage data, it was not possible for CPSC staff to perform this analysis and so

counts were presented in the incident data memorandum (Tab B) of the NPR briefing package. Comparisons between bath seats and infant bath tubs are not straightforward due to differences in the product and target population. Based on the ownership data that is available for infant bath seats and infant bath tubs, it is clear that infant bath tubs are far more prevalent than infant bath seats. It is also clear that many of those surveyed own both products, possibly using them at different stages in their child's development. It is also apparent that ownership rates for bath seats increased substantially between 1993 and 2002, but have since dropped off. In 2004, the ASTM standard was significantly modified (with additional changes made in 2007 and 2008), which means that determining the effectiveness of the voluntary standard requires examining the incidents with pre-2004 infant bath seats and comparing them to incidents involving post-2004 bath seats - in particular those that comply with the voluntary standard. Therefore, looking at only the number of annual incidents is insufficient to evaluate the current voluntary standard's effectiveness or to evaluate its likely effectiveness, were it mandatory.

Notwithstanding the difficulties involved with performing relative risk analyses, staff does understand and concur with the underlying message in the comments, i.e., the concern that submersion deaths and injuries continue to occur with certified bath seat products, regardless of whether they are certified to older or newer versions of the bath seat standard. In addition to issuing a final rule to make performance requirements for new bath seat products more stringent, staff plans to address the hazards associated with older products as part of its in-home drowning campaign in Fall 2011.

f) Unattended Bath Seats

The standard must address the primary hazard pattern with these products --leaving an infant unattended. We encourage the CPSC to explore technology to ensure that it would be difficult to use a bath seat unless a caregiver is in close proximity to the product. The system should be designed so that it could not be easily defeated by the user. Although this likely would increase the cost of bath seats, it could help reduce submersion incidents.

CPSC Staff Response

Staff is open to suggestions to overcome the tendency of caregivers to feel confident leaving children unsupervised in bath seats. To date, no practical solutions to this serious problem have been developed, except for warning labels, which were last strengthened in the ASTM voluntary standard in 2007.

TAB E

Draft Final Rule
Safety Standard for Infant Bath Seats

DRAFT 4-28-10

[Billing Code 6355-01-P]
CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1215

[CPSC Docket No. CPSC-2010-_____]

Safety Standard for Infant Bath Seats: Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”) requires the United States Consumer Product Safety Commission (“Commission,” “CPSC,” “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. We are issuing a safety standard for infant bath seats in response to the direction under section 104(b) of the CPSIA.

DATES: The rule will become effective on **[insert date 6 months after publication in *Federal Register*]** and apply to products manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of **[insert date 6 months after publication in *Federal Register*]**.

FOR FURTHER INFORMATION CONTACT: Carolyn Manley, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7607; cmanley@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA,” Pub. Law 110-314) requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Section 104 includes infant bath seats among these products. See CPSIA, section 104(f). The standards developed under section 104 of the CPSIA 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. Section 104(b)(2) of the CPSIA directs the Commission to begin rulemaking for two standards by August 14, 2009. Under this provision, the Commission published a notice of proposed rulemaking (“NPR”) in the FEDERAL REGISTER of September 3, 2009 (74 FR 45719) proposing a safety standard for bath seats. The proposed standard was substantially the same as a voluntary standard developed by ASTM International (formerly known as the American Society for Testing and Materials), ASTM F 1967-08a, “Standard Consumer Safety Specification for Infant Bath Seats,” with some modifications to strengthen the standard in order to reduce the risk of injury associated with bath seats. The Commission is now issuing a final standard for infant bath seats that is almost the same as the proposed standard it published in September 2009.

B. The Product

Infant bath seats are used in a tub or sink to support a seated infant while he or she is being bathed. They are marketed for use with infants between the age of approximately 5 months (the time at which infants can sit up unassisted) to the age of approximately 10 months (the time at which infants begin pulling themselves up to a

standing position). Currently, there are two manufacturers and one importer of bath seats active in the United States (one fewer than at the time the Commission published its proposed rule). All are members of the Juvenile Products Manufacturers Association (“JPMA”), which is the major United States trade association representing juvenile product manufacturers and importers. All produce a variety of children’s products in addition to bath seats.

The exact number of bath seats currently sold or in use is not known. Data from a 2005 survey by the American Baby Group (*2006 Baby Products Tracking Study*), in conjunction with Centers for Disease Control (“CDC”) birth data, indicated annual sales of bath seats of about 1.5 million and about 1.8 million bath seats in use. In 2000, JPMA estimated annual sales of bath seats at about one million and estimated up to 2 million bath seats in use for infants under one year of age.

C. ASTM Voluntary Standard

ASTM F 1967, “*Standard Consumer Safety Specification for Infant Bath Seats,*” was first published in 1999. Between 2003 and 2007, the ASTM standard was subsequently revised several times to exclude tub-like products and to include requirements that the Commission had proposed in a notice of proposed rulemaking it issued in 2003, 68 FR 74878 (December 29, 2003).

In response to changes in the ASTM standard, the design of bath seats changed significantly. The new designs use an arm that clamps onto the side of the bath tub rather than relying on suction cups for stability. The current voluntary standard for bath seats, ASTM F 1967-08a, was published in December 2008. The current version contains the same labeling, stability and leg opening requirements as the 2007 version.

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JPMA provides certification programs for juvenile products, including bath seats. Manufacturers submit their products to an independent testing laboratory to test the product for conformance to the ASTM standard. Currently only one bath seat model is certified to ASTM F 1967-08a.

The current ASTM standard includes general requirements common to many ASTM standards for children's products; performance requirements specific to bath seats to address the hazards of the bath seat tipping over or the child becoming entrapped and/or submerged in the leg openings; and labeling requirements to address the child coming out of the bath seat.

General requirements in the current ASTM standard, none of which the Commission is modifying, include:

- Requiring compliance with CPSC's standards concerning sharp points and edges, small parts, and lead paint (16 CFR parts 1303, 1500.48, 1500.49, 1500.50, 1500.51, and 1501);
- Requirements for latching and locking mechanisms;
- Requirements to prevent scissoring, shearing and pinching;
- Entrapment testing for accessible holes and openings;
- Torque/tension test for graspable components; and
- A requirement that warning labels be permanent.

The ASTM standard's requirements specifically related to hazards posed by bath seats (as discussed in part F of this preamble, the Commission's rule modifies aspects of some of these requirements) include:

- A test for stability performed on a test platform containing both a slip resistant surface and a smooth surface to test whether the bath seat may tip over during use;
- Requirements for restraint systems requiring passive crotch restraint to prevent a child from sliding through front or sides of the seat;
- Static load test to test whether the bath seat may break or become damaged during use;
- A requirement that suction cups (if used) adhere to the bath seat and the surface;
- A leg opening requirement to prevent children from sliding through these openings;
- A leg opening requirement restricting the expansiveness of the seating area to prevent the child from slumping and becoming entrapped in a reclined position; and
- Requirements for warning labels and instruction manual.

D. Incident Data

Since publication of the NPR in the FEDERAL REGISTER of September 3, 2009, the CPSC staff identified five new fatalities and five new non-fatal incidents, all of which occurred in 2009. Three deaths and three additional non-fatal incidents involved bath seat products (not combination infant bath tub-bath seat products) meeting the stability requirements of either F 1967-04 or F 1967-07. One death involved an earlier pre-2004 bath seat product and the remaining death involved a combination infant bath tub-bath seat product that was certified to the 2004 edition of the bath seat and bath ring standard (F 1967-04) but is no longer being produced. (Combination bathtub-bath seat

products are no longer covered by F 1967 and will be covered by a new separate infant bath tub- specific standard.) This fatality is not included in the frequency statistics. The data update for the final rule also located additional information enabling CPSC staff to identify two 2005 fatality case reports, previously considered to be independent, as being a single case.

Taking into account these changes in the data, from 1983 through November 30, 2009, there have been 174 reported fatalities involving bath seats, although more fatalities may have occurred because fatality reporting is not considered to be complete for 2006, 2007, 2008, and 2009. All of these fatalities were submersions.

There were 300 non-fatal bath seat incidents reported to CPSC staff in this 1983 through November 30, 2009 time frame. A submersion hazard was identified in 154 of these non-fatal incidents of which 117 were actual submersion incidents. (Submersion is defined as the act of placing, or the condition of being, under water. A submersion hazard indicates that submersion is possible, as a direct result of the incident. An actual submersion is when the victim actually became submerged as a result of the incident.) The remaining 146 reports were non-submersion hazards such as lacerations and limb entrapments.

None of the identifiable products involved in the fatal bath seat incidents were certified to meet ASTM F 1967-08a or its predecessor, ASTM F 1967-07. Four of the non-fatal incidents involved products certified to ASTM F 1967-07, neither of which were submersion hazards, and thus were not life threatening.

Of the 174 fatal incidents, 23 involved products that were identified as being certified to the 2004 version of the ASTM standard. Three of these were due to the arm

of the bath seat disengaging from the bath tub. Fifty-four of the non-fatal incidents involved bath seats certified to the 2004 version of the ASTM voluntary standard.

E. Response to Comments on the NPR of September 3, 2009

The Commission received seven comments on the NPR of September 3, 2009. Four comments from individual consumers supported a mandatory safety standard for infant bath seats. In addition, the Commission received three specific comments on various aspects of the NPR. These three comments were from IISG (an international testing laboratory); the Juvenile Products Manufacturers Association (JPMA); and one comment from various consumer groups (Consumers Union, Kids in Distressed Situations, and Consumer Federation of America). These comments and the Commission's responses to them are discussed below.

1. Leg Opening Requirement

a. Comment: One commenter asked that the rule be clarified to indicate that the torso probe shall be inserted in a straight direction and it is not allowed to be inserted partially and then rotated along some minor axis to make it pass through the hole.

Response: In the NPR, the Commission proposed a change to the voluntary standard that called for the torso probe to be inserted in all orientations of the leg openings to determine if any position can create a slip through and/or entrapment hazard. This change was proposed because the language in the current ASTM standard, which stated that the probe should be inserted in the most adverse orientation, was open to interpretation by the person performing the test. The language the commenter suggests would actually make the requirement less restrictive than what is already in the voluntary standard. For this reason, the Commission disagrees with the recommendation.

b. Comment: One commenter argued that the proposed change to the leg opening torso probe would not have prevented the two incidents discussed in the NPR when children fit both their legs and hips through a single leg hole of the bath seat. The commenter asserted that reducing the leg opening might exacerbate entrapment and ingress and egress conditions. The commenter believes that the ASTM standard has optimized this probe size, is consistent with other standards that provide similar submarining protection, and should not be changed.

Response: Although in these two incidents children did become entrapped in the leg holes, of more concern is the fact the victims' pelvis and torso were able to penetrate the leg openings. Once the pelvis goes through the leg hole, the victim is in serious danger of submersion because the waist and upper torso are more malleable and therefore more capable of squeezing through the leg holes. Therefore, contrary to the commenter's characterization of the incidents, the leg holes failed to prevent a potential submersion condition. The infants were not endangered by the entrapment as much as they were endangered by their position during their entrapment. These incidents show a failure in the design of the torso probe and the leg opening test which was developed to prevent the manufacture of leg holes that allow a pelvis to fit through them. As a photograph taken of the actual victim from one of the incidents clearly shows, in that incident the pelvis had fit through the leg opening. The current bath seat torso probe used to test the leg openings was based on probes from other juvenile products that do not normally entail use with wet, naked babies. The data associated with these two incidents suggest that the unique use of a bath seat in a watery, soapy environment requires a smaller probe.

Reducing the size of leg openings by making the torso probe more rounded at the corners and slightly smaller will prevent future submersion incidents.

The issue of entrapment during ingress and egress is irrelevant to the leg hole opening test method. The Commission is aware that consumers have encountered difficulties with getting infants in and out of some models of bath seats currently sold in the United States. However, the size and shape of the leg hole opening is only one factor in the overall design of a bath seat's occupant retention space. Such features as the shape of the seat, the slope of the supports, and the thickness and the type of materials used to make the bath seat are not determined by the performance requirements of the standard. The leg hole opening test does not dictate any other dimensional or design requirements for bath seats, leaving the designer ample freedom to design a bath seat that allows easy entry and exit.

c. Comment: One commenter approved of the proposed change to the torso probe and conducting testing in all orientations, but stated that incident data indicate that leg openings on models currently meeting the ASTM standard may still pose this hazard.

Response: The Commission concurs. The Commission's changes to the torso probe are intended to address such incidents.

2. *Stability Issues*

a. Comment: One commenter states that the pass/fail criteria in the ASTM standard were specifically created to require that both the attachment disengage from the test platform and that the product fail to return to the manufacturer's intended use position after being tested. The commenter asserts that both conditions must be present in order to constitute a failure. The commenter argues that the proposal to consider a tilt

angle of 12-degrees or more from the bath seat's initial starting position to be a failure is not indicative of an unsafe condition and "is a departure from the primary intent of the requirement which is to determine if the bath seat tips."

Response: The two parts of the criteria were added to the ASTM standard at different times, and there is no language to suggest that both conditions must be met in order to constitute a failure. If that were the intent, then there would be no need to add the second pass/fail criteria because if the bath seat disengaged from the test platform (condition #1), then obviously it would not return to the manufacturer's intended use position (condition #2). This second condition was added in the 2007 standard to address those situations where a bath seat started tipping, to a degree that could be hazardous, but did not fully disengage from the tub. The Commission's modification to the ASTM standard clarifies the intent, as well as ensuring that a bath seat which significantly tips during the stability test, but returns to a fully upright condition, is not in compliance with the requirement.

b. Comment: The same commenter argues that the 12 degree tilt test "is unrelated to submersion risk and would not reduce the risk of injury and submersion incidences identified in the incident data. The risk of submersion presents itself when the position of the product indicates that the child's head area would be in a compromising position."

Response: CPSC agrees with the last statement presented above which is why the Commission is modifying the ASTM standard to provide a clearer definition of the pass/fail criteria. If the bath seat is tilted, children can slump over, lean over, and expose their faces to the water more easily than if the bath seat is not tilted.

c. Comment: The same commenter states that the 17-pound force used in the stability testing in the ASTM standard was based on the assumption that the older user of a bath seat would apply his/her total weight in the head location when in a seated position. However, the commenter states, it is more likely that the child would exert only a percentage of his/her total body weight.

Response: According to the rationale in the ASTM standard (Appendix, part X1.17), the original basis for the 17-pound force is that it represents 60 percent of the 95th percentile (27.8 pound) body weight for oldest users (which was for 12 to 15 month old children at the time the requirement was developed), not the child's total body weight. A review of the incident data shows that fatal incidents that occurred in the newer style bath seats (which are designed for children who cannot yet pull themselves to a standing position) involved babies whose weights ranged from 15 to 30 pounds, with at least two of the victims (ages 8 and 9 months) being 30 pounds at the time of their deaths. Thus, it is foreseeable that a child of this size may use the product and, as the commenter recognizes, exert a percentage of his/her body weight. Thus, the 17-pound force is still valid.

d. Comment: The same commenter argues that the Commission's change to the failure definition (adding the 12 degree tilt angle test) would prohibit even "infinitesimal movements" of the bath seat with little affect on safety.

Response: The Commission disagrees that this additional requirement would prohibit infinitesimal movement. The ASTM standard could be interpreted very strictly to not allow any movement or tilt of the bath seat from the original position. By adding the 12 degree tilt limit, the stability test allows bath seats some controlled flexibility.

e. Comment: The same commenter asserts that the 12 degree tilt angle is random and lacks any rationale as to how exceeding this angle could result in a compromising unsafe condition.

Response: In developing this requirement, CPSC staff conducted an analysis looking at various water levels and possible head positions of occupants vs. angles of bath seats to determine what level of tilt was potentially hazardous. In addition, CPSC staff looked at other ASTM standards, such as those for infant bouncer seats and toys which use a 10 degree table or tilt when testing for stability. Lastly, staff acknowledged that the requirement must allow for the ductility of the aluminum rod test fixture combined with some expected ductility or flexing of the bath seat itself. Therefore, the staff conducted testing to determine the maximum level of tilt that might be expected solely due to the flexibility of the bath seat and the test rig. As a result of this work, staff selected a tilt angle of 12 degrees as the pass/fail criteria to insure passing products will remain in the manufacturer's intended use position.

Thus, the 12 degree angle will allow for some inherent flexibility in the system (the product and the test rig) as a whole, but would fail a bath seat that: 1) stayed firmly clamped to the bath tub but the bath seat itself experienced significant ductility (i.e., its ability to be fashioned into a new form or drawn out without breaking) or flexibility (12 degrees or more) during the testing; or 2) had a clamping mechanism that lost firm contact with the bath tub and allowed the bath seat to tilt 12 degrees or more during the test.

f. Comment: The same commenter argues that, so long as the product remains attached, the angle at which it may tilt during testing does not affect the safety of the bath

seat. The commenter asks, if the product were to reach a 15 degree angle, how would this angle result in an unsafe condition if the product remains attached?

Response: CPSC disagrees with the commenter's assertion that the condition of the product during the test has no bearing on safety. In the test, a 17-pound load is applied and then released. In real life, if a child leans over a bath seat railing, he/she may not be able to sit back upright. Young infants do not have a good sense of balance, and the more the bath seat allows them to tilt forward, the less likely they will be able to return to an upright position. If a child's body remains tilted forward, this could result in his/her face becoming submerged in the water. Once an infant's face is submerged, the infant may not pull his/her face out of the water. Infants may be physically capable of lifting their heads, but they may not do so because they do not recognize the need to do so or because they breathe in a lungful of water before trying to lift their head. Bath seats should never allow an infant's face to be submerged under water. In addition, another argument against allowing any significant tilt during the test is that the more the seat tilts forward, the higher the likelihood for a child to crawl out of the seat. When the seat is far enough forward, even if it has not tipped over, the child can stand (hunched over) on his/her feet with legs still through the leg holes, and this would also make a tilted seat hazardous.

g. Comment: One commenter agreed that the pass/fail criteria in the ASTM stability requirements need clarification, but recommended that the Commission consider any movement from the bath seat's originally fixed position to be a failure.

Response: There are three ways that a bath seat can fail the stability requirement as proposed in the NPR (and finalized in the rule): 1) if the bath seat tips over (and

remains tipped over after the test); 2) if any attachment point disengages from (is no longer in contact with) the test platform (bath tub) and the bath seat fails to return to the manufacturer's recommended use position after the test; and 3) if the measured tilt angle during the test ever exceeds 12 degrees.

The first two pass/fail criteria above were already required under the voluntary standard, and the third one was proposed by CPSC as a new additional requirement in the NPR, and is also in the final rule. With regard to the third criteria, there are two different ways in which a bath seat can tilt during stability testing. The first is the tilt that might occur when the bath seat attachment slips or moves from its original fixed position. The second is the tilt that can occur due to the flexibility between all the parts of the bath seat and the bath seat test fixture (the aluminum rod and clamping devices). Depending on the product, it is possible to have both factors contribute to the tilt, or just have the second factor contribute to the tilt.

There is no way to eliminate the flexibility of the system (the bath seat and the test fixture) entirely. The flexibility of the aluminum rod itself can result in a two degree tilt. When the clamping fixtures and then the expected flexibility of the plastic used in the product are added, there is inherent flexibility in the system that cannot be totally eliminated. A tilt test must allow for this flexibility among all the components of the system. Twelve degrees allows for some practical amount of flexibility that is inherent in a bath seat and the test rig, but is still not a significant tilt angle that might compromise the safety of the occupant.

3. Changes to Test Platform Preparation

Comment: One commenter stated that, while it agrees with the application of the soap solution inside and outside of the tub, it believes that the soap solution should be applied once the product has been installed, if manufacturers present this as a prerequisite to use in instructional literature because clamping mechanisms rely on a clean tub side surface for effectiveness.

Response: Regardless of instructional literature or warnings, it is foreseeable that caregivers will install the bath seat on a wet and soapy tub; therefore, bath seats should be tested under such conditions.

4. *Weighing the Seat Down*

Comment: One commenter recommended adding a statement requiring removal of the weight once the seat is flooded to eliminate the potential for a counterweight to be included during the test.

Response: The Commission agrees with this comment and has included such a statement in the final rule.

5. *Maximum Water Level*

Comment: One commenter recommended that all bath seats be labeled to indicate a maximum water level to be used. The comment stated that, because 96% of all deaths, injuries, and other incidents involve bath seats used in water depths greater than one or two inches, the fill line demarcation should be specified at depths of no greater than two inches.

Response: The Commission is concerned that a water line could imply a safe water level. However, children can drown in very little water. In addition, because of various bath seat designs, some of which may elevate the bath seat, two inches of water

in the tub can correspond to a water level insufficient to cover the occupant's legs. Thus, the maximum water level recommended would change based on the design of the bath seat, and would not necessarily reflect a "safe level." The Commission believes that the ASTM wording required in the user instruction, "Babies can drown in as little as 1 inch of water. ALWAYS bathe your infant using as little water as necessary," describes the risk associated with any level of water in a more accurate manner. If there was a water line indicator that could visually express the increasing risk with increasing water depth without implying that a shallow level was "safe," then CPSC staff may agree with the suggestion. At this time, CPSC staff does not believe a maximum water level requirement should be added to the standard, but does believe it is something that manufacturers could consider for their products. CPSC staff will continue to monitor this issue and the Commission could add such a requirement in the future if it is feasible.

6. *Incident Data*

Comment: One comment notes that the numbers of fatalities stated in the NPR do not reflect the increased fatality rate of recent years. Although the 171 reported fatalities involving bath seats from 1983 through 2008 represents an average of 6.6 reported deaths per year over the 26 year period, an analysis of the most recent years for which there is complete data (1998 through 2007) shows an average of 9.7 reported deaths per year – nearly 50 percent more than stated. The commenter notes that, in comparison, baby bath tubs (a popular alternative) showed an average fatality rate of only 1.7 deaths per year during this same time period.

Response: Some fatalities in recent years involved older products. Caution should be used in any analysis since this product, its standards, and markets have changed

significantly over the years. Comparisons between bath seats and infant bath tubs are not straightforward due to differences in the product and target population. Also, incidents are voluntarily reported and represent a minimum count. An updated memorandum of incident data was provided as part of the briefing package for the final rule.

7. Risks Related to Bath Seats and Risks Related to Bath Tubs

Comment: The same commenter noted that comparing the risks related to bath seats and those related to bath tubs indicates that the ASTM F 1967 standard has not been effective in reducing infant deaths in bath seats and that bath seats are inherently more dangerous than infant bath tubs.

Response: Risk analysis is very difficult to perform with these products due to changes in the market, standards, and product. Without accurate usage data, it was not possible for CPSC staff to perform this analysis. Comparisons between bath seats and infant bath tubs are not straightforward due to differences in the product and target population. Based on the ownership data that is available for infant bath seats and infant bath tubs, it is clear that infant bath tubs are far more prevalent than infant bath seats. It is also clear that many of those surveyed own both products, possibly using them at different stages in their child's development. It is also apparent that ownership rates for bath seats increased substantially between 1993 and 2002, but have since dropped off. In 2004, the ASTM standard was significantly modified (with additional changes made in 2007 and 2008), which means that determining the effectiveness of the voluntary standard requires examining the incidents with pre-2004 infant bath seats and comparing them to incidents involving post-2004 bath seats - in particular those that comply with the voluntary standard. Therefore, looking at only the number of annual incidents is

insufficient to evaluate the current voluntary standard's effectiveness or to evaluate its likely effectiveness, were it mandatory.

8. *Unattended Bath Seats*

Comment: One commenter stated that the bath seat standard must address the primary hazard pattern with these products -- leaving an infant unattended -- and encouraged the CPSC to “explore technology to ensure that it would be difficult to use a bath seat unless a caregiver is in close proximity to the product.”

Response: The Commission is open to suggestions to overcome the tendency of caregivers to feel confident leaving children unsupervised in bath seats. To date, no practical solutions to this serious problem have been developed, except for warning labels, which were last strengthened in the ASTM voluntary standard in 2007.

9. *CPSIA Process*

a. Comment: One commenter stated that the Commission “should not modify existing effective standards unless it can clearly substantiate on the record before it that such changes will provide a demonstrable reduction of injury.” The commenter noted that the ASTM standard was originally published in 1999 and has undergone several revisions since then through the ASTM subcommittee and task group process and that CPSC has participated in this process. The commenter states that it sees “little value in revising the current requirements in this standard by using the NPR regulatory process” and is “concerned that the imposition of additional requirements without demonstrable evidence that they will both enhance bath safety and not create unintended entrapment related hazards, will restrict the availability of potentially lifesaving products.”

Response: Section 104(b) of the CPSIA requires the Commission to use the notice and comment rulemaking process under the Administrative Procedure Act to promulgate consumer product safety standards for durable infant or toddler products. The CPSIA directs the Commission to issue a rule that is “substantially the same as” the applicable voluntary standard or “more stringent than” the voluntary standard if the more stringent standard “would further reduce the risk of injury associated with the product.” See section 104(b)(1)(B) of the CPSIA. The statute does not require that the Commission, in the commenter’s words, “clearly substantiate on the record before it that such change will provide a demonstrable reduction in injury.” Section 104 of the CPSIA takes durable infant or toddler products out of the Commission’s usual rulemaking procedure and all of the findings that would be required under sections 7 and 9 of the Consumer Product Safety Act (“CPSA”). For these products, Congress wanted “the highest level of safety for such products that is feasible.” See section 104(b)(2) of the CPSIA. The Commission recognizes that the ASTM standard has been in place for numerous years and has been refined through ASTM’s standard-setting process. Nevertheless, incidents continue to occur. Under the mandate of section 104 of the CPSIA, the Commission is promulgating more stringent requirements where necessary to address certain design features that CPSC staff believes contribute to some of these continuing deaths and torso entrapments. The staff has conducted testing and performed analyses to support the requirements that are different from the ASTM requirements and that it believes will reduce the risk of injury from infant bath seats.

b. Comment: The same commenter states that it believes “the most streamlined approach to following the primary congressional mandate that standards required to be

developed are to be ‘substantially the same as’ applicable voluntary standards, would be to adopt a regulation that wholly adopts the existing ASTM standard, with the ability to subject it to the ASTM update and review process. CPSC can assure itself veto authority as part of an implementing regulation, which provides it with the ability to restrict diminution of effective ASTM standard provisions, similar to the authority applicable under CPSIA Section 106, as a check to changes that reduce stringent protections.” The commenter suggests that CPSC adopt ASTM F 1967-08a as a consumer product safety standard issued by the Commission under section 9 of the CPSA and that any additional changes to the pending ASTM standard be submitted to the ASTM standard setting process. The commenter states, “this process could also incorporate a provision by rule that a reservation of right to the CPSC to object to any subsequent revisions to the ASTM Standard, similar to that afforded under CPSIA Section 106(g).”

Response: The standard the Commission proposed for infant bath seats incorporates by reference most of ASTM F 1967-08a with a few modifications to strengthen the standard. Section 104(b) of the CPSIA sets forth the procedure for these standards for durable infant or toddler products, and it is different from what Congress provided in section 106 of the CPSIA. It is doubtful that the Commission, by rule, could change the procedure Congress provided for rules under section 104 of the CPSIA to the one Congress provided for rules under section 106 of the CPSIA.

F. Assessment of Voluntary Standard ASTM F 1967-08a and Description of the Final Rule

1. Section 104(b) of the CPSIA: Consultation and CPSC Staff Review

Section 104(b) of the CPSIA requires the Commission to assess the effectiveness of the voluntary standard in consultation with representatives of consumer groups, juvenile product manufacturers and other experts. This consultation process began in October 2008 during the ASTM subcommittee meeting regarding the ASTM infant bath seat voluntary standard. The Commission has reviewed the incident data and the ASTM F 1967-08a standard and conducted testing on bath seats to assess the ASTM standard.

Consistent with section 104(b) of the CPSIA, this rule establishes a new 16 CFR part 1215, "Safety Standard for Bath Seats." The new part incorporates by reference the requirements for bath seats in ASTM F 1967-08a with certain changes to specific provisions to strengthen the ASTM standard as discussed below. These modifications are almost identical to the changes the Commission proposed in the NPR of September 3, 2009. Differences from the NPR are noted in the discussion below.

2. Description of the Final Rule, Including Changes to the ASTM Standard's Requirements

While most requirements of the current ASTM standard are sufficient to reduce the risk of injury posed by bath seats, the Commission has determined to modify several provisions in the standard to make them more stringent and further reduce the risk of injury and to clarify the test procedures. The following discussion describes the final rule, including changes to the ASTM requirements, and notes any changes from the NPR. In addition, some editing and formatting changes have been made which make the final text different from the NPR. These changes were made at the request of the Office of the Federal Register and do not alter the substance of the rule.

a. Scope (§ 1215.1)

The final rule states that part 1215 establishes a consumer product safety standard for infant bath seats manufactured or imported on or after a date which would be six months after the date of publication of a final rule in the FEDERAL REGISTER.

The Commission received no comments on this provision in the NPR and is finalizing it without change.

b. Incorporation by reference (§ 1215.2(a))

Section 1215.2(a) explains that, except as provided in § 1215.2(b), each infant bath seat must comply with all applicable provisions of ASTM F 1967-08a, “Standard Consumer Safety Specification for Infant Bath Seats,” which is incorporated by reference. Section 1215.2(a) also provides information on how to obtain a copy of the ASTM standard or to inspect a copy of the standard at the CPSC.

The Commission received no comments on this provision in the NPR and is finalizing it without change.

c. Definition of bath seat (§ 1215.2(b)(1)(i))

In the NPR, the Commission proposed changing the definition of bath seat to the definition in a previous NPR the Commission had issued in 2003 – “an article that is used in a bath tub, sink, or similar bathing enclosure and that provides support, at a minimum, to the front and back of a seated infant during bathing by a caregiver”

The Commission received no comments on this provision and is finalizing it without change.

d. Stability requirement

Limiting the tilt of the bath seat (§ 1215.2(b)(2)(i), (b)(6)(i), and (b)(7)(i)). As discussed in the preamble to the proposed rule (74 FR at 45720 through 45721), when

testing bath seats, CPSC staff found that the clamping mechanism on the JPMA-certified bath seat lifted from the side of the tub and continued to tip when force was applied. The clamp did not disengage from the tub, but the arm rest contact points were no longer in contact with the tub surface. This situation allows for possible misinterpretation of the ASTM standard's pass/fail criteria because the bath seat tilted from its original position while the clamp remained attached to the side of the tub. Moreover, this scenario could present a hazard to an infant using a bath seat. As explained in greater detail in the response to comments in section E of this preamble above, with the bath seat in this position an infant could submerge his/her face in the water, and the tilt of the seat could increase the likelihood the infant will crawl out of the seat. Thus, the NPR proposed a requirement to limit the allowable tilt angle of the bath seat during the stability test. This modification is added in several places of the ASTM standard: to section 6.1, between sections 7.4.2.2 and 7.4.2.3, and between sections 7.4.2.3 and 7.4.2.4. The Commission proposed that a bath seat capable of tilting 12 degrees or more during testing be considered a failure. This limit was determined after measuring, and allowing for the flexibility of, current products. CPSC staff also considered other ASTM standards such as those for infant bouncer seats and toys. These standards use a 10 degree table or tilt when testing stability, and so the Commission proposed a tilt angle just above that level.

The final rule retains the 12 degree tilt limit. (We discussed comments relating to stability at part E of this preamble.)

The final rule also clarifies the language in section 6.1 of the ASTM standard to make it consistent with the definition of bath seat. This is a change from the NPR. Thus, the final rule removes the beginning phrase in section 6.1: "for bath seats which provide

support for an occupant's back and support for the sides or front of the occupant or both.” Given the definition of bath seat in the final rule, this phrase is redundant, and the final rule, therefore, eliminates it.

Clarifying the order of steps in the stability test (§ 1215.2(b)(3)(i) and (5)(i)).

The final rule retains other proposed changes clarifying the order of steps to be performed when conducting the stability test. The Commission proposed re-ordering the steps specified in the ASTM standard for preparing the test surface and installing the bath seat to clarify that the test platform should be flooded before installing the bath seat.

Test solution application (§ 1215.2(b)(4)(i)). The Commission proposed that a test solution be applied to all areas where the product may make contact while in use. As explained in the NPR's preamble (74 FR at 45721), the current ASTM standard requires that a soapy test solution “thoroughly saturate the coverage area” which is defined in the ASTM standard as any internal surface of the tub well or tub bottom that makes contact with the product. In its testing of bath seats, CPSC staff found that spraying the soap solution on the top and outer surface contact points as well as the interior surfaces affected the final position of the bath seat and therefore could affect the results of the test. The Commission recognizes that the outside of a tub may become wet, and this may affect the ability of a bath seat's attachment arm to remain stable. The final rule retains this requirement. (We discussed comments relating to test platform preparation at part E of this preamble.)

Measuring water levels (§ 1215.2(b)(5)(i)). When testing the stability of bath seats, CPSC staff noted that it can be difficult to obtain accurate water level measurements because the unoccupied bath seat may float when the test platform is

flooded. To address this, the Commission proposed to add a clarifying statement: “For the purpose of measuring the water level, the product’s seating surface can be temporarily weighed down to prevent the seat from floating.”

In response to a comment to the NPR (see part E of this preamble), the final rule retains this change, but also adds the following clarifying language: “The weight shall be removed following the measurement of the water level and prior to conducting the test.”

e. Leg opening requirement (§ 1215.2(b)(8)(i) through (10))

According to recent incident reports, children have fit both legs and their hips through a single leg hole of a bath seat that complies with the current ASTM standard. The torso probe specified in the current ASTM standard used to test the size of the leg openings is not sufficiently analogous to the human infant in this wet environment. This has resulted in a child’s torso fitting through a leg hole when the ASTM torso probe does not. The Commission proposed decreasing the length of the vertical and horizontal axes of the wood torso probe specified in the ASTM standard by approximately five percent and rounding the corners of the probe resulting in a 1.45” radius rather than the current 1” radius size of the probe. To accomplish this, the Commission proposed modifications to Figure 4 in the ASTM standard that shows the torso probe. As explained in the preamble to the NPR (see 74 FR at 45721) and in the response to comments in section E above, the Commission believes that changes in the test probe would not restrict the utility of the product, but would still allow many possible designs for bath seats, even ones which would accommodate large children.

The NPR also proposed changing (at § 1215.2(b)(8)(i) and (9)(i)) the ASTM standard’s instruction in section 7.7.1 and 7.7.2 of the ASTM standard to insert the test

probe "...in the most adverse orientation into each opening." The Commission proposed changing this language because the terms "the most" appearing with respect to adverse orientation is open to interpretation. The final rule retains the proposed wording that the probe needs to be inserted "in all orientations to determine if any position can create a slip through and/or entrapment hazard."

G. Effective Date

In the NPR, the Commission proposed that the standard would become effective six months after publication of a final rule. The Commission received no comments on the proposed effective date. The final rule provides that the rule will become effective six months after publication and thus will require that bath seats manufactured or imported on or after that date must meet this standard.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") generally requires that agencies review final rules for their potential economic impact on small entities, including small businesses. 5 U.S.C. 604.

Three firms currently market infant bath seats in the United States: one large domestic manufacturer, one small foreign manufacturer and one small domestic importer. All of these companies' bath seats are expected to require modifications to meet the bath seat standard. This final regulatory flexibility analysis focuses on the small domestic importer.

As noted in the NPR preamble (see 74 FR at 45722), the effect of the regulation on importers of bath seats would be felt indirectly, requiring a shift in suppliers rather than the design and production of a different product. The impact on the small domestic

importer is expected to be small. The small domestic importer would most likely respond by discontinuing the import of its non-complying bath seat, either replacing the bath seat with a complying product or another juvenile product (the firm currently imports approximately 165 juvenile products, of which three are substitutes for its imported bath seat).

Hence, even if the cost of developing a compliant product did prove to be a barrier for individual small firms, the loss of bath seats as a product category is expected to be minor and would likely be mitigated by increased sales of competing products, such as multi-stage infant bathtubs, or entirely different juvenile products.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's safety standards from any requirement to prepare an environmental assessment or an environmental impact statement as they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(1). This rule falls within the categorical exclusion.

J. Paperwork Reduction Act

Sections 8 and 9 of ASTM F 1967-08 contain requirements for marking, labeling and instructional literature that are considered "information collection requirements" under the Paperwork Reduction Act, 44 U.S.C. 3501-3520. In a separate notice in this issue of the FEDERAL REGISTER, the Commission is publishing a notice requesting comments on this collection of information.

K. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a “consumer product safety standard under [the CPSA]” 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,” thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

L. Certification

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product or on a reasonable testing program or, for children’s products, on tests on a sufficient number of samples by a third party conformity assessment body recognized by the Commission to test according to the applicable requirements. As discussed above in section K, section 104(b)(1)(B) of the CPSIA refers to standards issued under that section, such as the rule for infant bath seats established in this notice, as “consumer product safety standards.” By the same

reasoning, such standards would also be subject to section 14 of the CPSA. Therefore, any such standard would be considered to be a consumer product safety rule to which products subject to the rule must be certified.

Because infant bath seats are children's products, they must be tested by a third party conformity assessment body accredited by the Commission. The Commission is issuing a separate notice of requirements to explain how laboratories can become accredited as a third party conformity assessment bodies to test to this new infant bath seat safety standard. (Infant bath seats also must comply with all other applicable CPSC requirements, such as the lead content requirements of section 101 of the CPSIA and potentially the phthalate content requirements in section 108 of the CPSIA should the bath seat incorporate a toy component, the tracking label requirement in section 14(a)(5) of the CPSA, and the consumer registration form requirements in section 104 of the CPSIA.)

List of Subjects in 16 CFR 1215

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

Therefore, the Commission amends Title 16 of the Code of Federal Regulations by adding part 1215 to read as follows:

PART 1215 – SAFETY STANDARD FOR INFANT BATH SEATS

Sec.

1215.1 Scope.

1215.2 Requirements for infant bath seats.

AUTHORITY: The Consumer Product Safety Improvement Act of 2008, Pub. Law 110-314, § 104, 122 Stat. 3016 (August 14, 2008).

§ 1215.1 Scope.

This part 1215 establishes a consumer product safety standard for infant bath seats manufactured or imported on or after **[insert date 6 months after date of publication in the FEDERAL REGISTER]**.

§ 1215.2 Requirements for infant bath seats.

(a) Except as provided in paragraph (b) of this section, each infant bath seat shall comply with all applicable provisions of ASTM F 1967-08a, Standard Consumer Safety Specification for Infant Bath Seats, approved November 1, 2008. 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; www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 502, 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 the ASTM F 1967-08a standard with the following additions or exclusions:

(1) Instead of complying with section 3.1.1 of ASTM F 1967-08a, comply with

the following:

(i) “3.1.1 *Bath seat, n* -- an article that is used in a bath tub, sink, or similar bathing enclosure and that provides support, at a minimum, to the front and back of a seated infant during bathing by a caregiver. This does not include products that are designed or intended to retain water for bathing.”

(ii) [Reserved]

(2) In addition to section 6.1 of ASTM F 1967-08a, comply with the following:

(i) “6.1 *Stability* - . . . If any time during the application of force, the seat is no longer in the initial ‘intended use position’ and is tilted at an angle of 12 degrees or more from its initial starting position, it shall be considered a failure.”

(ii) [Reserved]

(3) Instead of complying with section 7.4.1.2 of ASTM F 1967-08a, comply with the following:

(i) “7.4.1.2 Prepare the test surface as follows:”

(ii) [Reserved]

(4) Instead of complying with section 7.4.1.4 of ASTM F 1967-08a, comply with the following:

(i) “7.4.1.4 Using a spray bottle containing a 1:25 mixture of test solution (see table Z) to distilled water, immediately before each test run, thoroughly saturate all test platform surfaces above the water line where the product makes contact and where contact might be expected.”

(ii) [Reserved]

(5) Instead of complying with section 7.4.1.5 of ASTM F 1967-08a, comply

with the following:

(i) “7.4.1.5 Flood the test platform with clear water that is at an initial temperature of 100 to 105° F (37.8 to 10.6° C) and a depth of 2 in. (51 mm) above the highest point of the occupant seating surface. Install the product according to the manufacturer’s instructions onto the test platform specified in 7.4.3. For the purpose of measuring the water level, the product’s seating surface can be temporarily weighed down to prevent the seat from floating. The weight shall be removed following the measurement of the water level and prior to conducting the test.”

(ii) [Reserved]

(6) After section 7.4.2.2 and before section 7.4.2.3 of ASTM F 1967-08a, comply with the following:

(i) “Rigidly install an inclinometer to the test bar above the location where force is to be applied. The weight of the inclinometer and the fastening method shall be less than or equal to 2.2 pounds. The inclinometer shall have a measurement tolerance of less than or equal to 0.5 degrees. Measure and record the pre-test angle of the test bar.”

(ii) [Reserved]

(7) Between section 7.4.2.3 (including Note 2) and section 7.4.2.4 of ASTM F 1967-08a, comply with the following:

(i) “Measure and record the maximum angle of the test bar during the application of the 17.0 lbf load. Calculate the absolute value of the Change in Angle in degrees. $\text{Change in Angle} = (\text{Angle measured during test}) - (\text{Angle measured pre-test}).$ ”

(ii) [Reserved]

(8) Instead of complying with the first sentence in section 7.7.1 of ASTM F

1967-08a, comply with the following:

(i) “7.7.1 With the bath seat in each of the manufacturer’s recommended use position(s), insert the tapered end of the Bath Seat Torso Probe (see Fig. 4) in all orientations into each opening. . . .”

(ii) [Reserved]

(9) Instead of complying with the first sentence in section 7.7.2 of ASTM F 1967-08a, comply with the following:

(i) “7.7.2 With the bath seat in each of the manufacturer’s recommended use position(s), insert the tapered end of the Bath Seat Shoulder Probe (see Fig. 6) in all orientations into each opening. . . .”

(ii) [Reserved]

(10) Instead of Figure 4 of ASTM F 1967-08a, use the following:

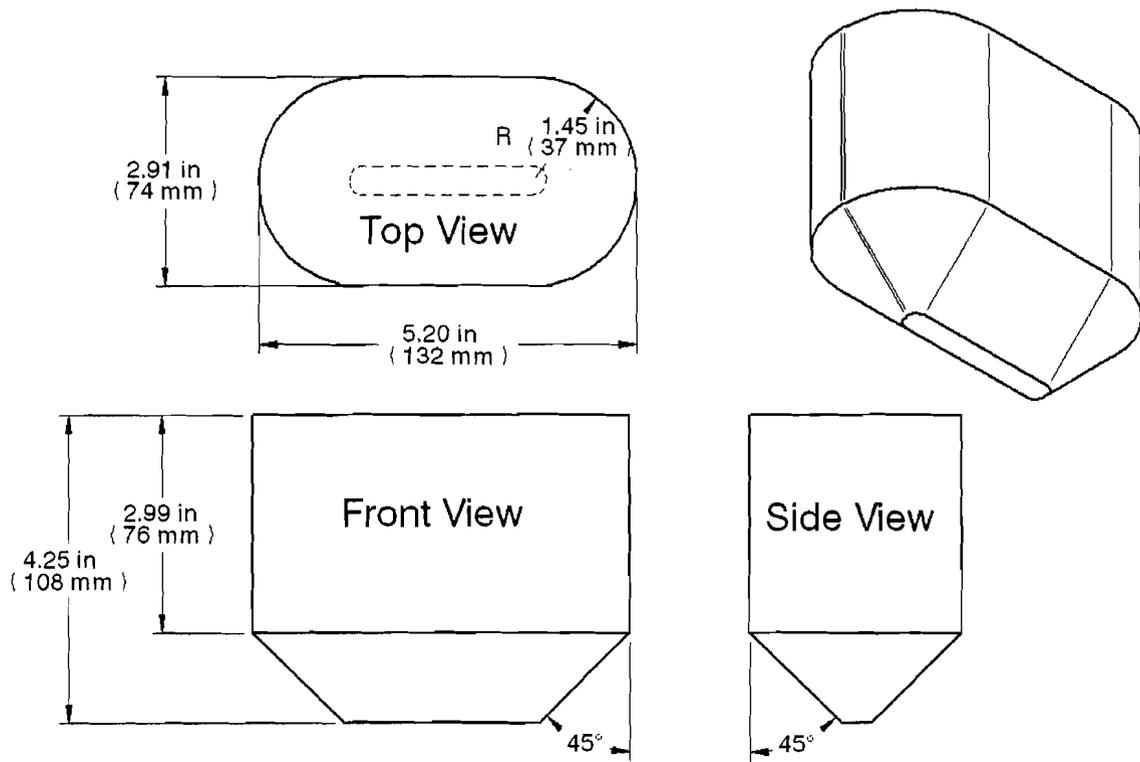


Figure 4: Modified Bath Seat Torso Probe

Dated: _____

Todd Stevenson, Secretary
U.S. Consumer Product Safety Commission