



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

Memorandum

Date: OCT 7 2003

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: W. H. DuRoss, III, General Counsel *WHD*
 Patricia M. Semple, Executive Director *PS*

FROM: Jacqueline Eldez, Assistant Executive Director, Office of Hazard Identification
 and Reduction
 Patricia L. Hackett, Project Manager, Baby Bath Seats *PH*

SUBJECT: Rulemaking Options for Baby Bath Seats - Response to Comments

On July 28, 2003, the U.S. Consumer Product Safety Commission (CPSC) staff briefed the Commission on baby bath seats and recommended that the Commission proceed with rulemaking. Four individuals submitted written testimony prior to, and gave oral testimony following the staff's briefing. Since the briefing, the Office of the Secretary has received an additional six written comments on this issue.

Attached is a staff memorandum that contains a brief outline of the testimonies and comments. Following the outline are staff responses to the major issues presented by the comments. The memorandum also includes an update of recent ASTM Bath Seat Subcommittee activity.

After a review and analysis of the testimonies and comments, the staff's recommendation remains the same as that presented at the July 28 briefing. Staff recommends that the Commission proceed with rulemaking by instructing the Office of the General Council to prepare a notice of proposed rulemaking (NPR).

Attachment

NOTE: This document has not been reviewed or accepted by the Commission.
 Initial *ph* Date 10/7/03
 CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

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10/7/03
[Signature]



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WASHINGTON, DC 20207

Memorandum

Date: October 7, 2003

To: Jacqueline Elder, Assistant Executive Director,
Office of Hazard Identification and Reduction

Through: Hugh McLaurin, Associate Executive Director, Directorate for Engineering
Sciences *Hm*
Susan Ahmed, Ph.D., Associate Executive Director, Directorate for Epidemiology *SA*
Mark Kumagai, Acting Division Director, Division of Mechanical Engineering *HM*
Russ Roegner, Ph.D., Division Director, Division of Hazard Analysis *RR (for R.R.)*
Robert B. Ochsman, Ph.D., Director, Division of Human Factors *RBO*

From: Patricia Hackett, Division of Mechanical Engineering *PH*
Debra Sweet, Division of Hazard Analysis *ds*
Jonathan Midgett, Ph.D., Division of Human Factors *JM*

Subject: Rulemaking Options for Baby Bath Seats – Response to Comments

I. COMMENTS

Four individuals submitted written testimony prior to, and gave oral testimony following the staff's on July 28, 2003. The following identifies the individuals, their affiliations, and the general position they conveyed about bath seats.

Rachel Weintraub, Assistant General Counsel for the Consumer Federation of America (CFA)

Ms. Weintraub, representing both CFA and Kids in Danger, supports a ban of bath seats. She provides several recommendations to the CPSC, if the Commission decides to pursue a mandatory standard in lieu of a ban. These recommendations pertain to a procedure used in the proposed stability requirement, the use of a water level mark on the product and various labeling issues.

Sally J. Greenberg, Senior Product Safety Counsel for Consumers Union (CU)

Ms. Greenberg supports a ban of bath seats. In her testimony, she provides specific comments or concerns regarding the three mandatory requirements proposed by staff.

Jack Walsh, Executive Director of The Danny Foundation

Mr. Walsh supports a ban of bath seats. If the Commission decides to proceed with a mandatory standard instead of a ban, Mr. Walsh provides further comments/recommendations with regard to the age grading of bath seats and the use of a water level mark on the product.

Frederick Locker, Counsel for the Juvenile Products Manufacturers Association (JPMA)

The JPMA supports the development and implementation of voluntary standards for bath seats and opposes a mandatory rule or a ban of the product. Mr. Locker's testimony provides some background history of the Commission's rulemaking activity, a discussion of drowning incident rates, comments regarding a study by Dr. Clay Mann and a review of the current voluntary standard for bath seats, ASTM F 1967-03.

The following outlines the six public comments submitted to the Office of the Secretary after the Commission briefing.

Letter from Heather Paul, Safe Kids Campaign

Ms. Paul supports the staff's recommendation for a mandatory standard and provides some suggestions on the labeling issue. Ms. Paul also encourages the CPSC to undertake an educational campaign to reinforce that babies should never be left alone in water.

Letter from Paul Ware, PW Resources

Mr. Ware recommends that the Commission terminate rulemaking based on the progress of the ASTM voluntary standard. He discusses the standard and its anticipated future improvements.

Letter from Renae Rauchschalbe, no affiliation

Ms. Rauchschalbe outlines a "mini-study" on parental behavior that indicates why she supports a ban of bath seats. In her letter, Ms. Rauchschalbe presents data regarding the bathing environment for children ages 5 to 10 months old in support of her conclusion that parents/caregivers behave differently depending on the bathing environment.

Email from Kelly Grimmond, Government of Australia

Ms. Grimmond supports a ban of bath seats. She proposes a ban on products that would provide "an opportunity for a carer to leave an infant where none would have otherwise existed."

Email from Ken Romney, no affiliation

Mr. Romney states his support of Commissioner Gall for her comments made at the briefing.

Email from N. Clay Mann, PhD, MS, University of Utah School of Medicine

Dr. Mann responds to comments made by Mr. Frederick Locker during the Commission briefing in regard to a phone conversation held between the two several years ago. Dr. Mann disagrees with Mr. Locker's comments and discussed the study he presented in 2000.

II. STAFF RESPONSES TO COMMENTS/TESTIMONY

CPSC staff has provided responses to recommended changes to the staff's proposed requirements. In addition, staff has responded to those substantive portions of the comments and testimonies where we disagree with the commentor or feel that clarification is needed.

A) Stability Performance Test

1) Ms. Weintraub, representing the Consumer Federation of America (CFA), recommends a change to the stability performance test proposed by the staff. The staff proposal includes a requirement to wipe the test surface with alcohol before conducting the test. Ms. Weintraub believes that this is inconsistent with foreseeable consumer use and that the test should better emulate real life conditions.

Staff Response: The test surface Ms. Weintraub is referring to is the slip-resistant surface that simulates a non-skid tub surface specified in staff's proposed requirement. Specifications for preparing a test surface, such as described above, are typically included in performance standards in order to obtain consistent test results. This preparation procedure is not meant to duplicate or represent behavior of parents who use bath seats. Ensuring a clean surface each and every time a bath seat is tested eliminates a potential variable that could potentially affect test consistency.

2) Ms. Greenberg, representing Consumers Union (CU) states: "if the commissioners choose not to support a ban of this product, and instead adopt the staff recommendation on suction cups, CU can only hope that the staff is correct in believing that the larger and more durable suction cups will reduce injuries and deaths."

Staff Response: Staff believes that Ms. Greenberg misunderstood our discussion of the bath seat testing with larger suction cups. As discussed in Tab B of the 2003 briefing package,¹ staff's testing showed that current model bath seats with large suction cups can be applied to a wet, slip-resistant surface and will sometimes hold a seal. This seal is temporary, but may last for up to 20 minutes before loosening. Staff discussed this testing to provide an example of how consumers may believe that the bath seat they purchased (with large suction cups) is adequate for use on their slip-resistant tub because it appears to hold a seal. Staff does not believe that large suction cups provide adequate and reliable stability to bath seats. Staff has intentionally specified a rough test surface and dry surface application of the bath seat for the proposed stability requirement, therefore preventing the use of suction cups or any other attachment method that is intended to work only on smooth surfaces.

B) Water Level Mark

Ms. Weintraub and Mr. Walsh (Danny Foundation) recommend the use of a water level mark on the bath seat to indicate that the bath water should not be higher than that level. Mr. Walsh also discussed incident data to support his opinion. Ms. Paul, representing the National Safe Kids Campaign recommends the following be added to the warning label or to the instructional literature: "ALWAYS use the least amount of water necessary when bathing a child."

Staff Response: Staff is concerned that a water level mark may be interpreted by some caregivers as implying a safe water level and thus does not support the recommendation. The current ASTM voluntary standard for bath seats contains a wording requirement equivalent to that recommended by Ms. Paul: "Babies can drown in as little as 1 inch of water. ALWAYS bathe

¹ Baby Bath Seats Rulemaking Options Briefing Package, May 2003

your infant using as little water as necessary.” This wording is required to be included on the instructional literature and staff believes it is adequate.

With regard to the incidents cited by Mr. Walsh, many of those involved overflowing bathtubs where parents or siblings turned on the water and failed to turn it off. Staff does not believe that the presence of a water level mark on the product would have addressed these incidents.

C) *Labeling*

1) Ms. Weintraub and Mr. Ware (PW Resources) both commented on the proposed warning label for bath seats. Ms. Weintraub believes that it is counterintuitive to come up with a warning label to address the coming out hazard.² On the other hand, Mr. Ware does not believe that there is adequate rationale for changing the wording from what is currently in the ASTM standard to the wording recommended by CPSC staff.

Staff Response: With regard to Ms. Weintraub’s concern, staff explored using a performance requirement to address this hazard and concluded this approach was not practical (see pages 11-13 of the briefing memo from the 2003 briefing package).

In response to Mr. Ware’s comments, CPSC staff believes the current warnings are inadequate. The current warning label “Prevent Drowning” allows parents to rationalize that children have not actually drowned while using a bath seat. Staff believes its proposed warning label is an improvement because it uses language to warn parents that children actually *have* drowned while using a bath seat. Incidents involving the absence of caregivers continue to occur, and no other strategy directly addresses this caregiver behavior. Staff believes that strengthening the label may more strongly influence caregiver behavior and thereby reduce drowning incidents.

2) Ms. Weintraub and Ms. Paul request CPSC to require a label on bath seats that indicates the product meets the mandatory rule.

Staff Response: This requirement has been included in other CPSC regulations, such as bike helmets, and staff believes this is a reasonable suggestion for differentiating old products from newer models. Staff is prepared to include this requirement in an NPR if the Commission agrees.

3) Ms. Weintraub recommends that a warning stating that the product not be used on a slip-resistant surface be on the product as well as on the package.

Staff Response: The staff’s proposed requirements contain a stability performance requirement that is conducted on a slip-resistant surface. Therefore, if a bath seat complies with this requirement, it would be suitable for use on slip-resistant surfaces and a label such as discussed above would not be needed.

² The coming out hazard involves incidents in which the children were found outside of the bath seat and the bath seat was found upright in the bathtub.

4) Ms. Weintraub requests that there be a requirement that the warning label be "readable" when tested for permanence. Ms. Paul also recommends a stronger permanency test for labels than what is currently required in the ASTM standard.

Staff Response: The ASTM standard for bath seats contains a requirement for labels to withstand submersion for 20 minutes. CPSC is not aware of any consumer complaints or incidents with regard to illegible labeling on bath seats. Therefore staff has no basis to recommend a change to the current ASTM test.

5) Ms. Paul recommends that the warning label on the product also be required to be on the front and back of the packaging.

Staff Response: Staff believes this is a reasonable suggestion to better ensure that consumers are made aware of the hazards associated with bath seats. Staff is prepared to include this requirement in an NPR if the Commission agrees.

6) Ms. Paul points out that the recommended label uses both the words "baby" and "child" in the label. She suggests that either one or the other be used for consistency.

Staff Response: Staff purposefully used both words "baby" and "child" in the proposed warning. "Baby" was used to convey a personal, emotional imperative within the statement of how to prevent the drowning hazard. "Child" was used in the first line to be as descriptive as possible in that factual statement.

D) Age Range

Mr. Walsh and Ms. Weintraub contend that the suggested age range of 5 to 10 months is too broad. Mr. Walsh suggests a 6 to 8 month age recommendation.

Staff Response: The user recommendation of the ASTM Subcommittee is based on developmental milestones that usually occur during the time from 5 to 10 months of age. Milestone-based user recommendations take into account a range of children who stretch above and below the average, accounting for the variability found in children. The relevant milestones for bath seat use are "sitting unassisted" and "pulling to a standing position." The resulting useful user recommendation for bath seats is sometimes shortened for some children while lengthened for others. Staff also addressed this issue in the 2003 briefing package (see page 15 of the 2003 briefing memo).

E) Clarification of Data

Ms. Weintraub states: "Each year, almost five babies die and almost eight are injured as a result of a drowning or near-drowning associated with bath seat use."

Staff Response: The figures stated in the testimony are the average number of fatal incidents (104) and non-fatal incidents (162) reported to the CPSC since 1983. Staff prefers to use recent figures in discussion of averages particularly since data collection efforts have been increased

since the mid-1990s giving a more accurate figure. From 1994 through 2003 (previous 10 years), CPSC has an annual average of 8.8 reported fatalities and 12.5 reported non-fatal incidents involving bath seats.

F) Data Regarding Bathing Environments of Infants

Ms. Rauchschalbe presents data on bathing environments for a group of children age 5-10 months old who drowned in bathtubs from 1994-1999. From these data, she draws conclusions about parental behavior, sibling presence, and the potential effects of a ban of bath seats.

Staff Response: Ms. Rauchschalbe puts forth the contention that bath seats lead parents to leave their babies alone in the bath, which leads to their greater risk of drowning. This conclusion cannot be drawn from the data she presents. In order to draw conclusions about bath seats leading parents to leave children unattended, we would need to have data on how many bath seat users leave their children unattended and how many non-bath seat users leave their children unattended. These data do not exist.

In addition, in order to draw conclusions about whether bath seat users are at greater or lesser risk of drowning (regardless of the reason), we need to have data on the number of babies bathed in bath seats and the number bathed without bath seats. These data are not presented by Ms. Rauchschalbe. The only source of any data on this topic is the Baby Products Tracking Study discussed in the staff's 2001 briefing package³ and 2003 briefing package. CPSC staff has calculated death data and risk estimates derived from this study. These estimates are summarized in the table below. This information is similar to that presented in the staff's briefing packages, however, in the table below we have used the death counts presented by Ms. Rauchschalbe (which differ somewhat from those presented in the staff memo because she has dropped cases which she believes have confounding issues).

***Bathtub Drownings of Children Ages 5-10 Months
(1994-1999)***

| | 5-10 Months | | 5-7 Months | | 8-10 Months | |
|-------------------------------------|-------------|-------------|------------|-------------|-------------|------------|
| | Deaths | Death Rate* | Deaths | Death Rate* | Deaths | Death Rate |
| Bath Seat | 43 | 7.28 | 20 | 7.66 | 23 | 6.98 |
| No Bath Seat | 91 | 11.08 | 26 | 5.85 | 65 | 17.27 |
| Bath Seat to Bath Tub Relative Risk | | 0.66 | | 1.31 | | 0.40 |

*Death Rates are per 10 million bath seat users and 10 million non-bath seat users

³ Briefing Package, Petition No. HP 00-4, Request to Ban Baby Bath Seats, March 30, 2001

These data indicate that the risk of drowning in a bathtub is about 30% greater with a bath seat than without a bath seat for 5-7 month olds. The risk of drowning with a bath seat is less than half that of drowning without a bath seat for 8-10 month olds.

Given this analysis, and given that this information alone cannot be used to predict what effect a ban of bath seats may have on caregiver behavior, the staff concluded that available information cannot predict whether a ban of bath seats would reduce bathtub related drownings.

The staff is recommending performance requirements for bath seats that address the mechanical design characteristics that contribute to bath seat drowning incidents. By making bath seats safer, the staff believes that the number of drowning fatalities can be reduced.

G) Adequacy of ASTM F 1967-03

Mr. Ware and Mr. Locker (representing JPMA) both comment on the current ASTM standard for bath seats. Mr. Ware states, "the current ASTM standard for bath seats is adequate now, and may be further strengthened in the very near future. . . ." Mr. Locker states "The Association (JPMA) believes that ASTM 1967-03 adequately addresses dynamic performance requirements with bath seats. Furthermore, the Association believes that the standard addresses the very issues raised by the Commission when it voted in May 2001 to explore rulemaking options to enhance performance requirements."

Staff Response: Staff believes that the current ASTM standard for bath seats (ASTM F 1967-03) is not adequate. Specifically, there are no performance requirements to ensure that all bath seats are stable on slip-resistant surfaces. This was an issue that was discussed during the May 2001 Commission briefing and it is not addressed in the newest version of the standard. In addition, it is staff's opinion that the labeling requirements of ASTM F 1967-03 need to be strengthened to more effectively alert caregivers to possible hazards associated with bath seats.

H) March 2003 ASTM Subcommittee Vote

Mr. Ware and Mr. Locker both comment on the future development of the ASTM standard for bath seats. Mr. Ware states that at the March 3, 2003 Subcommittee meeting, a vote was taken to include the proposed revision to the stability requirement on the next ballot for bath seats. Mr. Locker states, "Indeed, further revisions to the standard were recently voted upon and are awaiting balloting and publication."

Staff Response: The vote that took place in March of 2003 was a vote of the Subcommittee members on whether to include the stability requirement on the next ballot. A decision was made at the meeting not to issue a ballot at that time, but to defer it to a later date. The vote did not include a time frame as to when the next ballot would be issued, nor was there a vote on the technical merits of the stability requirement itself.

III. ASTM SUBCOMMITTEE UPDATE

An ASTM bath seat Subcommittee meeting was held on October 1, 2003. At the meeting, the Subcommittee voted to issue a concurrent Main and Subcommittee ballot that will include proposed new stability and labeling requirements. It is anticipated that the ballot will be issued sometime in the next four months, so that the results can be reviewed and discussed at the next Subcommittee meeting, set for March 2004. The stability requirement to be included in the ballot is identical to the one developed and proposed by staff. The labeling requirement that the Subcommittee voted to put on the ballot is different from the one proposed by staff.⁴ The ASTM proposed label is similar to the first two lines of CPSC staff's proposed label:

▲ WARNING

Children have drowned when left unattended in bath seats.
ALWAYS keep baby within arm's reach.

The last two lines of staff's proposed label were not included. No changes to the packaging labeling or instructional literature were included in the ballot.

The fastest track in the development of this revised standard would be if ASTM issues the ballot in the next 30 days, and receives no negatives or comments. ASTM could then approve the new requirements for inclusion in the standard, and publication would occur two to four months following approval. The revisions to the ASTM standard are typically included as part of JPMA's certification program approximately six months following publication of the standard. Therefore, if the ASTM standard development went as quickly as outlined above, there could be complying bath seats in the marketplace by the end of 2004.

The scenario presented above is an optimistic, best-case scenario. Staff cannot predict if ASTM will approve the stability and labeling requirements or adhere to the time frame noted above. Staff experience with ASTM has shown that first time ballots typically receive several negatives and comments, all of which need to be resolved before the standard can be revised. Not only does this process take time, but if any negatives are found persuasive, this would result in the development of a different requirement than what was balloted. Staff currently anticipates one negative from a manufacturer contesting the stability requirement. The adequacy of any modified requirement to account for the negatives is unknown. Therefore, staff recommends that the Commission proceed with the rulemaking process by issuing an NPR. If ASTM proceeds and develops adequate requirements and there is substantial compliance with those requirements, the Commission has other opportunities in the future to terminate rulemaking prior to issuing a final rule.

⁴ Staff's proposed warning label reads:

▲ WARNING

Children have drowned while using bath seats.
ALWAYS keep baby within arm's reach.
This bathing aid is NOT a safety device.
Stop using when a child is able to pull up to a standing position.