TAB B

Memorandum

Date: April 7, 2003

TO

Patricia Hackett, Project Manager, Baby Bath Seats

THROUGH:

Hugh M. McLaurin, Associate Executive Director, Hom

Directorate for Engineering Sciences

Mark Kumagai, Acting Director, Division of Mechanical Engineering

FROM

Caroleene Paul, Division of Mechanical Engineering ex.

SUBJECT:

Draft Proposed Requirements for Bath Seats

Background and Introduction

On August 1, 2001 an Advance Notice of Proposed Rulemaking (ANPR) was published in the Federal Register (Vol. 66, No. 148) to initiate rulemaking for baby bath seats. CPSC staff is aware of 96 deaths and 153 non-fatal incidents and complaints involving bath seats in the U.S. from January 1983 through December 2002. A review of the identifiable hazard scenarios provided a basis for engineering analysis and testing to develop performance requirements to address certain hazard scenarios. This memorandum introduces the draft requirements for a staff proposed mandatory rule to address tip-over and entrapment hazards associated with bath seats.

The hazard scenarios associated with bath seats were grouped into three areas: 1) those that involved problems with the product design and materials, 2) those in which the bath seat stayed upright and held the child in the seat, and 3) those in which the circumstances of the incident were unknown or uncertain. The majority of the 96 deaths and 153 non-fatal incidents fall into the product design/materials category. The stability of the bath seat and size of the side/leg openings of the bath seat were identified as two properties of the bath seat that could be defined by performance requirements to address tip-over and entrapment hazards associated with bath seats.

The voluntary standard for bath seats is ASTM F 1967, Standard Consumer Safety Specification for Infant Bath Seats. The current published version is ASTM F 1967-01, which contains requirements to address product stability, occupant retention, resistance to folding, release mechanisms, static loading, and labeling. Engineering Sciences (ES) staff reviewed ASTM F 1967-01 and determined that it could be revised to have an impact on incidents that involve tipovers and entrapment.²

Proposed Requirements

Stability

Current bath seats depend on surface adhesion (suction cups) for all or part of their stability. Based on In Depth Investigations (IDIs), analysis of bath seat designs, reviews of product safety assessment reports (PSAs) and suction cup operation, staff determined that the stability or resistance to tip-over of bath seats is dependent on the performance of the suction cup.³ Failure of this component could result in an unstable bath seat that would increase the likelihood of the product tipping over. Suction cups fail by detaching from the product or by detaching from the tub surface.

The 2001 revision to ASTM F 1967 added a suction cup integrity test to address incidents where the suction cups detached from the product. A detached suction cup reduces the bath seat stability because an attachment point is lost and the bottom surface is no longer level. The suction cup tests in ASTM F 1967-01 are intended to prevent suction cup detachment from a bath seat over the life of the product.

ES and Laboratory Sciences (LS) staff performed stability tests with bath seats on smooth and slip-resistant surfaces. The bath seats represented the current product market and each relied on surface adhesion (suction cups) for all or part of its stability. Test results indicate that bath seats that rely on smooth surface adhesion for stability fail the stability tests on abrasive surfaces, on surfaces with molded patterns, and on surfaces with slip-resistant treads or appliques. Suction cups operate on a pressure differential created when air or water is forced out from the underside of the cup. On smooth surfaces, an air/water tight seal between the surface and the bottom of the cup maintains the "suction" -- lower pressure under the cup and ambient pressure outside the cup. On uneven surfaces, a tight seal cannot be maintained between the cup and surface, and air or water will leak under the cup. Slip-resistant surfaces rely on some type of uneven surface to provide traction against slipping. The surface can be made to be abrasive or uniformly patterned with raised edges (either surface molded or externally applied).

In 30 deaths associated with bath seats and in 80 non-fatal incidents and complaints, the bath seat tipped over during use. Most of the complaints about tip-over were based on incidents where suction cups on the bottom of the bath seat failed to adhere to the tub surface. The tub surface condition is unknown, but failure of the bath seat to adhere to the surface resulted in an unstable product because its stability was dependent on smooth surface adhesion -- a condition that may be compromised if the tub surface is textured or dirty. The current ASTM standard specifically exempts bath seats from stability tests on slip-resistant surfaces if the manufacturer's instructions state that the product should be used only on a smooth surface. Staff is not aware of bath seats on the market that are recommended for a slip-resistant surface.

Staff proposes a requirement for the proposed mandatory rule that requires stability testing of bath seats on slip-resistant surfaces. Staff tested bath seat stability on three different slip-resistant surfaces (abrasive, molded pattern, and slip-resistant tread strips) and observed failure of the suction cups to adhere to each surface. However, staff discovered that suction cups can temporarily form a seal on abrasive surfaces if the surface has already been flooded with water.

The suction does not last more than a few seconds with smaller suction cups, but some of the larger suction cups held a seal for more than 20 minutes. The ability of suction cups to temporarily adhere to wet abrasive surfaces may confuse some users into believing that the tub surface is smooth and therefore a suitable surface on which to use bath seats. Human Factors (ESHF) staff has stated that identifying slip-resistant surfaces (as instructed by bath seat manufacturers as a condition for their product use) can be difficult and when the most obvious test of slip-resistance can be misleading, warning the user against using the bath seats on slip-resistant surfaces will not be effective. To avoid potential confusion on the slip-resistance of a tub surface and its suitability for bath seat use, staff believes bath seats should be stable when installed on a dry slip-resistant surface and tested under foreseeable use conditions.

The measurement of slip-resistance is a subject of continuing debate due to the various methods of measurement and lack of correlation between different test methods. The U.S. Department of Labor Occupational Safety and Heath Administration (OSHA) conducted studies of slip-resistance on structural steel and published Safety Standards for Steel Erection (29 CFR 1926.754(c)(3)). While the standard requires a minimum slip value as measured by one ASTM test method, the provisions were drafted with the knowledge that "development and refinement of various reliable methods of testing the slip-resistance" is still required and therefore enforcement of the standard is delayed until July 2006.

Staff proposes that for purposes of the proposed mandatory rule, a slip-resistant surface be defined as a surface on which commercially available adhesive backed slip-resistant tread strips (also known as safety tread strips) have been applied. Slip-resistant tread strips are used in many applications such as walkways and stairs, as well as bath tubs, to provide traction against slipping. Staff is not aware of any standard for slip-resistant tread strips, but the desired result of an uneven surface is an inherent characteristic of any slip-resistant tread. Slip-resistant tread strips for bath tub use are readily available from home improvement retailers, medical suppliers, or safety related retailers. Staff tested bath seat stability on several types of slip-resistant treads (rectangular strips and various shaped appliques) typically used in bath tubs and found that the suction cups on the bath seats were unable to adhere to dry surfaces on which any of the slip-resistant treads had been applied. The bath seats subsequently failed the stability tests due to failure of the suction cups.

A requirement that all products remain stable on slip-resistant bathing surfaces should reduce the likelihood of tip-over incidents due to surface adhesion failure. Designing a product to be stable on slip-resistant surfaces can be accomplished by making the product's stability dependent on its geometry and construction. An object will fall over when its center of gravity lies outside its supporting base. The supporting base of bath seats can be designed to be wide enough to prevent tip-overs. Another potential approach is a design that attaches the bath seat to one or both of the tub sides.

The proposed stability test method follows one already included in ASTM F 1697-01 with the modification of testing the product on a slip-resistant surface. Wherever possible, the original language and format of the ASTM standard was retained.

Leg/Side Openings

ASTM F 1697-01 requires a passive crotch restraint but does not address the size of the openings in a bath seat through which an infant can slide and/or slouch into the seating area, called the "occupant retention space". Staff is aware of three fatal and 17 non-fatal incidents in which an infant became entrapped in the product. The three fatal incidents involved entrapment in the seat where both legs were through an opening and the victim's face was partially or completely submerged in the bath water.

In the last two years, ES staff has been working as part of an ASTM task group to address the leg opening hazards. To prevent future incidents of this type, the task group developed a method to test all side and leg openings with two test probes — a torso probe and a shoulder probe. The task group has specified that the torso probe shall not pass through any side or leg openings, and the shoulder probe shall not slide through any side or leg openings and be able to rotate in a manner that allows the upper end of the probe to contact the seating surface.

The torso probe is identical to the probe used in the current high chair standard ASTM F 404-99a since high chairs are intended for the same minimum developmental stage occupants. Prohibiting passage of the probe is intended to prevent the torso of the occupant from sliding through a side or leg opening. The design of current bath seats can be modified to eliminate openings that are large enough for an infant to slide through, for example by adding more vertical "bars" or increasing the width of existing "bars".

The dimensions of the shoulder probe represent the shoulder breadth and buttock depth of the smallest intended occupant.⁴ Prohibiting the probe from rotating down such that the upper shoulder end contacts the seating surface is intended to prevent an occupant from sliding and rotating in the bath seat to a point where the occupant's shoulder and face is under water. The interior volume of current bath seats can be reduced to prevent an infant from lying down (and possibly becoming entrapped underwater) without preventing older users from occupying the seat.

ES staff is recommending these leg opening requirements for the proposed mandatory rule. In addition, these same requirements were recently balloted and approved by ASTM. The revised standard will be ASTM F 1967-03 and will include the leg openings performance test as described above. This revised standard is expected to be published in the summer of 2003.

Marking and Labeling

ASTM F 1967-01 requires labeling that states: "Warning: Prevent drowning. Always keep baby within arm's reach." ESHF staff has proposed changes to the existing ASTM warning label to strengthen the message⁴. Below is an example of the recommended warning label:

A 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 can pull to a standing position.

Conclusion

The attached proposed requirements are expected to address incidents of bath seat tip-overs and entrapment/submersion incidents. Staff believes that if bath seats are manufactured to comply with the proposed requirements, future tip-overs due to surface adhesion failure or occupant entrapments due to submarining should be significantly reduced.

¹ Sweet, D. J. (April 8, 2003). memorandum <u>Hazard Analysis Memorandum for Bath Seat NPR Briefing Package</u>. U.S. Consumer Product Safety Commission: Bethesda, MD.

² Kumagai, M. (March 2001). memorandum <u>Review of Bath Seat ASTM Standard F1967 and Response to Comments to Petition HP 00-4</u>. U.S. Consumer Product Safety Commission: Bethesda, MD.

³ Kumagai, M. (March 2001). memorandum <u>Evaluation of Bath Seat Design</u>. U.S. Consumer Product Safety Commission: Bethesda, MD.

⁴ Midgett, J. D. (April 10, 2003). memorandum <u>Human Factors Issues in Bath Seat Design and Use</u>. U.S. Consumer Product Safety Commission: Bethesda, MD.

DRAFT PROPOSED REQUIREMENTS FOR BATH SEATS

DEFINITIONS

Bath seat -- A product intended to be placed in a bath tub, sink, or similar bathing enclosure that provides back, side and/or front support to a seated infant during bathing by an adult caregiver.

REQUIREMENTS

- 1. Stability
- 1.1 The geometry and construction of the product shall not allow for any parts of the product to become separated, shall not allow the product to sustain permanent damage, and shall not allow the product to tip-over after being tested in accordance with 3.1.
- 2. Leg Openings
- All openings on the sides of the product through which a seated occupant can slide or otherwise insert any extremity shall not permit the passage of the Bath Seat Torso Probe when tested in accordance with 3.3.1.
- 2.2 All openings on the sides of the product through which a seated occupant can slide or otherwise insert any extremity, shall not permit any portion of the top 1 inch perimeter of the shoulder breadth end of the Bath Seat Shoulder Probe to contact the seating surface of the product when tested in accordance with 3.3.2.
- 3. Test Methods
- 3.1 Stability -- Install the product according to the manufacturer's instructions onto the clean and dry test surface coverage area(s) specified in 3.2.
- 3.1.1 The tests for stability shall be conducted after the installed test product and test surface have been flooded with water that is at an initial temperature of 100 to 105° F (37.8 to 40.6° C) and a depth of 2 in. (51 mm) above the highest point of the occupant seating surface.
- 3.1.2 Rigidly attach a 1 by ¼-in. (25 x 6-mm) aluminum flat bar to the inside edge of the occupant seating space in a vertical orientation at the most adverse position of the bath seat. The length of the flat bar must be such that it extends beyond the uppermost edge or surface of the bath seat at least as far as the maximum distance D (see Figure 1).
 - NOTE -- The phrase "most adverse" is a commonly accepted term used to describe a test condition that produces the most severe result that would indicate failure of the test.

3.1.3 Calculate the distance D for a tip-over force to be applied to the aluminum bar using the following formula:

D = (20.4 in. - H)/2; [(518 mm - H)/2]

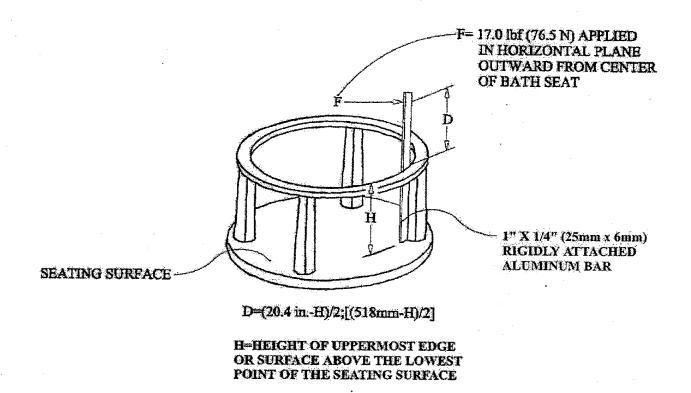


FIG. 1 Diagram of Force Application

- 3.1.4 Apply a force of 17.0 lbf (76.5 N) to the aluminum bar at this distance D above the height H. Apply the force in a horizontal plane and outward from the center of the bath seat over a period of 5 s (see Figure 1). Maintain this force for an additional 10 s. If the bath seat begins to release from the test surface, continue to maintain this force and its orientation relative to the aluminum bar until the bath seat tips over or the 10 s time limit is attained.
 - NOTE -- If necessary, to prevent the bath seat from sliding horizontally on the test surface during this test protocol, the bottom edge of the bath seat may be blocked or wedged to prevent such sliding; however, such blocking should in no way move the fulcrum point of the tip-over to a location that increases the tip-over force.
- 3.1.5 Repeat this test protocol three additional times at 90 degree increments, including the recalculation of the distance D.

- 3.1.6 Repeat this test protocol with the product in each of the manufacturer's recommended use position(s) as a bath seat.
- 3.2 Test Surface and Coverage
- 3.2.1 Surface -- Any smooth surface on which commercially available adhesive backed safety tread strips (for bath tub use) have been applied. The safety tread strips shall be rectangular in shape, approximately .75 inch (1.9 cm) wide by 7 inches (17.8 cm) or greater in length, and shall be evenly applied .5 inch (1.3 cm) or less apart from edge to edge.
- 3.2.2 Prior to applying the tread strips to the test surface, the surface shall be cleaned thoroughly using an alcohol or other solvent based cleaner to remove all foreign material. The surface shall be dry during tread application.
- 3.2.3 Test surface coverage area(s) -- A minimum of 1 inch (2.5 cm) beyond the perimeter outlined by any part of the bath seat that is designed to contact a surface.
- 3.3 Leg Openings
- 3.3.1 With the bath seat in each of the manufacturer's recommended use positions, insert the tapered end of the Bath Seat Torso Probe (Figure 2) in the most adverse orientation into each opening from the direction of the occupant seating surface. Apply a force of 15 lbf (67 N) in the direction of the major axis of the probe. The force shall be applied gradually within 5 s and maintained for an additional 10 s.
- 3.3.2 With the bath seat in each of the manufacturer's recommended use positions, insert the tapered end of the Bath Seat Shoulder Probe (Figure 3) in the most adverse orientation into each opening from the direction of the occupant seating surface. Apply a force of 15 lbf (67 N) in the direction of the major axis of the probe. The force shall be applied gradually within 5 s and maintained for an additional 10 s. Release the force, leaving the probe in position. Apply a force of 10 lbf (44.4 N) to the highest point on the probe, in a direction vertically downward towards the seating surface. The force shall be applied gradually within 5 s and maintained for an additional 10 s.
- 4. Markings and Labeling
- Each unit of product and its packaging shall be labeled with the safety alert symbol (exclamation mark in an equilateral triangle), the word WARNING, and the following warning list:

A 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 can pull to a standing position.
- 4.2 The signal word shall be written in all capital letters using a sans serif type face with letters not less than 0.2 inches (5 mm) in height, with all the remainder of text not less than 0.1 inch (2.5 mm) in height. They shall also be in contrasting color to the background on which they are located. The words "ALWAYS" and "NOT" in the list of warnings shall be capitalized. The word "drowned" shall be underlined.
- 4.3 Specified warning(s) on the product shall be located so that they are visible to the adult caregiver when the product is in the manufacturer's recommended use position(s) and the occupant is in the product.

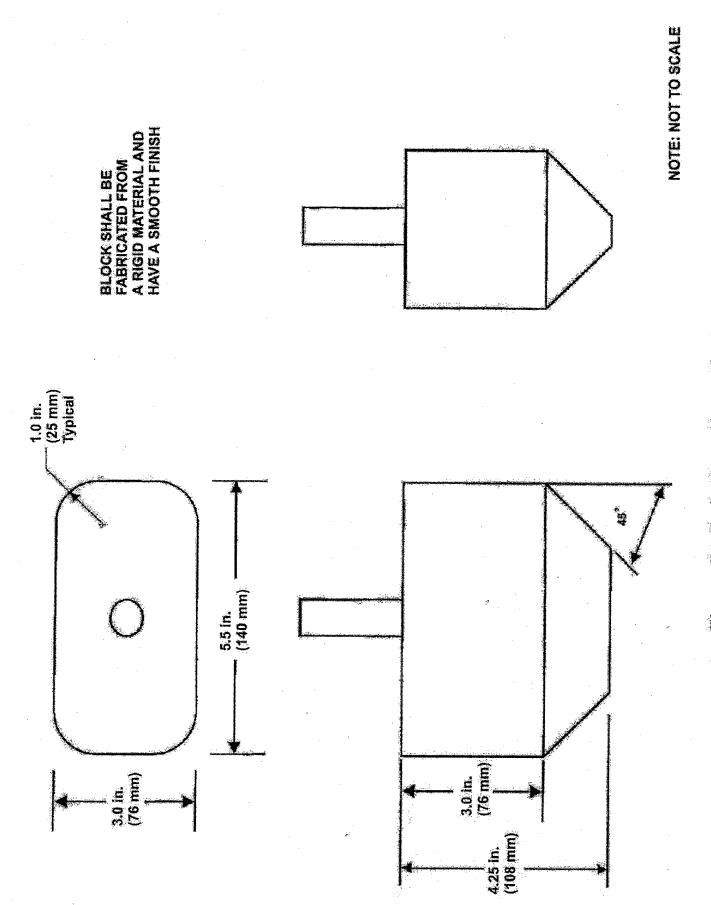


Figure 2. Bath Seat Torso Probe

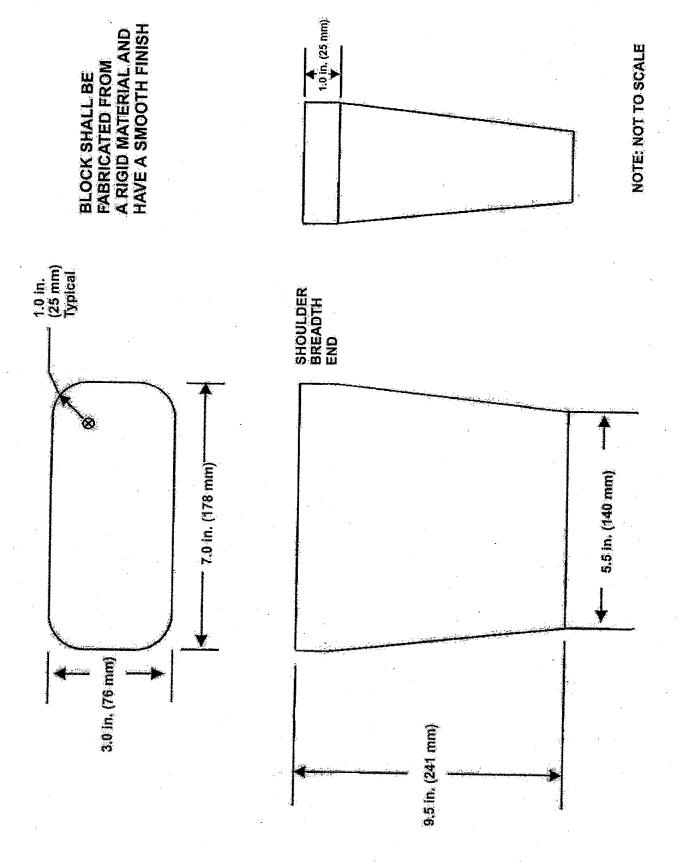


Figure 3. Bath Seat Shoulder Probe

TAB C



Memorandum

Date:

April 10, 2003

TO

Patricia L. Hackett, Project Manager, Bath Seats

Directorate for Engineering Sciences

THROUGH:

Hugh McLaurin, Associate Executive Director

Directorate for Engineering Sciences Robert B. Ochsman, Ph.D.

Director, Division of Human Factors (ESHF)

FROM

Jonathan D. Midgett, Ph.D.

Engineering Psychologist, ESHF

SUBJECT:

Human Factors Issues in Bath Seat Design and Use

On August 1, 2001, an Advance Notice of Proposed Rulemaking (ANPR) was published in the Federal Register (Vol. 66, No. 148) to initiate rulemaking for baby bath seats under the Federal Hazardous Substances Act. This notice was in response to a petition filed in July 2000 by the Consumer Federation of America and eight other organizations asking the Commission to ban baby bath seats. Since March 2001, the CPSC has become aware of an additional 27 deaths and 59 non-fatal incidents involving baby bath seats for a total of 96 deaths and 153 non-fatal incidents from January 1983 through December 2002.

CPSC staff is recommending two performance requirements for a mandatory rule. The first requirement will address the stability of a bath seat by requiring that the product be stable on slip-resistant surfaces. The second is a leg-opening requirement that involves two probe tests. These proposed requirements are presented in detail in a separate Engineering Sciences (ES) memo (Paul, 2003). Together, these two requirements should address tip-over (stability) and entrapment/submersion hazards. Staff is not recommending a performance requirement to add restraints to prevent children from coming out of bath seats, but instead is proposing a requirement for a stronger warning label. That issue will be discussed in detail in this memo.

Human Factors (HF) staff was asked to address several issues regarding bath seats. This memo will review the following:

- A) Will the leg opening performance requirement adopted by ASTM affect the utility of the product?
- B) Will the proposed performance requirements affect the consumer's perceived "false sense of security"?
- C) Can consumers properly identify a slip-resistant tub?

- D) What can be done to address the coming out hazards associated with bath seats?
- E) Development of a stronger warning label.

A. Leg Opening/Probe Testing and Product Utility

The leg-opening requirement proposed by the staff and recently approved to be included in the voluntary standard ASTM F1967-03, uses two hardwood test probes for performance tests of occupant retention. These performance tests were developed to address entrapment/submersion hazards, i.e. the hazards of children sliding (submarining) through leg holes and torso-entrapment drownings. HF staff was asked if this might force manufacturers into making much smaller bath seats in order to comply with the requirement. If so, this may affect the utility and the potential market for the product.

The two probes will test the interior dimensions of bath seats, restricting the seats to sizes and shapes that limit sliding down and getting trapped underwater. The torso probe, based on the hip breadth and buttock depth of the smallest (5th percentile, 5-to 6-month olds) intended child occupants, tests the leg openings of a bath seat to ensure that a small child cannot submerge through those openings. The 5th percentile measurements¹ were chosen for the smallest intended users because those children are the most vulnerable. These measurements match ASTM's current high chair probe. The ASTM subcommittee proposed and balloted a replica of that probe for this purpose, since this keeps the number of probes required by testing facilities to a minimum.

The shoulder probe test, based on the hip, shoulder, and hip-to-shoulder dimensions of the smallest intended child occupant, restricts the expansiveness of the seating area, called the "occupant retention space," to ensure that a child cannot slump into the seating area and become entrapped in the reclined position. These hazard scenarios are described in the Commission staff's draft ANPR on baby bath seats as "entrapment and submersion." Three deaths and 17 non-fatal incidents have been associated with these scenarios.

In general, the shape of the occupant retention space of bath seats that pass the probe tests will not have to significantly differ from bath seat designs currently on the market. However, the occupant retention space will probably have to be modified, in that the shape and volume of the space that receives a child's thigh, and the space occupied by a child's pelvis, may have to be decreased from current dimensions. This necessity to decrease occupant seating area dimensions, upon a superficial analysis, may lead some manufacturers to conclude that the seat will no longer easily allow a child to be placed into the seat. This is only a concern, however, if the products maintain their current structural shape and merely shrink the internal dimensions in order to pass the probe tests. Changing the shape of the occupant retention spaces rather than just shrinking current designs may also allow a bath seat to pass the probe tests. For example, bath seats do not have to be circular flat pans with an upper ring on posts. The intention of the probe tests is not to make all aspects of the product smaller, but rather to make just its seating space smaller. The

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¹ In the case of hip breadth, the 5th percentile 6-to-8-month old measurement was chosen because it is smaller, and therefore more stringent a test, than the next youngest age grouping available (3-to-5-month olds) whose average measurement (50th percentile) was *larger* than the smallest (5th percentile) 6-to-8-month olds (Snyder, et al. 1977).

entry/exit space of the product could actually be larger than any current bath seat designs and still pass the probe tests. The leg-opening probe is based on the breadth of a child's hips to prevent their whole body from going through the opening; therefore, a leg opening that meets the test could have sufficient space for the leg of a child up to twice the age of the oldest recommended users. The same is true of the shoulder probe, which is designed to prevent interior volumes within bath seats wide enough for a child to lie down. The probe's width and length are based on the shoulder breadth and torso length of a small child, and since these dimensions are much larger than the space required for a child to sit upright within, they allow older children to occupy the seat. A seating area that meets the test could hold the seated torso of the maximum 20- to 23-month old child (58.2 cm hip circumference (Snyder, et al. 1977)) with 35 cm to spare, circumferentially. The diameter of a seat with this circumference is about 30 cm. That is about 10 cm larger than the hip breadth of a maximum 20- to 23-month old child. This is due to significantly overlapping variation within the youngest and oldest bath seat users.

This may seem counter-intuitive because current designs of bath seats have perpendicular side-structural members and flat seat pans, which if made smaller, would <u>not</u> permit a larger child to easily get into them. The subject test probes, however, do not affect the huge variation possible for entry and egress designs for bath seats (for example, see Figure 1). The limits these probes place on the size of the occupant retention space are large enough to let manufacturers make seats that accept large children. The two probes still allow designs that permit a child to be easily seated and easily removed. HF staff believes that this performance requirement will not limit the market of potential users for products that pass the test.

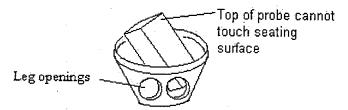


Figure 1: A Large Bath Seat Passing the Shoulder Probe Test

In conclusion, the leg opening requirement will help prevent entrapment/submersion incidents, but will still let manufacturers design bath seats that accept all of the intended user population. Staff believes that utility does not have to be compromised. Both test probes allow openings sufficient to comfortably contain the thighs and pelvis of maximum-sized children up to and possibly over twice the age of the recommended users.

B. Performance Requirements and "False Sense of Security"

Caregivers of victims of bath seat incidents may not know that the victim can get out of the seat. In these cases, the caregivers may incorrectly believe that the seat is acting as an effective "restraint." This contributes to the "false sense of security" mentioned by the petitioners: the caregivers may feel safe in leaving the bathroom momentarily because they think the child cannot get out of the seat. The bath seat gives the false appearance of being a restraint, rather than a bathing aid. HF staff believes that there already exists a level of false sense of security with current bath seat designs. The question arises, "Will the proposed requirements create a product that will increase this false sense of security in consumers?"

Until a product is actually produced, it is difficult to predict whether or not it will appear safer to consumers and influence their perceived sense of security. The performance requirements do not mandate a specific design. Some designs that comply with the requirements might appear to more strongly restrain children, but others might not. It is difficult to estimate how much, if any, future changes in design will increase any false sense of security.

It should also be noted that a stronger warning label could reduce the level of false sense of security. Thus, even if new designs might possibly enhance this sense, it is staff's opinion that the proposed warning label can serve as a counterbalance and potentially reduce it. The warning label is addressed in more detail in section E of this memo.

C. Identifying Slip-Resistant Tubs

Many current bath seat designs rely on suction cups to provide stability. These suction cups are intended to hold the product onto the tub surface during a child's entire bath. Many incidents have occurred after the suction cups failed to remain attached to the tub. This can happen for several reasons including degradation of the suction cups over time, or dirty or soapy surfaces that affect adhesion of the cups to the tub. In addition, suction cups will not reliably adhere to "slip-resistant" tubs, which have textured surfaces. The ASTM subcommittee for bath seats identified this problem and recommended that manufacturers include warnings against using them on slip-resistant surfaces in bath seat literature.

However, identifying a "slip-resistant" tub can be difficult. Although many slip-resistant tubs have easily identified texturing such as a sandpaper-like finish, a pattern of ridges, or consumer-added appliqués, some slip-resistant surfaces have a very subtle finish. A convenience sampling of slip-resistant tubs at a store by ES staff showed some tubs that appeared to be smooth, even though they were "slip-resistant." Many consumers will not know whether their tub is slip-resistant. ES staff discovered that some suction cups held briefly on a slip-resistant tub, but after a short time (up to 20 minutes) failed to hold. Because identifying slip-resistant tubs is difficult, and brief testing can be misleading, HF staff believes that warning against the use of bath seats on slip-resistant surfaces will not be effective at preventing incidents.

D. Coming Out Hazards

One of the identified incident scenarios involves the bath seat remaining upright, but the child is found out of the seat. Exactly how children are getting out of the bath seats is not known, although many are probably climbing out. The children most at-risk are just learning to stand up but are not advanced enough to be skilled at the task. This incident scenario occurs almost exclusively with unsupervised children, or children left in the supervision of another child. The caregiver's absence may contribute to a child's motivation to escape the bath seat.

Even though the ASTM age recommendation is to stop using the bath seat when a child can pull to a stand, some children on the cusp of developing this skill will be at risk because they can only support themselves unsteadily, and may fall into the water and drown. Of the 19 fatalities on record categorized by this incident scenario, the estimated average age of the victim was roughly

around 9 months. This age makes sense because children of this age are strong enough to pull themselves up with vigor, certainly with more strength than 6-month-olds, but are not experienced enough to keep their balance for long, like 12-month-olds can.

The probe requirements allow seat dimensions that could let some children come out. The proposed age recommendations, 5 to 10 months, include an age during which children will be at a high risk of drowning if they come out.

1) Bath Seat Purpose: Support vs. Restrain

Bath seats were never designed as "restraints." Rather, bath seats are designed to offer "support," having various configurations of surfaces that hold children upright. These "support surfaces" tend to act in a manner similar to "restraints." However, that functional similarity does not make them effective as restraints. (This appearance of being a "restraint" contributes to the "false sense of security" discussed previously and below.) Essentially, bath seats maintain a seated posture as loosely as possible, so that caregivers have room for their hands to wash children without worrying that the children will fall over or slip down. Bath seats are "loose supports." They are very poorly adapted to restraining functions because it is extremely difficult to make an effective "loose restraint." Restraints usually need to be as tight as clothing at key points on the human body.

The possibility of incorporating effective restraints into bath seats warrants further discussion and analysis. One's initial impression may be that it would be beneficial to make bath seats into effective restraints if that could be done effectively, safely, inexpensively, without affecting utility or increasing foreseeable misuses. However, as discussed in the following sections, meeting all these requirements may not be feasible.

2) Increasing Bath Seat Restraining Characteristics

Mechanical methods of holding children in bath seats would need to be complicated systems, not simple straps. HF staff extensively considered likely restraint methods. Preventing children from coming out of a bath seat requires a system of barriers that are reasonably comfortable and still allow washing. Children's escape efforts are facilitated because they are naked and wet. Restraining their slippery bodies comfortably, with room to wash, is extremely difficult because humans are so flexible and jointed.

Active vs. Passive Restraints

To make current examples of bath seats into effective restraints would require significant redesign. Several design strategies are possible: active and passive. 'Active restraints' require the user to snap, clip, wrap, tighten, or otherwise adjust the restraint mechanism so it works. They are called 'active' because the user must 'activate' them before they work. Active restraint methods of holding children are not desirable because users may avoid them, or they require complex, often mis-adjusted settings, rendering them less effective than 'passive restraints.' 'Passive restraints' are in place whenever the product is used, cannot be avoided by the user, do not require adjustments, and do not require user performance to work.

Passive restraints, i.e. those that require no action on the part of the consumer during use, would be more effective than active restraints for enhancing bath seats. One concept of a passive restraint is simply to reduce the occupant retention area so that it is "tighter" on the child. Bath seats conforming to the leg-opening requirement may or may not have this type of passive restraining capability. They can still allow some children to escape, or be pulled out, but a bath seat that passes the probe tests may coincidentally enhance the likelihood that it will passively restrain children. For instance, some parts of the seating area will be smaller than previous designs because of the test probe requirements, and these smaller areas may make coming out more difficult for some larger children.

Because the seating area may have some portions that are smaller than current designs, some people may assume that requiring a standard size could prevent all coming out incidents. This is not true. Standardized size limitations alone are insufficient to create an effective passive restraint system because of the great range of child size within the intended user population. Bath seats that fit large 6-month olds may still allow small 10-month olds ample clearance to fit into the seat and come out. The large variability in sizes among same-age children is far greater than the growth from age 5 months to 10 months. In fact, the looseness of a bath seat needed to wash a child (basically, the width of an adult hand) is more than enough room to allow some children twice as old as the intended population to fit into the bath seat (discussed earlier). Children do not physically grow enough in that critical time frame between being unable to pull to a stand and being very good at it to design a rigid, standardized shape that fits the youngest ones but excludes the oldest. Some coordinated children who can escape a bath seat could be smaller than some children who are too immature to get out, so it is not feasible to make a rigid, non-adjusting seat that excludes potential 'escapers' by rigid size limitations. For rigid, non-adjusting seats, if a child can be put in it, then the child can get out of it.

One obvious solution to this problem is to make bath seats adjustable for different sizes. Unfortunately, using the adjustments would be an active restraint strategy and the caregiver could use the seat adjusted for a large child with a small child, thereby canceling any effect of the size adjustments. This would be readily foreseeable because the more loose the seat is, the easier it is to wash the child and the less likely children will protest being put into the seat.

Another possibility is to make a few sizes of seats for the different sizes of children, like clothing: small, medium, and large. This is also an active restraint mechanism, and seems impractical for a standard, requiring multiple similar items for the same child to serve the same, limited purpose over a very short period.

Self-Adjusting, Passive Restraints

Acknowledging the cleverness of children intent on escaping from a product, HF staff believes that one important restraint method for any juvenile product involves blocking a child from bending his/her knee into the seating compartment of a seat. Blocking a child from getting a foot or a bent knee down on the floor of the seat will prevent many escape attempts, although not reliably all of them. If a bath seat restricts the upper thighs of a very small child (5th percentile 9-11 month old) from being able to bend at the knee and be pulled into the seating space, it may

prevent some coming-out incidents. A performance test approximating this bending motion of the legs could be created², but not without problems. For instance, when a seat is designed to pass this kind of a performance test, it will have a very small seating compartment that will hinder attempts to put the child into the seat. Most likely these seats would require special mechanisms for placing children into the seat, such as a foldaway back rest or leg chutes that rotate upwards. Such restraints would have to automatically adjust to the size of the user. This automatic, or passive, adjustment would likely increase the complexity and cost of the bath seat. Automatic size adjustments that can restrain without being easily unfastened are a challenge to design, however a product with self-adjusting restraint mechanisms may effectively restrain the intended user population. Manufacturers could possibly make self-adjusting passive restraint systems with structures that limit key internal dimensions of a seating space according to the size of the occupant's legs or waist.

3) Effective Restraints May Increase False Sense of Security

If a bath seat were designed with obvious, visible attention and care to preventing coming-out, this could increase a caregiver's false sense of security and tempt them to leave a child unattended.

Even if a bath seat could be designed with effective restraints, HF believes that bath seats would never be safe enough to allow caregiver absence. There are several reasons for this: 1) when left alone children are highly motivated to escape, 2) a child can drown very quickly, and 3) other hazards of leaving a child alone in the water, such as hypothermia, scalding, overflow-drowning, and sibling interventions, will remain. Since we cannot ensure that the bath seat restraint would be effective under all circumstances, the sense of security associated with the appearance of the seat is "false." As long as a bath seat appears to be a restraining device, it may invite the foreseeable act of leaving a child unattended, which is never a safe activity, no matter how well the bath seat is designed.

If the goal of making a bath seat into a more effective restraint is attempted, manufacturers are faced with the challenge of making a product that performs as an effective restraint, but does not appear to be a restraint. Adding an effective restraint function to a bath seat could make it look like it is intended for leaving a child unattended, despite warnings to the contrary. And as stated earlier, if a device were created to restrain a child, it would arguably not be a "bath seat" any longer, but a "bath restraint." Unless a product could be made with unobtrusive, automatic self-adjusting restraints, HF staff does not favor requiring restraint systems on bath seats.

Since HF staff believes that a requirement for restraints is not viable at this time, then the other intervention for protecting children from coming out of bath seats is to *increase caregiver vigilance*. This will be addressed in Section E of this memo.

² Construct a bar the length of the rump-to-knee measurement of the 5th percentile 9-11 month old (15.8 cm). The tester would hold this bar with one end placed at the point on the seat pan corresponding to the position of a seated occupant's rump, perhaps determined by using the edge of the torso probe, and then freely move the other end of the bar around with the goal of trying to bring it into the occupant seating space. This would simulate a seated child trying to draw his/her knee into the seat to help pulling up to a standing position. If the knee-end of the bar can be moved into the seating compartment unhindered, the seat would fail the performance test. Any barrier to this movement would significantly hinder the occupant's efforts to climb out. However, depending on the seat, other methods of escape are likely.

4) Conclusion

HF staff believes that an effective performance requirement to prevent children from coming out is not viable for bath seats because:

- Making a bath seat's seating area smaller by requiring a standard size will not prevent the entire user population from coming out.
- Active restraint methods for holding children in bath seats may be not effective because users may avoid them, or they require complex, often mis-adjusted settings.
- Restraint systems (that would not be 100% effective) on bath seats might increase consumers' false sense of security, possibly resulting in more children left unattended while using the product.

Because a performance standard is not a viable approach to address coming-out incidents, staff recommends a forceful label to warn about the need for constant caregiver vigilance. The elements of a forceful warning label are discussed below.

E. Warning Labels

Since 1999, the warning label specified in the ASTM standard (F1967-99 and F1967-01) has stated, "Warning: Prevent drowning. Always keep baby within arm's reach." HF staff believes that this label needs to be stronger because as it is it may not convince consumers that the danger of drowning is a reasonable possibility. Caregivers have observed how well their child can sit upright in the seat and how quietly and contentedly the child plays in the water. Caregivers may not realize how little water is needed to precipitate a serious incident. Repeated successful use of the bath seat may reinforce their belief that the child can be left alone in it. When caregivers are present, the child looks safe and does not try to get out of the seat. They may appear to be securely held. This is the "false sense of security" that was previously discussed. Unfortunately, caregivers have never observed what happens when they leave the child. When caregivers leave, the child may become distressed, struggle to get out of the seat, and can then be at risk for injury or drowning.

Consumers report (U.S. CPSC, 1993) that leaving a child unattended momentarily is "understandable," to get a towel, answer the phone, or help another child, even though some admit they understand that it is a risk. This is the classic behavioral issue of "risk compensation," or the phenomena of a safety device (even one not intended for safety) increasing risky behavior because the user trusts the safety device to prevent serious injury. Bath seat users may rationalize that they are still "attending" to the child if they can "hear what's going on," or if they are "just in the next room" and will soon return. The "sense of security" is false because children can get out of bath seats, although caregivers may not have ever seen them do so, and drown in very little water in a very short time. They can also be pulled out by siblings, scalded by hot water, or drowned in an overflow situation. Caregivers reading the current warning label may admit that drowning is possible, but may rationalize that it has never happened before. Since they think the

event is *unlikely*, they feel comfortable ignoring the warning and believing the hazard is unlikely. They trust the bath seat and over-apply the success of their prior experiences with it when their child did not come out.

To counteract this temptation to believe the bath seat is an effective restraint, the warning labels could be strengthened. A strong warning may counteract *some* of the sense of security invoked by a bath seat's appearance.

HF staff recommends an explicit, forceful warning, such as:

A WARNING

Children have <u>drowned</u> 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.

Increasing the forcefulness of the warning label may counteract some of the appearance of security associated with bath seats. Staff is not able to guarantee the level of effectiveness of this warning label. However, this label is written according to recommendations of warning experts (Sanders & McCormick, 1993), including a signal word, a clear statement of the hazard, its consequences, and the instructions for reducing or eliminating the hazard. Staff does not believe that this warning label will measurably affect the marketability of the product by deterring consumers from buying the product because current warnings already use the keyword, "drowning," and the instructions for reducing the hazard are unchanged.

F. Summary

Bath seats are loose-fitting bathing aids, not restraints. Because the seats are loose fitting, sometimes children come out when unattended. Unfortunately, bath seats often appear to be effective restraints, leading to a false sense of security and tempting caregivers to leave children in them unattended, despite warnings. Adding restraint systems may not be feasible. In order to increase caregiver attendance, HF staff recommends strengthening the warning label. Increasing the severity of the warnings may counteract some of the effects of the appearance of security.

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TAB D

Comments to the Baby Bath Seat ANPR

An Advance Notice of Proposed Rulemaking (ANPR) on Baby Bath Seats and Rings was published in the Federal Register on August 1, 2001 (Volume 66, No. 148). A total of 10 comments from nine individuals were received during the ANPR comment period. One commenter sent in two separate comments, representing two different groups. Eight of the 10 comments supported a ban of the product. One of the 10 supported a mandatory performance standard and the other commenter supported the development of a voluntary standard. An outline of the comments received is below:

- CH 01-5-1

 E. Marla Felcher, Ph.D. (no affiliation)

 Dr. Felcher "strongly urges CPSC to proceed with a rulemaking to ban baby bath seats and rings."
- <u>CH 01-5-2</u> Nancy Cowles, Executive Director, Kids In Danger
 Kids In Danger "urges the US Consumer Product Safety Commission (CPSC) to proceed with rulemaking to ban baby bath seats and rings."
- <u>CH 01-5-3</u> <u>Mary E. Fise, General Council, Consumer Federation of America</u>

 Consumer Federation of America "strongly urges CPSC to ban baby baths seats and rings."
- CH 01-5-3a Mary E. Fise, On behalf of various State and Local Consumer
 Organizations
 The representative consumer groups "strongly urge Consumer Product
 Safety Commission ("CPSC") to proceed with a rulemaking to ban baby
 bath seats and rings."
- CH 01-5-4

 Heather Paul, Executive Director, National Safe Kids Campaign

 The National Safe Kids Campaign "is in full support of a U.S. Consumer Product Safety Commission (CPSC) mandatory standard for baby bath seats/rings that would eliminate the risk of injury associated with the current form of the product."
- CH 01-5-5

 Rachel Weintraub, Attorney, U.S. Public Interest Research Group (PIRG)

 U.S. PIRG "urges Consumer Product Safety Commission ("CPSC") to
 proceed with a rulemaking to ban baby bath seats and rings."
- CH 01-5-6

 Sally Greenberg & Janell M. Duncan, Consumers Union of U.S. Inc.

 Consumers Union "strongly urges the Commission to issue a rule declaring baby bath seats and rings to be 'banned hazardous substances'."
- CH 01-5-7

 Beth Vozenilek, Consumer

 Ms. Vozenilek "strongly urges the CPSC to move forward with a rulemaking to ban baby bath seats and rings..."

CH 01-5-8 John Lineweaver, Chairman, The Danny Foundation The Danny Foundation "urges the Consumer Product Safety Commission, (CPSC), to proceed with a rulemaking that will ban Baby Bath Seats and Baby Bath Rings from the market."

<u>CH 01-5-9</u> <u>Christopher Pierre (no affiliation)</u>

Mr. Pierre does not support a ban of bath seats. Instead, he recommends that CPSC "choose the alternative of a voluntary standard."

TAB E

Memorandum

Date:

April 7, 2003

TO

Patricia Hackett, Project Manager, Baby Bath Seats

THROUGH:

Hugh M. McLaurin, Associate Executive Director.

Directorate for Engineering Sciences

Mark Kumagai, Acting Director, Division of Mechanical Engineering

FROM

Caroleene Paul, Division of Mechanical Engineering

SUBJECT:

Response to ANPR Comments on Baby Bath Seats CH 01-5

An Advance Notice of Proposed Rulemaking (ANPR) on Baby Bath Seats and Rings was published in the Federal Register on August 1, 2001 (Volume 66, No. 148). This memorandum responds to comments on the ANPR (CH 01-5).

1. Standards Inadequate to Address Bath Seat Deaths and Injuries

Comment: Several comments (CH 01-5-3; 5; 6; 7; 8) state that no standard can adequately address the risk of death and injury associated with bath seats and that ASTM F 1967-01 does not adequately address these issues.

Response: While a standard may not eliminate all deaths and injuries associated with any product, a standard can address primary hazard scenarios. CPSC staff believes that the leg opening requirements recommended by CPSC staff and adopted by ASTM in the latest revision to the voluntary standard can significantly reduce incidents that involve infants slipping through side/leg openings. In addition, the stability requirements recommended by CPSC staff can reduce incidents that involve tip-over of unstable bath seats.

2. Bath Seat Designs and Bath Seat Standard on Slip-Resistant Surfaces

Comment: Several comments (CH 01-5-3; 3a; 5; 6) specifically concern the compatibility of bath seats with slip-resistant surfaces. In a similar vein, several comments stated the current bath seat standard ASTM F 1967-01 is not compatible with slip-resistant surfaces. Some refer to ASTM F 462-79, the voluntary standard for slip-resistant bathing facilities.

Response: Current bath seat designs that rely on suction cups for stability will not reliably adhere to non-smooth surfaces such as textured tub surfaces, non-slip abrasive surfaces, or surfaces on which non-slip adhesive treads have been applied. Products that do not rely on suction cups or any kind of surface adhesion for stability should not encounter the same stability problems identified with current bath seats when used on non-slip or slip-resistant surfaces.

The ASTM bath seat voluntary standard does not require testing bath seats on slip-resistant surfaces if the manufacturer's instructions state that the product should only be used on a smooth surface. CPSC staff is not aware of any current bath seat that states the product can be used on slip-resistant surfaces.

The voluntary standard for slip-resistant bathing facilities, ASTM F 462-79, defines a slip-resistant surface by a specifically measured coefficient of friction value. The value is low enough that many bath seats with suction cups as part of their design could pass stability tests performed on some surfaces that qualify as "slip-resistant" as defined by ASTM F 462-79. However, most bathtubs with slip-resistant surfaces either exceed the ASTM F 462-79 value or use different surfaces that are not subject to ASTM F 462-79.

3. Inadequate Bath Seat Design - Suction Cups

Comment: Three comments (CH 01-5-1; 2; 6) concentrated on the poor performance of suction cups in terms of ability to adhere to surfaces and ability to remain on the bath seat itself. Two commenters stated that suction cups are a design flaw that cannot be designed out, and the other commenter stated that the current bath seat standard fails to address the shortcomings of suction cups.

Response: Suction cups will not reliably adhere to slip-resistant surfaces. The bath seat voluntary standard does not require bath seats to be tested on slip-resistant surfaces if the manufacturer states that the product should only be used on smooth surfaces. In addition, the standard requires a 25-pound pull test on the suction cup away from the bath seat and requires that the suction cup adhere properly after 2000 cycles of use. However, the requirements do not address dirty suction cups or dirty bath surfaces.

CPSC staff believes that bath seats can be redesigned to address the hazard scenarios associated with their stability. CPSC staff is recommending that stability tests must be performed on a slip-resistant surface. Bath seats can depend on product configuration (such as a wide and stable base) or some type of external attachment to achieve stability without depending on surface adhesion. Bath seats that do not rely on suction cups or any kind of surface adhesion for stability should not encounter the same stability problems identified with current bath seats when used on slip-resistant surfaces.

4. Inadequate Bath Seat Design -- Leg Openings

Comment: Several comments (CH 01-5-1; 4; 5; 6) state that the size of the leg openings in bath seats allowed submarining (entrapment and submersion incidents).

Response: ASTM International recently approved a performance requirement for bath seat leg openings, which includes two probe tests that are designed to prevent entrapment and submersion incidents. The dimensions of the two probes, one for leg openings and one for shoulder entrapment, are based on the anthropometrics of the smallest potential users. CPSC staff has proposed identical requirements in draft proposed requirements for bath seats. CPSC staff believes that these requirements for testing leg and side openings in bath seats will adequately address entrapment and submersion hazards.

TAB F



Memorandum

Date:

April 10, 2003

TO

Patricia L. Hackett, Project Manager, Bath Seats

Directorate for Engineering Sciences

THROUGH:

Hugh McLaurin, Associate Executive Director

Directorate for Engineering Sciences Robert B. Ochsman, Ph.D.

Director, Division of Human Factors (ESHF)

FROM

Jonathan D. Midgett, Ph.D. JDM

Engineering Psychologist, ESHF

SUBJECT:

Human Factors Staff Responses to Comments about Bath Seats

On August 1, 2001, an Advance Notice of Proposed Rulemaking (ANPR) was published in the Federal Register (Vol. 66, No. 148) to initiate rulemaking for baby bath seats under the Federal Hazardous Substances Act. This notice was in response to a petition filed in July 2000 by the Consumer Federation of America and eight other organizations asking the Commission to ban baby bath seats. Since March 2001, the CPSC has become aware of an additional 27 deaths and 59 non-fatal incidents involving baby bath seats for a total of 96 deaths and 153 non-fatal incidents from January 1983 through December 2002. This memorandum addresses comments submitted by the public about bath seats in response to the Federal Register notice.

A False Sense of Security and Caregiver Absence

Comment: Several commenters mentioned that caregivers are tempted to leave a child alone in a bath seat because the child looks safe in one and warning labels are insufficient to prevent this behavior (CH-01-5-1; 2; 3; 4; 5; 6; 7; 8). For example, Commenter 3 wrote, "...caregivers are deceived by the products' appearances. They mistakenly believe that this is a safety device and no labeling will be sufficient to overcome this belief." Commenter 4 wrote that bath seats "... encourage dangerous consumer behavior by making caregivers believe that a baby is in a relatively safe setting..." Commenter 1 wrote, "Yet, for whatever reason, adults choose to engage in this risky behavior when they see their infant sitting up in the tub in a bath seat. Everything about the product – its design, the packaging, and the name Safety 1st – screams, 'your child is safe in this seat!' It's no accident that the fine print warning label, 'never leave a child unattended,' is often overshadowed by these more salient product attributes."

Response: The above commenters may be correct that a warning label is insufficient to always prevent the foreseeable misuse of leaving a baby unattended in a bath seat. If consumers believe

that a bath seat is safe due to its appearance or features, they may choose to ignore the warning. This phenomenon, called "risk compensation," can occur with many products, even those not intended to be safety devices, if the user trusts the device to prevent serious injury. However, strengthening the warning on the products may help combat any appearance of safety in bath seats. For this reason, the warning should be as powerfully worded as possible.

Holds Child Underwater

Comment: Commenter 01-5-2 wrote, "The suction cups needed to keep the seat upright will not stick to new tub surfaces. And if the suction works well enough to keep the seat always upright, it will also work to hold the child underwater, even with a parent struggling to free the child, if the child submarines or slips out of the bath seat."

Response: CPSC staff is proposing a performance test to address bath seat tip-over hazards that will require bath seats to be tested on slip-resistant surfaces. The danger of being unable to free a child in a stable, upright seat is only possible if the child can submerge in the seat, which should be prevented by bath seat leg opening requirements, recommended by CPSC staff and recently adopted by ASTM.

Utility Age Range

Comment: Commenter 01-5-8 questions the current age recommendations (5 to 10 months) for bath seats (paragraph 3). This commenter suggests that "6 to 8 months is a much more realistic age range for average children to sit securely and to begin to pull up on objects."

Response: HF staff agrees that this is a reasonable average. However, the age recommendation is not solely based on an average. It takes into account a wider range of children which stretches above and below the average, attempting to account for the variability found in human populations. Developmental averages, being only a single number, do not reflect the wide range of possible ages at which perfectly "normal" children can achieve various milestones. The relevant milestones for bath seat use are "sitting unassisted" and "pulling to a standing position." A significant portion of the population will sit unassisted somewhere between 5 months and 6 months of age, even though the average will fall somewhere just after 6 months. As well, a significant portion of the population will not be able to pull to a stand until sometime after their 9-month birthday. To encompass a reasonable majority of typical users, HF staff agrees with the ASTM subcommittee that bath seat usage will likely occur in the 5- to 10-month age range. However, some users may well achieve the milestones in shorter or longer time spans. The ASTM age recommendation is milestone-based, thereby accounting for individual differences in maturation.

The ASTM subcommittee on bath seats recently approved a modification to its standard to include an age recommendation of 5 to 10 months, based on a comparison of commonly available child development sources' reported ages for "sitting upright unassisted" and "pulling to a stand." CPSC Human Factors staff concurs with this recommendation. The ASTM subcommittee approved the following developmental milestones for labeling bath seat packaging and instructions: "Product is suitable for children able to sit up unassisted. Product is not

suitable for children able to pull up to a standing position who may attempt to climb out." Children within this age range are capable of using the support offered by a bath seat but are not too old for one. Younger children are not able to hold themselves up in a bath seat and so would slump over with their head lolling from side to side. Older children, who can pull to a stand, are unlikely to want to remain in a bath seat, or to need one to remain upright while bathing. Following a milestone-based age recommendation is preferable to using a numerical age because precocious children who can climb out of a bath seat before their more "average" peers are not put at risk.

Designer's Intent vs. Design Capability

Comment: Comment CH-01-5-9 implied the problem is not with bath seat designs, but with the people who leave children unattended. This commenter also states "If the bath seat/ring was 'designed and manufactured' to allow the caregiver to place the child in the tub and walk away then I would heartily agree that these articles constitute a 'mechanical hazard'. But the fact is, these bath aides were not designed or manufactured to be used in such a way."

Response: Staff agrees that some caregivers perceive that the bath seat provides a greater degree of safety than it does, and this false sense of security leads to foreseeable misuse of the product. Staff also believes that the product is not adequately designed to protect children against the consequences of this foreseeable misuse. However, it should be noted that some mechanical failures have occurred in the presence of a caregiver.

Adding Safety Features

Comment: Comment CH 01-5-9 asserted that certain design safety measures can be added to make bath seats safer, including the addition of user-activated restraints, and that ASTM should include these safety measures in the voluntary standard.

Response: CPSC staff agrees that bath seats can be made safer by implementing design safety measures to address the tip-over hazard and the entrapment and submersion hazard. However, the staff concludes that a user-activated restraint system that prevents a child from coming out of a seat could make the bath seat impractical for its intended purpose. In addition, staff is concerned that caregivers may not use such restraints. As a result, a performance requirement for a restraint system is not a viable approach at this time. The staff recommends that the coming out hazard be addressed with a forceful warning label to stress the need for constant caregiver attendance.

TAB G



Memorandum

Date:

April 9, 2003

TO

Patricia Hackett, Project Manager, Baby Bath Seats

THROUGH:

Warren J. Prunella, AED BC W

FROM

Mary F. Donaldson, EC

SUBJECT:

Preliminary Regulatory Analysis of Proposed Rule for Baby Bath Seats

Introduction

In 2000, the Consumer Federation of America, the Drowning Prevention Foundation, and others petitioned CPSC to ban baby bath seats and bath rings due to the potential for drowning. The Commission granted the petition and an Advanced Notice of Proposed Rulemaking (ANPR) was published in the *Federal Register* on August 1, 2001.

The Commission is now considering a mandatory rule (hereafter, the "proposed" rule) for baby bath seats. The proposed rule would be issued under the Federal Hazardous Substances Act (FHSA). When the Commission proposes a rule under the FHSA, it must publish a preliminary regulatory analysis that includes:

- a preliminary description of the potential benefits and potential costs of the proposed regulation, including any benefits or costs that cannot be quantified in monetary terms, and an identification of those likely to receive the benefits and bear the costs;
- a discussion of reasonable alternatives to the proposed regulation, including voluntary standards, and a brief explanation of why such alternatives should not be published as a proposed regulation.

In addition to the requirements of the FHSA, the Commission is required by the Regulatory Flexibility Act of 1980 to consider the possible effects of the proposed rule on small businesses. The National Environmental Policy Act of 1969 also requires the Commission to consider the potential environmental impact of the proposed rule.

This report presents a summary of the baby bath seat market, the preliminary regulatory analysis, and a discussion of the likely effects of the proposed rule on small businesses and the environment.

The Products

Currently, baby bath seats are marketed as an aid for bathing infants from the time they can sit up, usually between 5 and 6 months. According to the Juvenile Products Manufacturers Association (JPMA), they are usually discontinued when the children can stand up or escape the confines of the product. They are generally used in bathtubs and allow the child to be held in a seated position, thus freeing the caregiver from holding onto the child during bathing. Currently, bath seats contain a seating area and are usually held in place by suction cups located at the bottom of the seat. Some infant bathtubs also convert to bath seats.

Producers and Market Share

Baby bath seats are produced and/or marketed by juvenile product manufacturers and distributors. At the present time, there are two manufacturers and one importer of baby bath seats active in the U.S. market. The manufacturers are Safety 1st, which has several models of bath seats on the market, including a convertible infant tub/seat, and The First Years, which has a convertible infant tub/seat. The importer is Juvenile Solutions, which currently imports a bath seat from France.

Baby bath seats and rings are available in many other countries, including Canada. Although only three firms are currently supplying bath seats in the U.S., any foreign manufacturer is a potential supplier to the U.S. market.

Based on a survey of new and expectant mothers conducted in 1999 for American Baby Group², Safety 1st is the leading brand of baby bath seat in use. In that survey, 46 percent of respondents who specified the brand of bath seat owned indicated Safety 1st. Fisher Price (which no longer produces bath seats) and The First Years followed with 14 percent each. However, it should be noted that 63 percent of bath seat owners did not specify their bath seat brands.

Products in Use

In 2000, the JPMA estimated that there may be up to two million baby bath seats in use.³ This is generally consistent with an estimate derived from the *Baby Products Tracking Study*, 2000. According to the Tracking Study, about 33 percent of new mothers own baby bath seats or rings. Given the approximately four million annual births in the U.S., the 33 percent ownership rate suggests about 1.3 million bath seats are available for use for infants under the

¹ "Initial Comments in Opposition by the Juvenile Products Manufacturers Association" in response to Petition HP00-4, October 20, 2000.

² Baby Products Tracking Study 2000: Nursery Décor and Accessories, conducted for American Baby Group, Bruno and Ridgeway Research Associates, Inc, #5861.

³ "Initial Comments in Opposition by the Juvenile Products Manufacturers Association" in response to Petition HP00-4, October 20, 2000.

age of one. Including bath seats used by infants older than one, the total number of bath seats in use may be close to two million, as estimated by JPMA.

Retail sales of new baby bath seats may range from 700,000 to 1,000,000 annually. The American Baby Group survey indicated that 46 percent of baby bath seats or rings owned by new or expectant mothers were obtained after being used for an older child or borrowed. This suggests that about 54 percent of the bath seats were acquired new, resulting in annual sales of about 700,000 (.54 x 1.3 million). The JPMA estimate of sales is somewhat higher, about 1 million annually.

Table 1 shows the ownership rates for new mothers for the American Baby Group survey years 1987 to 1999. In 1987, only 22 percent of new mothers owned them. By 1999, the rate was 33 percent, which is a 50 percent increase in baby bath seat ownership.

Table 1: Trends in Baby Bath Ring/Seat Ownership Rates, 1987-1999

Year	Ownership Rate (% of New Mothers)
1987	22
1990	24
1993	31
1996	32
1999	33

Sources: Baby Products Tracking Study, 1987, 1990, 1993, 1996, 1999, American Baby Group.

Trade Associations and Standards

The JPMA is the major trade association that represents juvenile product manufacturers and importers. All three suppliers of baby bath seats in the U.S. are members of this association.

ASTM has recently approved a revised voluntary standard for infant bath seats. The latest version, as of April 10, 2003, will be ASTM F 1967-03 Standard Consumer Specifications for Infant Bath Seats. This standard addresses various issues including safe use instructions, stability, durability of latching mechanisms and suction cups, and limits the size of leg openings.

Discussion of Proposed Rule

The proposed rule would require infant bath seats to meet certain requirements, some of which are not currently covered by the voluntary standard. The requirements involve additional criteria for stability, openings, and labeling.

The proposed stability requirement will require the product to resist tip-over when the bath seat is installed on a smooth surface to which commercially available adhesive backed slip

resistant tread strips (for bathtub use) have been applied. The bath seat would be subjected to the stability test protocol that is currently a part of the voluntary standard while installed on this surface. When tested by CPSC staff, current bath seat designs, using only suction cups for stability, did not pass this test. Some other method will need to be developed to impart stability to the product. CPSC staff is aware of one prototype of a bath seat that maintains stability by being manually attached to the side of the tub.

In addition to the stability requirement, two probe tests are being proposed that would limit the size of the product's leg openings as well as the seating space, to address the hazards of submersion and entrapment below the water surface. This requirement, referred to as the "leg opening requirement," is part of the newly approved ASTM voluntary standard. Leg opening sizes would be limited by a torso test probe. The seating space area would be limited by a shoulder test probe that would not be allowed to lie flat on the seating surface. The test probes are designed to prevent the smallest recommended users from becoming entrapped or submerged when using bath seats. Currently marketed bath seats in the U.S. do not meet the leg opening requirements. Depending upon the dimensions of the redesigned product, there is the potential that the age range of users could be affected. However, the Human Factors Division does not believe that limiting the size of the openings will necessarily preclude children older and larger than the recommended users from being able to use the seats.

The labeling requirement would also change from what is currently specified in the voluntary standard. The proposed labeling requirement specifies that the product and its packaging be labeled with the safety alert symbol (exclamation mark within an equilateral triangle), the single word WARNING in all capital letters, as well as the following: "Children have <u>drowned</u> while using bath seats. ALWAYS keep baby within arm's reach. This bathing aid is NOT a safety device. Stop using when child is able to pull up to a standing position."

Potential Costs of the Proposed Rule

Efforts are underway by at least one U.S. manufacturer to develop a bath seat that will conform to the requirements of the proposed rule. Costs to manufacturers to meet the proposed rule include product development costs and increased costs of production. Product development costs involve costs associated with redesign of the product and retooling of manufacturing equipment. According to an industry representative, new molds for the redesigned product are estimated to cost about \$350,000. Product development overhead costs include product design, development and marketing staff time, product testing and focus group expenses. However, these "product development costs" will be treated as with any new product development and be amortized over time.

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⁴ Memorandum from Caroleene Paul, Directorate for Engineering Sciences, March 2003, Subject: Proposed Mandatory Rule for Bath Seats.

⁵ CPSC does not know if any current bath seats will pass the shoulder probe test, because a probe is not available at this time.

⁶ Memorandum from Jonathan D. Midgett, ESHF, March 2003, Subject: Human Factors Issues in Bath Seat Design and Use.

Manufacturers report that there will be an increase in the cost of production associated with additional material, labor and shipping. According to an industry representative, its redesigned bath seat will be larger, heavier, and more complex to assemble. At the present time, most bath seats are manufactured in the U.S. However, according to an industry representative, some of the manufacturing or assembly of the redesigned bath seats may be accomplished outside the U.S. due to the increased labor requirements and complexity of the manufacturing process.

The proposed rule would require that bath seats entering commerce meet the new requirements within a year of publication of the final rule. Bath seats already in commerce (for example, those on store shelves) will not be affected and will still be saleable. According to one manufacturer, they plan to have bath seats that meet the new voluntary standard leg opening requirement as well as the stability requirement that is part of the proposed rule by the end of the year. Also, the second manufacturer will probably have bath seats that meet the leg opening requirement by the end of the year.

Revenues may be affected if sales do not match current levels. Sales may be reduced because of price increases and possible reductions in the utility of the new, safer bath seats. Consumer utility could be reduced if the product is more difficult to use or the age range of users is reduced. On the other hand, the added safety of the product may increase the utility of the product to some consumers, a factor that may be a positive influence on sales.

Currently, bath seats sell for about \$10 to \$16. Convertible seats, which convert from an infant bathtub to an infant bath seat, sell for about \$20 to \$25. Based on discussions with an industry representative, bath seat prices will increase to reflect the increased cost associated with producing a complying product. Although exact costs and price increases are not known at this time, industry representatives estimate that complying bath seats will retail for about \$20 to \$25, with a likely price closer to \$25.

All else equal, a price increase of \$10 (which represents an increase of more than 50 percent) may reduce the quantity of bath seats demanded, and hence sales. The magnitude of such a reduction is unknown, but would be affected by a number of other factors, including the perceived usefulness of the product, the expected useful life of the product, and other variables such as the number of births, household incomes, and the availability of substitutes.

Despite the relatively large price increase over that of existing bath seats, the reduction in sales may be small if consumers find the product convenient and useful, and expect to use it for a long time. If, for example, a consumer would use a bath seat for a year or more (i.e., for one or more children) the price increase would amount to less than \$1 per month. Moreover, all else is not equal. The product will change -- it will be presumably safer than the earlier models. If consumers perceive the increased safety, and if safety is an important factor when they purchase products for use with their infant children, the demand for bath seats could increase. Thus, product improvements can conceivably mitigate or even offset the reduction in the quantity demanded associated with the price increase.

Although product design is not specified by the proposed requirement, consumer utility could be affected if changes intended to make bath seats safer also make them more difficult to use, or if the changes tend to limit the age of children that can use them. The analysis by Human Factors indicates that bath seats meeting the proposed requirements could still accommodate the current user population, without a loss of utility. However, since the design is not specified and we don't know how manufacturers will modify the seats to meet the proposed requirements, we cannot predict if the new designs will provide the same level of usefulness or convenience to caregivers. Any reductions in utility could lead to the reduced use of bath seats, either by reducing sales or actual amount of use. While reduced use would also reduce the risk of drowning in bath seats, the overall risk of drowning would not be eliminated since other modes of bathing children also present the drowning risk.

Potential Benefits of the Proposed Rule

The benefits of the proposed rule will result from a reduction in deaths and injuries due to product failure from tip-over, entrapment and submersion. CPSC is aware of 96 deaths associated with bath seats from January 1983 through December 2002. Eighty-three of these reported deaths occurred in the past ten years (1993 through 2002), a period during which about one-third of all new mothers owned bath seats and the number of baths seats in use remained relatively constant at about two million. Of the 83 reported deaths since 1993, the hazárd scenario is known in 57 of the deaths (leaving 26 with unknown scenarios).

Of the 57 deaths in which the scenario is known, 28 (about 50 percent) involved hazards addressed by the proposed rule (26 involved the tip-over hazard and two involved entrapment/submersion). While we do not know the hazard scenarios in the remaining 26 deaths, if we assume that they are distributed proportionally to the known cases, another 13 deaths (i.e. 50 percent) might be also be addressed by the proposed rule. This amounts to about 2.8 to 4.1 deaths annually (i.e. 28 deaths/10 years to 41 deaths/10 years), or about 1.4 to 2.05 deaths per million bath seats in use (since about two million were in use annually).

⁸ Memorandum from Debra Sweet, Directorate for Epidemiology, April 2003, Subject: Hazard Analysis Memorandum for Bath Seat NPR Briefing Package.

⁷ The potential for non-fatal injuries resulting from tip-over and entrapment/submersions would also be reduced. However, because most incidents either resulted in no injury or resulted in death, and because CPSC has little information on non-fatal injuries, the discussion of benefits in this analysis will be limited to those resulting from the prevention of death.

The benefits assessment is limited to the 1993 to 2002 time frame because the number of baby bath seats in use, which is needed to calculate the risk that will be addressed by the proposed rule, was less clear prior to 1993. In addition, there has been improved reporting and collecting of death data in the later years.

Comparison of Costs and Benefits

As described above, the proposed rule may result in an increase in the retail price of baby bath seats by about \$10. Assuming a \$10 price increase, the costs of the proposed rule (i.e., the costs of making baby bath seats safer) will increase consumer outlays by \$10 million per million bath seats sold. Additionally, according to the *Baby Products Tracking Study*, about half of the bath seats were acquired used and therefore are likely used for more than one child. If we assume that bath seats are used for an average of about two years (i.e. more than one use cycle), and there are about 1.4 to 2.05 deaths per million bath seats in use annually, each million bath seats would be associated with about 2.8 to 4.1 deaths over their two-year product life.

If the proposed rule eliminates all of these tip-over deaths and entrapment and submersion deaths (i.e., is 100 percent effective in preventing the deaths addressed), then the cost per life saved would range from about \$2.4 million to about \$3.6 million (\$10 million/4.1 deaths to \$10 million/2.8 deaths). If the rule were 50 percent effective in preventing the tip-over and entrapment/submersion deaths, then the cost per life saved would range from about \$4.9 to \$7.1 million per death prevented (\$10 million/(4.1*.5) deaths to \$10 million/(2.8*.5) deaths). Based on current economic literature, empirical estimates of the statistical value of life have generally ranged from about \$3 million to \$7 million. Thus, for purposes of cost-benefit analysis, even the high estimates of the cost per life saved are generally within the accepted range and suggest that the benefits of the rule would be in line with the costs even if the standard were only 50 percent effective in preventing addressable deaths.

The proposed rule has the potential to bring about a reduction in deaths from tip-over and entrapment/submersion hazards. However, it is not clear at this time whether manufacturers will design baby bath seats that are safer, while maintaining the current level of consumer utility. If some consumers do not accept the redesigned seats, or use them less frequently (or for a shorter period), and decide instead to bathe their children by other means, the risk of drowning from these alternative bathing methods will be substituted for the bath seat drowning risk.

Alternatives

Alternatives to the regulation include a total ban of infant bath seats, relying on a voluntary standard, promulgating a subset of the requirements of the above proposed rule and taking no action.

Option to Ban

If the Commission decides that baby bath seats cannot be designed to adequately reduce the risk of injury, it could ban them. Since a ban would eliminate bath seats from the marketplace entirely, the costs would consist of the lost use value, or utility, that consumers

¹⁰ W. Kip Viscusi, "The Value of Risks to Life and Health," *Journal of Economic Literature*, Vol. 31, December 1993, pp. 1912-1946.

derive from the product. Money not spent on bath seats will be spent on other products that provide utility, but there is expected to be some loss in utility that cannot be quantified.

The benefits of a ban would be the net reduction in deaths that would be prevented by the action. The primary alternative to a ban is the proposed rule for baby bath seats already discussed. Since the proposed rule addresses about half of the child drownings, the additional drownings addressed by a ban would be only a subset of all bath seat drownings - the remaining half.

Furthermore, while a ban would effectively address (on net) only about half of the bath seat drownings, it would expose all bath seat users (i.e., those who would be precluded from using bath seats) to the drowning risks in alternative bathing settings. ¹¹ The risk in alternative settings is not trivial. For example, the analysis by the Directorate for Epidemiology suggests that, for some restricted age groups (e.g., drownings involving children age 8-10 months), the risk of drowning in a bath seat may be substantially lower than in alternative bathing settings. ¹² Moreover, when all children age 5-10 months were grouped together in the analysis (the age group for which bath seats are generally recommended), the average bath seat drowning risk was almost 40 percent lower than that of alternative bathtub scenarios. While grouping children across the 5 to 10 month age categories may mask the drowning risk disparities associated with the developmental differences between the younger and older children, as noted by the Directorate for Epidemiology, it nonetheless highlights the fact that the risks associated with alternative bathing methods are substantial and should not be ignored.

While the analysis of relative risks was based on several underlying assumptions, the comparison of risks highlights the potential weaknesses of a bath seat ban. If the proposed rule were fully effective in preventing the deaths it addresses, it would likely reduce the risk of drowning in a bath seat by about 50 percent. On the other hand, while a ban would address all bath seat drownings (by precluding the use of bath seats), it would also expose all the children who would have been bathed in bath seats to the drowning risks in other bathing settings.

In summary, a ban of bath seats from the marketplace would result in some reduction in consumer utility; however, the impact on child drownings is uncertain and could increase.

A Subset of the Performance Requirements: Excluding the Leg Opening Requirement in the Proposed Rule

The Commission could decide to promulgate a subset of the three requirements developed by the staff and discussed earlier as a proposed rule. One reasonable alternative may be to publish as a proposed rule the stability and labeling requirements and not the requirement

¹¹ Alternative bathing settings include non-bath seat bathing scenarios, such as adult and infant bathtubs, with or without the use of other aids. For details of these scenarios, see Memorandum from Debra Sweet, dated March 2003.

¹² For the younger 5-7 month old children, in contrast, the risks in bath seats are higher than in alternative bathing settings.

to prevent submarining and entrapment, i.e. the leg opening performance requirement. This is because ASTM recently approved a revision to the voluntary standard that incorporates the same requirements that CPSC staff developed for addressing the submarining and entrapment hazards. The two firms that currently manufacture bath seats participated in the adoption of this standard and have indicated that they plan to have complying products on the market within about six months of the standard's publication. On the basis of the development of a voluntary standard with expectation of compliance by the manufacturers, the Commission could decide to only promulgate those aspects of the staff's proposal not covered by the newest voluntary standard, e.g., the stability and labeling requirements.

If this alternative were promulgated, the costs and benefits which were discussed in the analysis of the proposed rule would change little. Since the entrapment and submarining deaths accounted for only two of the 57 deaths for which the cause was known, exclusion of the leg opening requirement would reduce the benefits by only about 3.5 percent (i.e., 2/57). At the same time, the elimination of the leg opening requirement will not reduce the costs of the proposed rule by much. Based on discussions with the manufacturers of bath seats, the stability requirement requires product redesign and will drive most, if not all, the cost increase associated with the proposed rule. The leg opening requirement, by itself, would not necessitate a product redesign, but would require "modification" to the current design, resulting in perhaps a small increase in the product's retail price. Therefore, the elimination of the leg opening requirement would have, at best, a very small impact on the overall cost of the proposed rule as well as its potential benefits.

No Action

A decision by the Commission to take no action would eliminate the retail price increase associated with making baby bath seats safer. At the same time (and assuming no change in the voluntary standard), absent any intervention by the Commission, additional preventable deaths will likely continue as new parents buy and use baby bath seats that are currently available in the marketplace.

Voluntary Standards

As an alternative to a proposed rule, the Commission could decide that a voluntary standard is adequate and terminate rulemaking. ASTM has recently revised the voluntary standard to address hazards associated with bath seat submersion and entrapment. It is possible that later revisions might incorporate tip-over and labeling requirements that are similar to the proposed rule. If the voluntary standard addresses the same tip-over hazards that are addressed in the proposed rule with equivalent effectiveness, and all suppliers of baby bath seats comply with the voluntary standard, the net benefits of the voluntary standard would be virtually the same as those of the proposed rule. However, at this time, the voluntary standard does not address the tip-over deaths.

Initial Regulatory Flexibility and Environmental Analyses

No available information indicates that the proposed baby bath seat requirements will have a *significant adverse* impact on a *substantial number* of small businesses. Currently, three companies, two U.S. manufacturers and one importer, are known to supply baby bath seats in the U.S. Two of the firms (one of the manufacturers and the one importer) are small, meeting the U.S. Small Business Administration's definition of small businesses. The two U.S. manufacturers are aware of the progress of this rulemaking and at least one manufacturer is in the process of developing baby bath seats to meet the requirements of the proposed rule. The third firm, an importer, may have to find another source for baby bath seats that would meet the proposed rule.

The transition to baby bath seats that meet the proposed rule is not expected to have an adverse environmental impact, especially if the effective date of a rule enables the firms to substantially deplete existing non-complying inventory. The U.S. manufacturers are already aware of the Commission's actions and since there is a proposed one-year lead-time before the rule becomes effective, no environmental impact is expected. Moreover, any existing inventory in manufacturers' stocks has the potential to be recycled, i.e. reground in order to reuse the plastic components, which constitute the bulk of the seats' construction.