



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

VOTE SHEET

Date: MAY 8 2003

TO : The Commission
 Todd Stevenson, Secretary

FROM : W.H. DuRoss, III, General Counsel *W.D.*
 Stephen Lemberg, Assistant General Counsel *SL*
 Patricia M. Pollitzer, Attorney *PM*

SUBJECT : Notice of Proposed Rulemaking for Bath Seats

Attached is a briefing package from the staff recommending that the Commission direct the Office of General Counsel ("OGC") to prepare a notice of proposed rulemaking ("NPR") for bath seats proposing that bath seats meet requirements for (1) stability, (2) leg openings, and (3) a warning label. The staff discusses other options in its briefing package.

Please indicate your vote on the following options.

- I. Direct OGC to prepare a NPR for the Commission's approval:
 - A. With the three requirements recommended by the staff.

 Signature

 Date

B. Other (please specify):

 Signature

 Date

NOTE: This document has not been reviewed or accepted by the Commission.

Initial tlh Date 5/8/03

CPSC 6 (b)(1) Cleared
 5/8/03
 No Mfrs/Prvtlbrs or
 Products Identified
 Accepted by *Stephen Lemberg*
 Firms Notified,
 .. processed.

II. Direct OGC to prepare a Federal Register notice terminating the rulemaking.

Signature

Date

III. Take other action (please specify):

Signature

Date

**BABY BATH SEATS
RULEMAKING OPTIONS
BRIEFING PACKAGE**

May 2003

For Further Information, Contact:

**Patricia L. Hackett
Directorate for Engineering Sciences
(301) 504-7577**

CPSA 6 (b)(7) Clear
5/8/03
No Mfrs/Prv/LEAs or
Products Identified
Excepted by Patricia Hackett
Firms Notified,
Comments Processed.

**NOTE: This document has not been
reviewed or accepted by the Commission.**
Initial rh Date 5/8/03

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ATTACHMENTS

- TAB A** CPSC Memorandum from Debra Sweet, Division of Hazard Analysis, to Patricia Hackett, Directorate for Engineering Sciences, entitled "Hazard Analysis Memorandum for Bath Seat NPR Briefing Package," April 8, 2003.
- TAB B** CPSC Memorandum from Caroleene Paul, Directorate for Engineering Sciences, to Patricia Hackett, Directorate for Engineering Sciences, entitled "Draft Proposed Requirements for Bath Seats," April 7, 2003.
- TAB C** CPSC Memorandum from Jonathan D. Midgett, Ph.D., Division of Human Factors, to Patricia L. Hackett, Directorate for Engineering Sciences, entitled "Human Factors Issues in Bath Seat Design and Use," April 10, 2003.
- TAB D** Outline of Baby Bath Seat ANPR Comments, CH 01-5
- TAB E** CPSC Memorandum from Caroleene Paul, Directorate for Engineering Sciences, to Patricia Hackett, Directorate for Engineering Sciences, entitled "Response to ANPR Comments on Baby Bath Seats CH 01-5," April 7, 2003.
- TAB F** CPSC Memorandum from Jonathan D. Midgett, Ph.D., Division of Human Factors, to Patricia L. Hackett, Directorate for Engineering Sciences, entitled "Human Factors Staff Responses to Comments about Bath Seats," April 10, 2003.
- TAB G** CPSC Memorandum from Mary Donaldson, EC to Patricia Hackett, Directorate for Engineering Sciences, entitled "Preliminary Regulatory Analysis of Proposed Rule for Baby Bath Seats," April 9, 2003.

*Rulemaking Options for Baby Bath Seats
Executive Summary*

On May 30, 2001, the U.S. Consumer Product Safety Commission (CPSC) voted to initiate rulemaking for baby bath seats after it considered a petition filed by the Consumer Federation of America and eight other groups in August 2000. The petition requested that the Commission ban baby bath seats, claiming that these products present an unreasonable risk of death and injury to children. The CPSC published an advance notice of proposed rulemaking (ANPR) on August 1, 2001, under the Federal Hazardous Substances Act (FHSA).

A bath seat is a product intended to be placed into a bathtub, sink or similar bathing enclosure to provide support to a seated infant during bathing by an adult caregiver. The product is intended for use with an infant who is capable of sitting upright unassisted but who cannot yet pull up to a standing position (generally 5-10 months).

CPSC has reports of 96 drowning deaths and 153 non-fatal incidents involving baby bath seats that occurred from January 1983 to December 2002. Ten of the deaths occurred since the Commission voted to initiate the ANPR in May 2001.

Approximately one fifth of the fatal and non-fatal incident reports are missing important details, such as the position of the bath seat and/or the occupant when the incident occurred. For these incidents, the staff cannot determine the hazard scenario. From the remaining reported incidents, CPSC staff has identified several hazard scenarios for which the bath seat design or materials contributed to the incident. Of these, the following scenarios resulted in fatalities:

- 1) Tip-over: The bath seat tipped over while in use, submerging/trapping the child or allowing the child to escape the seat.
- 2) Entrapment and submersion: The bath seat remained upright and the child became submerged and/or entrapped.
- 3) Coming out: The bath seat remained upright and the child came out of the bath seat.

Staff is aware of 30 fatalities where the bath seat was found tipped over. All bath seats being sold today are made with suction cups to hold them in place. Suction cup performance can be degraded by dirty or soapy surfaces, and can degrade naturally with age and repeated exposure to water. Suction cups only work reliably on smooth surfaces. There are no bath seats currently made that are suitable or recommended for textured or slip-resistant tubs. Yet many bathtubs in homes today have slip-resistant surfaces. To address the hazard from a bath seat tipping over, CPSC staff developed a performance requirement that requires bath seats to remain stable when tested on a slip-resistant tub surface.

Three fatalities have been associated with entrapment and submersion scenarios. CPSC staff has participated with the ASTM bath seat subcommittee in the development of a leg opening performance requirement to address underwater entrapment in bath seats. The leg opening requirement was adopted in a recently approved revision to the standard, designated as ASTM F 1967-03 "Standard Consumer Safety Specification for Infant Bath Seats."

Nineteen fatalities have been associated with children coming out of bath seats. After extensive analysis of potential approaches, CPSC staff has not been able to develop a reasonable performance requirement that effectively addresses this hazard. However, staff believes that this hazard might be reduced by the addition of a stronger warning label regarding the danger of drowning associated with bath seats.

Staff is not recommending a ban of bath seats. With available data, staff cannot predict the effect a ban of bath seats would have on the number of infant drownings. It is conceivable that fatalities may either decrease or increase with a ban of bath seats, when caregivers bathe children in bathtubs or use other bathing aids.

In order to address tip-overs, entrapments/submersions, and children coming out of bath seats, the staff recommends that the Commission continue the rulemaking process by instructing the Office of the General Council (OGC) to draft a notice of proposed rulemaking (NPR) incorporating 1) the stability performance requirement, 2) the leg opening performance requirement and 3) the labeling requirement as set forth in this briefing package.

A preliminary analysis of the potential costs and benefits of the proposed regulation suggests that the benefits would be in line with the costs, even if the rule were only 50 percent effective in preventing addressable deaths.



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

Memorandum

DATE: MAY 8 2003

TO: The Commission
 Todd Stevenson, Secretary

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

FROM: Jacqueline Elder, Assistant Executive Director
 Office of Hazard Identification and Reduction
 Patricia Hackett, Project Manager *PH*
 Directorate for Engineering Sciences

SUBJECT: Rulemaking Options for Baby Bath Seats

I. ISSUE

The issue discussed in this briefing package is whether the Commission should propose a regulation, under the Federal Hazardous Substances Act (FHSA), to require baby bath seats to comply with certain performance and labeling requirements addressing hazards that result in children drowning. Other options available to the Commission are to propose a ban of all baby bath seats, defer a decision until more information is known, or take no further action.

A baby bath seat is a product intended to be placed into a bathtub, sink or similar bathing enclosure to provide support to a seated infant while being bathed by an adult caregiver. The product is intended for use only with an infant who is capable of sitting upright unassisted and cannot yet pull to a standing position. Figure 1 shows examples of two bath seats currently on the market.

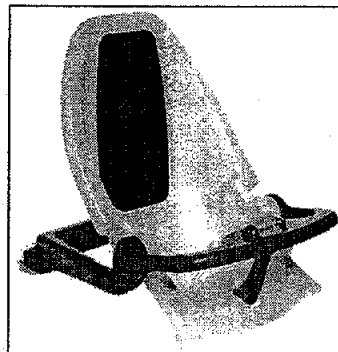
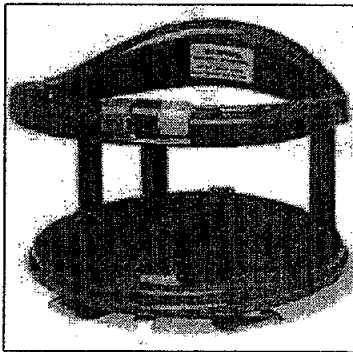


Figure 1: Examples of Bath Seats Currently Being Sold

CPSC 6/11/03
 No. Mfrs/Producers of
 Products *1*
 Excepted
 Firms Not
 Comments Processed

II. BACKGROUND

A petition from the Consumer Federation of America and eight other groups, docketed on August 4, 2000, requested that the Commission ban baby bath seats and bath rings (for the remainder of this briefing package, all of these products will be referred to as bath seats). The petitioners asserted that bath seats pose an unreasonable risk of injury and death, primarily because they create a false sense of security that the child is safe in the bathtub.

On May 30, 2001, the Commission granted the petition and voted to issue an advance notice of proposed rulemaking (ANPR). The ANPR was published in the Federal Register (66 Fed. Reg. 39, 692) on August 1, 2001, initiating rulemaking for bath seats under the FHSA.

The briefing package for the ANPR, dated March 2001, contained information about 69 fatal incidents and 95 non-fatal incidents. Those incidents occurred between January 1983 and November 2000. CPSC has reports of an additional 27 deaths and 59 non-fatal incidents since preparation of the 2001 briefing package, including some incidents that occurred prior to November 2000 but were previously unreported. Ten of the additional 27 deaths occurred since the Commission voted to initiate the ANPR in May 2001.

In the ANPR, the Commission solicited written comments concerning the risk of injury associated with bath seats, the regulatory alternatives discussed in the notice, other possible ways to address these risks, and the economic impact of the alternatives. The Commission also invited interested persons to submit an existing standard or a statement of intent to modify the current, or develop a new, voluntary standard to address the risk of injury described in the notice.

This briefing memo discusses and reviews incident data associated with bath seats, the status of the applicable voluntary standard, staff's recommended bath seat requirements, and a preliminary regulatory analysis. In addition, the comments received on the ANPR are addressed. Following a discussion of the issues, the alternatives and options available to the Commission are reviewed, and the staff's recommended course of action is presented.

III. DISCUSSION

A. Incident Data (Tab A)

The March 2001 briefing package cited 69 deaths and 95 non-fatal incidents/complaints¹ involving bath seats in the U.S. from January 1983 through November 2000. Since that briefing package was prepared, the CPSC has reports of an additional 27 deaths and 59 non-fatal incidents (through December 2002) for a total of 96 deaths and 153 non-fatal incidents.

All of the 27 additional drowning deaths occurred in the absence of a caregiver. Sixty-six of the 69 fatalities discussed in the 2001 briefing package took place when the caregiver was absent. Some reasons that caregivers have cited for leaving children unattended are answering

¹ One non-fatal incident from the March 2001 briefing package was removed from the count after further review of the incident data.

unexpected phone calls, retrieving towels, tending to another child in the home, performing household chores, or watching television.

The water depth was reported numerically (or as an overflow) in 15 of the 27 incidents. The minimum water depth reported was three inches and the maximum was an overflowing bathtub. The victims involved in the 27 fatal drowning incidents ranged in age from 5 months to 14 months old. Four different manufacturers' products were involved in 19 of the 27 incidents; Safety 1st, Fisher-Price, Gerry and The First Years. The manufacturer information was unknown in the remaining eight incidents.

Thirteen of the 27 victims were put into the bathtub with another young child. In 10 of these 13 incidents, the sibling was in the bathtub with the victim for the duration of the bath. In the other three incidents, either the caregiver took the sibling out of the tub during the bath or the sibling got out of the bathtub while the caregiver was out of the room, leaving the victim alone and unattended. There were no siblings present at any time during the bath in the remaining 14 incidents.

The hazard scenarios associated with all the deaths and non-fatal incidents can be grouped into three areas: 1) those that involved problems with the bath seat 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 are unknown or uncertain. The following two tables contain a breakdown of incidents by hazard scenario as reported in the 2001 briefing package as well as for the updated data. The tables are separated for fatal incidents (Table 1) and non-fatal incidents and complaints (Table 2). A review of the updated incidents that pertain to the bath seat design scenarios follows.

Table 1: Bath Seat Fatal Incidents by Hazard Scenario

Hazard Scenario	Fatalities Reported in 2001 Briefing Package (1/83-11/00)	Updated Additional Fatalities²	Total Number of Fatalities (1/83-12/02)
<i>Problems with the Bath Seat Design and Materials</i>			
Tip-Over	21	9	30
Children Coming Out of the Bath Seat	11	8	19
Entrapment and Submersion	3	0	3
Bath Seat Breaking	0	0	0
<i>Bath Seat Remained Upright and Retained the Child</i>			
Children Slumped Over	9	1	10
Overflowing Bathtub	2	2	4
<i>Known Scenario Totals</i>	<i>46</i>	<i>20</i>	<i>66</i>
<i>Fatalities with Some Unknown Circumstances</i>			
Children Found in Water; Bath Seat Position Unknown	17	7	24
Bath Seat Upright; Child Position Unknown	2	0	2
Unknown or Uncertain Circumstances	4	0	4
<i>Unknown Scenario Totals</i>	<i>23</i>	<i>7</i>	<i>30</i>
Total Fatalities	69	27	96

² This column represents the fatalities reported to CPSC after Nov 2000. Of the 27 reported deaths, 11 occurred prior to Nov. 2000 and 16 occurred from Nov. 2000 to Dec. 2002.

Table 2: Bath Seat Non-Fatal Incidents and Complaints by Hazard Scenario

Hazard Scenario	Non-Fatal Incidents and Complaints Reported in 2001 Briefing Package (1/83-11/00)	Updated Additional Non-Fatal Incidents and Complaints³	Total Number of Non-Fatal Incidents and Complaints (1/83-12/02)
<i>Problems with the Bath Seat Design and Materials</i>			
Tip-Over	51	29	80
Children Coming Out of the Bath Seat	7	6	13
Entrapment and Submersion	13	4	17
Bath Seat Breaking	5	12	17
<i>Bath Seat Remained Upright and Retained the Child</i>			
Children Slumped Over	2	0	2
Overflowing Bathtub	0	1	1
<i>Known Scenario Totals</i>	<i>78</i>	<i>52</i>	<i>130</i>
<i>Non-Fatal Incidents with Some Unknown Circumstances</i>			
Children Found in Water; Bath Seat Position Unknown	5	4	9
Bath Seat Upright; Child Position Unknown	0	0	0
Unknown or Uncertain Circumstances	11	3	14
<i>Unknown Scenario Totals</i>	<i>16</i>	<i>7</i>	<i>23</i>
Total Non-Fatal Incidents	94	59	153

³ This column represents the non-fatal incidents reported to CPSC after Nov 2000. Of the 59 reported incidents, 27 occurred prior to Nov. 2000 and 32 occurred from Nov. 2000 to Dec. 2002.

1. Problems with the Bath Seat Design and Materials

Hazard scenarios associated with the design and materials of the bath seat include cases in which:

- 1) the bath seat tipped over, submerging the occupants in the water or allowing them to escape the seat (to be referred to as tip-over for the remainder of this memo);
- 2) the bath seat remained upright and the occupant was found outside of the bath seat, presumably by coming over the top of the bath seat (to be referred to as "coming out");
- 3) the bath seat remained upright and the occupant became submerged in the water and/or entrapped in the bath seat presumably by slipping (or "submarining") through one of the leg openings (to be referred to as entrapment and submersion); and
- 4) the bath seat was reported to have broken while in use.

Tip-Over

Since the 2001 briefing package, CPSC has received reports of nine drowning deaths that resulted from a bath seat that tipped over while the occupant was seated in the product. All of the incidents occurred while the caregiver left the child unattended.

CPSC has also received reports of 29 non-fatal incidents of bath seats tipping over or the suction cups releasing, creating the potential for tip-over. Twenty-two of the incidents occurred when the caregiver was present and bathing the child. Three incidents occurred while the child was unattended. The caregiver's location at the time of the four remaining incidents is unknown.

Combining fatal and non-fatal incidents reported since the 2001 briefing package, there have been 38 bath seat tip-over incidents involving children ages 4 to 14 months. Twelve incidents occurred without the presence of a caregiver, resulting in nine deaths. In 22 incidents, the caregiver was present at the time of the incident. Caregiver supervision is unknown in the remaining four incidents.

The total number of reported tip-over incidents, from January 1983 through December 2002, includes 30 fatalities and 80 non-fatal incidents or complaints.

Children Coming Out of the Bath Seat

Since the 2001 briefing package, CPSC has received reports of eight children who drowned when they came out of the bath seat. The children were found out of the bath seat in the bath water and the bath seat was still in its upright position. The scenario suggests the inability of the bath seat to restrain the child in the seat. All of the children were unattended when the incidents occurred.

CPSC has also received six reports of non-fatal incidents where the child came out of the bath seat. Of the six incidents, two occurred when the caregiver was present, three were when the child was left unattended, and the supervision is unknown in the last incident. In the two supervised incidents, it was noted that the child was attempting to stand, or stood up, in the seat.

Combining fatal and non-fatal incidents reported since the 2001 briefing package, there have been 14 children who came out of bath seats. The children were 6 to 12 months old - approaching, or at the age, where a child can stand up with some assistance. Eleven of the children were left unattended in the bathtub when the incident occurred, two were attended by the caregiver, and caregiver attendance in the last incident is unknown. Eight of the 11 unsupervised incidents resulted in death.

The total number of reported coming out incidents, from January 1983 through December 2002, includes 19 fatalities and 13 non-fatal incidents or complaints.

Entrapment and Submersion

CPSC received no reports of fatalities and four reports of non-fatal incidents of entrapment in bath seats since the 2001 briefing package. A caregiver was present in two of the four incidents. For one of the incidents, the caregiver stated that a 6-month-old child's shoulder became wedged inside the bath seat. For the other supervised incident, it was reported that a 10-month-old child's body slid through one leg opening and the child became entrapped. Supervision in the other two incidents is unknown. These cases involved 7- and 9-month-old children who slipped through a leg opening and became stuck.

The total number of reported entrapment and submersion incidents, from January 1983 through December 2002, includes three fatalities and 17 non-fatal incidents or complaints.

Bath Seat Breaking During Use

Since the 2001 briefing package, 12 non-fatal incidents or complaints were reported to CPSC in which the bath seat broke, without leading to a tip-over or submersion. Most of the incidents involved various models of bath seats that experienced a structural failure of part of the product. The children involved in these incidents ranged in age from 4 to 15 months old. Nine of the incidents occurred when the caregiver was present. Supervision is unknown in the remaining three incidents.

The total number of reported bath seats breaking, from January 1983 through December 2002, includes no fatalities and 17 non-fatal incidents or complaints.

The incident data for the hazard scenarios that are not related to the bath seat design or materials are detailed in Tab A.

B. Voluntary Standard

1. History and Development of ASTM Standard F 1967

On October 5, 1994, the American Society for Testing and Materials (now ASTM International) initiated the development of a voluntary standard for bath seats. CPSC staff took part in the development of the standard.

During the development of the bath seat standard, various requirements were discussed for possible inclusion in the standard. These included performance requirements for stability, suction cup integrity, static load, latching/locking mechanisms, restraint systems, leg opening sizes and other requirements commonly found in juvenile product standards. The standard, ASTM F 1967-99 "Standard Consumer Safety Specification for Infant Bath Seats," was published in June of 1999 and included marking, labeling and literature requirements as well as performance requirements addressing the issues mentioned above, with the exception of suction cup integrity and leg opening sizes.

In September 1999, ASTM balloted a new requirement for suction cup integrity (addressing attachment to the bath seat and to the bathing surface) and a durability requirement for latching/locking mechanisms. The revised standard was published as ASTM F 1967-01 in June 2001.

On July 15, 2002, ASTM balloted five separate revisions to ASTM F 1967-01, including a test procedure change and warning label additions. One of the five items balloted was the addition of a performance requirement for the size of the leg openings and occupant seating space to address entrapment and submersion incidents. This requirement specifies testing of all openings in the bath seat with two test probes - a torso probe and a shoulder probe - and is detailed below and in Section C: Draft Proposed Requirements. On March 10, 2003, the five items were approved as part of the revised standard, ASTM F 1967-03.

2. *Performance Requirements of ASTM F 1967-03*

The following is a summary of the performance requirements and their respective test methods specified in ASTM F 1967-03 (those added to the standard since 1999 are noted):

Restraint System: If the seat provides back support and side or front support, then a passive crotch restraint must be provided. The standard does not allow additional restraints that require any action on the part of the caregiver to secure the restraint.

Stability: The bath seat is tested on a smooth surface, in 2 inches of water. A 17-pound force (lbf.) is applied horizontally from the seat. The bath seat complies if it does not tip over. Testing is not required on slip-resistant surfaces unless the manufacturer recommends use on slip-resistant surfaces⁴.

Static Load: A 30-pound load is placed in the seat for 20 minutes. There shall be no breakage or deformation of the product.

Requirements for Suction Cups (added in 2001): Seats with suction cups are tested as follows:

1. After soaking in water, a 25-pound pull test is performed in an attempt to remove the suction cups from the seat.
2. After soaking in water, a 25-pound pull test is performed on a seat installed on a smooth bathing surface, in an attempt to disengage the suction cups from bathing surface.
3. The seat is installed/removed 2000 times on a smooth bathing surface and pull test #2 is repeated.

⁴ CPSC staff is not aware of any bath seats currently sold that are recommended for use on slip-resistant surfaces.

Leg Openings (added in 2003):

1. A torso probe is inserted in the most adverse orientation into each opening of the bath seat from the direction of the occupant seating surface. A 15-pound force is applied. To comply, the bath seat shall not permit passage of the torso probe.
2. The tapered end of a shoulder probe is inserted in the most adverse orientation into each opening of the bath seat from the direction of the occupant seating surface. A 15-pound force is applied to the probe in the direction of the major axis. The force is released and a 10-pound force is applied to the top 1.0 inch perimeter of the probe in a direction vertically toward the seating surface. To comply, the 1.0 inch perimeter shall not be permitted to contact the seating surface of the bath seat.

ASTM F 1967-03 is expected to be published in the summer of 2003. The Juvenile Products Manufacturers Association (JPMA) has indicated that the new leg opening performance requirements will become part of its certification program six months after publication of the revised standard. Thus, any bath seat that is intended by the manufacturer to be JPMA certified to the revised standard should be available for purchase by the winter of 2003-2004.

3. Performance Requirements Not Included in ASTM F 1967

During the fall 2002 subcommittee meeting, CPSC staff proposed requirements addressing the stability of bath seats on slip-resistant surfaces and enhanced product labeling. The proposed requirements were reviewed at the March 4, 2003 subcommittee meeting. There was limited discussion of the proposed requirements and the subcommittee deferred any decision on balloting of the requirements until after the next subcommittee meeting, tentatively set for fall 2003.

CPSC staff believes that ASTM F 1967-03 does not adequately address the drowning risks presented by bath seats. As currently revised, the ASTM standard addresses hazards associated with entrapment and submersion, but there are not adequate provisions to address the hazards associated with tip-over or children coming out. In the following section, the new leg opening requirement included in ASTM F 1967-03 and other staff recommended requirements are reviewed.

C. Draft Proposed Requirements (Tab B & C)

CPSC staff is recommending three draft proposed requirements for the proposed rule to help address the hazards associated with bath seats: 1) a stability performance requirement to address the tip-over hazard, 2) a leg opening performance requirement to address the entrapment and submersion hazard⁵, and 3) a labeling requirement to help address incidents of children coming out of the bath seat. CPSC staff believes that to adequately address the hazards, bath seats should conform to these requirements.

⁵ This is the same performance requirement that was recently approved and added to ASTM F 1967-03.

Tab B is a memo from CPSC's Division of Mechanical Engineering (ESME) that outlines and details the development of the draft proposed requirements. Tab C contains a memo from CPSC's Division of Human Factors (ESHF) that contains details and justifications for some of the requirements. The following sections address each of the draft proposed requirements.

1. Tip-Over Hazard/Stability Performance Requirement

As discussed previously, the tip-over scenario was involved in a total of 110 incidents, involving 30 deaths and 80 non-fatal incidents. Bath seats currently being sold depend on surface adhesion (suction cups) for all or part of their stability. Failure of the suction cups can 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.

Most of the reports concerning tip-over were based on incidents where suction cups on the bottom of the bath seat failed to adhere to the bathtub surface during a child's entire bath. 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. In these incidents, failure of the bath seat to continuously adhere to the surface resulted in an unstable product. The ASTM subcommittee for bath seats identified this problem and ASTM F 1167-03 requires that manufacturers include warnings against using bath seats on slip-resistant surfaces.

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 appliques, some slip-resistant surfaces have a very subtle finish. A convenience sampling of slip-resistant tubs at a home improvement store by CPSC staff showed some tubs that appeared to be smooth, even though they were "slip-resistant." During testing, CPSC staff noted 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. Because identifying slip-resistant tubs might be difficult, and testing can be misleading, CPSC staff believes that warning against the use of bath seats on slip-resistant surfaces will not be effective at preventing incidents.

Based on testing conducted by Engineering Sciences (ES) and Laboratory Sciences (LS) staff, CPSC staff proposes a performance requirement that addresses bath seat stability on slip-resistant surfaces. Staff proposes that the slip-resistant test surface be defined as a surface on which commercially available, adhesive backed, slip-resistant tread strips have been applied. Slip-resistant tread strips are used in many applications such as walkways and stairs, as well as bathtubs, 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.

A performance requirement that requires all products to 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 performance requirement, as outlined in Tab B, is similar in nature to the stability requirement in ASTM F 1967-03, but instead of testing on a smooth surface, it requires the product to be tested on a slip-resistant surface.

2. *Entrapment & Submersion Hazard/Leg Opening Performance Requirement*

Over the last two years, CPSC staff has been working as part of an ASTM task group to develop a performance requirement to address the entrapment and submersion hazard. This performance requirement tests all side and leg openings with two test probes -- a torso probe and a shoulder probe. To comply with the requirement, 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 nor 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. During the test, the shoulder probe is inserted into each leg opening and a force is applied to the "shoulder" end of the probe in an attempt to push it through the opening, or to have it contact the seat base. Prohibiting the probe from contacting 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.

This leg opening performance requirement was recently approved by ASTM and is included in ASTM F 1967-03, to be published in the summer of 2003.

3. *Coming Out Hazard/Performance Requirement vs. Labeling Requirement*

One of the identified incident scenarios involves the bath seat remaining upright, with the child found out of the seat. CPSC staff's assessment of this hazard reached the following conclusions:

- *Adding an effective restraint system to the seat may change the utility of the product.* CPSC staff believes that adding a restraint system could change the product from a bath aid to a bath restraint, making it impractical for its intended purpose of aiding caregivers when bathing children. Essentially, current bath seats maintain the children's 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 poorly adapted to restraining functions because it is difficult to make an effective “loose restraint.” Preventing children from coming out of a bath seat requires a restraint system that is reasonably comfortable and still allows 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.

- *Making the product seating area smaller by requiring a standard size will not prevent all users from coming out of the bath seat.* One concept of a restraint is simply to reduce the occupant retention area so that it is “tighter” on the child. This will not be effective for all users due to the great range of child size within the intended user population. Bath seats that fit large 6-month-old children may still allow small 10-month-old children ample clearance to fit into the seat and come out. The large variability in sizes among same-age children in this age range is greater than the growth from age 5 months to 10 months. Thus, requiring bath seats to conform to a smaller, standardized size would be insufficient to create an effective passive restraint system for bath seats.

Since a restraint performance requirement does not appear to be a practical approach for preventing children from coming out of a bath seat, staff recommends a forceful warning label to warn about the need for constant caregiver attendance.

Labeling Requirements

The label specified by ASTM F 1967-01⁶ (found on bath seats currently being sold) is:

▲ WARNING
Prevent Drowning
ALWAYS keep baby within arm’s reach

Staff believes that this label needs to be stronger so consumers understand that the danger of drowning is a reasonable possibility. Some consumers report that leaving a child unattended momentarily is “understandable,” to get a towel, answer the phone or doorbell, or help another child, even though some admit they understand that it is a risk. They 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. 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. A strong warning may counteract *some* of the sense of security invoked by a bath seat’s appearance. CPSC staff recommends strengthening the ASTM warning label with statements that clearly explain the danger. Staff recommends the following:

⁶ The warning label for the recently approved standard, ASTM F 1967-03, contains the identical wording as ASTM F 1967-01, along with two additional warnings : “Use ONLY on Smooth Surfaces” and “Suction Cups Will Not Stick to Slip-Resistant Surfaces”.

▲ WARNING

Children have drowned while using bath seats.

ALWAYS keep baby within arm's reach.

This bathing aid is NOT a safety device.

Stop using when a child is able to pull up to a standing position.

4. *Draft Requirements and "False Sense of Security"*

Some caregivers may perceive that bath seats provide a greater degree of safety than they actually do. The staff believes that the recommended requirements will improve the safety of bath seats. However, it will still be unsafe to leave a child alone even in a bath seat that meets the recommended requirements.

Compliance with the two recommended performance requirements does not mandate a specific design and therefore will not necessarily result in a bath seat design that will look more secure and safer than the ones currently available. Thus, staff is unable to estimate how much, if any, a change in design may increase the false sense of security.

It should be noted that a stronger warning label, such as the one recommended by CPSC staff, could reduce the sense of security. Thus, even if a new design might possibly enhance this sense, it is staff's opinion that the recommended warning label requirement can serve as a counterbalance and potentially reduce it.

D. *Response to Comments to the ANPR*

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 included in Tab D. Staff responses to the comments can be found in Tabs A, E, and F. A summary of the responses to the primary issues is included below. The numbers found in parentheses after a comment refer to the commenter number assigned by the Office of the Secretary and found in the outline included in Tab D.

1. *Adequacy of Bath Seat Designs and the Voluntary Standard*

Comment: Several comments (CH 01-5-3; 5; 6; 7; 8) stated 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. Some commenters (CH 01-5-1; 4; 5; 6) specifically pointed out that the size of the leg openings was hazardous.

Response: CPSC staff believes that the leg opening requirement recommended by staff and recently added to the ASTM voluntary standard will address incidents that involve entrapment/submersion and that the stability requirement recommended by CPSC staff can adequately address tip-over incidents.

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.

2. *Bath Seat Suction Cups and Performance on Slip-Resistant Surfaces*

Comment: Several comments (CH 01-5-3; 3a; 5; 6) specifically concerned the compatibility of bath seats with slip-resistant surfaces and stated that ASTM F 1967-01 is not compatible with slip-resistant surfaces. Three comments (CH 01-5-1; 2; 6) concentrated on the poor performance of suction cups in terms of ability to adhere to surfaces.

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. 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. CPSC staff recommends that stability tests on bath seats be performed on a slip-resistant surface.

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 where the instructions state the product can be used on slip-resistant surfaces.

Comment: Comment CH 01-5-2 stated "*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 submerges or slips out of the bath seat.*"

Response: The danger of being unable to free a child in a stable, upright seat is only possible if the child can submarine and become entrapped in the seat. The leg opening requirement recommended by CPSC staff and recently added to the ASTM standard should prevent this from occurring.

3. *A False Sense of Security and Parental Absence*

Comment: Several comments (CH 01-5-1; 2; 3; 4; 5; 6; 7; 8) mentioned that caregivers are more likely 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.

Response: 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 injury. However, strengthening the warning on the product may help combat any appearance of safety in bath seats. For this reason, the warning should be as powerfully worded as possible.

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. In addition, some mechanical failures have occurred in the presence of a caregiver.

4. *Utility Age Range*

Comment: Comment CH 01-5-8 questioned the age recommendation of 5 to 10 months for bath seats. The 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: 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, CPSC staff believes 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 time spans.

ASTM recently approved a modification to its standard to include an age recommendation for the product of between 5 and 10 months. In addition, the revised standard also requires packaging and instructions wording as follows: *“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.”* CPSC staff concurs with this recommendation.

5. *Bath Seat Incident Rates*

Comment: Two comments (CH 01-5-1 and 8) stated that the *“...standard has done nothing to slow the bath seat mortality rate.”* and *“... the standard has failed to reduce the numbers of drowning and near drowning incidents...”*

Response: Since the date of manufacture of the bath seats involved in the incidents is not recorded, CPSC staff cannot determine if the bath seat was manufactured prior to the effective date of a particular ASTM standard. However, as noted earlier in this memo, CPSC staff has concerns about the adequacy of the voluntary standard in addressing deaths and incidents associated with bath seats.

E. Adequacy of the Proposed Requirements (Tab A)

The CPSC staff's recommended performance requirements primarily address two of the identified hazard scenarios associated with bath seats. CPSC staff examined each of the fatal and non-fatal incidents related to tip-over and entrapment/submersion and only a few non-fatal incidents were identified that may not be addressed by the recommended performance requirements. If one assumes that future incidents would follow the situations and patterns of the incidents seen in CPSC's data, the provisions of the recommended performance requirements would address approximately 97 percent of tip-over incidents and approximately 95 percent of entrapment and submersion incidents. Details of this analysis can be found in Tab A.

Failure to retain the child within the bath seat is another hazard pattern associated with bath seats. There are no direct performance requirements recommended by staff to address this. Indirect requirements include a recommended stronger warning label to increase caregiver attendance and the potential decrease in occupant retention space due to the leg opening requirements (see Tab C). A smaller occupant retention space could prevent some users from coming out of the bath seat. While both of the indirect requirements may help address the coming out hazard, an effectiveness level has not been ascribed for either one because it is unknown at this time to what extent they may contribute to a reduction in incidents.

F. Option of Banning Bath Seats

In order to consider a ban of all bath seats, the Commission would need to determine the effect that such a ban would have on the number of drowning fatalities associated with bathing infants.

Similar to an analysis presented in the March 2001 briefing package, staff conducted another relative risk analysis and compared bath seat-related deaths to bathtub-related deaths (Tab A). CPSC has complete death certificate data from 1994 through 1998 and 99 percent complete data for 1999. Since CPSC collects all death certificates for bathtub-related deaths, staff believes the CPSC data contains most, if not all, of the U.S. deaths in bathtubs for children under 1 year old. Therefore, the data from 1994 through 1999 were used for the relative risk analysis.

In order to calculate the risk of drowning for this analysis, a user population had to be estimated. Staff used the Baby Products Tracking Study⁷ for data on bath seat ownership to estimate the proportion of parents who owned a bath seat. This proportion was applied to the population of children age 5 to 10 months old during the time period to calculate the number of children who were bathed with a bath seat. Since there is no exposure data for bath seats, staff assumed that the percentage of parents who owned a bath seat was equal to the percentage of parents who used

⁷ *Baby Products Tracking Study 2000: Nursery Décor and Accessories*, conducted for American Baby Group, Bruno and Ridgeway Research Associates, Inc, #5861.

a bath seat. Another assumption associated with the bath seat users was that a parent who owned a bath seat used the bath seat during every bath for the child. The relative risk analysis is presented in Table 3, grouped by age 5 to 7 month-old children and 8 to 10 month-old children, as well as the aggregate data across the intended user population. These groupings were chosen to highlight differences in relative risk seen in sub-groups of the intended user population. A month by month breakdown of the analysis can be found in Tab A.

**Table 3: Relative Risk of Death:
Bath Seat-Related Deaths vs. All Bathtub-Related Deaths,
5- to 10-month-old Children, 1994 through 1999**

Age of Victim	Total Bath Seat Deaths (1994-1999)	Bath Seat Deaths per 10 Million Bath Seat Owners	Total Bathtub Deaths (1994-1999)	Bathtub Deaths per 10 Million Bathtub Users	Bath Seat to Bathtub Relative Risk*
Grouped Data					
5-7 months	21	8.04	24	5.40	1.49
8-10 months	24	7.29	79	20.99	0.35
Aggregate					
5-10 months	45	7.62	103	12.54	0.61

* A relative risk number greater than one implies that children bathed in a bath seat are at a higher risk of drowning than children bathed in a bathtub. A number less than one implies that children in a bathtub are at a higher risk of drowning than children bathed in a bath seat.

The analysis suggests that children ages 5 to 7 months are more at risk of drowning when bathed in a bath seat as opposed to being bathed in a bathtub. Children ages 8 to 10 months, as a group, are at a higher risk of drowning when bathed in a bathtub than when bathed in a bath seat. When children are grouped together across the entire recommended user age group (5-10 months), the data suggest the children are at a higher risk of drowning when in a bathtub than in a bath seat. However, staff does not consider this to be an appropriate way to view the data and believes it may result in a misleading conclusion. Within the 5- to 10-month-old age range, there are distinct and important differences in a child's development and size as they relate to the use of bath seats. Therefore, the aggregate risk analysis masks differences in relative risk when examining the smaller groupings within the age range of the intended user population.

Based on the analysis, CPSC staff cannot measure the effect that a ban would have on bathing-related drownings for the following reasons:

- The analysis suggests that bathing while using a bath seat is riskier for younger bathers, while bathing in bathtubs without using a bath seat is riskier for older bathers.
- Assumptions were made to estimate a bath seat user population for the analysis. The accuracy of the estimates will affect the accuracy of the results.
- The analysis cannot be applied to children outside of the 5 to 10 month age range, and therefore a portion of bathing-related deaths are not addressed by the analysis.

G. Preliminary Regulatory Analysis (Tab G)

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 a proposed rule on small businesses. The National Environmental Policy Act of 1969 also requires the Commission to consider the potential environmental impact of a proposed rule.

This section presents a summary of the bath seat market, the preliminary regulatory analysis and a discussion of the likely effects of a proposed rule on small businesses and the environment. Tab G contains a memorandum from the Directorate for Economic Analysis (EC) with details related to the summary information provided below.

1. Producers and Market Share

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 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 tub/seat, and The First Years, which has a convertible tub/seat. The importer is Juvenile Solutions, which currently imports a bath seat from France.

Bath seats 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 the Baby Products Tracking Study, 2000, Safety 1st is the leading brand of 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.

2. Products in Use

In 2000, JPMA estimated that there may be up to two million bath seats in use. 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 bath seats. 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 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 bath seats may range from 700,000 to 1,000,000 annually. The American Baby Group survey indicated that 46 percent of bath seats owned by new or expectant mothers were borrowed or obtained after being used by an older child. 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 higher, about 1 million annually.

3. *Potential Cost of a Proposed Rule*

If the Commission promulgates a rule requiring bath seats to conform to the stability and leg opening performance requirements and the labeling requirement, the costs to manufacturers would 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 a 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.

Manufacturers report that there will be an increase in the cost of production associated with additional material, labor and shipping costs. 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 redesigned bath seats may be accomplished outside the U.S. due to the increased labor requirements and complexity of the manufacturing process.

In addition to product development costs and increased production costs, revenues may be affected if sales do not match those of existing bath seats. Sales may be reduced because of price increases and possible reductions in the utility of the new, safer bath seats. 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.

4. *Potential Benefits of a Proposed Rule*

The benefits of a proposed rule that contains both performance requirements and the labeling requirement will result from a reduction in deaths and injuries⁸ 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 bath seats in use remained relatively constant at about two million.⁹ Of the 83 reported deaths since 1993, the hazard 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 requirements (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 of 26) might also be addressed by the proposed requirements. 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).

5. *Discussion of Costs and Benefits of a Proposed Rule*

As described above, conformance to the proposed requirements may increase 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. According to *Baby Products Tracking Study*, about half of bath seats are acquired used and therefore are likely to be used for more than one child. If it is assumed that bath seats are used for an average of about two years (i.e. two use cycles), 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 and entrapment/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.¹⁰ Thus, for purposes of cost-benefit analysis, even

⁸ 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.

⁹ 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.

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

the high estimates of the cost per life saved are within the generally 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.

6. *Discussion of Costs and Benefits of a Proposed Rule with Two Requirements*

The Commission could decide to promulgate a subset of the three proposed 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 requirements to prevent entrapment and submersion, 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 entrapment and submersion hazard. The Commission may determine that the voluntary standard is adequate to address this hazard and that a high level of conformance can be expected. As discussed in Tab G, the elimination of the leg opening requirement from a proposed mandatory rule would have, at most, a very small impact on the overall cost of the proposed rule as well as its potential benefits.

7. *Discussion of Costs and Benefits for a Ban of Bath Seats*

A ban to eliminate bath seats from the marketplace entirely would result in costs associated with the lost use value, or utility, that consumers derive from the product. Money not spent on bath seats might be spent on other products that provide utility, but there is expected to be some loss in utility that cannot be quantitatively estimated.

The benefits of a ban of bath seats from the marketplace would be the net reduction in child drowning deaths that would result. However, such benefits (if any) are unclear. While a ban would eliminate drownings involving bath seats, it would also expose those children who would have been bathed in a bath seat to drowning risks in alternative bathing settings. According to the relative risk analysis, staff cannot determine whether a ban would reduce the number of children who drown in bathtubs, with or without bathing aids.

8. *Initial Regulatory Flexibility and Environmental Analyses*

No available information indicates that the proposed 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 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 bath seats to meet the staff's recommended performance requirements. The third firm, an importer, may have to find another source for bath seats that would meet a rule, if it is enacted.

The transition to bath seats that meet the draft recommended requirements 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.

H. Proposed Effective Date

If the Commission votes to instruct the Office of the General Counsel (OGC) to draft an NPR, CPSC staff recommends a proposed effective date for the mandatory rule of one year after the final rule is published in the Federal Register. At this time, the two U.S. manufacturers are aware of the staff's recommended requirements. Staff is also aware that at least one manufacturer has already begun product development on a bath seat to meet the draft proposed requirements, thus one year should allow sufficient time for the manufacturers to develop a product that meets the requirements of a rule.

IV. OPTIONS

The options available to the Commission include deferring action, terminating rulemaking, or initiating a notice of proposed rulemaking (NPR) that either bans bath seats or proposes a mandatory rule with specified requirements. Each of these options is presented below.

1) Defer Action - If the Commission believes there is insufficient information to make a decision, it can defer action at this time, and instruct the staff to gather more data and/or continue working with ASTM to develop an adequate voluntary standard.

2) Terminate Rulemaking - If the Commission believes that available information does not indicate that a mandatory rule is necessary to address an unreasonable risk of injury, or that the recently approved ASTM standard on bath seats is adequate to address the hazards outlined in this briefing package, it can terminate the rulemaking.

3) Initiate NPR for a Ban of Baby Bath Seats - If the Commission believes there is an unreasonable risk of injury and that bath seats cannot be made safer with a mandatory rule or a voluntary standard, it can instruct OGC to draft an NPR to ban all baby bath seats.

4) Initiate NPR with all Three Requirements for a Proposed Mandatory Rule - If the Commission believes that the recently approved ASTM voluntary standard for bath seats does not adequately address the tip-over and coming out hazards outlined in this briefing package, and that it cannot determine the level of likely conformance to the new leg opening requirement, it can instruct OGC to draft an NPR containing performance requirements to address tip-over and entrapment/submersion hazards and a labeling requirement to help address coming out hazards as presented in this briefing package.

5) Initiate NPR with Two Requirements for a Proposed Mandatory Rule - If the Commission believes that the recently approved ASTM voluntary standard for bath seats does not adequately address the tip-over and coming out hazards outlined in this briefing package but believes there will be high likelihood of substantial conformance with the new leg opening requirement, it can instruct OGC to draft an NPR that contains a performance requirement to address the tip-over hazard and a labeling requirement to help address the coming out hazard as presented in this briefing package.

V. DISCUSSION OF OPTIONS & STAFF RECOMMENDATION

CPSC staff recommends that the Commission proceed with the rulemaking process for baby bath seats by instructing OGC to draft a notice of proposed rulemaking incorporating the stability performance requirement, the leg opening performance requirement and the labeling requirement as set forth in this briefing package. ASTM has recently revised the voluntary standard to include the leg opening requirement to address the entrapment and submersion hazards. If the leg opening requirement is included in the proposed rule, the Commission would have an opportunity to determine what level of compliance is likely with the voluntary standard before it determines whether it is necessary to include the provision in a final rule.

The Commission could decide to defer taking action in order to assess further progress with the voluntary standard. Staff does not recommend this option because past ASTM subcommittee actions have shown that the time between identifying a need for a requirement and inclusion into an ASTM standard can sometimes take several years. If the Commission decides to defer action or terminate rulemaking, bath seats that are potentially hazardous will continue to be manufactured and sold in the US.

CPSC staff does not support a ban of bath seats. Staff has developed proposed performance requirements that address most of the incidents involving tip-over and entrapment/submersions. In addition, staff recommends a forceful warning label to help draw attention to the hazards that can result when caregivers leave children unattended. A ban of bath seats from the marketplace would result in some reduction in consumer utility, and there is no means to predict the effect that a ban of bath seats would have on the fatality rate associated with infant drownings. Staff believes that making bath seats safer should result in a reduction in fatalities.

TAB A



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: April 8, 2003

TO : Patricia Hackett, Project Manager
Division of Mechanical Engineering

THROUGH: Sue Ahmed, Associate Executive Director *SA*
Directorate for Epidemiology
Russ Roegner, Division Director *RR*
Division of Hazard Analysis

FROM : Debra Sweet, *dls*
Division of Hazard Analysis

SUBJECT : Hazard Analysis Memorandum for Bath Seat NPR Briefing Package

This memorandum provides updated incident data on baby bath seats. Information was obtained from the following U.S. Consumer Product Safety Commission (CPSC) databases: the Injury and Potential Injury Incident file (IPII), the In-Depth Investigation file (INDP), the Death Certificate file (DTHS), and the National Electronic Injury Surveillance System (NEISS). These data are anecdotal and should not be used to project national estimates. DTHS is not complete for 1999 through 2002.

I. REVISIONS TO PREVIOUS BRIEFING PACKAGE

The memorandum included in the March 2001 briefing package detailed 69 bath seat-related drowning deaths and 95 non-fatal incidents and complaints of potential drowning.¹ After gathering more information, some of the characteristics of the incidents were reclassified. The information below reflects the changes made within the 69 fatal incidents and 95 non-fatal incidents.

A. Changes in Fatal Incidents

One fatal drowning incident included in the previous briefing package was under investigation at the time the memorandum was written. Table 1 shows the changes in classification for document number 001020CBB2042.

¹ "Petition No. HP00-4, Request to Ban Baby Bath Seats." Jacqueline Elder, U.S. Consumer Product Safety Commission, Office of Hazard Identification and Reduction. March 2001.

Table 1.
Changes in Incident 001020CBB2042

	Old Classification	New Classification
Supervision	No	No
Caregiver	Parent	Parent
Water Depth	Unknown	7 inches
Victim Age	10 months	10 months
Other Children in Bathtub	No	Yes
Manufacturer	Safety 1 st	Safety 1 st
Hazard Scenario	Unknown	Child in water, seat position unknown

Taking these changes into account, the number of children supervised at the time of the drowning, the caregiver that was present for the bath, the median water depth at the time of the incident, the mode of the victims' ages, and the manufacturer distribution did not change from those discussed in the previous briefing package. The number of other children present at some time during the bath increased from 26 incidents to 27. The number of children reported as found in the water with the position of the bath seat unknown increased from 16 to 17 (thus dropping the number of unknown scenarios from 5 to 4).

After reviewing the fatal drowning incidents, one was found to be mis-classified in the previous briefing package. One incident, document number 941104CBB1051 was classified as a tip-over incident; however, upon further review, the incident should have been classified as a child who was found slumped over in the seat. The fatal tip-over incidents included in the previous briefing package should equal 21 (was 22) and the number of fatal slumped over cases should equal 9 (was 8) incidents.

B. Changes in Non-Fatal Incidents and Complaints

Nine non-fatal incidents and complaints of potential drowning incidents were reviewed and reclassified since the previous briefing package. Table 2 details the nine incidents and the characteristic that was changed.

Table 2.
Changes in Non-Fatal Incidents and Complaints

Document Number	Old Classification	New Classification
H89A0098A	Entrapment/submersion	Tip-over
H89B0032A	Break	Child came out of seat
X90A0146A	Break	Unknown
930106CWE4000	Break	Tip-over
NEISS 9/27/96	Child in water, seat position unknown	Unknown
970122CEP9009	Tip-over	Child in water, seat position unknown
990413CCC3293	Entrapment/submersion	Break
990922CEP9005	Child in water, seat position unknown	Case was completely removed from count.
NEISS 12/29/99	Unknown	Child in water, seat position unknown

II. UPDATE OF BATH SEAT DEATHS

CPSC is aware of 96 deaths in the U.S. from January 1983 through December 2002 resulting from infants drowning while using a baby bath seat.² The previous briefing package cited 69 drowning deaths involving bath seats in the U.S. from January 1983 through November 2000. This memorandum provides details on the 27 incidents that have been reported to the Commission since the previous briefing package. These 27 fatal incidents occurred from 1996 through 2002.

A. Supervision by Caregiver

All of the 27 drowning deaths occurred while the caregiver left the child unattended in the bathroom. Some reasons for leaving the child unattended were unexpected phone calls, retrieving towels, or to tend to another child in the home. Some caregivers left the victims unattended for more deliberate reasons such as performing household chores or watching television.

B. Caregiver

The children who died in the bath seat-related drowning incidents were being cared for predominately by parents, but also by baby sitters. Twenty-four of the victims were under the care of one or both of their parents. The remaining three children died while under the supervision of a baby sitter - all were adult, extended family members.

² Appendix B contains the distribution of the deaths by the age of the victim.

C. Water Depth

The water depth was reported numerically (or as an overflow) in 15 incidents. The minimum water depth in these reports was three inches and the maximum was an overflowing bathtub. The median reported water depth was 7 inches. Two reports of water depth were given as fractions of the tub height, but these were not included in the calculation of the median since bathtub heights vary. The remaining ten incidents do not have a recorded water depth at the time of the incident.

D. Victim Age

The victims involved in these 27 fatal drowning incidents with bath seats ranged in age from 5 months old to 14 months old. The age of the victims most frequently involved in these incidents was 7 months (9 children). Staff's assessment of the appropriate age range of bath seat users is 5 to 10 months old. Twenty-three of the 27 victims were in this age range of users.

E. Other Children in Bathtub

Thirteen of the 27 victims were put into the bathtub with another young child. In ten of these 13 incidents, the sibling was in the bathtub with the victim for the duration of the bath. In one of the ten incidents, the caregiver returned to find the sibling pulling on the victim's arm and heard the sibling telling the victim to "get up." In the eleventh incident, the caregiver took the sibling out of the tub, leaving the victim in the bathtub alone and unattended. In the twelfth and thirteenth incidents, the siblings got out of the bathtubs while the caregivers were out of the rooms, leaving the children alone and unattended. There were no siblings present at any time of the bath in the remaining 14 incidents.

F. Manufacturer Information

Four different manufacturers' products were involved in 19 of the 27 incidents. The manufacturer information was unknown in the remaining eight incidents. The majority of the products in these incidents were manufactured by Safety 1st, the producer of the majority of bath seats. Table 3 shows the breakdown of deaths by manufacturer and year.

Table 3.
Bath Seat Deaths: Product Manufacturer by Year of Incident

Manufacturer	1996	1998	1999	2000	2001	2002	Total
Safety 1 st , Inc.			1	3	6	2	12
Fisher-Price					1		1
Gerry Baby Products	1		2	1	1		5
The First Years, Inc.					1		1
Unknown		1	1	2	1	3	8
Total	1	1	4	6	10	5	27

Source: CPSC incident reports and in-depth investigations.

III. BATH SEAT DEATHS, INCIDENTS, AND COMPLAINTS BY SCENARIO

The hazard scenarios associated with bath seat deaths and injuries can be grouped into three areas: 1) those that involved problems with the bath seat 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 are unknown or uncertain.

The deaths reported in the following sections are the same 27 mentioned previously. In addition to the deaths, there have been 59 non-fatal incidents involving bath seats reported to the Commission since the previous briefing package. Not all reports of non-fatal incidents or complaints resulted in injury. The complaints are often associated with unknown ages of victims and unknown caregiver supervision.

Table 4 is a breakdown of the hazard scenarios seen in the newly reported cases and the number of deaths and non-fatal incidents associated with the scenarios. Appendix A is a table of deaths by hazard scenario and the year of the death.

Table 4.
Bath Seat Deaths and Non-Fatal Incidents by Hazard Scenario
(Reported since March 2001 Briefing Package)

Hazard Scenario	Age Range Of All Victims	Fatalities	Non-Fatal Incidents and Complaints	Total Number of Updated Incidents
Problems with the Bath Seat Design and Materials				
Tip-Over	4-14 months	9	29	38
Children Coming Out of the Bath Seat	6-12 months	8	6	14
Entrapment and Submersion	6-10 months	0	4	4
Bath Seat Breaking	4-15 months	0	12	12
Bath Seat Remained Upright and Retained Child				
Children Slumped Over	14 months	1	0	1
Overflowing Bathtub	2-8 months	2	1	3
Deaths and Injuries with Some Unknown Circumstances				
Children Found in Water; Bath Seat Position Unknown	5-11 months	7	4	11
Bath Seat Upright; Child Position Unknown	No incidents of this scenario in update.			
Unknown or Uncertain Circumstances	8-17 months	0	3	3
Total Incidents	2-17 months	27	59	86

A. Problems with the Bath Seat Design and Materials

Hazard scenarios associated with the design and materials problems of the bath seat include cases in which 1) the bath seat tipped over submerging the occupant in the water or allowing the child to escape the confines of the seat; 2) the occupant was found outside of the bath seat, presumably by coming over the top of the bath seat and the bath seat remained upright; 3) the bath seat remained upright and the occupant became entrapped in the bath seat; and 4) the bath seat broke and could have led to subsequent tip-over, child coming out of the seat or entrapment if the incident was not discovered in time.

1. Tip-overs

Table 5.
Tip-over Incidents
(Reported since March 2001 Briefing Package)

		Fatalities	Non-Fatal Incidents and Complaints	Total Number of Updated Incidents
Total Incidents		9	29	38
Supervision	Supervised	0	22	22
	Unsupervised	9	3	12
	Unknown	0	4	4
Median Water Depth		4 inches	Unknown	Unknown
Age Range of Victims		5-8 months	4-14 months	4-14 months
Sibling in Bathtub		2	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations.

a. Fatalities

Since the March 2001 briefing package, the Commission has received reports of nine drowning deaths that resulted from a bath seat that tipped over while the occupant was seated in the product. All of the incidents occurred while the caregiver left the child unattended in the bathroom.

The median reported water depth was four inches. The victims ranged in age from 5 months old to 8 months old. Safety 1st bath seats were involved in five of the nine incidents, The First Years' bath seat was involved in one incident, and the manufacturers of the remaining three products are unknown.

A sibling was in the bathtub with the victim in two of the tip-over drowning deaths. Both siblings were in the bathtub throughout the bath and are not believed to have been involved in the tipping of the bath seats.

b. Non-Fatal Incidents and Complaints

Since the previous briefing package, the Commission has received reports of 29 non-fatal incidents of bath seats tipping over or the suction cups releasing, creating the potential for tip-over. Twenty-two of the incidents occurred when the caregiver was present and bathing the child. Three incidents occurred while the child was unattended. The attendance of the caregiver at the time of the four remaining incidents is unknown. The children ranged in age from 4 months old to 14 months old.

c. Total Number of Updated Incidents

Combining fatal and non-fatal bath seat tip-overs reported since the 2001 briefing package, there have been 38 bath seat tip-overs. Twelve incidents occurred without the presence of a caregiver, resulting in nine deaths. Twenty-two children were supervised during the incident. Caregiver supervision is unknown in the remaining four incidents. These data show that bath seat tip-over incidents can occur regardless of the caregiver supervision at the time of the incident.

2. Children Coming Out of the Bath Seat

**Table 6.
Incidents with Children Coming Out of the Bath Seat
(Reported since March 2001 Briefing Package)**

		Fatalities	Non-Fatal Incidents and Complaints	Total Number of Updated Incidents
Total Incidents		8	6	14
Supervision	Supervised	0	2	2
	Unsupervised	8	3	11
	Unknown	0	1	1
Median Water Depth		7 inches	Unknown	Unknown
Age Range of Victims		6-12 months	7-11 months	6-12 months
Sibling in Bathtub		5	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations.

a. Fatalities

The Commission received reports of eight children who drowned when they came out of the bath seat. The children were found out of the bath seat floating in the bath water and the bath seat was still in its upright position. Staff believes these incidents occurred when the child flipped or floated over the top of the bath seat and into the open bath water. The scenario suggests the inability of the bath seat to restrain the child in the seat. All of the children were unattended when the incidents occurred.

The median reported water depth in these eight drowning deaths is seven inches. The children who died after coming out of the bath seat ranged in age from 6 months old to 12 months old.

Gerry Baby Products' bath seats were involved in four incidents in which the child came out of the bath seat. Safety 1st made three of the eight bath seats involved in the incidents and Fisher Price made one of the bath seats involved in these deaths.

In five incidents, a sibling was in the bathtub with the victim during the entire bath. One of these children was heard saying, "get up," to the victim and, upon re-entering the bathroom, the caregiver saw the sibling pulling on the victim's arm. The other four siblings are not believed

to have been involved in the incidents. One of these four children screamed, which caused the mother to return to the bathroom.

b. Non-Fatal Incidents and Complaints

Since the previous briefing package, CPSC has received reports of six other children who came out of the bath seat. Of the six incidents, two occurred when the caregiver was present, three were when the child was unattended, and the supervision is unknown in the last incident. The children were 7 to 11 months old - approaching, or at the age, where a child can pull himself to a standing position. In the two supervised incidents, it was noted that the child was attempting to stand, or stood up, in the bath seat.

c. Total Number of Updated Incidents

There have been a total of 14 children who came out of the bath seat, as reported to the Commission since the March 2001 briefing package. Eleven of the children were left unattended in the bathtub when the incident occurred, two were being supervised, and the caregiver-attendance of the last is unknown. Eight of the 11 unsupervised incidents resulted in death.

3. Entrapment and Submersion

CPSC received reports of four non-fatal incidents of entrapment and submersion in bath seats since the previous briefing package. A caregiver was present in two of the incidents. In one of the two supervised incidents, the caregiver stated that the 6-month-old victim's shoulder became wedged inside the bath seat. In the second of the supervised incidents, the 10-month-old victim's body slid entirely through one leg opening submerging the child in the water. Supervision in the remaining two incidents is unknown. These two cases involved a 7 and a 9-month-old child who slipped through a leg hole and became stuck.

4. Bath Seat Breaking During Use

Since the May 2001 briefing package, 12 complaints were reported to CPSC, in which the bath seat broke, but did not result in a tip-over or submersion.

Three incidents involved Gerry Baby Products' bath seats that broke when the side arm of the product detached from the base of the bath seat. This attachment is a plastic pin that fits from the side arm to the base. The victims leaned against the side arms and the pins dislodged, allowing the children to slide out. Two other incidents also involved attachment points on Gerry Baby Products' bath seats. In these incidents, the screw that secures the t-bar (crotch bar) to the base of the seat was stripped or loosened. The t-bar then released from the base of the seat and became ineffective. One other incident involved a t-bar that broke apart from the bottom of the bath seat on a The First Years bath seat.

In four incidents, the ring of the bath seat broke away from the pillars (or legs) of the seat. The manufacturers of these bath seats were Safety 1st (2), Sanitoy (1), and an unknown manufacturer. In one incident, the caregiver stated that the bottom of the seat fell out and the victim fell in the water. In the final report, the caregiver stated that the bath seat broke during use.

The children involved in these incidents ranged in age from 4 to 15 months old. Nine of the incidents occurred when the caregiver was present. Supervision remains unknown in the remaining three incidents.

B. Bath Seat Remained Upright and Retained Child

1. Children Slumped Over

Since the last briefing package, the Commission has received one report of a child who drowned in the bathtub while staying seated in an upright bath seat. A 14-month-old child was placed in the bath seat by his father and enjoyed playing with cups in the bathtub. The father left the child to retrieve a towel and returned to find the victim slumped over in the seat with a cup in his hand. There was no statement as to whether the child's face was in the water and it is unknown if the water from the cup was involved in the death or if the child fell face-first into the water. The water was reported to have been seven inches deep.

2. Overflowing Bathtubs

a. Fatalities

The Commission has reports of two children who drowned after being placed in a bath seat and the water overflowed the bathtub. A 7-month-old victim was seated in a Gerry Baby Products bath seat and was placed in the tub with an older sibling. The mother removed the sibling from the bath and dressed the sibling. The sibling returned to the bathroom and the mother started to talk on the telephone. It is believed that the sibling turned the water on in the bathtub when she returned to the bathroom. The mother returned to find the water at the top of the tub and the victim drowned.

In the second incident, the mother placed the 8-month-old victim into the tub with a sibling and went outside to talk with a neighbor. The sibling was standing in the tub and is not reported to have been injured. The victim was found out of the seat and the water was overflowing the tub.

b. Non-fatal Incidents and Complaints

CPSC received one report of a near-drowning incident from an overflowing bathtub. The caregiver left the child unattended in a bath seat, with the water running in the bathtub, to check on other children. Upon return, the caregiver found the 2-month-old victim at the bottom of the bathtub. The child was admitted to the hospital for several days and survived.

c. Total Number of Updated Incidents

The Commission received three reports of overflowing bathtubs with bath seats since the March 2001 briefing package. All of the children were unsupervised in the bathtub. Only one of the children survived the incident.

C. Deaths and Injuries with Some Unknown Circumstances

1. Children Were Found in the Water and the Bath Seat Position was Unknown

**Table 7.
Incidents in which Children were Found in the Water and
the Bath Seat Position was Unknown
(Reported since March 2001 Briefing Package)**

		Fatalities	Non-Fatal Incidents and Complaints	Total Number of Updated Incidents
Total Incidents		7	4	11
Supervision	Supervised	0	1	1
	Unsupervised	7	3	10
	Unknown	0	0	0
Median Water Depth		Unknown	Unknown	Unknown
Age Range of Victims		7-11 months	5-11 months	5-11 months
Sibling in Bathtub		4	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations.

a. Fatalities

In seven deaths reported to the Commission since the previous briefing package, the child was reported to have been found in the water, but the position of the bath seat and the relationship of the bath seat and the child were unknown. It cannot be determined how the incidents occurred and specifically how much of the child or what part of the child was in the water. All of the children were left unattended in the bathtub at the time of the incident.

The reported water depth ranged from four inches to three-quarters full. The children ranged in age from 7 months to 11 months old.

In four of the seven fatal incidents, a sibling was in the bathtub with the victim at the start of the bath. In one incident, the sibling got out of the tub, unplugged the drain and left the water running with the victim in the tub. The report states that another sibling re-plugged the drain. It is unknown if these actions played a role in the drowning. The water depth was not reported. The caregiver was out of the residence for 45 minutes. In another incident with a sibling, the sibling got out of the tub and told the mother that the victim was sleeping. The siblings in the remaining two incidents remained in the tub the entire bath. They are not believed to be involved in the incidents.

b. Non-Fatal Incidents and Complaints

Since the previous briefing package, there have been four reports of non-fatal incidents in which the child was found in the water, but the position of the seat was not reported. The caregivers were not present during three of these incidents. The caregivers reported that they

returned to the bathrooms to find the victims face down in the water. In the fourth incident, the caregiver was present and reported that the child had fallen face first into the water. It is unknown if the child tipped over in the bath seat or if the child came out of the seat. The children were between 5 months old and 11 months old.

c. Total Number of Updated Incidents

Combining the fatal and non-fatal incidents reported since the March 2001 briefing package in which the children were stated as found in the water and the seat position was not stated produces 11 incidents. Ten of the children were left unattended in these incidents and seven resulted in deaths.

2. Unknown or Uncertain Situations

Since the March 2001 briefing package, the Commission has received reports of three potential drowning incidents but the information about the incidents remains unknown. The victims ranged in age from 8 months old to 17 months old.

Two of the children were described as having submerged in the bathtub, after having been placed in the bath seat. One of the children was not supervised and it is unknown if the other child was supervised at the time. In the third incident, the report states that the child fell out and hit his face on the tub. Supervision is unknown in this incident, also.

IV. BATHTUB DEATHS FROM 1994 THROUGH 1999

Similar to the analysis from the March 2001 briefing package, staff compared bath seat-related deaths to bathtub-related deaths. CPSC has complete death certificate data from 1994 through 1998 and 99% complete data for 1999. Since CPSC collects all death certificate data for bathtub-related deaths, staff believes the CPSC data contains most, if not all, of the U.S. deaths in bathtubs for children under 1 year old.

For comparison of bathtub-related deaths to bath seat-related deaths, staff narrowed the focus only to bathtub deaths by drowning in which the victim was placed in the bathtub for the purpose of taking a bath. This eliminated incidents in which the victim climbed or fell into a bathtub, another sibling placed the child in the bathtub, and scalding incidents. The recommended age of bath seat users is 5 to 10 months old, thus this was the age range for the analyses. Two analyses were performed for this briefing package. The methodology for each analysis is described below with the respective results. Since the results are similar for the two analyses, the conclusion is stated after both results are discussed.

The analysis included in the 2001 briefing package addressed questions raised about the risk of drowning while using a bath seat compared to the risk of drowning while in an adult bathtub *without* a bathing aid. Therefore, drowning deaths involving children 5 to 10 months old in which a child was using a bathing aid were excluded from the number of drowning deaths associated with bathtubs only. Statements describing this methodology were included in the previous briefing memoranda.

To update this analysis, staff reviewed incident data to find the number of children age 5 to 10 months old who drowned while bathed in a tub with a bath seat from 1994 through 1999. Staff also found the number of children who drowned while in a bathtub when no other bathing

aid was being used. Staff is aware of 45 children age 5 to 10 months old who drowned while in bath seats and 90 children age 5 to 10 months old who died while in a tub without an additional bathing aid.

In order to calculate the risk of drowning for this analysis, a user population had to be estimated. Staff used the Baby Products Tracking Study for data on the proportion of parents who owned a bath seat.³ This proportion was applied to the population of children age 5 to 10 months old during the time period to calculate the number of children who were bathed with a bath seat. These figures can be found in Appendix C. Since there is no exposure data for bath seats, staff assumed a direct relationship between ownership and usage. Therefore, the percentage of parents who owned a bath seat equaled the percentage of parents who used a bath seat. Another assumption associated with the bath seat users was that a parent who owned a bath seat used the bath seat during every bath for the child.

The user population for non-bath seat owners was calculated in a similar manner. Since a percentage of parents reported owning a bath seat in the Baby Products Tracking Study, the remaining percentage (1.0 – percentage of bath seat owners) of parents was believed to not own a bath seat. While we know that there is a small percentage of 5- to 10-month-old children bathed in a bathtub with other bathing aids, there was no information available to measure this percentage. For this reason, staff did not subtract this percentage of the population of “other bathing aid” users from the non-bath seat owners. The percentage of non-bath seat owners was applied to the population of children age 5 to 10 months old to calculate the number of children bathed in a bathtub without a bath seat or any other additional bathing aid. An assumption was that the non-bath seat owners always bathed their children in a bathtub without an additional bathing aid.

Table 8 is an updated risk analysis that is consistent with the analysis performed in the 2001 briefing package. The relative risk analysis is presented for each month of age, grouped by the younger children and older children, and for the entire age group of recommended users. A relative risk number greater than one implies that children bathed in a bath seat are at a higher risk of drowning than children bathed in a bathtub without any bathing aids and a number less than one implies that children in a bathtub without an additional aid are at a higher risk of drowning than children bathed with a baby bath seat.

³ *Baby Products Tracking Study 2000: Nursery Decor and Accessories*, conducted for American Baby Group, Bruno and Ridgeway Research Associates, Inc., #5861.

Table 8.
Relative Risk of Death:
Bath Seats-Related Deaths Versus Bathtubs-Related Deaths Without Bathing Aids,
5- to 10-month-old Children, 1994 through 1999

Age of Victim	Total Bath Seat Deaths (1994-1999)	Bath Seat Deaths per 10 Million Bath Seat Owners	Total Bathtub Deaths, w/o Bathing Aids (1994-1999)	Bathtub Deaths per 10 Million Non-Bath Seat Owners	Bath Seat to Bathtub Relative Risk
5 months	4	6.54	2	1.15	5.69
6 months	4	4.15	6	4.32	0.96
7 months	13	12.56	8	6.07	2.07
8 months	8	7.73	22	16.70	0.46
9 months	11	8.99	20	17.71	0.51
10 months	5	4.83	32	24.29	0.20
Grouped Data					
5-7 months	21	8.04	16	3.60	2.23
8-10 months	24	7.29	74	19.66	0.37
Aggregate					
5-10 months	45	7.62	90	10.96	0.70

A second analysis was performed for this briefing package that includes drowning deaths in a bathtub *involving* other bathing aids such as bathinettes or baby bath tubs, pool flotation toys, and an infant carrier (observed fatal drowning-related products during this time period). This addresses questions about the risk of drowning while using a bath seat compared to the risk of drowning while not using a bath seat.

While reviewing the bathtub drowning incident data for 1994 through 1999, staff also identified incidents in which a child drowned in a bathtub while using a bathing aid. Therefore, 13 children who drowned while using another type of bathing aid were added to the number of children who drowned in a bathtub without an additional bathing aid. The number of fatalities used in this analysis are 45 children who died while using a bath seat and 103 children who died in a bathtub regardless of whether an additional bathing aid was used.

The same calculations were used for the number of children who used a bath seat during the 1994 through 1999 period as were made for the first analysis. Again, the percentage of parents who owned a bath seat from the Baby Products Tracking Study was applied to the population of children 5 to 10 months old. The direct relationship of ownership and usage was assumed, as was the assumption that a parent who owns a bath seat uses it during every bath.

The non-bath seat user population was calculated in this analysis the same way as it was in the previous analysis. The percentage of parents who reported not owning a bath seat was applied to the population of children age 5 to 10 months old. Recall in the previous analysis, the calculated population of non-bath seat owners was slightly larger than it should have been because staff could not measure the number of parents who bathe their children in the tub with additional bathing aids. So the parents who bathed their children with other aids were included in the population but the number of deaths with other bathing aids was not included in the death data. During this analysis, the number of deaths used in relation to this population *does* include those involving other bathing aids. As assumed previously, the parents who did not own bath seats were assumed to always bath their child without a bath seat.

Table 9 contains the data for this analysis. The relative risk analysis is presented for each month of age, grouped by the younger children and older children, and for the entire age group of recommended users. A relative risk number greater than one implies that children bathed in a bath seat are at a higher risk of drowning than children bathed in a bathtub without a bath seat and a number less than one implies that children in a bathtub without a bath seat are at a higher risk of drowning than children bathed with a baby bath seat.

Table 9.
Relative Risk of Death:
Bath Seats-Related Deaths Versus All Bathtubs-Related Deaths,
5- to 10-month-old Children, 1994 through 1999

Age of Victim	Total Bath Seat Deaths (1994-1999)	Bath Seat Deaths per 10 Million Bath Seat Owners	Total Bathtub Deaths (1994-1999)	Bathtub Deaths per 10 Million Bathtub Users	Bath Seat to Bathtub Relative Risk
5 months	4	6.54	4	2.30	2.85
6 months	4	4.15	11	7.92	0.52
7 months	13	12.56	9	6.83	1.84
8 months	8	7.73	25	18.98	0.41
9 months	11	8.99	22	19.48	0.46
10 months	5	4.83	32	24.29	0.20
Grouped Data					
5-7 months	21	8.04	24	5.40	1.49
8-10 months	24	7.29	79	20.99	0.35
Aggregate					
5-10 months	45	7.62	103	12.54	0.61

The two tables show similar patterns for the relative risk ratios. Thus the conclusions are the same, regardless of which analysis is used. As shown in the "Grouped Data," the average relative risk of drowning for children ages 5 to 7 months is slightly higher when bathed in a bath seat as opposed to being bathed in a bathtub with or without other bathing aids. Children ages 8 to 10 months are at a higher risk of drowning when bathed in a bathtub than when bathed in a bath seat. Grouping children together across the entire recommended user age group, the data suggest that children are at a higher risk of drowning when in a bathtub than in a bathtub with a bath seat. However, staff does not feel this is an appropriate way to view the data and leads to a misleading conclusion. Within the 5 to 10 month old age range, there are distinct and important differences in a child's development and size as they relate to the use of bath seats. Therefore, the aggregate risk analysis masks the differences in risk observed through the different ages of the children.

The death data together with the data on non-fatal incidents revealed some hazards where design modifications may be needed. The proposed performance requirement would reduce, if not eliminate, incidents of tip-over, submarining, and entrapment; thus reducing the number of fatal bath seat-related incidents.

V. OPTION OF BANNING BATH SEATS

Staff does not feel that there is a feasible means by which to calculate the effect that a ban of bath seats will have on reducing drowning fatalities associated with bathing babies.

As previously stated, we made the assumption that ownership equaled usage of bath seats for 5 to 10 month old children. However, this assumption does not hold for older children and is necessary to compare the risk of drowning in bath seats and without any bathing aids for all children. The ownership function is a cumulative function in that as the child ages, the parent may still own the bath seat. In other words, the parent of a 15-month-old child may still own a bath seat that the child used at 7 months old, but does not use currently. The data show that 50% of the mothers with children over 12 months own a bath seat. Based on our original assumption, this would assume that the 50% of mothers of children over 12 months that own a bath seat still use the bath seat and staff does not believe this is true. Because the assumption does not hold, staff cannot calculate a population of bath seat users for this older age group and thus cannot perform a comprehensive risk analysis.

Staff also investigated the possibility of using the risk analysis for 5- to 10-month-old children to calculate the effect of a ban. In order to calculate the number of children 5 to 10 months old at risk of drowning in a bathtub had the bath seat not been available, staff would have to assume that the behavior of parents who did not own bath seats is the same as those parents that own bath seats. Staff does not feel this is an appropriate assumption to make, since we do not know if the parent would have left the child unsupervised had the bath seat not been there to help support the child.

VI. RESPONSE TO PUBLIC COMMENTS

CPSC received 10 public comments in response to the August 1, 2001 Federal Register notice for an Advanced Notice of Proposed Rulemaking (ANPR) on baby bath seats.

Comment: Seven of the comments (CH 01-5-1; 2; 3; 3a; 5; 6; 7) reference 78 deaths and 110 non-fatal incidents reported to the Commission from January 1983 through May 2001.

Response: The incident data for deaths and incidents was updated for the public Commission Briefing on May 23, 2001 and published in the Federal Register. The March 2001 briefing package discussed information on incident data reported through March 2001 (69 deaths and 95 non-fatal incidents and complaints), whereas the Federal Register discussed incident data reported through May 2001 (78 deaths and 110 non-fatal incidents and complaints). The references to incident data in the aforementioned public comments are correct, as quoted from the Federal Register.

This memorandum for the Notice of Proposed Rulemaking updates the incident data from the March 2001 briefing package, thus the reference to 69 deaths and 95 non-fatal incidents and complaints.

Comment: The following statements were taken from two comments (CH 01-5-1; 8) submitted after the ANPR. "... standard has done nothing to slow the bath seat mortality rate." "... standard has failed to reduce the numbers of drowning and near drowning incidents..."

Response: Since the date of manufacture of the bath seats involved in the incidents is not recorded, CPSC staff cannot determine if the bath seat was manufactured prior to the effective date of a particular version of the ASTM standard.

Comment: **Public comment CH 01-5-4 stated "... drowning is the leading cause of unintentional injury-related death among children ages 1 to 4..." as rationale for the National Safe Kids Campaign's support of a mandatory standard for baby bath seats.**

Response: According to the 2001 Edition of the National Safety Council's *Injury Facts*, drowning is the second leading cause of unintentional injury-related deaths among children ages 1 to 4. However, bath seats are not intended for children of this age group. As mentioned previously, bath seats are intended for children age 5 months to 10 months. Therefore, the appropriate injury fact to convey would be that drowning is the fourth leading cause of unintentional injury-related deaths to children under 1 year old (2001 *Injury Facts*).

VII. POTENTIAL ADEQUACY OF RECOMMENDED PERFORMANCE REQUIREMENTS

The recommended performance requirements for baby bath seats primarily address two of the identified hazard scenarios associated with bath seats. Table 10 shows the different hazard scenarios associated with fatal drowning incidents and non-fatal incidents and complaints of potential drowning situations with bath seats. The data includes all drowning, or potential drowning, incidents reported to the Commission from January 1983 through December 2002.

Table 10.
Hazard Scenarios Associated with Bath Seats
January 1983 through December 2002

Hazard Scenario	Fatalities	Non-Fatal Incidents and Complaints
Problems with the Bath Seat Design and Materials		
Tip-Over	30	80
Children Coming Out of the Bath Seat	19	13
Entrapment and Submersion	3	17
Bath Seat Breaking	0	17
Bath Seat Remained Upright and Retained Child		
Children Slumped Over	10	2
Overflowing Bathtub	4	1
Total of Known Scenarios	66	130
Deaths and Injuries with Some Unknown Circumstances		
Children Found in Water; Bath Seat Position Unknown	24	9
Bath Seat Upright; Child Position Unknown	2	0
Unknown or Uncertain Circumstances	4	14
Total of Unknown Scenarios	30	23
TOTAL INCIDENTS	96	153

The first hazard scenario that the recommended performance requirements address is bath seat tip-overs. From January 1983 through December 2002, CPSC has received reports of 30 children who have died in the bathtub when the bath seat they were seated in tipped over. During the same time period, the Commission has received reports of 80 additional tip-over, or potential tip-over (when the suction cups release presenting the opportunity for tip-over) incidents in which the child did not drown.

The recommended performance requirements strengthen the existing standard's stability test by performing the test on a textured surface. This change would address incidents in which

the suction cups on the bottom of the bath seats (since all bath seats involved in tip-overs relied on suction) failed to stay attached to the surface of the bathtub. Suction cups do not reliably attach to textured surfaces; therefore, these seats involved in the incidents would have had to rely on another mechanism for their support and stability. The stability test also involves a force applied to the bath seat without the child's weight placed in the seat. If the suction cups detach from the product or the bathtub surface during the test or if the seat tips at any point, the product would not pass the test. For these reasons, staff feels the test would address incidents in which the suction cups detached from the product during use, detached from the bathtub surface, or in which the victim was able to push the seat over. After a case by case review of the fatal and non-fatal incidents and complaints, the provisions of the recommended performance requirements would address all of the situations in the 30 fatalities and 77 of the 80 non-fatal incidents or complaints.

The three incidents or complaints that the provisions of the recommended performance requirements do not address involved the bath seat tipping over after a component broke on the seat or when a sibling outside of the bath seat tipped the seat over. The force that the sibling applied to the bath seat is unknown; therefore, staff cannot assume that it was less than, or equal to, the amount required during the stability test that staff has proposed.

The second hazard scenario that the recommended performance requirements are designed to address is entrapment within the bath seat. Since 1983, the Commission is aware of three children who drowned after they became entrapped in openings in the bath seat. Additionally, 17 other children either became entrapped or could have become entrapped in openings in the bath seat, but did not die as a result of the incident. The voluntary standard subcommittee for bath seats recently approved the leg opening performance requirement recommended by CPSC staff to address entrapment within the bath seat.

The leg opening performance requirement includes provisions for the use of a torso probe and a shoulder probe in performance tests, to address the hazards of submarining through leg holes and entrapment within the bath seat. The probes are modeled after the dimensions of appropriately aged bath seat users. Therefore, if the user is of the appropriate age for the bath seat, and the bath seat passes this proposed performance test, the user should not become entrapped in any part of the product or submarine through the leg holes. The three entrapment deaths and 16 of the non-fatal incidents or complaints involved situations in which a user of the appropriate age became entrapped in some part of the product or submarined through the leg holes. Thus, these reported incidents are the type of incidents addressed by the leg opening requirement.

The one remaining non-fatal incident report was from a consumer who called to describe the potential for entrapment because of the openings in the bath seat. While the leg opening requirement addresses the size of the openings, staff does not know if this complaint would have been reported if the bath seat had been designed to pass the performance requirement.

Failure to retain the child within the bath seat is a frequently reported problem with the product. Since January 1983, CPSC is aware of 19 children who have drowned and 13 children involved in non-fatal incidents when the child came out of the bath seat and the seat remained upright in the bathtub. There are no direct performance requirements recommended by staff to address this hazard scenario. Indirect requirements include a recommended stronger warning label to increase caregiver attendance and the potential decrease in occupant retention space due to the leg-opening requirements. This decrease in space may occur as a result of design changes

made by manufacturers to meet the leg-opening requirement. A smaller occupant retention space could prevent some older users from coming out of the bath seat.

While the staff believes that both of the indirect requirements for incidents in which the child came out of the bath seat will contribute to making the seats safer, an effectiveness level has not been ascribed for either one because it is unknown at this time to what extent they may contribute.

If one assumes that future incidents would follow the situations and patterns of the incidents seen in CPSC's data, the provisions of the recommended performance requirements would address approximately 97% of tip-over incidents (addressed tip-over incidents/total tip-over incidents). Taking the same assumption, the recommended performance requirements would address approximately 95% of entrapment incidents (addressed entrapment incidents/total entrapment incidents). Staff does not ascribe a value to the warning's effectiveness for addressing incidents in which the child came out of the bath seat.

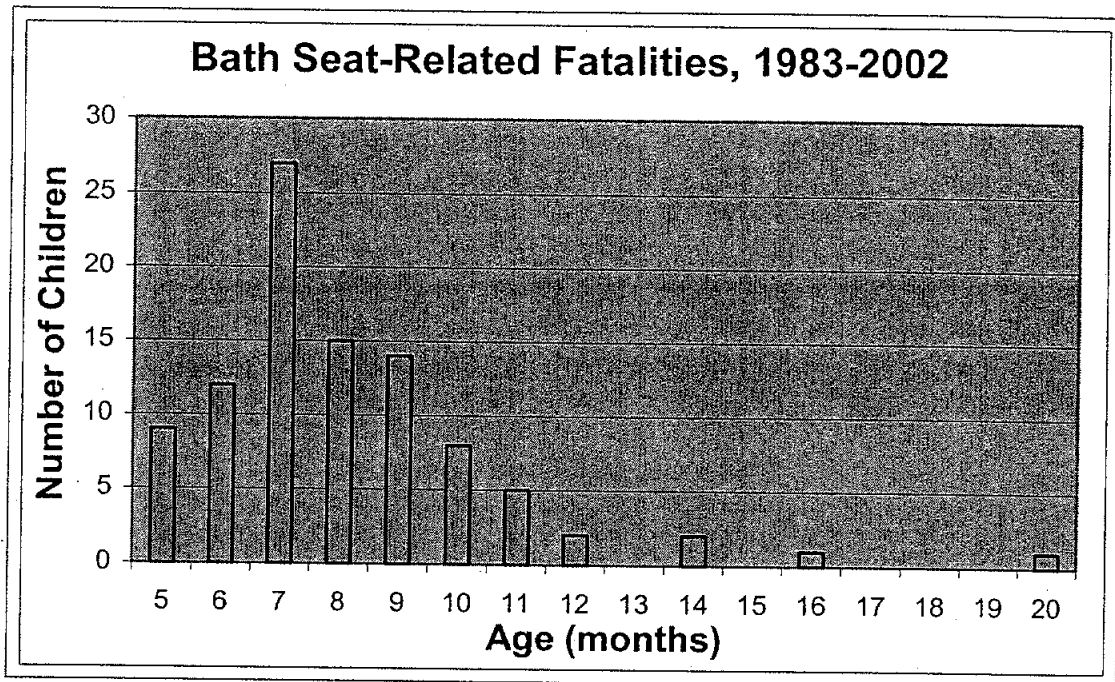
Appendix A

Fatal Incidents: Hazard Scenario by Year of Death

	Tip-Over	Children Coming Out of Seat	Entrapment/ or Submersion	Bath Seat Broke	Slumped Over	Overflow	Child in Water, Seat Unknown	Seat Upright, Child Position Unknown	Unknown or Uncertain	Total
1983-1990	1	2	1	0	0	0	1	0	0	5
1991	1	0	0	0	0	0	1	1	0	3
1992	2	0	0	0	1	1	1	0	0	5
1993	1	1	0	0	0	0	0	1	0	3
1994	1	1	1	0	4	0	1	0	0	8
1995	5	1	0	0	0	0	5	0	1	12
1996	2	3	0	0	0	2	2	0	1	10
1997	4	2	1	0	1	0	1	0	0	9
1998	2	1	0	0	0	0	2	0	1	6
1999	1	2	0	0	1	0	1	0	1	6
2000	5	2	0	0	2	0	5	0	0	14
2001	4	4	0	0	0	0	2	0	0	10
2002	1	0	0	0	1	1	2	0	0	5
Total	30	19	3	0	10	4	24	2	4	96

Appendix B

This chart shows a distribution of the bath seat-related deaths by the age of the victims. The total number of deaths is 96, as reported to the Commission as having occurred between January 1, 1983 and December 31, 2002.



Appendix C

The following table contains the percentage of new mothers with children of each age that own a bath seat. This information is pooled data from the Baby Products Tracking Study, 1996 and 1999. Also included in the table is the percentage of new mothers who did not own bath seats. Both of these percentages were applied to the population of 5-month-old children, 6-month-old children, etc over the 6-year time period. The population for each of the age groups was 23,525,714.

Age of Children	Percentage of New Mothers Who:	
	Owned a Bath Seat	Did Not Own a Bath Seat
5 months	26	74
6 months	41	59
7 months	44	56
8 months	44	56
9 months	52	48
10 months	44	56