CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Bath Seats; Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is proposing a rule to ban bath seats that do not meet certain requirements under the authority of the Federal Hazardous Substances Act. Bath seats are used to support infants in a tub or sink while they are bathed. The Commission is aware of 106 deaths and 163 non-fatal incidents and complaints from January 1983 through October 2003 involving bath seats. The Commission proposes three requirements with which bath seats must comply.

DATES: Written comments in response to this document must be received by March 15, 2004.

ADDRESSES: Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207–0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland; telephone (301) 504–7923. Comments also may be filed by telefacsimile to (301) 504–0127 or by e-mail to *cpsc-os@cpsc.gov.* Comments should be captioned ''NPR for Bath Seats.''

FOR FURTHER INFORMATION CONTACT: Patricia Hackett, Directorate for Engineering Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–7577.

SUPPLEMENTARY INFORMATION:

A. Background

In July 2000, the Consumer Federation of America and eight additional organizations petitioned the Commission to ban bath seats under the Federal Hazardous Substances Act (''FHSA'').[1] In August 2000, an additional organization, U.S. Public Interest Research Group, submitted a letter requesting to be added to the list of petitioners. On May 30, 2001, the Commission voted to grant the petition and issue an advance notice of proposed rulemaking (''ANPR'') to begin a rulemaking proceeding. The ANPR was published in the **Federal Register** on August 1, 2001. 66 FR 39692. The Commission received 10 comments on the ANPR. The Commission held a public briefing on bath seats on July 28, 2003. Four people submitted written testimony and gave oral testimony at the briefing. Since the briefing, the Commission received six additional written comments. Significant issues raised by these comments and the Commission's responses are discussed in section G below. On October 16, 2003, the Commission voted to issue a notice of proposed rulemaking (''NPR'') proposing that bath seats meet requirements for stability, leg openings and labeling or be considered banned hazardous substances.[2]

When the ANPR was published, the Commission had reports of 78 deaths and 110 non-fatal incidents and complaints associated with bath seats (or bath rings, which are no longer marketed in the U.S.) between January 1983 and May 2001. 66 FR 39693. When the staff presented a briefing package to the Commission in May 2003, the Commission had reports of 96 deaths and 153 non-fatal incidents involving bath seats that occurred from January 1983 to December 2002.[2] [3] As of October 2003, the Commission has reports of 106 deaths and 163 non-fatal incidents involving bath seats. As discussed more fully below, the staff identified three major scenarios that were related to the bath seats' design and materials: (1) The bath seat tipping over during use; (2) the child coming out of the bath seat; and (3) the child becoming entrapped and/or submerged in the leg openings of the bath seat.

B. Statutory Authority

This proceeding is conducted pursuant to the FHSA, 15 U.S.C. 1261 *et seq.* Section 2(f)(1)(D) of the FHSA defines ''hazardous substance'' to include any toy or other article intended for use by children that the Commission determines, by regulation, presents an electrical, mechanical, or thermal hazard. 15 U.S.C. 1261(f)(1)(D). An article may present a mechanical hazard if its design or manufacture presents an unreasonable risk of personal injury or illness during normal use or when subjected to reasonably foreseeable damage or abuse. Among other things, a mechanical hazard can include a risk of injury or illness ''(3) from points or other protrusions, surfaces, edges, openings, or closures, * * * or (8) because of instability, or (9) any other aspect of the article's design or manufacture.'' 15 U.S.C. 1261(s).

Under section 2(q)(1)(A) of the FHSA, a toy, or other article intended for use by children, which is or contains a hazardous substance accessible by a child is a ''banned hazardous substance.'' 15 U.S.C. 1261(q)(1)(A).

Section 3(f) through 3(i) of the FHSA, 15 U.S.C. 1262(f)–(i), governs a proceeding to promulgate a regulation determining that a toy or other children's article presents an electrical, mechanical, or thermal hazard. As provided in section 3(f), this proceeding began with an ANPR. 66 FR 39692. After considering the comments submitted in response to the ANPR, the Commission is now issuing a proposed rule and a preliminary regulatory analysis in accordance with section 3(h) of the FHSA. The Commission will then consider the comments received in response to the proposed rule and decide whether to issue a final rule and a final regulatory analysis. 15 U.S.C. 1262(i)(1). Before the Commission can issue a final rule it must find: (1) If an applicable voluntary standard has been adopted and implemented, that compliance with the voluntary standard is not likely to adequately reduce the risk of injury, or compliance with the voluntary standard is not likely to be substantial; (2) that benefits expected from the regulation bear a reasonable relationship to its costs; and (3) that the regulation imposes the least burdensome alternative that would adequately reduce the risk of injury. *Id.* 1261(i)(2).

C. The Product

Bath seats are used in a tub or sink to support a seated infant while he/she is bathed. They are marketed for use only by infants capable of sitting upright unassisted and who cannot yet pull to a standing position. Current bath seats contain a seating area and are usually held in place by suction cups located at the bottom of the seat. When the Commission first began looking at this issue, bath rings were also being manufactured and marketed in the U.S. Bath rings consisted of a plastic ring with three or four legs with suction cups. The infant would sit directly on the tub or on a sponge pad that was fitted within the ring. Such bath rings are no longer manufactured for the U.S. market, but they would be covered

[1] The other petitioners are Drowning Prevention Foundation; Danny Foundation for Crib and Child Product Safety; Intermountain Injury Control Research Center; California Coalition for Children's Safety and Health; California Drowning Prevention Network; Contra Costa County Childhood Injury Prevention Coalition; Greater Sacramento SAFE KIDS Coalition; and Kids in Danger.

[2] Commissioners Mary Sheila Gall and Thomas H. Moore issued statements. Copies of these statements are available from the Commission's Office of the Secretary or from the Commission's Web site, *http://www.cpsc.gov.*

[3] Numbers in brackets refer to documents listed at the end of this notice.

under the proposed definition of ''bath seat'' if they were to be re-introduced into the U.S. market.[2] As used in this NPR, the term ''bath seat'' includes bath rings.

Current bath seats provide a molded plastic seat for the infant to sit on. They provide support to a seated infant. In addition, there are now some infant bathtubs that convert to bath seats. These convertible bath seats would also be included in the proposed rule's definition of ''bath seat'' because, in the bath seat configuration, they provide support to the front and back of a seated infant.[2]

The traditional infant bath tubs that are used to bathe a reclining infant are not within the scope of the proposed rule. Essential to the proposed definition of ''bath seat'' is that the item provides support at least to the back and front of an infant in a seated position. Although there have been drowning incidents involving infant bath tubs, the hazard scenarios are different from incidents involving bath seats. The bath tub incidents do not involve tipovers, leg opening entrapments and children coming out of the products as the bath seat incidents do.

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.[2&8]

In 2000, the Juvenile Products Manufacturers Association (''JPMA'') estimated that there may be up to two million bath seats in use. This is generally consistent with an estimate derived from the American Baby Group's *Baby Products Tracking Study,* 2000. According to the Tracking Study, about 33 percent of new mothers own bath seats or rings. Given the approximately four million annual births in the U.S., the 33 percent ownership rate suggests about 1.3 million bath seats are available for use for infants under the 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 or rings owned by new or expectant mothers were obtained after being used for an older child or borrowed. This suggests that about 54 percent of the bath seats were acquired new, resulting in annual sales of about 700,000 (.54 × 1.3 million). The JPMA estimate of sales is somewhat higher, about 1 million annually.

Bath seats currently sell for about $10 to $16. Bath seats which convert from an infant bath tub to a bath seat sell for about $20 to $25.

D. The Risk of Injury

1. Incident Data

The Commission has reports of 106 deaths and 163 non-fatal incidents and complaints associated with bath seats between January 1983 and October 2003. One hundred-three of the deaths occurred in the absence of a caregiver. In many incidents it is difficult to know the amount of time the caregiver was out of the room. Some reasons that caregivers have cited for leaving children unattended are answering unexpected phone calls, retrieving towels, tending to another child in the home, performing household chores, or watching television. The victims involved in fatal drowning incidents ranged in age from 5 months to 20 months.[2&3]

2. Hazard Scenarios

After examining the bath seat incident reports, the Commission staff identified three major hazard scenarios that were related to the bath seats' design and materials. These are: (1) The bath seat tipping over during use; (2) the child coming out of the bath seat; and (3) the child becoming entrapped and/or submerged in the leg openings of the bath seat.[2&3]

Bath seat tipping over. The staff identified 32 fatalities and 85 non-fatal incidents or complaints involving bath seats tipping over that were reported from January 1983 through October 2003. The children involved ranged from 4 months to 15 months in age. In most of the fatal incidents, a caregiver was not present. However, a caregiver was present in two of the fatalities. The majority of non-fatal incidents were supervised.[2&3]

In many of the tip-over incidents, it appears that the suction cups may not have completely adhered to the tub's surface. It is often difficult to determine the type of surface involved in individual incidents.[2]

Child coming out of bath seat. The staff identified 22 fatalities and 13 non-fatal incidents and complaints involving children coming out of bath seats that were reported from January 1983 through October 2003. In these incidents, 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 that the bath seat was unable to restrain the child in the seat. Children involved in these incidents ranged in age from 6 months to 14 months. In all of the fatal incidents and in the majority of non-fatal incidents no caregiver was present.[2&3]

Entrapment and submersion. The staff identified 3 fatalities and 18 non-fatal incidents and complaints involving children entrapped or submerged in bath seats that were reported from January 1983 through October 2003. The children involved in these incidents ranged in age from 3 to 16 months. In one of the fatalities the child was supervised. In the other two, no caregiver was present. The majority of non-fatal incidents were supervised.[2&3]

E. Voluntary Standard

Currently, there is a voluntary standard for bath seats, ASTM F 1967–03. The standard was first published in June 1999. At that time, the standard included marking, labeling, and literature requirements as well as performance requirements addressing stability, static load, latching/locking mechanisms, restraint systems, leg opening sizes and other requirements commonly found in juvenile product standards. A revised standard with requirements for suction cup integrity and a durability requirement for latching/locking mechanisms was published in June 2001. The current version of the standard, ASTM F 1967–03, contains additional revisions that were approved in March 2003 and published in April 2003.[2]

Following is a summary of the performance requirements and their respective test methods specified in ASTM F 1967–03.[2]

Restraint System: If the seat provides back support and side or front support, then a passive crotch restraint must be provided. The ASTM 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 with the voluntary standard if it does not tip over. Testing is not required on slip-resistant surfaces unless the manufacturer recommends use on slip-resistant surfaces (the Commission is unaware of any bath seats currently sold that are recommended for slip-resistant surfaces).

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

Leg Openings (added in 2003): 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 must not permit passage of the torso probe. 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.

October 2003 ASTM Meeting. On October 1, 2003, the ASTM Bath Seat Subcommittee met and voted to issue a concurrent Main and Subcommittee ballot that will include proposed new stability and labeling requirements.[1] The proposed stability requirement is identical to the stability requirement the Commission is proposing in this NPR. The proposed labeling requirement being balloted is similar to the first two lines of the label the Commission proposes in this NPR. The ASTM proposed label states:

WARNING

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

The ballot with these two proposals was issued on November 3, 2003, and results are due back December 8, 2003. The results should be reviewed and discussed at the next ASTM Bath Seat Subcommittee meeting in March 2004.[1]

F. The Proposed Ban

The proposed rule would ban bath seats that do not meet specified requirements for stability, leg openings, and labeling. After considering the incident reports, the Commission believes that these proposed requirements will address the major hazard scenarios involved in bath seat drownings.

1. Stability Requirement

As discussed above, 117 reported incidents involved the bath seat tipping over (32 deaths and 85 non-fatal incidents or complaints). Bath seats currently on the market depend on suction cups for all or part of their stability. If the suction cups fail, either by detaching from the product or detaching from the tub surface, the bath seat can become unstable and tip over.[2]

Most of the reports concerning bath seats tipping 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 results in an unstable product.[2]

The ASTM subcommittee for bath seats identified this problem, and the current ASTM F 1167–03 requires that manufacturers include warnings against using bath seats on slip-resistant surfaces. However, the current voluntary standard does not require testing on slip-resistant surfaces.[2]

It can be difficult for a consumer to identify a ''slip-resistant'' tub. Although many slip-resistant tubs have texturing that is easily identified (such as a sandpaper-like finish, a pattern of ridges, or consumer-added appliqués) some slip-resistant surfaces have a very subtle finish. A convenience sampling of slip-resistant tubs at a 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 some abrasive surfaces if the surface has already been flooded with water, but the seal does not last.[2]

Because identifying slip-resistant tubs might be difficult, and testing can be misleading, the Commission believes that warning against the use of bath seats on slip-resistant surfaces will not be effective at preventing incidents. Therefore, the Commission proposes that bath seats' stability be tested on slip-resistant surfaces.

The proposed performance requirement is similar 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. The Commission 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. The Commission 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.[2&4]

A performance requirement that requires all products to remain stable on slip-resistant bathing surfaces should reduce the likelihood of tip-over incidents that are due to surface adhesion failure. A bath seat that is stable on slip-resistant surfaces could depend on its geometry and construction for stability rather than on suction cups. An object will fall over when its center of gravity lies outside its supporting base. The supporting base of bath seats could be designed to be wide enough to prevent tip-overs. Another potential approach might be a bath seat that attaches to one or both of the tub sides.[2&4]

2. Leg Opening Requirement

As discussed above, 21 reported incidents involved children submerged or entrapped in bath seats (3 deaths and 18 non-fatal incidents or complaints). Over the last two years, CPSC staff worked as part of an ASTM task group to develop a performance requirement to address the entrapment and submersion hazard. The performance requirement the task group developed 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 must not pass through any side or leg openings, and the shoulder probe must 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 touch the seating surface.[2&4]

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.''[2&4]

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 touch 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.[2&4]

This leg opening performance requirement was recently approved by ASTM and is included in ASTM F 1967–03, published in April of 2003.[2] The Commission is including it in this NPR because, at this time, the leg opening requirement of the voluntary standard has not been implemented. According to relevant legislative history, a voluntary standard is implemented when ''substantial industrywide production of products that comply with the standard has begun.'' H.R. Cong. Rep. No. 208, at 875; U.S. code cong. & Admin. News, 97th Cong., 1st Sess. 1982, Vol. 2 at 1237. This has not yet occurred.

3. Labeling Requirement

As discussed above, 35 reported incidents involved children coming out of bath seats (22 deaths and 13 non-fatal incidents or complaints). The Commission staff considered the incident reports to determine whether performance criteria could be developed that would address this hazard scenario. For the reasons explained below, the staff concluded that no performance criteria could effectively address the hazard scenario of children coming out of the bath seats at this time.

The Commission is concerned that adding an effective restraint system to the seat may change the utility of the bath seat. It 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. Moreover, in a bathing environment it is easier for children to escape 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.[2&5]

The Commission is also concerned that making the bath seat's seating area smaller by requiring a standard size will not prevent all users from coming out of the bath seat. One approach for a restraint might be simply to reduce the occupant retention area so that it is ''tighter'' on the child. However, this would not be effective for all users because children who may use the bath seat range greatly in size. For example, 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. Moreover, 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 that bath seats be made in a smaller, standardized size would be insufficient to create an effective passive restraint system for bath seats.[2&5]

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

The Commission believes that the label currently specified in the ASTM standard (see above) needs to be stronger so that consumers understand that the danger of drowning is a real 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 to the infant. 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 this behavior. The Commission proposes strengthening the ASTM warning label with statements that expressly explain the danger. The Commission proposes the following language:

⚠ 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 to a standing position.

G. Response to Comments

The Commission received ten comments from nine individuals during the ANPR comment period. 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. In addition, four individuals submitted written testimony before the Commission's public briefing and gave oral testimony at the briefing. Three of these supported a ban of all bath seats and one supported voluntary standards. After the briefing, the Commission received six additional comments, two supporting a ban of all bath seats, one supporting a mandatory standard, and one supporting terminating the rulemaking (the other two did not express support for any of the options).

Responses to the primary issues raised by the comments follow. The numbers found in parentheses after a comment refer to the commenter number assigned by the Office of the Secretary.

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: The Commission believes that the proposed leg opening requirement will address incidents that involve entrapment/submersion, and that the proposed stability requirement 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: The Commission 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, 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, the Commission 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 Commission proposes 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 commenters (CH 01–5–3; 3a; 5; 6) were concerned about the compatibility of bath seats with slip-resistant surfaces, and they 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. The Commission proposes 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. The Commission 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 submarines 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 proposed leg opening requirement 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) asserted 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: As the Commission stated in the ANPR: ''Some caregivers may perceive that the product provides a greater degree of safety than it does. Leaving the child alone could be considered a reasonably foreseeable abuse of the product.'' 66 FR 39697. Existing bath seats do not appear to be adequately designed to protect children against the consequences of this foreseeable misuse. In addition, some mechanical failures—*e.g.*, the seat tipping over or children slipping into leg openings—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 developmental 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, the Commission 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.'' The Commission 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: Because the date of manufacture of the bath seats involved in the incidents is not recorded, the Commission cannot determine if the bath seat was manufactured prior to the effective date of a particular ASTM standard. However, as noted in this NPR, the Commission has concerns about the adequacy of the current voluntary standard in addressing deaths and incidents associated with bath seats.

6. Water Level Mark

Comment: Two statements submitted at the Commission briefing (by Rachel Weintraub for CFA and Jack Walsh for the Danny Foundation) recommended putting a water level mark on the bath seat to indicate that the bath water should not be higher than that level. One of the commenters discussed incident data that he claimed supported his opinion. The other commenter recommended that the following be added to the warning label or instructional literature: ''ALWAYS use the least amount of water necessary when bathing a child.''

Response: The Commission is concerned that a water level mark may be interpreted by some caregivers to mean there is a safe water level at which children do not drown. There is no such level. Therefore, the Commission does not support this recommendation. The current ASTM standard requires the following wording on instructional literature: ''Babies can drown in as little as 1 inch of water. ALWAYS bathe your infant using as little water as necessary.'' The Commission believes this is adequate. With regard to incidents cited by the commenter, many of those involved overflowing bath tubs where parents or siblings turned on the water and failed to turn it off. The Commission does not believe that the presence of a water level mark on the product would have addressed these incidents.

7. Labeling

Comment: One statement at the Commission briefing (by Rachel Weintraub for CFA) and one comment submitted after the briefing (by Paul Ware, Chair of ASTM F15.20 Subcommittee) commented on the proposed warning label for bath seats. One stated that it is counterintuitive to come up with a warning label to address the coming out hazard. Another commenter stated that he does not believe that there is adequate rationale for changing the wording from what is currently in the ASTM standard to the wording the Commission is proposing.

Response: As discussed in section F.3 above, the staff explored whether a performance requirement could be developed that would address the coming out hazard, but concluded that no practical and effective performance criteria were possible. As for the need for improvements to the label required by the ASTM standard, the Commission believes that the current label allows parents to rationalize that children have not actually drowned while using a bath seat. The Commission believes its proposed warning label is an improvement because it uses language to warn parents that children actually have drowned while using a bath seat. Incidents involving the absence of caregivers continue to occur, and no other strategy directly addresses this caregiver behavior. The Commission believes that strengthening the label may more strongly influence caregiver behavior and thereby reduce drowning incidents.

Comment: Two commenters (Ms. Weintraub of CFA and Heather Paul of National Safe Kids Campaign) asked that the Commission require a label on bath seats that indicates the product meets the mandatory rule.

Response: The Commission has included such a requirement in other CPSC regulations, such as bike helmets, and believes that this is a reasonable suggestion. Therefore the Commission proposes this requirement in the NPR.

Comment: One commenter (Ms. Weintraub of CFA) requested that there be a requirement that the warning label be ''readable'' when tested for permanence. Another commenter recommended a stronger permanency test for labels than what is currently required in the ASTM standard.

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

Comment: One commenter (Ms. Paul of Safe Kids Campaign) recommends that the warning label on the product also be required to be on the front and back of the packaging.

Response: The Commission believes this is a reasonable suggestion to better ensure that consumers are made aware of the hazards associated with bath seats. Therefore the Commission is including this in the NPR.

8. Data Regarding Bathing Environments of Infants

Comment: One commenter (CH 03–3–5) presented data on bathing environments for a group of children age 5 to 10 months old who drowned in bath tubs from 1994–1999. From these data, she drew conclusions about parental behavior, sibling presence, and the potential effects of a ban of bath seats.

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

In addition, in order to draw conclusions about whether bath seat users are at greater or lesser risk of drowning (regardless of the reason), we need data on the number of babies bathed in bath seats and the number bathed without bath seats. These data are not presented by the commenter. The only source of any data on this topic is the Baby Products Tracking Study discussed in the staff's 2001 briefing package and 2003 briefing package. CPSC staff has calculated death data and risk estimates derived from this study.

These data indicate that the risk of drowning in a bathtub is greater with a bath seat than without a bath seat for 5–7 month olds. The risk of drowning with a bath seat is less than that of drowning without a bath seat for 8–10 month olds. Given this analysis, and given that this information alone cannot be used to predict what effect a ban of bath seats may have on caregiver behavior, the Commission concluded that available information cannot predict whether a ban of bath seats would reduce bathtub related drownings.

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

9. Adequacy of ASTM F 1967–03

Comment: Two commenters (Mr. Ware, Chair of ASTM F15 Subcommittee and Frederick Locker, Counsel for the Juvenile Products Manufacturers Association) stated that they believed the existing voluntary standard is adequate and addresses issues previously raised by the Commission.

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

to be strengthened to more effectively alert caregivers to possible hazards associated with bath seats.[1]

H. Alternatives

The Commission has considered other alternatives to address the drowning hazard posed by bath seats. As discussed below, the Commission does not believe that any of these would adequately reduce the risk of injury.

1. *Propose only two requirements.* The Commission could issue a proposed rule that requires bath seats to comply only with a stability requirement and labeling requirement (or else they would be banned hazardous substances). The Commission considered proposing a rule without a leg opening requirement because the ASTM standard approved in March 2003 includes a leg opening requirement that is identical to the one the staff recommended to the Commission.[2] However, the Commission believes it is appropriate to propose all three requirements since the industry has not had time yet to produce bath seats that comply with the ASTM leg opening requirement. The Commission will re-examine the question of including a leg opening requirement in its rule when the Commission considers whether to issue a final rule.

2. *Ban of all bath seats.* The Commission considered proposing a rule declaring that all bath seats are hazardous substances and therefore banned. However, at this time, it is unclear what the effect of removing all bath seats from the market would be. Available information cannot predict whether fewer children would drown if bath seats were unavailable or if more would drown. CPSC staff examined bath seat-related deaths and bath tub-related deaths for the period 1994 through 1999. The staff's analysis suggests that children ages 5 to 7 months are more at risk from drowning when bathed in bath seats as opposed to being bathed in a bathtub. However, 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. The staff concluded that it could not measure the effect a ban would have on bathing-related drowning because: (1) The analysis suggests that bathing while using a bath seat is riskier for younger bathers, while bathing in bathtubs without a bath seat is riskier for older bathers; (2) the staff necessarily made assumptions to estimate a bath seat user population—these assumptions could affect the accuracy of the results; and (3) the analysis cannot be applied to children younger than 5 months and older than 10 months, so deaths in those age groups are not addressed by the analysis.[2&3]

In contrast to these questions about the possible effect of a total ban on drowning deaths, the Commission believes that the three requirements it proposes should make bath seats safer. The proposed requirements are directed to addressing the specific hazard scenarios that are identified in most fatal incidents.

3. *Voluntary Standard.* The current voluntary standard, ASTM F 1967–03, contains many provisions that the CPSC staff has recommended, including a leg opening requirement. However, it does not require stability testing on slip-resistant surfaces. As discussed above, the suction cups currently used to attach bath seats to a tub's surface do not reliably adhere to slip-resistant surfaces. Many of today's bath tubs have slip-resistant surfaces, and they can be difficult for consumers to identify.[2] The Commission believes that bath seats should be stable when used on the surfaces that are likely to be in consumers' homes. The existing ASTM standard is not adequate in this respect.

The label currently specified in the ASTM F 1967–03 standard may not advise caregivers forcefully enough that a child can drown in a bath seat. The Commission believes that the proposed label would send a stronger message that the caregiver should remain with the child by expressly stating that children have drowned in bath seats and that the bath seat is not a safety device.

I. Preliminary Regulatory Analysis

The Commission has preliminarily determined to ban bath seats that do not meet specified requirements for stability, leg openings, and labeling. Section 3(h) of the FHSA requires the Commission to prepare a preliminary regulatory analysis containing a preliminary description of the potential benefits and costs of the proposed rule, including any benefits or costs that cannot be quantified in monetary terms; an identification of those likely to be affected; discussion of existing or developing standards submitted in response to the ANPR; and a description of reasonable alternatives. 15 U.S.C. 1261(h). The following discussion addresses these requirements.[8] The preliminary regulatory analysis is based on incident data that was reported in the staff's briefing package of May 8, 2003. Since that time there have been additional incidents reported which are included in the incident data discussion at section D.1 of this notice.

Discussion of Proposed Rule

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

The proposed stability requirement will require the product to resist tip-over when the bath seat is installed on a smooth surface to which commercially available adhesive backed slip resistant tread strips (for bathtub use) have been applied.

In addition to the stability requirement, two probe tests are being proposed that would limit the size of the product's leg openings as well as the seating space, to address the hazards of submersion and entrapment below the water surface. This requirement is part of the newly approved ASTM voluntary standard, but currently marketed bath seats do not meet it.

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

Potential Costs of the Proposed Rule

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

Manufacturers report that there will be an increase in the cost of production associated with additional material, labor and shipping. According to an industry representative, its redesigned bath seat will be larger, heavier, and

more complex to assemble. At the present time, most bath seats are manufactured in the U.S. The proposed rule would require that bath seats entering commerce meet the new requirements within a year of publication of the final rule. Bath seats already in commerce (for example, those on store shelves) will not be affected and will still be saleable. According to one manufacturer, they plan to have bath seats that meet the new voluntary standard leg opening requirement as well as the stability requirement that is part of the proposed rule by the end of 2003. Also, the second manufacturer will probably have bath seats that meet the leg opening requirement by the end of 2003.

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

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

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

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

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

Potential Benefits of the Proposed Rule

The benefits of the proposed rule will result from a reduction in deaths and injuries due to product failure from tip-over, entrapment and submersion. CPSC is aware of 96 deaths associated with bath seats from January 1983 through December 2002. Eighty-three of these reported deaths occurred in the past ten years (1993 through 2002), a period during which about one-third of all new mothers owned bath seats and the number of bath seats in use remained relatively constant at about two million.[4] 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 performance requirements of the proposed rule (26 involved the tip-over hazard and two involved entrapment/submersion). While we do not know the hazard scenarios in the remaining 26 deaths, if we assume that they are distributed proportionally to the known cases, another 13 deaths (*i.e.* 50 percent) might be also be addressed by the proposed rule. This amounts to about 2.8 to 4.1 deaths annually (*i.e.* 28 deaths/10 years to 41 deaths/10 years), or about 1.4 to 2.05 deaths per million bath seats in use (since about two million were in use annually).

Comparison of Costs and Benefits

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

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

The proposed rule has the potential to bring about a reduction in deaths from tip-over and entrapment/submersion hazards. However, it is not clear at this time whether manufacturers will design baby bath seats that are safer, while maintaining the current level of

[4] 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.

consumer utility. If some consumers do not accept the redesigned seats, or use them less frequently (or for a shorter period), and decide instead to bathe their children by other means, the risk of drowning from these alternative bathing methods will be substituted for the bath seat drowning risk.

Alternatives

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

Option To Ban

The Commission considered the option of proposing a ban that would eliminate bath seats from the marketplace entirely. With this option, the costs would consist of the lost use value, or utility, that consumers derive from the product. Money not spent on bath seats will be spent on other products that provide utility, but there is expected to be some loss in utility that cannot be quantified.

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

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

If the proposed rule were fully effective in preventing the deaths it addresses, it would likely reduce the risk of drowning in a bath seat by about 50 percent. On the other hand, while a ban would address all bath seat drownings (by eliminating bath seats), it would also expose all the children who would have been bathed in bath seats to the drowning risks in other bathing settings.

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

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

The Commission considered a subset of the three requirements developed by the staff and discussed earlier as a proposed rule. One reasonable alternative is to publish as a proposed rule the stability and labeling requirements and not the leg opening performance requirement.

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

No Action

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

Voluntary Standards

As an alternative to a proposed rule, the Commission has the option of finding that the voluntary standard is adequate and terminating rulemaking. ASTM has recently revised the voluntary standard to address hazards associated with bath seat submersion and entrapment. It is possible that later revisions might incorporate tip-over and labeling requirements that are similar to the proposed rule. If the voluntary standard addresses the same tip-over hazards that are addressed in the proposed rule with equivalent effectiveness, and all suppliers of baby bath seats comply with the voluntary standard, the net benefits of the voluntary standard would be virtually the same as those of the proposed rule. However, at this time, the voluntary standard does not address the tip-over deaths. Nor does it require the stronger label that the staff recommended.

J. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (''RFA''), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact that the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities. *Id.* 605(b).

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 requirements of the proposed rule. The third firm, an importer, may have to find another source for baby bath seats that would meet the proposed rule.[8]

For these reasons, the Commission certifies that the proposed rule banning bath seats that do not meet the specified requirements would not have a

significant effect on a substantial number of small entities.

K. Environmental Considerations

Pursuant to the National Environmental Policy Act, 15 U.S.C. 4321–4347, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, 40 CFR part 1500 and 16 CFR part 1021, the Commission has assessed the possible environmental effects associated with the proposed rule banning certain bath seats.

The Commission's regulations state that rules providing design or performance requirements for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this proposed rule alters that expectation.

The transition to bath seats that meet the proposed rule is not expected to have an adverse environmental impact, especially if the effective date of a rule enables the firms to substantially deplete existing non-complying inventory. The U.S. manufacturers are already aware of the Commission's actions, and since there is a proposed one-year lead-time (after issuance of a final rule) before the rule becomes effective, no environmental impact is expected. Moreover, any existing inventory in manufacturers' stocks has the potential to be recycled, *i.e.* reground in order to reuse the plastic components, which constitute the bulk of the seat's construction.[8]

Therefore, because the proposed rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

L. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state the preemptive effect, if any, of new regulations.

The FHSA provides that, generally, if the Commission issues a banning rule under section 2(q) of the FHSA to protect against a risk of illness or injury associated with a hazardous substance, ''no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.'' 15 U.S.C. 1261n(b)(1)(B). Upon application to the Commission, a State or local standard may be excepted from this preemptive effect if the State or local standard (1) Provides a higher degree of protection from the risk of injury or illness than the FHSA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical requirement that provides a higher degree of protection than the FHSA requirement for the hazardous substance for the Federal, State or local government's own use. 15 U.S.C. 1261n(b)(2).

Thus, with the exceptions noted above, the proposed rule banning certain bath seats would preempt non-identical State or local requirements applicable to bath seats designed to protect against the same risk of injury.

The Commission has also evaluated this proposed rule in light of the principles stated in Executive Order 13132 concerning federalism, even though that Order does not apply to independent regulatory agencies such as CPSC. The Commission does not expect that the proposed rule will have any substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among various levels of government.

M. Effective Date

The rule would become effective one year from publication of a final rule in the **Federal Register** and would apply to bath seats entering the chain of distribution on or after that date. The two U.S. manufacturers are aware of the Commission's proposed requirements. At least one manufacturer has begun product development on a bath seat that meets the proposed requirements. Thus, one year should allow sufficient time for the manufacturers to develop a product that meets the requirements.[2&8]

N. Proposed Findings

When the Commission issues a rule under section 2(q)(1) of the FHSA classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include these findings in the regulation. 15 U.S.C. 1262(i)(2). The Commission proposes the following findings.

Voluntary standard. The FHSA requires the Commission to make certain findings concerning compliance with and adequacy of a voluntary standard if a relevant voluntary standard has been adopted and implemented. 15 U.S.C. 1262(i)(2). The voluntary standard, ASTM F 1967–03, as it is currently adopted and implemented does not adequately reduce the risk of injury. The current stability provisions do not require testing on slip-resistant surfaces. The current label prescribed by the ASTM standard does not state a strong enough warning. The leg opening requirement has been adopted, but at this time has not yet been implemented. Thus, the Commission proposes to find that the voluntary standard, as it is currently adopted and implemented, does not adequately reduce the risk of injury.

Relationship of benefits to costs. The FHSA requires the Commission to find that the benefits expected from a regulation bear a reasonable relationship to its costs. The Commission estimates the potential benefits of its proposed changes to bath seats to be elimination of 2.8 to 4.1 deaths annually. The Commission estimates that the costs of the rule will be about $10 million per million bath seats sold. If the proposed rule eliminates all of the tipover and entrapment/submersion deaths, the cost per life saved would range from about $2.4 million to about $3.6 million. Even if the proposal were only 50% effective, then the cost per life saved would be from about $4.9 to $7.1 million. Thus, the Commission proposes to find that there is a reasonable relationship between the expected benefits of the rule and its costs.

Least burdensome requirement. The FHSA requires the Commission to find that a regulation imposes the least burdensome alternative that would adequately reduce the risk of injury. *Id.* The Commission considered proposing only two requirements (stability and labeling requirements, but not a leg opening requirement), banning all bath seats, or taking no action and following the ASTM voluntary standard. The Commission is proposing three requirements because at this time, the leg opening requirement in the ASTM standard has not been fully implemented. The Commission will reconsider this issue when it considers a final rule. As discussed above, it is not clear that a ban of all bath seats would reduce drowning deaths any more than the proposed three requirements, and could have the effect of increasing bathtub-related drowning deaths. Thus, the Commission proposes that a ban of bath seats that do not meet the proposed requirements for stability, leg openings and labeling is the least burdensome alternative that would adequately reduce the risk of injury.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Toys.

Conclusion

For the reasons stated above, the Commission preliminarily concludes that infant bath seats that do not meet the requirements for stability, leg openings, and labeling that are specified in the proposed rule are hazardous substances under section 2(f)(1)(D) of the FHSA. Such bath seats are intended for children and present a mechanical hazard under section 2(s) of the FHSA because in normal use or when subjected to reasonably foreseeable damage or abuse their design or manufacture presents an unreasonable risk of injury. 15 U.S.C. 1261(s). The risk of injury is from the bath seats' instability, openings, and other aspects of their design or manufacture. Therefore, the Commission proposes to amend title 16 of the Code of Federal Regulations as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278.

2. Section 1500.18 is amended to add a new paragraph (a)(18) to read as follows:

§ 1500.18 Banned toys and other banned articles intended for use by children.

(a) * * *

(20) Any bath seat (as defined in § 1514.2 of this chapter) that does not comply with the requirements of part 1514 of this chapter.

* * * * *

3. Add part 1514 to read as follows:

PART 1514—REQUIREMENTS FOR BATH SEATS

Sec.

Authority: 15 U.S.C. 1261, 1262.

§ 1514.1 Scope.

This part 1514 sets forth the requirements for a bath seat as defined in § 1514.2. Bath seats meeting these requirements are exempted from 16 CFR 1500.18(a)(20).

§ 1514.2 Definitions.

As used in this part 1514:

(a) *Bath seat* means an article that is used in a bath tub, sink, or similar bathing enclosure and that provides support, at a minimum, to the front and back of a seated infant during bathing by a caregiver.

(b) *Most adverse* means a test condition that produces the most severe result that would indicate a failure of the test.

(c) *Test surface* means a smooth surface (cleaned thoroughly with an alcohol or other solvent-based cleaner and dried) upon which commercially available adhesive backed safety tread strips (for bath use) have been applied over the Test Surface Coverage Area in the following manner. The safety tread strips shall be rectangular in shape, approximately .75 inch (1.9 cm) wide by 7 inches (17.8 cm) or greater in length, and evenly applied from edge to edge so that they are .5 inch (1.3 cm) or less apart from each other.

(d) *Test Surface Coverage Area* means the area of the test surface that extends a minimum of 1 inch (2.5 cm) beyond the perimeter outlined by any part of the bath seat that is designed to contact a surface.

§ 1514.3 Requirements.

(a) *Stability.* The geometry and construction of the bath seat shall not allow the bath seat to tip over after being tested in accordance with § 1514.4(a).

(b) *Leg openings.* (1) All openings on the sides of the bath seat through which a seated occupant can slide or otherwise insert any extremity shall not permit the passage of the Bath Seat Torso Probe when tested in accordance with § 1514.4(b)(1).

(2) All openings on the sides of the bath seat through which a seated occupant can slide or otherwise insert any extremity shall not permit any portion of the top 1 inch (2.5 cm) perimeter of the shoulder breadth end of the Bath Seat Shoulder Probe to contact the seating surface of the bath seat when tested in accordance with § 1514.4(b)(2).

§ 1514.4 Test methods.

(a) *Stability.* (1) Install the bath seat according to the manufacturer's instructions onto the prepared Test Surface. Flood the Test Surface with water that is at an initial temperature of 100 to 105° F (37.8 to 10.6° C) and a depth of 2 inch (51 mm) above the highest point of the occupant seating surface.

(2) Rigidly attach a 1 by ¼-inch (25 × 6-mm) aluminum flat bar to the inside edge of the occupant seating space in a vertical orientation at the most adverse position of the bath seat. The length of the flat bar must be such that it extends beyond the uppermost edge or surface of the bath seat at least as far as the maximum distance D as shown in Figure 1.

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

$D = (20.4 \text{ inch} - H)/2; [(518 \text{ mm} - H)/2]$

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

(5) Repeat this test protocol three additional times at 90 degree increments, including the re-calculation of the distance D.

(6) Repeat this test protocol with the bath seat in each of the use positions recommended by the bath seat's manufacturer.

(b) *Leg openings.* (1) For each of the use positions recommended by the bath seat's manufacturer, insert the tapered end of the Bath Seat Torso Probe (Figure 2) in the most adverse orientation into each opening from the direction of the occupant seating surface. Apply a force of 15 lbf (67 N) in the direction of the major axis of the probe. The force shall be applied gradually within 5 seconds and maintained for an additional 10 seconds.

(2) For each of the use positions recommended by the bath seat's manufacturer, insert the tapered end of the Bath Seat Shoulder Probe (Figure 3) in the most adverse orientation into each opening from the direction of the occupant seating surface. Apply a force of 15 lbf (67 N) in the direction of the major axis of the probe. The force shall be applied gradually within 5 seconds and maintained for an additional 10 seconds. Release the force, leaving the probe in position. Apply a force of 10 lbf (44.4 N) to the highest point on the probe, in a direction vertically

downward toward the seating surface. The force shall be applied gradually within 5 seconds and maintained for an additional 10 seconds.

§ 1514.5 Marking and labeling.

(a) Each bath seat, and the front and back of its packaging, shall be labeled with the safety alert symbol (exclamation mark in an equilateral triangle), the word WARNING, and the following warning:

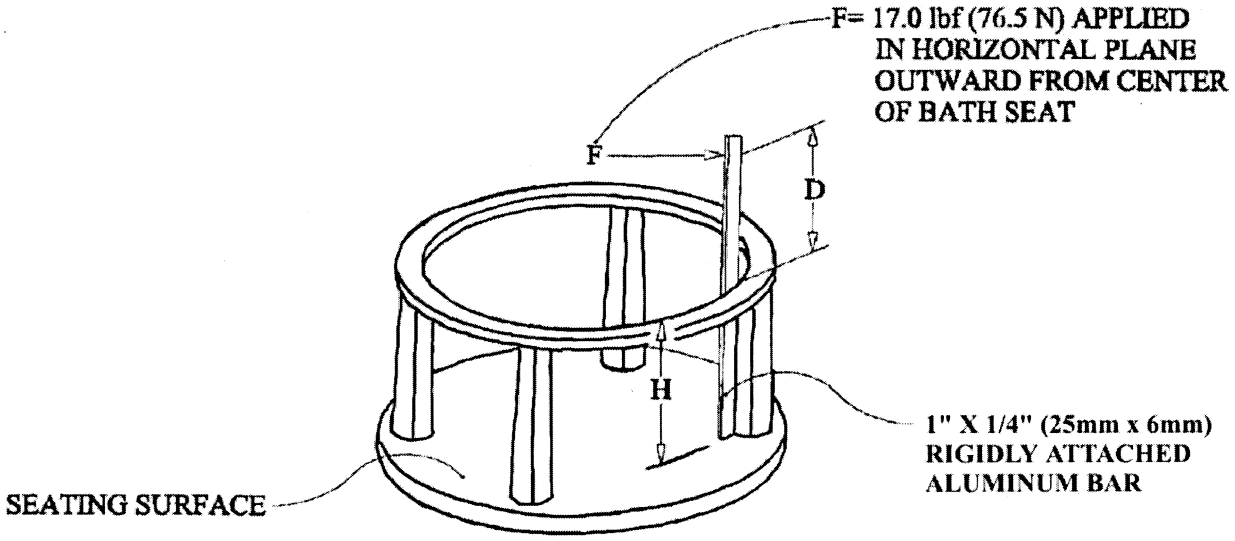
Proposed Bath Seat Warning Label

⚠ 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 child is able to pull to a standing position.

(b) The signal word shall be written in capital letters using a sans serif type face with letters not less than 0.2 inches (5 mm) in height, with all the remainder of text not less than 0.1 inch (2.5 mm) in height. The words shall also be in contrasting color to the background on which they are located. The words ''ALWAYS'' and ''NOT'' in the list of warnings shall be capitalized. The word ''drowned'' shall be underlined.

(c) The specified warning label shall be located so that it is visible to the caregiver when the bath seat is in the use position recommended by the manufacturer and the occupant is in the bath seat.

(d) Each bath seat and its packaging shall display a label stating that the bath seat complies with U.S. CPSC Requirements for Bath Seats.



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

H=HEIGHT OF UPPERMOST EDGE OR SURFACE ABOVE THE LOWEST POINT OF THE SEATING SURFACE

FIG. 1 Diagram of Force Application

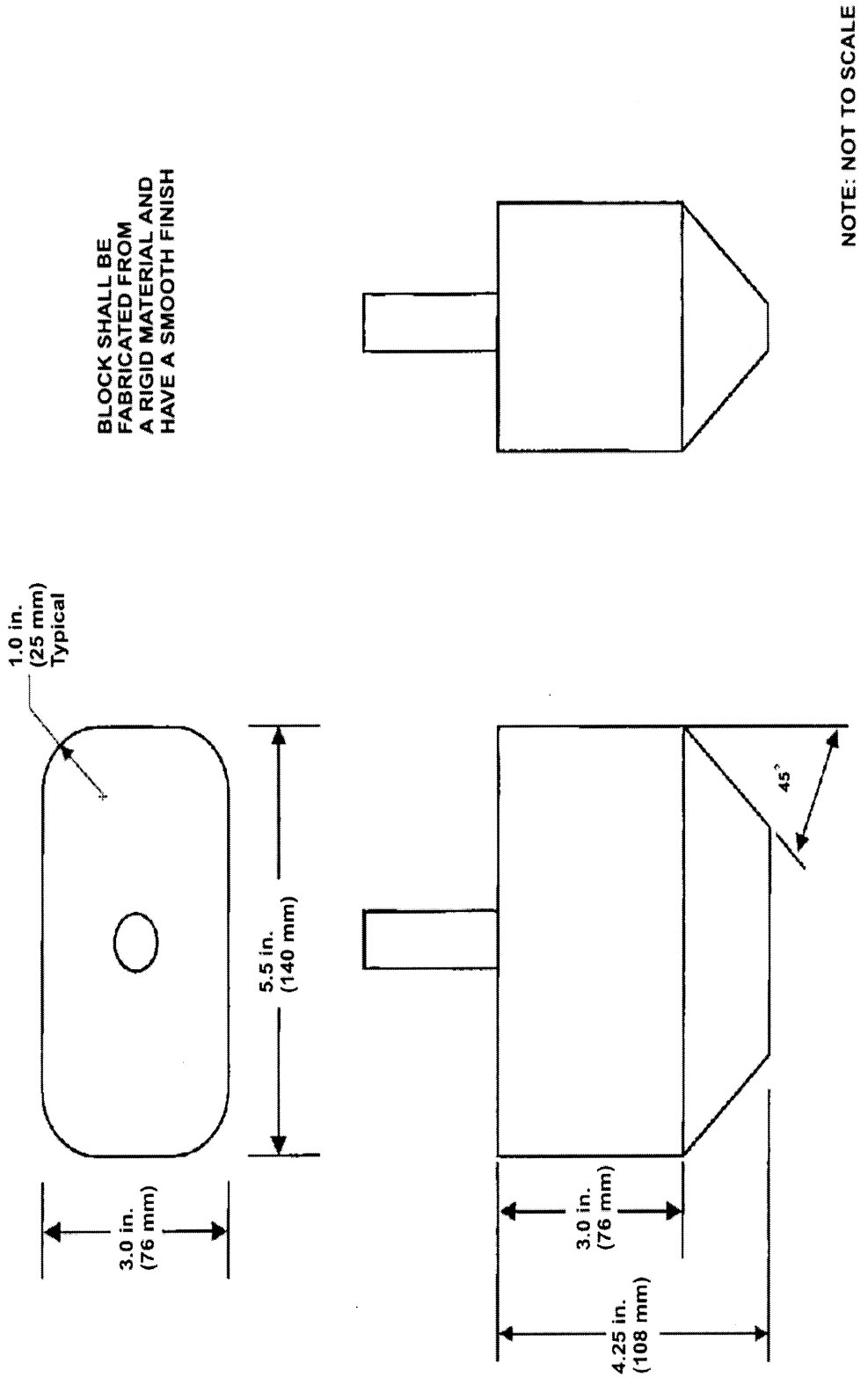


Figure 2. Bath Seat Torso Probe

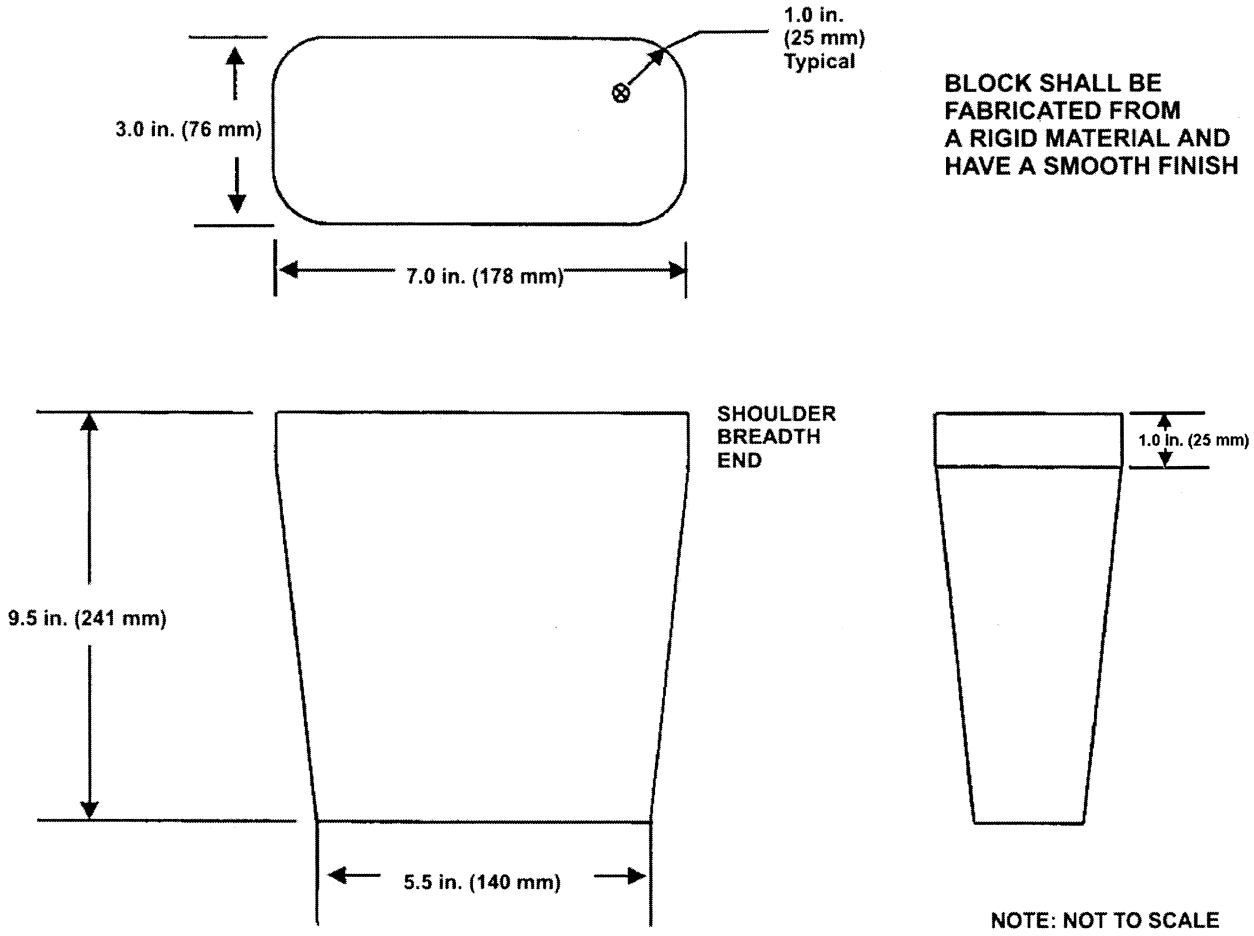


Figure 3. Bath Seat Shoulder Probe

BILLING CODE 6355–01–C

Dated: December 12, 2003.

Todd Stevenson,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Memorandum from Jacqueline Elder, AED, Office of Hazard Identification and Reduction and Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Rulemaking Options for Bath Seats—Response to Comments,'' October 7, 2003.

2. Briefing memorandum from Jacqueline Elder, AED, Office of Hazard Identification and Reduction and Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Rulemaking Options for Bath Seats,'' May 8, 2003.

3. Memorandum from Debra Sweet, Division of Hazard Analysis, to Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, ''Hazard Analysis Memorandum for Bath Seat NPR Briefing Package,'' April 8, 2003.

4. Memorandum from Caroleene Paul, Directorate for Engineering Sciences, to Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, ''Draft Proposed Requirements for Bath Seats,'' April 7, 2003.

5. Memorandum from Jonathan Midgett, Ph.D, Division of Human Factors, to Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, ''Human Factors Issues in Bath Seat Design and Use,'' April 10, 2003.

6. Memorandum from Caroleene Paul, Directorate for Engineering Sciences, to Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, ''Response to ANPR Comments on Baby Bath Seats,'' January 27, 2003.

7. Memorandum from Jonathan Midgett, Ph.D, Division of Human Factors, to Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, ''Human Factors Staff Responses to Comments about Bath Seats,'' April 10, 2003.

8. Memorandum from Mary Donaldson, Directorate for Economic Analysis, to Patricia L. Hackett, Project Manager, Directorate for Engineering Sciences, ''Preliminary Regulatory Analysis of Proposed Rule for Baby Bath Seats,'' April 9, 2003.

9. Briefing memorandum from Ronald Medford, Assistant Executive Director, Office of Hazard Identification and Reduction and Celestine Kiss, Project Manager, Division of Human Factors, to the Commission, March 30, 2001.

10. Petition HP 00–4 from the Consumer Federation of America, The Drowning Prevention Foundation, *et al.* to Ban Baby Bath Seats, July 25, 2000.

11. Memorandum from Mary F. Donaldson, Directorate for Economic Analysis, ''Baby Bath Seat Petition, HP–00–4,'' February 16, 2001.

12. Memorandum from Suad W. Nakamura, Ph.D., Physiologist and Sandra E. Inkster, Ph.D., Pharmacologist, Directorate for Health Sciences, ''The Pathophysiology of Drowning,'' December 7, 2000.

13. Memorandum from Debra Sweet, Division of Hazard Analysis, ''Hazard Analysis Memorandum for Bath Seat Petition,'' January 29, 2001.

14. Memorandum from Celestine T. Kiss, Division of Human Factors, ''Human Factors Response to Bath Rings/Seats Petition (HP–00–04),'' January 25, 2001.

15. Memorandum from M. Kumagai, Directorate for Engineering Sciences, ''Review of BATH SEAT ASTM STANDARD

F1967 and Response to Comments to Petition HP 00–4,'' March 2, 2001.

16. Memorandum from M. Kumagai, Directorate for Engineering Sciences, ''Evaluation of Bath Seat Design,'' March 2, 2001.

17. Letter dated May 7, 2001 from Dr. Kimberly Thompson to Chairman Ann Brown re: Comments on Briefing Package Petition No. HP 00–4, Request to Ban Baby Bath Seats.

18. Memorandum dated May 21, 2001 to the Commission from Debra Sweet, Statistician, Division of Hazard Analysis, re: Comments from Kimberly M. Thompson, Sc.D., on Briefing Package for Petition HP 00–4, Request to Ban Baby Bath Seats.

[FR Doc. 03–31135 Filed 12–24–03; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP–1088–P]

RIN 1120–AB20

Administrative Safeguards for Psychiatric Treatment and Medication

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) amends its regulations on Psychiatric Treatment and Medication. We make several minor word changes to conform more closely with the language of 18 U.S.C. 4241–4247 on psychiatric hospitalization. We remove from the rule two elements of the standard for determining whether treatment or psychotropic medication is necessary because this element is inconsistent with community standards and case law. We also change the rules to conform with statutory authority regarding military prisoners and District of Columbia (DC) Code violators in Bureau custody. Previously, our procedures for involuntary psychiatric treatment and medication did not apply to military prisoners or DC Code violators. Under new statutory authority, military prisoners who are incompetent to stand trial, or who have been found not guilty by reason of lack of mental responsibility may now be committed to the Bureau's custody. Sentenced DC Code offenders may now be involuntarily committed to a Bureau psychiatric hospital. Such military prisoners and DC Code violators are subject to our regulations. We revise the applicability statement accordingly.

DATES: Please submit comments by February 27, 2004.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: The Bureau amends its regulations on providing psychiatric treatment and medication to inmates. We published a final rule on this subject in the **Federal Register** on September 25, 1995 (60 FR 49444).

The following is a section-by-section analysis of the changes we are making:

Section 549.40 Use of Psychotropic Medications. In this rule, we merely clarify that psychotropic medication is to be used only for a diagnosable psychiatric disorder or *symptoms* for which such medication is accepted treatment. Previously, the rule allowed medication for ''symptomatic behavior.'' The word ''symptoms'' is more accurate medical terminology.

Section 549.41 Voluntary Admission And Psychotropic Medication. In this section, we revise subparagraph (a) to more closely conform with the language of 18 U.S.C. 4241–4247. We change the words ''psychiatric treatment and medication'' to ''psychiatric hospitalization and treatment.'' We also clarify that inmates may be voluntarily admitted for psychiatric hospitalization and treatment when determined necessary by a clinician with hospital-admitting privileges, which is more accurate than the former term ''qualified health personnel.''

Section 549.42 Involuntary Admission. In this section, as in the previous section, we alter the first sentence by changing the words ''psychiatric treatment'' to ''psychiatric hospitalization'' to more closely conform with the language of 18 U.S.C. 4245.

Section 549.43 Involuntary Psychiatric Treatment and Medication. In this section, we revise the second sentence of the introductory paragraph by deleting'', and no further judicial authorization is needed for the admission decision.'' and inserting ''for the involuntary admission.'' The current rule explains that ''[c]ourt commitment for the hospitalization provides the judicial due process hearing.'' The remaining phrase, which states that no further judicial authorization is needed, is redundant and unnecessary. We therefore make this change to streamline and clarify the language of this rule.

In subparagraph (a)(5), we clarify that the psychiatrist conducting a hearing to determine whether treatment or psychotropic medication is necessary will no longer consider whether the inmate is unable to function in the open population of a mental health referral center or a regular prison as a separate basis to justify involuntary administration of medication. We make this change because we found this element to be inconsistent with community standards and applicable case law. *See Cochran* v. *Dysart,* 965 F.2d 649 (8th Cir. 1992).

Also in subparagraph (a)(5), we delete language that allowed the psychiatrist conducting an administration hearing to determine whether psychotropic medication is necessary to make an inmate competent to stand trial. This revision stems from the Supreme Court decision in *Sell* v. *U.S.*, 2003 WL 21372478, decided on June 16, 2003. Under the *Sell* decision, where involuntary treatment is considered solely for the purpose of rendering the defendant competent to stand trial, only the trial court may order involuntary medication after applying the standards set forth by the Court.

Finally, we change subparagraph (c) for the following reasons: Title 18 U.S.C. 4241–4247 and various Federal court decisions required certain due process procedures before involuntary hospitalization or involuntary psychiatric treatment. Under former 18 U.S.C. 4247(j), these due process procedures did not apply to military prisoners or DC Code violators.

However, new 10 U.S.C. 876b provides that military prisoners who are incompetent to stand trial or who have been found not guilty by reason of lack of mental responsibility may be committed to the custody of the Attorney General and that the procedures authorized under 18 U.S.C. 4241(d), 4246, and 4243 apply. Likewise, under new 18 U.S.C. 4247(j), DC Code violators are subject to commitment procedures specified at 18 U.S.C. 4245 and 4246.

Accordingly, we revise the list of exceptions in 28 CFR 549.43(c) to remove the reference to military prisoners and DC Code violators. We also clarified the last sentence of paragraph (c).

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'', section 1(b), Principles of Regulation. The Director has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this rule has not been