committee reviewed and unanimously recommended 2001–02 expenditures of $4,338,774. Prior to arriving at this budget, the committee considered information and recommendations from various sources, including, but not limited to: the Management Services Committee, the Research Subcommittee, the International Programs Subcommittee, the Grade and Size Subcommittee, the Domestic Promotion Subcommittee, and the Grower Relations Subcommittee. Some of these subcommittees discussed alternatives to increasing the assessment rate, such as permitting the rate to remain the same or increasing the rate to $0.19 or $0.195 per 25-pound container or container equivalent. The assessment rate of $0.20 per 25-pound container or container equivalent, is expected to result in an operating reserve of $214,138, more in line with committee financial needs. The $0.20 rate was subsequently recommended to the committee by the Management Services Committee.

As noted earlier, the committee then considered the total estimated expenses, the total estimated assessable 25-pound containers or container equivalents, the estimated income from other sources such as interest income, and additional funds required from the committee's financial reserve at varying assessment rates, as the subcommittees had done, prior to recommending a final assessment rate. Depending on the assessment rate established, the committee would require more or less funds from the financial reserve, which the committee uses to meet its obligations prior to billing and receiving handler assessments the following year. Based on those deliberations, an assessment rate of $0.20 per 25-pound container or container equivalent was agreed upon and recommended to the Department. Such an assessment rate would result in an adequate financial reserve.

A review of historical and preliminary information pertaining to the upcoming fiscal period indicates that the grower price for the 2001–02 season could range between $5.50 and $6.00 per 25-pound container or container equivalent of nectarines. Therefore, the estimated assessment revenue for the 2001–02 fiscal period as a percentage of total grower revenue could range between 3.35 and 3.65 percent.

This action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived from the operation of the marketing order. In addition, the committee's meeting was widely publicized throughout the California nectarine industry and all interested persons were invited to attend the meeting and participate in committee deliberations on all issues. Like all committee meetings, the May 3, 2001, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/fv/moab.html.* Any questions about the compliance guide should be sent to Jay Guerber at the previously-mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposal. Thirty days is deemed appropriate because: (1) The committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; (2) the 2001–02 fiscal period began on March 1, 2001, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable nectarines handled during such fiscal period; (3) handlers are aware of this action which was unanimously recommended by the committee at public meetings and is similar to other assessment rate actions issued in past years; and (4) this proposed rule provides a 30-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 916

Nectarines, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 916 is proposed to be amended as follows:

PART 916—NECTARINES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 916 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 916.234 is revised to read as follows:

§ 916.234 Assessment rate.

On and after March 1, 2001, an assessment rate of $0.20 per 25-pound container or container equivalent of nectarines is established for California nectarines.

Dated: July 26, 2001.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 01–19100 Filed 7–31–01; 8:45 am]

BILLING CODE 3410–02–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Baby Bath Seats and Rings; Advance Notice of Proposed Rulemaking; Request for Comments and Information

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Commission has reason to believe that baby bath seats and rings, as currently designed, may present an unreasonable risk of injury. The Commission is aware of 78 deaths and 110 non-fatal incidents and complaints from January 1983 through May 2001 involving baby bath seats and rings. Forty-one of these non-fatal incidents/complaints occurred when a caregiver was present. In July 2000, the Commission received a petition from the Consumer Federation of America and eight other organizations asking the Commission to ban baby bath seats. This advance notice of proposed rulemaking (''ANPR'') initiates a rulemaking proceeding under the Federal Hazardous Substances Act. The Commission solicits written comments concerning the risks of injury associated with baby bath seats and rings, the regulatory alternatives discussed in this notice, other possible ways to address these risks, and the economic impacts of the various regulatory alternatives. The Commission also invites interested persons to submit an existing standard, or a statement of intent to modify or develop a voluntary standard, to address

the risk of injury described in this notice. During the decision meeting, the Commission stated that the staff should undertake an aggressive, ongoing information and education initiative to inform new caregivers about the danger of leaving babies unattended in the bath or any source of water. The Commission solicits comments on this initiative.

DATES: Written comments and submissions in response to this notice must be received by October 1, 2001.

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) 504–0800. Comments also may be filed by telefacsimile to (301)504–0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned ''ANPR for Baby Bath Seats.''

FOR FURTHER INFORMATION CONTACT: Patricia Hackett, Directorate for Engineering Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0494, ext. 1309.

SUPPLEMENTARY INFORMATION:

A. Background

In 1994, the CPSC staff prepared for the Commission a briefing package discussing options for baby bath seats. At that time, the staff was aware of 13 infant deaths and seven non-fatal injury incidents that were associated with baby bath seats and rings. Most of the victims were between 6 and 11 months of age. The Commission also had reports of approximately 30 incidents in which the seats tipped over or the children slipped down in their seats, but for which no injuries were reported. The 1994 briefing package reported that in 1992, sales of bath seats/rings were around 660,000 units with a retail value of $9 million. Bath seats were owned by an estimated 28 percent of mothers with infants, with an estimated 1.4 million available for use in homes with infants in 1992.

Approximately 10 out of 66 firms that manufactured or imported bathing accessories for infants were identified as suppliers of baby bath seats/rings. In 1994, staff was not aware of any voluntary or mandatory safety standards for bath seats/rings.

In 1994, the Commission staff recommended that the Commission begin a rulemaking with the publication of an advance notice of proposed rulemaking (''ANPR''). On June 15, 1994, the Commission voted 2–1 against initiating a rulemaking, but instructed the staff to work with industry on a public information campaign. The staff asked the Juvenile Products Manufacturers Association (''JPMA'') to disseminate the message that caregivers should never leave a baby unattended in a tub of water. The staff also produced two safety alerts on the hazard and included the message in some safety publications.

In July 2000, the Consumer Federation of America and eight additional organizations petitioned the Commission to ban baby bath seats.[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. The petition was docketed under the Federal Hazardous Substances Act (''FHSA'') (Petition No. HP 00–4), and a notice requesting comments was published on August 22, 2000 in the **Federal Register**, 65 FR 50968.

The petitioners state that at least eight babies a year die due to drowning associated with baby bath seats. They state that these drownings ''typically occur when the infant tips over, climbs out of, or slides through the product.''

The petitioners also argue that the bath seats create a ''false sense of security,'' which ''leads to increased risk-taking behavior among those using the product even when the irresponsible nature of the caregivers is taken into account.''

B. The Product

This rulemaking covers baby bath rings and baby bath seats. Bath rings typically consist of a plastic ring with three or four legs equipped with suction cups. The infant sits directly on the bathtub surface or on a fitted sponge pad within the ring, straddling a bath ring leg. As defined here, bath rings are no longer manufactured for the U.S. market. However, they may still be available in the secondhand market. Baby bath seats are similar to bath rings, but provide a molded plastic seat for the infant to sit on. Suction cups are attached to the underside of the molded plastic seat.

Bath seats and rings are not intended to be used with textured or non-skid bathtub surfaces. Textured and non-skid bathtubs represent a substantial portion of the residential tubs sold today.

The Juvenile Products Manufacturers Association (''JPMA''), a trade association of manufacturers, importers, and distributors of juvenile products, noted in its comments on the petition that ''bath seats and rings are generally not recommended for use until six months of age or when the children can sit upright unassisted. They are usually discontinued in use when a child seeks to escape the confines of the product or can stand up while holding onto other objects. Theses [sic] products have a useful product life of several months with both lower and upper limits being determined by the development and ability of the child.'' Developmental literature indicates that infants begin to pull up on objects around 9 months of age. Based on this information, and allowing for developmental differences in individual children, bath seats/rings are most appropriate with infants from about 5 to 10 months of age.

At the time of the 1994 Commission briefing there were approximately 10 firms supplying baby bath seats/rings. Currently, however, there are only two manufacturers of bath seats in the U.S. market, with one of these controlling the majority of the market. Their estimated retail sales of new baby bath seats may range from 700,000 to 1,000,000 annually.

Commission staff estimates that there are between 1.3 and 2 million bath seats available for use in homes with infants. This estimate is based on 1999 survey results that indicated 33 percent of new mothers own bath seats or rings, census data that show about 4 million infants born per year in the United States, and an industry estimate of 2 million bath seats/rings in use.

Prices for infant bath seats range from about $10 to $16. Seats that convert from an infant bathtub to an infant bath seat sell for about $20 to $25.

C. The Risk of Injury

1. Incident Data

The Commission has reports of 78 deaths and 110 non-fatal incidents and complaints associated with baby bath rings or seats between January 1983 and May 2001.[2] Forty-one non-fatal incidents/complaints occurred while the caregiver was present.

The victims involved in the fatal incidents ranged in age from 5 months old to 20 months old. Sixty-eight of the

[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] The identified cases do not represent a complete count nor a sample of known probability of selection. The cases do provide information about the types of incidents associated with baby bathing aids.

victims were between 5 and 10 months of age. The age of victims most frequently involved in the fatal incidents was 7 months (22 of the 78). Seventy-five of the 78 deaths took place when the victim was left unattended (by the caregiver) in the bathtub for a few minutes or longer. The times that the caregiver was out of the room varied from a reported 2 minutes to over one hour. Some of the reasons stated for leaving the child unattended were to respond to unexpected phone calls or company, to retrieve towels or clothing, or to tend to another child in the home. Some caregivers left the victims unattended for more deliberate reasons such as performing household chores, playing video games, or watching television.

The remaining three deaths reportedly occurred while the caregiver was with the child in the bathroom. In two of these cases, the caregivers reportedly turned away momentarily and looked back at the victims to find them face down in the water. In the other case, the caregiver saw the incident occur but panicked briefly.

In 31 of the 78 deaths (40%), the victim was put into the bathtub with another child (or children). However, not all of these other children were still in the bathtub when the drownings occurred.

Most of the caregivers involved in the reported incidents were parents. Sixty-six of the victims were being cared for by a parent or a parent and another family member. The remaining twelve children died while under the supervision of a baby sitter. The youngest caregiver was 11 years old.

2. Hazard Scenarios

The Commission staff has identified six main hazard scenarios associated with bath seat/ring deaths and incidents. While not all of the deaths and near misses under each listed hazard scenario would be addressable due to the unusual circumstances in some of the cases, six identified hazard scenarios are discussed below.

Bath seat tipping over. In 24 fatalities and 56 non-fatal incidents and complaints the bath seat/ring was reported to have tipped over submerging the child in the water or allowing the child to escape the confines of the seat. In the incidents in which the seat was reported to have tipped over, the suction cups may have contributed because they failed to adhere to the tub surface; they adhered but the legs of the seat separated from the suction cups; or the suction cups were missing. It does not appear that one manufacturer's products were involved in significantly more fatal tip-over incidents than any other manufacturer's products.

Infant came out of the seat. In 14 fatalities and eight non-fatal incidents it was reported that the infant was found outside of the upright seat. Presumably in these incidents the child came over the top of the seat.

Entrapment and submersion. In 3 deaths and 15 non-fatal incidents and complaints it was reported that the infant slid through the leg opening, becoming trapped and submerged in the water. In the 3 fatalities the leg openings on the bath seats were large enough for the infants to fit both legs through one opening but not large enough to allow the shoulders and head to pass through. The infants died because their faces were partially or completely submerged in the bath water.

Infant slumped over bath seat. In 8 fatalities and 2 non-fatal incidents and complaints the infant was reported to have ''slumped over'' the bath seat rim. Although the water depth data provided in these cases is limited, water depth could have played a role in these incidents.

Overflowing water. In 2 fatalities and one non-fatality the bath water was reported to have overflowed. One death involved a 5-month-old child in a laundry tub. The other death involved an 8-month-old victim in a bathtub.

Bath seat breaking. The Commission received 11 complaints of bath seats breaking during use. The complaints included bath seat legs breaking or detaching, the rings around the child breaking, mats ripping away from the legs/suction cups and the bath seat cracking.

No scenario determined. In the remaining 27 fatalities and 17 non-fatal incidents and complaints, information was insufficient to determine a hazard scenario. These include incidents where children were found in water, but the position of the bath seat was unknown; incidents where the bath seat was upright, but the position of the child was unknown, and incidents where the circumstances were unknown or uncertain.

D. 1993 Focus Group

In preparation for the 1994 Commission briefing on bath seats/rings, Human Factors staff worked with a contractor to conduct consumer focus groups to learn more about how consumers use bath seats/rings. The groups provided a variety of information regarding bathing children, bath time supervision habits, and use of bath seats/rings. The following points summarize participants' responses regarding leaving children in the bathtub for a short period of time:

(1) Despite an intellectual knowledge of the hazard of drowning, and agreement that children should never be left alone in the bath, some participants acknowledged having done so, albeit infrequently, and typically for only a few moments.

(2) Responses suggested that, although emergency situations occur, they are not the primary reason that caregivers turn away from a child in the bath. Participants reported that practical, non-emergency reasons, such as needing a towel, pajamas, or a diaper were more likely reasons for leaving the child.

(3) Participants' responses indicated that uneventful experiences with leaving a child unattended in the bath tended to encourage repetition of this behavior.

(4) In general, participants perceived bath rings as convenience items rather than as safety devices. However, responses suggested that some users gained a sense of security from the sets/rings, and believed the child was safer in a bath seat/ring. These included comments that they believed their child was less likely to stand up or slip around if they were restrained in a bath seat/ring.

(5) The sturdier, more luxurious-looking bath rings/seats were preferred by most participants, and were perceived to be safer than more basic models.

(6) Young children are frequently bathed with their older siblings. Therefore, the bathtub is typically filled to meet the needs of the oldest child in the tub. In addition, the presence of older siblings, especially those considered mature, increases parents' confidence that their young child will be safe if they must leave the bathroom for a moment. Participants were unable to come to any consensus regarding at what age a child can be trusted in the bath alone or at what age a sibling is old enough to supervise a younger child in the bath.

E. Research reported by Dr. N. Clay Mann

Petitioners refer to recent research conducted by Dr. N. Clay Mann under the auspices of a co-petitioner, the Intermountain Injury Control Research Center at the University of Utah. Dr. Mann compared infant drowning deaths in bathtubs with infant drowning deaths in bathing aids in bathtubs. The petitioners cite two main conclusions from Dr. Mann's presentation. First, Dr. Mann characterized caregivers' recollections as to why they left a child unattended in the bathtub as more likely

to be willful as opposed to impulsive when there was a bath seat present in the bathtub. Second, Dr. Mann's analysis found that the water at the time of the fatal incident was deeper in incidents involving baby bath seats than in bathtubs without a bath seat, and that the difference was statistically significant.

CPSC staff analyzed the bath seat and bathtub data Dr. Mann used in his research. Although the staff's analysis yielded slightly different results, the basic conclusions were the same. CPSC staff found that when a bath seat was involved caregivers were more likely to cite a conscious or willful decision for leaving the child alone than when there was a bathtub drowning with no bath seat involved. Staff also found a slightly higher water depth for those deaths where children were in bath seats.

According to CPSC staff's analysis of the hazard scenarios, the water depth may be an issue in the situations in which the bath seat is upright and the infant slumps over the seat rim or when the infant comes out over the top of the seat; however, the water depth data was very limited and therefore no conclusions could be made.

F. Relevant Statutory Provisions

The petition was docketed under 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 ''in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness.'' 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 is commenced by issuance of this ANPR. After considering any comments submitted in response to this ANPR, the Commission will decide whether to issue a proposed rule and a preliminary regulatory analysis in accordance with section 3(h) of the FHSA. If a proposed rule is issued, the Commission would then consider the comments received in response to the proposed rule in deciding whether to issue a final rule and a final regulatory analysis. 15 U.S.C. 1262(i).

G. Regulatory Alternatives

One or more of the following alternatives could be used to reduce the identified risks associated with baby bath seats and rings.

1. *Mandatory standard.* The Commission could issue a standard that would ban any baby bath seats or rings that did not comply with the specified standard. Thus, if the Commission found that some modifications to baby bath seats/rings were possible that would adequately reduce or eliminate the risk of injury associated with the current product, the Commission could issue such a standard-setting rule.

2. *Mandatory labeling rule.* Similarly, the Commission could issue a rule banning bath seats and rings that did not contain specified warnings if it found that such warnings could sufficiently reduce the risk of injury associated with baby bath seats/rings.

3. *Voluntary standard.* If the Commission determined that a voluntary standard was adequate to address the risk of injury associated with the product, the Commission could defer to the voluntary standard in lieu of issuing a mandatory rule.

4. *Banning rule.* The Commission could issue a rule declaring baby bath seats and bath rings to be banned hazardous substances.

H. Existing Standards

When the Commission first examined baby bath seats in 1994, no mandatory, voluntary or international standards addressed drowning while using baby bath seats and rings. Currently, the Commission is aware of one voluntary standard relating to bath seats, the ASTM F1967–99 Standard Consumer Safety Specification for Infant Bath Seats (first published in June 1999). During August and September 1999, additional requirements for improved performance of suction cups and latching/locking mechanisms were balloted; ASTM estimates that the revised standard will be published by July 2001.

1. Provisions of the Bath Seat Voluntary Standard

According to the statement of scope in the standard, ''This consumer safety specification establishes performance requirements, test methods, and labeling requirements to promote the safe use of infant bath seats.'' A summary of the major requirements in this standard follows:

Stability. This requirement addresses the bath seat's resistance to tipping over during normal use. The provision is intended to ensure that new bath seats' suction cups properly attach to the bathtub surface.

Restraint. Bath seats must provide a passive crotch restraint to prevent the occupant from sliding out through the product. For bath seats on the market this requirement is met by a fixed vertical bar between the infant's legs. The standard also specifies that bath seats shall not include additional restraints that require action by the user. The rationale for this requirement was that a redundant system would give the caregiver a false sense of security.

Resistance to Folding. If the bath seat folds, it is required to have a latch or locking mechanism to prevent the unit from unintentionally folding during use.

Labeling. The standard requires a warning label on the product, instructions, and packaging consisting of the safety alert symbol (an equilateral triangle surrounding an exclamation point), the signal word WARNING in all capital letters and the following two sentences: ''Prevent drowning. ALWAYS keep baby within arms reach.'' The signal word and all other capital letters shall be in san serif type-face with letters not less than 5 mm (0.2 inches) in height, with all remainder of the text not less than 2.5 mm (0.1 inches) in height. The warning must be located on the product so that it is visible to the adult caregiver and must be a contrasting color to the background. If the bath seat is not recommended for use on a slip-resistant surface, an additional warning label stating this is required only on the package.

2. Concerns About the Bath Seat Voluntary Standard

After reviewing the voluntary standard, the staff is concerned that provisions for stability of the seat, suction cup operation, occupant retention and labeling may not adequately address the drowning hazard.

All bath seats currently on the market rely on suction cups to keep the seat stable. The stability of the seat is greatly affected by the existence or performance of the suction cups. If suction cups are missing or detach from the tub surface or the bath seat, it is more likely that the bath seat will tip over when the occupant leans out over the rail. The stability test in the voluntary standard addresses suction cup performance but not performance over time or on non-smooth or dirty surfaces. The suction

cups operate by creating an air or watertight seal between the bathtub surface and the bottom of the suction cup material. A leak in the seal between the suction cup and bathtub surface allows air or water to leak under the suction cup resulting in detachment of the suction cup from the tub surface. A rough tub surface would allow such a leak to occur. The suction cups used on bath seats will not adhere to textured bath surfaces or slip resistant surfaces. Dirt or soap scum build up could also degrade the performance of the suction cups.

The occupant retention system currently required by the ASTM F1967 standard for bath seats is a passive crotch restraint. A center post is the most common form of passive restraint used on bath seats and is intended to prevent the infant from slipping down and out of the bath seat. However, the standard does not have any leg opening size requirements, and staff is aware of three deaths when infants got both legs through a leg opening and became trapped and submerged under water because their shoulders and head could not pass through the opening.

Moreover, this type of passive restraint does not prevent the infant from climbing out of the bath seat. Also, the ASTM F1967 bath seat standard does not allow additional user activated restraints because the subcommittee believed that this would provide the caregiver with a false sense of security and could increase the likelihood that a parent might leave a child unattended.

According to the Division of Human Factors, warning labels have limited effectiveness on user behavior when the product is familiar and perceived to be benign. Warning labels are the least effective way to address a hazard and, if possible, should not be relied upon as the sole means of preventing deaths and injuries. This is particularly true when the product is familiar and perceived to be benign.

The voluntary standard also requires a label on the packaging of the product, but not the bath seat itself, advising consumers not to use the product on non-skid bathtub surfaces. This label is likely to have limited effectiveness because (1) it fails to explain to the user the hazard of using the product on a slip-resistant surface (i.e., suction cup failure), and (2) the product's packaging is not likely to remain with the product and the message is lost to anyone who does not see the packaging. This type of product is likely to be handed down to family and friends with young children or sold at garage sales without the packaging.

3. Voluntary Standard for Slip Resistant Tub Surfaces

The Commission is aware of an ASTM standard for slip-resistant bathtub surfaces, ASTM F 462–79 (reapproved 1999) ''Standard Consumer Safety Specification for Slip-Resistant Bathing Facilities.'' According to the Plumbing Manufacturers Institute (''PMI''), this standard is used for most enameled-coated steel tubs but not for plastic tubs. Suction cups will not adhere to slip resistant surfaces. Therefore, this standard could affect the performance of bath seat suction cups.

I. Public Comments on the Petition

The Commission published a **Federal Register** notice asking for comments on the petition when it docketed the petition. 65 FR 50968 (August 22, 2000). The Commission received 66 comments in response to the notice. Of those 66 comments, 45 were a form letter expressing the same concerns as those of the petitioner and asking the Commission to support the petition to ban bath seats. Seventeen other comments also supported the petition and expressed concerns about the hazards involving bath seats. Three comments discussed in-depth why the CPSC should deny the petition. Finally, one consumer provided information both supporting and opposing the petition.

Discussed below are the eight primary issues raised in the comments and the Commission's responses to those issues. The numbers found in parentheses after a comment refer to the commenter number assigned by the Office of the Secretary. The letters ''FL'' refer to the form letter used by many of the commenters.

1. Unreasonable Risk

Comment: According to most commenters, 66 deaths from January 1983 to June 2000 and 37 near-drownings are too many. They note that when the Commission first looked into the hazards involving bath seats there had been 13 deaths in 10 years. In the following 6 years, 53 additional deaths occurred. They viewed this as an unreasonable risk because of the ''alarming'' number of deaths with a product that they stated had a useful life of only 2 months. (FL, #20, 24, 28, 56, 58, 60)

CPSC Response: The Commission is also concerned about the number of deaths. CPSC staff has identified 78 deaths and 110 non-fatal incidents from January 1983 to May 2001. However, the large number of incidents reported to CPSC from 1995 through 2001 are not necessarily due to an increase in frequency of the events. After the Commission's actions in 1994, staff increased data collection efforts by investigating all bathtub drowning deaths. Media attention increased public awareness of the hazard and number of deaths, thus increasing the reporting of the incidents. Because of the increased efforts of data collection on infant drownings, CPSC staff is confident in the completeness of the bathtub drowning data. These continued efforts should allow for trend analysis in bath seat-related drowning deaths. Death data prior to 1994 and incident data are anecdotal and should not be used to suggest trends.

2. False Sense of Security

Comment: Many commenters quoted research conducted by Dr. N. Clay Mann that suggests parents and caregivers of infants who use bath seats engage in more risk-taking behavior than non-bath seat users. These commenters argue that bath seats are viewed as safety devices and thereby provide the user with a false sense of security. The petitioners and almost all of the comments from consumers in favor of granting the petition indicated that the product leads the user to believe that the child is ''safe'' in the bath seat in the water. (FL, #1, 54, 56, 59, 60, 62)

Some commenters stated that the product may not claim to be a ''safety device'' but it certainly gives the impression it is, especially those with the brand name ''Safety 1st'' on the package. (#13, 16, 28, 40, 64)

One commenter, who opposes the petition, stated that the product does not cause a false sense of security, but rather the caregiver undertakes risky behavior because previous behavior resulted in no injury. (#53)

Another commenter, who also opposes the petition, stated, ''The unreasonable actions of caregivers who leave infants unattended in bathtubs, whether or not a bath seat or ring is used, results in the hazards, with tragic consequences. This behavior itself defies the common sense approach used by 99.999% of the population and is unreasonable. As we have noted, the products themselves performed properly and as intended. It was not the normal or even foreseeable misuse of the product that creates the hazard, but rather the unreasonable behavior of the caregiver. No standard, whether mandatory or voluntary, can address this risk.'' (#63)

CPSC Response: Various sources [3] indicate that many consumers purchase the product for safe handling of babies and convenience reasons. Consumers may not be ready to bathe their infants in a regular size bathtub and, therefore, are looking for a device to help them contain a wet, slippery, squirmy infant.

In determining whether a product presents a mechanical hazard, the Commission considers the product's normal use and reasonably foreseeable abuse. *See* 15 U.S.C. 1261(s). 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.

The Commission agrees that babies should never be left alone in water, whether with a bath seat or not and intends to undertake an aggressive information and education campaign to reinforce this message. In some incidents, the hazard scenario was unclear. However, the available information indicates that some aspects of bath seat design appear to have been a factor in the deaths of a number of infants. In the course of rulemaking, the Commission will examine ways to address these design-related hazards.

3. Bath Seat Incompatible With Bathtubs

Comment: Several comments pertained to the current voluntary standard, ASTM F 462–79 (reapproved 1999) ''Standard Consumer Safety Specification for Slip-Resistant Bathing Facilities.'' This standard establishes slip-resistance surface requirements to minimize injuries in tubs and showers. The commenters indicated that suction cups that are used to adhere the bath seats to the tub surface do not work on slip-resistant surfaces. (FL, #2, 28, 59, 60, 64)

Another commenter, who opposes the petition, stated, ''As we have noted, the products themselves performed properly and as intended.'' However, that same commenter indicated that the data show suction cups on the seats failed on smooth surface bathtubs not just slip-resistant surfaces. (#63)

CPSC Response: According to CPSC Engineering Sciences staff, adherence of the suction cup to the bathtub surface requires an adequate seal between the mating surfaces. Suction cups used on bath seats will not adhere to textured bath surfaces or slip-resistant surfaces. Dirt or soap scum build up could also degrade the performance of the suction cup. However, dissolved or suspended particles in the bath water such as oils and soap should not affect the suction cup adherence to the tub.

The Commission disagrees with the commenter's statement that the ''products themselves performed properly and as intended.'' In certain of the incidents, the products did not perform as intended. In 24 of the 78 fatalities and 56 reported non-fatalities, the bath seats detached from the tub surface and tipped over. In addition, many consumers reported on an opinion website that they were using the bath seat when all of a sudden, without any warning the seat tipped over and the child was under the water. In some of these incidents the consumers stated that they had used the product a number of times before and occasionally had difficulty removing the suction cups when bath time was over. Other consumers indicated that right from the start they had trouble with the suction cups only working some of the time.

CPSC data are inconclusive about the types of surfaces on which the tip-overs occurred, so CPSC is unable to verify the commenter's assertion that data show seats failed on smooth surface tubs. However, there were a number of comments on the Internet in which consumers specifically state that their tubs had smooth surfaces and the suction cups failed.

4. Labeling—Slip Resistant Surfaces

Comment: A few commenters stated that the label warning against the use of the bath seat on non-skid tubs should be on the product, not just the package. Due to the short useful life of the product, the bath seat is likely to be passed on to other family members or friends without the box. This makes the label ineffective for these other users. (#2, 59)

CPSC Response: CPSC agrees with the comments that a warning label only on the packaging and not on the product is likely to be less effective than a label placed on the product. The effectiveness of this label is limited for two reasons. First, it fails to explain to the user why the product should not be used on non-skid bathtub surfaces (suction cup failure). Second, the product's packaging is not likely to remain with the product; therefore, the message is lost to anyone who does not see the packaging.

5. Labeling—Keep Child Within Arm's Reach

Comment: Regarding the labeling warning to keep the child within arm's reach, a commenter who is against the petition, referenced information from CPSC focus groups that were conducted in 1993. The commenter states ''Almost all of the parents surveyed recalled the warnings on the product, packaging or instructions and view it as an important reminder that the consequences of leaving an infant alone in the bathtub could be drowning. This fact undercuts the Petitioners' argument that the warnings are not noticed and are ineffective.'' (#63)

CPSC Response: The Commission disagrees with the commenter's conclusion that the focus group results which showed that consumers recalled the warning label are evidence that undercuts the arguments that warnings are not noticed and ineffective. According to the focus groups, consumers were able to recall the warning not to leave a child unattended. However, the focus group members also reported situational variables that made them comfortable leaving a child unattended. Those variables include using a bath ring/seat, having an older sibling in the bath, and being able to see and hear the child even though they had physically left the bathroom.[4] Judging from the focus group's comments and the actions of the caregivers in the fatal and non-fatal incident data who left the child alone in bath rings/seats, in those instances the warnings were ineffective.

6. Water Depth

Comment: A couple of commenters expressed the belief that if parents are not given proper guidance they will fill the tub with more water than is necessary. They stated that the bath seats should be marked with a ''water line'' so caregivers don't fill the water higher than the ''safe level'', since too much water increases chances of drowning. (#2, 64)

One comment from a consumer against the petition states, ''The marker should be set at a point where in case the baby fell out of the seat, he or she would not be in danger of drowning.'' (#53)

CPSC Response: The Commission will consider the merits of having a ''waterline'' on the product. There is no ''safe'' water level to prevent drownings that occur in the tub, but outside of the bath seat (or in cases where a seat tips over with the child still in it). However, a maximum water level mark, as reflected by guidance on the product, could help prevent drownings that occur when overly deep water either causes infants to come out of the seat or

[3] Sources included: CPSC focus groups results, IDIs, consumer opinions on internet website and marketing information.

[4] ''A Focus Group Study to Evaluate Consumer Use and Perceptions of Baby Bath Rings/Seats CPSC–R–93–5839'' by Shugoll Research.

covers their faces if they slump forward or backward in the seat.

7. Bath Seat vs. Bathtub

Comment: One of the comments against the petition states that on average 4 children per year drown in bath seats while ''in excess of 50 infants under one year of age are estimated to drown because caregivers fail to watch infants in bathtubs.'' This commenter believes that ''statistically, it seems that children are safer when caregivers use bath seats compared to when they are not in use.'' (#63) Another comment, also against the petition, stated that on average there are 9 bath seat drownings and 41 bathtub drownings as a result of the primary caregiver leaving the child alone. (#61)

CPSC Response: Averaging the 78 deaths over 18 years produces an average of 4 bath seat deaths a year. However, due to incomplete reporting, especially in the first years of data collection on this subject, this average is not an adequate statistic. The commenter fails to incorporate the number of users into his comparison of bathtub deaths and bath seat deaths. Since more children are bathed in a bathtub than in a bath seat, one would expect the number of children who die in bathtubs to be greater than the number of children who die in bath seats. In addition, the quoted 50 deaths per year includes bath seat deaths and deaths in bathtubs with other products.

The Commission staff has performed a more detailed analysis in an attempt to calculate the relative risk of children drowning in bathtubs with and without a bath seat. Staff analyzed drowning data from 1994 through 1998 in conjunction with bath seat ownership rates from the Baby Products Tracking Study. The focus was on children between 5 and 10 months old and children who were placed in the bathtub or seat by the caregiver for the purposes of receiving a bath.

Based on this analysis, the overall risk of death of drowning for children between 5 and 10 months old is slightly lower when a bath seat is present than when no additional bath aid is present. Due to the developmental differences in children between 5 and 10 months, staff felt it necessary to look at the risk of drowning for each month of age of the recommended user. This data showed similarities among 5, 6, and 7 month old children and similarities among children 8, 9, and 10 month olds. The data suggest that children 5 to 7 months old may be more at risk of death when bathed in a bath seat than when bathed in a bathtub. At 8 to 10 months, the risk of death is greater in a bathtub than in a bath seat. The Commission cautions that the small numbers and the use of ownership data as opposed to usage data make it difficult to draw firm conclusions about relative risk.

The Commission reviewed data from the National Center for Health Statistics (''NCHS'') on bathtub drowning deaths to children under one year of age to look at long-term drowning data. The number of bathtub drowning deaths and the risk of death per live birth slightly increased through the 1980's and has declined in the 1990's. These data, however, include incidents with bath seats, other bathing products, and incidents where children climbed or fell into bathtubs, as well as incidents where children drowned while taking a bath. Therefore, we cannot extract trends in bath seat deaths over this time period. The Commission does not have information from which to attribute a cause of the decline in infant bathtub drowning deaths.

8. Current Bath Seat Voluntary Standard

Comment: Three of the comments supporting the petition stated that the current ASTM F1967–99 ''Standard Consumer Safety Specification for Infant Bath Seats'' is ineffective in addressing the hazard of bath seat drownings. One consumer called the standard a ''performance'' standard rather than a ''safety'' standard. (#40) Another stated that the standard failed to adequately address the leg opening problem, the efficacy of suction cups, the lack of a water line, and the failure to label the product regarding non-skid surfaces. (#2) The third consumer felt the standard was inadequate because it called for ''no significant structural changes to existing bath seat designs.'' (#54)

One comment against the petition states that ''the voluntary standard addressed most of all of the CPSC staff recommendations.'' (#63)

CPSC Response: The Commission agrees that there are concerns with the adequacy of the voluntary standard. These concerns are discussed in detail in section H.2. above. The current voluntary standard was not intended to address all hazard scenarios. As noted, the current voluntary standard does not address leg-opening requirements. CPSC is aware of 3 fatalities and 15 non-fatalities in which infants slipped partially through the leg opening and became trapped and submerged under water. Although the voluntary standard has requirements for testing the stability of the seat, the test is performed using a new bath seat on a simulated bathtub surface and does not address suction cup performance over time or suction cup performance on non-smooth or dirty surfaces. CPSC data show 24 fatalities and 56 non-fatalities occurred when the seat tipped over. In most of these cases the suction cups played a part in the tip-over by either failing to adhere to the tub surface; adhering to the surface but separating from the seat legs; or from being missing. The adequacy of the requirement for labeling on the package concerning non-skid surfaces is also questionable because it does not specifically identify the hazard and because the label is only required for the package.

The voluntary standard does not require a waterline, and Commission staff in the past has agreed with this approach. While there is no ''safe'' water level for children who are in the tub but outside of their bath seat (or where the seat tips over and the child remains in it), encouraging less water in the tub through some mark on the product could reduce the incidents of infants drowning by coming out of the bath seat or when they slump over in their seats.

The staff recommendations that were provided to the voluntary standards' working group were intended to make bath rings/seats less dangerous. The staff's position as reported in the May 1994 briefing package stated: ''Based on current research, labeling is known to have limited effect on user behavior, particularly when the product is familiar and perceived to be benign. Judging from the IDIs, the effectiveness of the current label is questionable, but for the sake of those who may read and heed it, a more specific and direct warning such as 'Stay in arm's reach of baby in bath seat * * *' was recommended.'' The ASTM committee did adopt the staff recommended labeling and adopted certain requirements for suction cups at the Commission staff's request. Also, staff recommended leg-opening requirements that were not included in the standard.

J. Solicitation of Information and Comments

This ANPR is the first step of a proceeding that could result in a mandatory rule for baby bath seats and rings to address the described risk of injury. All interested persons are invited to submit to the Commission their comments on any aspect of the alternatives discussed above. In accordance with section 3(f) of the FHSA, the Commission solicits:

1. Written comments with respect to the risk of injury identified by the Commission, the regulatory alternatives

being considered, and other possible alternatives for addressing the risk.

2. Any existing standard or portion of a standard which could be issued as a proposed regulation.

3. A statement of intention to modify or develop a voluntary standard to address the risk of injury discussed in this notice, along with a description of a plan (including a schedule) to do so.

In addition, the Commission solicits the following specific information:

1. Information on the useful life of currently produced bath seats;

2. Information on the potential effect of any regulatory action on firms, including small entities;

3. Information on potential loss of consumer utility from any regulatory action;

4. Information on mechanisms to enhance stability/retention, especially in tubs with non-skid surfaces;

5. Information on the appropriate mechanisms to prevent infants from sliding through the bath seat (''submarining'');

6. Any exposure data and/or any calculations relative to the risk of drowning in bath tubs with or without bath seats;

7. Any other information available related to the potential costs and benefits of a rule.

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 20814; telephone (301) 504–0800. Comments also may be filed by telefacsimile to (301) 504–0127 or by email to cpsc–os@cpsc.gov. Comments should be captioned ''ANPR for baby bath seats.'' All comments and submissions should be received no later than October 1, 2001.

Dated: July 26, 2001.

Todd Stevenson,

Acting Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. 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.

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

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

4. 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.

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

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

7. 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.

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

9. 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.

10. 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.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA65

Civilian Health and Medical Program of the Uniformed Services; Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC)

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: The Department of Defense (DoD) proposes to amend its regulations on the Individual Case Management Program (ICMP) to implement requirements stipulated by Section 703 of the Fiscal Year (FY) 2000 National Defense Authorization Act, Section 8118 of the FY 2000 Defense Appropriations Act, Section 701 of the FY 2001 National Defense Authorization Act and Section 8100 of the FY 2001 Defense Appropriations Act. Other administrative amendments are also proposed to clarify specific policies that relate to the program. Public comments are invited and will be considered for possible revisions to the final rule.

DATES: Written comments will be accepted until October 1, 2001.

ADDRESESES: Please address all comments concerning this proposed rule to Mary Stockdale, Program Development Division, TRICARE Management Activity (TMA), Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041.

FOR FURTHER INFORMATION CONTACT: Mary Stockdale 703–681–0039.

SUPPLEMENTARY INFORMATION:

I. Background

Congressional actions in the last two fiscal years make important changes to the TRICARE Individual Case Management Program (ICMP). These actions continue the long-standing TRICARE/CHAMPUS definition of custodial care for purposes of the statutory exclusion from coverage under the basic TRICARE program. In addition, they reaffirm congressional policy of addressing the health care needs of custodial care patients through the TRICARE ICMP.

To distinguish this special waiver program from other normal case management functions under the basic TRICARE program and to more clearly identify the type of beneficiaries for which it is intended, the program name is now expanded to the Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC). It is also important to distinguish the ICMP–PEC from the Program for Persons with Disabilities (PFPWD). The PFPWD is applicable only to family members of active duty service members and the benefit is limited to $1,000 per month. Its purpose is to provide financial assistance to reduce the effects of mental retardation or a serious physical disability. It is not a stand-alone program, is subject to certain restrictions, and it may be used concurrently with other TRICARE medical programs like the ICMP–PEC.

II. Synopsis

This brief synopsis summarizes the primary requirements that are now applicable to the ICMP–PEC.