

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION 4330 EAST WEST HIGHWAY BETHESDA, MD 20814 This doc The contents of this document will be discussed at the open Commission Meeting (Briefing) scheduled for September 7, 2011.

This document has been electronically approved and signed. **DATE:** August 17, 2011

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: September 14, 2011

- **TO:** The Commission Todd A. Stevenson, Secretary
- **THROUGH:** Cheryl A. Falvey, General Counsel Kenneth R. Hinson, Executive Director
- **FROM:** Philip L. Chao, Assistant General Counsel Leah Wade, General Attorney
- **SUBJECT:** Notice of Proposed Rulemaking: Safety Standard for Play Yards

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice on a proposed rulemaking. The proposed rule would establish a safety standard for play yards pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options:

I. Approve publication of the attached document in the *Federal Register*, as drafted.

(Signature)

(Date)

CPSC Hotline: 1-800-638-CPSC(2772) H CPSC's Web Site: http://www.cpsc.gov

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Page 2 of 2

(Signature)

II.

III.

IV.

(Date)



Staff Briefing Package

Section 104(b) of the Consumer Product Safety Improvement Act of 2008: Safety Standard for Play Yards Notice of Proposed Rulemaking

August 17, 2011

COMMISSION.

Table of Contents

| Proposed Changes to ASTM F 406-11, <i>Standard Consumer Safety Specification for Non-Full-</i> <i>Size Baby Cribs/Play Yards</i> , for Incorporation in Notice of Proposed Rulemaking (from the Office of Hazard Identification and Reduction) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| TAB A: Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between November2007–Present (from the Directorate for Epidemiology)15 |
| TAB B: Proposed Change to ASTM F 406-11, Standard Consumer Safety Specification for Non- Full-Size Baby Cribs/Play Yards, for Incorporation into Staff's Draft Proposed Rule (from the Directorate for Engineering Sciences)23 |
| TAB C: Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard forPlay Yards (from the Directorate for Economic Analysis)40 |
| TAB D: Federal Register Notice of Proposed Rulemaking to establish a Safety Standard forPlay Yards (from the Office of the General Counsel)48 |



UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION BETHESDA, MD 20814

Memorandum

This document has been electronically approved and signed.

Date: August 17, 2011

| TO: | The Commission Todd A. Stevenson, Secretary |
|-----------|--------------------------------------------------------------------------------------------------------------|
| THROUGH: | Kenneth R. Hinson, Executive Director Cheryl A. Falvey, General Counsel |
| FROM: | DeWane J. Ray, Acting Assistant Executive Director Office of Hazard Identification and Reduction |
| | Gregory K. Rea, Project Manager Division of Mechanical Engineering Directorate for Laboratory Sciences |
| SUBJECT · | Proposed Changes to ASTM F 406-11 Standard Consumer |

SUBJECT : Proposed Changes to ASTM F 406-11, *Standard Consumer Safety Specification* for Non-Full-Size Baby Cribs/Play Yards, for Incorporation in Notice of Proposed Rulemaking

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC) to study and develop safety standards for certain infant and toddler products. The list of products in section 104 includes: full-size and non-full-size cribs; toddler beds; high chairs, booster chairs, and hook-on chairs; bath seats; gates and other enclosures for confining a child; play yards; stationary activity centers; infant carriers; strollers; walkers; swings; and bassinets and cradles. The Commission is charged with examining and assessing the effectiveness of any voluntary consumer product safety standards and for promulgating mandatory consumer product safety standards for these products.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the voluntary standards. This consultation process commenced in the summer of 2010, with staff participation in an ASTM International (formerly known as the American Society for Testing and Materials) Task Group within Subcommittee F15.18 – Cribs, Toddler Beds, Play Yards, Bassinets, Cradles and Changing Tables. This Task Group was formed at staff's request, specifically for this purpose. Consultations with stakeholders are ongoing.

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

This briefing package assesses the effectiveness of voluntary standards for play yards and presents staff's recommendations for a draft proposed rule.

II. BACKGROUND

A. Product Review

The voluntary standard, ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, defines "play yard" as a "framed enclosure that includes a floor and has mesh or fabric sided panels primarily intended to provide a play or sleeping environment for children."¹ Play yards are defined in this manner to distinguish them from rigid-sided, non-full-size (NFS) and full-size (FS) baby cribs (see Fig. 1). All play yards known to staff fold for travel or storage. The intended user of a play yard, per F 406-11, is a child who cannot climb out of the play yard and who is less than 35 inches (890 mm) in height.



Figure 1: Infant Sleeping Products

Play yards currently are not explicitly regulated by the CPSC. The non-full-size crib standard,² which adopts by reference ASTM F 406-10a, specifically excludes play yards from the §1220.2 performance requirements for NFS cribs. It is important to note that although the CPSC decided to promulgate mandatory rules for play yards separately from NFS cribs, ASTM has combined NFS cribs with play yards under the ASTM voluntary standard, F 406.

ASTM F 406 also covers bassinets, changing tables, and similar attachments to play yards. This memorandum does not present hazard or incident data that directly relate to play yard attachment products. Those hazards and incidents are being addressed in other CPSC regulatory work for those specific products. Incident and hazard data related to attachments that indirectly affect the play yard occupant space are addressed in this memorandum.

¹ Definition 3.1.19 "play yard (aka playpen)," ASTM F 406-11, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards, June 2011.

² 16 CFR Part 1220, §1220.1 *Safety Standards for Full-Size Baby Cribs and Non-Full-Size Baby Cribs*; Federal Register/Vol. 75, No. 248/Tuesday, December 28, 2010/Rules and Regulations.

B. Voluntary Standards Overview

1. ASTM Play Yard Standard F 406

The voluntary standard, ASTM F 406, *Standard Consumer Safety Specification for Play Yards*, was first published in 1977, to address identified hazard patterns associated with the use of mesh/fabric cribs or play yards. In 1997, ASTM published a standard for non-full-size cribs, ASTM F 1822, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs*, to address incidents associated with both NFS wooden cribs and mesh/fabric cribs. Realizing that the product categories overlapped, and desirous of eliminating standard duplication, in June 2002, ASTM combined the two standards into ASTM F 406-02, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*.

ASTM F 406 has been revised several times since 2002. In 2005, ASTM revised the standard twice. The changes included testing requirements for play yard accessories and modified the scope to eliminate the dimensional restrictions. Revisions that affect play yards, published in March and October 2008, were the addition and clarification of requirements that address the strangulation hazard posed by straps that hang from an attachment into the sleep/play area.

The most substantial revision since 2002, ASTM F 406-10, was approved on June 1, 2010, and modified the previous version in response to the CPSC's notice of proposed rulemaking (NPR) for crib standards. This was followed quickly by revisions F 406-10a and -10b. Together, these three revisions aligned the NFS crib standard with the FS crib standard, F 1169-10. By the end of 2010, both NFS and FS cribs were subject to the same ASTM performance requirements and were both aligned with the crib NPR—with one exception—removal of the fastener retightening allowance between tests.

The most recent revision, F 406-11, was published in June 2011, and includes several new requirements developed by CPSC staff jointly with other stakeholders in the ASTM play yard subcommittee Task Group.

2. Other Play Yard Standards

CPSC staff compared the performance requirements of ASTM F 406-11 to other international play yard standards:

- Europe EN 12227-1 & -2:2010
- Australia/New Zealand–AS/NZS S2195:2010
- Canada–Health Canada C.R.C., c. 932

Table 2 in the Appendix of Tab B presents a summary of these standards' performance requirements.

There are differences between all of the international standards and CPSC staff's recommended proposed rule. The differences have been reviewed and evaluated by staff. It is believed that the requirements already found in ASTM F 406-11, plus staff-recommended changes are the most stringent requirements among all of the standards or are adequate to address the incidents seen in the data and reduce the risk of injury from these products.

C. Juvenile Products Manufacturers Association Certification

The Juvenile Products Manufacturers Association (JPMA) has a certification program for a variety of juvenile products, including play yards. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current ASTM voluntary standard. Members have 6 months after the publication of new or revised standards to certify compliance. ASTM F 406-11 was published in June 2011; accordingly, manufacturers who produce JPMA-certified play yards have through December 2011 to comply with its requirements. Currently, there are 11 firms (eight manufacturers and three importers) that offer JPMA certified play yards.

III. DISCUSSION

A. Stakeholder Input

ASTM holds subcommittee meetings for play yards twice a year, typically in the spring and fall. Over the past year, there have been two additional play yard subcommittee meetings in an effort to decrease the time needed to incorporate changes into the standard. Attendees included representatives from manufacturers, retailers, JPMA, third party test laboratories, consumer advocacy groups, Health Canada, independent juvenile product technical consultants, and interested members of the public. CPSC technical staff attend these meetings consistently; and typically, staff supplies the subcommittee with incident data, either in the form of redacted indepth investigation reports (IDIs) or summary spreadsheets.

On August 28, 2010, staff updated the subcommittee on the progress of the CPSC play yard rulemaking project. The presentation concluded with staff requesting that the subcommittee form a task group to develop requirements addressing three issues:

- 1. Corner bracket structural integrity,
- 2. Mattress pad displacement restraint, and
- 3. Side rail V-shape prevention.

ASTM has since balloted and approved new requirements addressing all of these issues; they are now included in the latest version of the play yard/NFS crib standard, F 406-11.

B. Recent Compliance Activity

Since 2009, the CPSC has issued four recalls of more than 1.4 million play yards. All of these recalls were for product defects that created a substantial product hazard. The last three were recalled after staff determined that one or more rails can collapse unexpectedly, posing a fall or entrapment hazard to young children. The recalls³ are listed below:

³ Details of each of these recalls can be found in the Recall section on the CPSC.gov website by clicking on the links provided.

- Dorel Juvenile Group Recalls Play Yards with Bassinets Due to Suffocation Hazard (December 30, 2009) <u>CPSC.gov link;</u>
- Kolcraft Recalls 1 Million Play Yards Due to Fall Hazard (July 8, 2009) CPSC.gov link;
- Simplicity Play Yards Recalled by Various Retailers Due to Fall and Entrapment Hazards (April 7, 2009) <u>CPSC.gov link</u>; and
- Fisher-Price Recalls Simplicity's Rainforest Portable Play Yards Due to Fall and Entrapment Hazards (January 15, 2009) <u>CPSC.gov link</u>.

C. Incident Characterization (Tab A)

CPSC staff from the Directorate for Epidemiology, Division of Hazard Analysis characterized the number of deaths and injuries and the types of hazards related to play yards. Staff is aware of a total of 2,128 incidents involving 49 fatalities and 2,079 nonfatal incidents related to play yards—reported over a period of more than 3 years—beginning in November 2007 through early April 2011. These characterizations are based on incident reports received by CPSC staff.

1. Incident Data

A total of 49 play yard-related fatalities have been reported since late 2007. In one case, the age of the decedent was unknown; of the remaining fatalities, 69 percent were 1 year olds or younger, while the rest were between 1 and 3 years old. The majority of the deaths (37 out of 49, or 76 percent) were related to the environment in or around the play yard:

- <u>Unsafe environment within the play yard</u>: 27 deaths were due to an unsafe sleep environment involving prone placement of the infant and soft or extra bedding, and/or the infant getting wedged between the side of the play yard and extra padding or bedding;
- <u>Unsafe environment around the play yard</u>: 10 strangulation deaths involved window covering and computer cords, and crib tents and other covers.

Seven reported fatalities (14 percent) were product-related. An incident was classified as product-related if CPSC subject matter experts felt that a design change or modification to the performance requirements could have mitigated the hazard. These included:

- Two fatalities of unsupervised infants who climbed out of the play yard and drowned in a nearby pool.
- Two deaths occurred in a manner very similar to each other. In both cases, the children's' bodies were found reaching outside the play yard but suspended from the top rail. The fatalities were attributed to mechanical positional asphyxia/strangulation.
- One death resulted from a play yard collapse that entrapped the infant.
- One death resulted from strangulation of the infant in the play yard on a looped strap that was hanging below an accessory above the child in the play yard.
- One fatality was attributed to a tri-fold mattress pad that was unfolded incompletely. The child was found in the crease between the mattress pad and liner.

The remaining five fatality reports (10 percent) provided insufficient information to determine the associated hazard. Two incidents only report that a child was found unresponsive in a play yard. The remaining three incidents reported more information, but the hazard was still unknown.

Approximately 8 percent (165) of the 2,079 nonfatal incidents involved reports of an injury to an infant using the play yard at the time of the incident. Eighty-six percent of the injuries in which the age of the victim was given reportedly were sustained by infants 1-year-old or younger. Although the remaining 1,914 nonfatal incidents reported that no injury had occurred, many of the descriptions indicated the potential for a serious injury or even death.

Four play yard-related injuries reportedly required hospitalization. The most severe injury was of a 7-week-old infant left unattended for a few hours, whose face was buried in soft bedding; the child suffered brain damage. Two other incidents, one of a child falling out of the play yard and one of a play yard collapsing on the child, reportedly involved head injuries requiring hospitalization. The fourth injury, a severe finger laceration, occurred when the infant got a finger caught while the play yard was being set up by the caregiver. Among the rest of the injuries that did not require hospitalization, there were reports of three limb fractures and one broken nose. Some of the remaining injuries reported included: bruises, contusions, abrasions, lacerations, and dental injuries.

2. Hazard Pattern Identification

 Table 1. Distribution of Reported Incidents by Hazard Patterns Associated with Play Yards

 Reporting Period: November 1, 2007–April 10, 2011

| Issues | Total In | cidents Deaths | | | Injuries | | | |
|-----------------------|----------|----------------|-------|------------|----------|------------|--|--|
| | Count | Percentage | Count | Percentage | Count | Percentage | | |
| Product-Related | 2,083 | 98 | 7 | 14 | 163 | 99 | | |
| Side Rail Collapse | 1,902 | 89 | 1 | 2 | 124 | 75 | | |
| Structural Integrity | 72 | 3 | | | 8 | 5 | | |
| Fabric/Mesh | 27 | 1 | | | 5 | 3 | | |
| Floor Board/Pad | 24 | 1 | | | 5 | 3 | | |
| Accessory | 13 | 1 | 1 | 2 | 2 | 1 | | |
| Assembly | 12 | 1 | 1 | 2 | 2 | 1 | | |
| Fall/Climb Out | 8 | <1 | 2 | 4 | 5 | 3 | | |
| Impact on Play Yard | 5 | <1 | | | 4 | 2 | | |
| Other Product-Related | 20 | 1 | 2 | 4 | 8 | 5 | | |
| Unsafe Environment | 38 | 2 | 37 | 76 | 1 | <1 | | |
| Within the Play Yard | 28 | 2 | 27 | 55 | 1 | 1 | | |
| Around the Play Yard | 10 | < 1 | 10 | 20 | | | | |
| Other | 7 | < 1 | 5 | 10 | 1 | <1 | | |
| Total | 2,128 | 100 | 49 | 100 | 165 | 100 | | |

Source: U.S. Consumer Product Safety Commission's epidemiological databases IPII, INDP, and DTHS.

Note: The percentages have been rounded to the nearest integer. Subtotals do not necessarily add to heading totals.

CPSC staff considered all 2,128 incidents (49 fatal and 2,079 nonfatal) to identify the hazard patterns associated with play yards. The distribution of the incidents by the hazard patterns described in categories a through c below are shown in Table 1 above. The incidents were grouped into three broad categories:

- a. Product-related Issues:
 - Side rail collapse (1 fatality and 124 injuries with 1 hospitalization)
 - Accounts for the majority of the incident reports (89 percent)
 - Most pertained to the recall notices in 2009
 - Lack of structural integrity (8 injuries)
 - Climbing/falling out (2 fatalities [drownings] and 5 injuries with one hospitalization)
 - Fabric- or mesh-related (5 injuries)
 - Mattress pad/floor board (5 injuries)
 - Impact on play yard from fall (4 injuries)
 - Accessories (1 fatality, 2 injuries)
 - Assembly issues (1 fatality and 2 injuries with 1 hospitalization)
 - Other product-related problems (2 fatalities [asphyxiation on top rail] and 8 injuries)
- b. <u>Non-product-related Issues</u>:
 - Unsafe environment within or around play yard (27 fatalities and 1 severe injury [brain damage])
 - Hazardous surroundings around the play yard (10 fatalities)
- c. <u>Miscellaneous Other Issues</u>:

For the remaining incident reports, there was insufficient information available for CPSC staff to identify the hazard scenario. These include reports of 5 fatalities and 1 injury.

3. National Injury Estimates

There were an estimated total of 4,300 injuries related to play yards that were treated in U.S. hospital emergency departments over the time period November 2007 through December 2010. There was no statistically significant increase or decrease observed in the estimated injuries from one complete year to the next, nor was there any statistically significant trend observed over the same timeframe.

No deaths were reported through the NEISS. The data included the age range from birth to 3 years. Thirty-three percent of the injured were between 5 months old and 1 year; 62 percent were between 1 year and 2 years old; and the remaining 5 percent between 2 and 3 years of age. For the emergency department-treated injuries related to play yards, the following characteristics occurred most frequently:

- Hazard—falls either inside the play yard, out of the play yard, or unspecified (83%).
- Disposition—treated and released (92%).
- Injured body part—head (37%), mouth (16%), and face (14%).
- Injury type—internal organ (23%), soft tissue (22%), laceration (19%), and fracture (15%).

4. Excluded Incidents

The ASTM standard F 406-11 also covers bassinets, changing tables, and similar attachments, but for this analysis, CPSC staff excluded incidents involving these products if the product failure derived from the attachment, rather than the play yard structure. Those failures are being addressed in other CPSC regulatory work. Furthermore, CPSC staff limited the data to incidents reporting user age to be 3 years old or younger, although there is no upper age limit of the user recommended by the ASTM standard. Three years of age was considered a reasonable maximum, given the limits placed on occupant height (35 in.) and physical development (the ability to climb out) stated in the scope of F 406-11.

D. Hazard Severity Summary/Assessment of ASTM F 406-11 (Tab B)

The data analysis described above presented a listing of the hazard patterns by frequency of incident reports but not necessarily by severity of the hazard. What follows is a listing of the identified hazard patterns, starting with those with the most fatalities, followed by the those with no fatal incidents (bold font indicates a hazard where fatalities have been reported). Following that list is a discussion regarding each hazard and how it relates to the current voluntary standard, F 406-11.

- 1. Unsafe sleep environment and other non-product-related issues
- 2. Climbing/Falling out
- 3. Side rail collapse
- 4. Accessories
- 5. Assembly/Other product-related problems
- 6. Lack of structural integrity
- 7. Mattress pad/floor board
- 8. Fabric- or mesh-related issues
- 9. Other changes to ASTM voluntary standard F 406

1. Unsafe Sleep Environment and Other Non-product-related Issues

The greatest hazard found in the fatality data was unsafe sleep environments within play yards. This category includes 27 fatalities, where children were put to sleep on their stomachs, resulting in positional asphyxia; the addition of extra bedding, such as pillows or comforters to the play yards, in combination with the prone sleep position may have contributed to the positional asphyxia hazard. This hazard is associated with caregiver action and is not due to the design or construction of the play yard; there are no performance requirements that can address this hazard adequately. ASTM F 406-11 already contains labeling requirements that point out how deadly this hazard can be. Staff is not making any recommended changes to the voluntary standard to attempt to address unsafe sleep environment issues further. Staff believes that a strong education and information campaign is a more effective way to address the issue of safe sleep environment for infants.

There were 10 other fatalities associated with non-product-related issues. These included hazardous surroundings around the play yard, such as window blind and computer cords in or

near a play yard and various improvised covers, such as wood, mesh gates, or crib tents placed on top of a play yard to prevent the child from climbing out. With the exception of warning labels, these issues are also not addressable in a play yard standard and are addressed more effectively with an education and information program.

2. Climbing /Falling Out⁴

Of the eight incidents involving climbing/falling out of a play yard, two were fatalities (drownings) and five resulted in minor injuries. Some play yard escapes may be performed without injury, but it is reasonable to expect falls and injuries to occur. A play yard designer faces limited options for preventing children from climbing out. The play yard is basically a lidless box. Play yards that prevent climbing out would require either higher sides or lids to be effective. Both designs would introduce other problems that are potentially of more concern than the problem of climbing out. For instance, making the sides higher increases the difficulty caregivers have placing their children, especially the youngest ones, into the play yards or lifting them out. This could increase the use of alternative sleeping arrangements, such as allowing children to sleep in adult beds, which have serious hazards associated with them. Introducing a lid or some other kind of cover to a play yard creates more movable parts with more possibilities for mechanical failures that could lead to entrapment, entanglement, or strangulation.

Staff has been unable to identify a performance criterion for inclusion in the play yard standard that would effectively reduce incidents of children climbing out of play yards without simultaneously introducing other potential hazards. The warnings in the play yard standard F 406-11 are placed in an optimal order in the warning lists required for that product. Staff believe that the warnings in the standard are adequate and are the most effective way to address this hazard.

3. Side Rail Collapse

The highest number of incidents (89 percent or 1,902 out of the 2,128) and one death pertained to side rail collapse. Most of these incident reports involved recalled products and were received from manufacturers and retailers. These incidents almost universally involved a child who fell when a side rail latch collapsed. The corresponding recalls are the last three listed in Section III.B in this memorandum, above. These recalls led to the addition of a new performance requirement in ASTM F 406-09 to test for a false latching situation. CPSC staff reviewed these incidents in detail and determined that the current ASTM standard adequately addresses this hazard scenario.

4. Accessories

One death resulted from strangulation of an infant in a play yard on a looped strap that hung below an accessory into the occupant's play/sleep area. This occurred in May 2007, and led directly to the addition of a new requirement in F 406-08a, prohibiting hazardous loops from being formed by straps that hang from an attachment inside the play yard enclosure. Staff

⁴ Based on crib fall out discussion from: Midgett, Jonathan "Human Factors Analysis of Children Climbing Out of Cribs and Getting Limbs Caught Between Slats," Full-Size Crib NPR Briefing Package; June 3, 2010.

believes this requirement is adequate and is not recommending any new requirements to address this hazard at this time.

5. Assembly Difficulties/Other Product-related Problems

There were 12 assembly-related incidents with one fatality and two injuries. In the fatal incident, the child was found in the crease between the mattress pad and play yard's floor liner. The mattress pad had not been secured to the play yard base per the instructions. One injury required hospitalization. It was a finger laceration that required eight stitches and was caused by the victim's finger being in the gap between the corner bracket and side rail when the side rail was lifted and latched. Although the finger laceration injury was severe, staff's hazard analysis indicated that this scenario was neither an emerging nor established trend.

The voluntary standard addresses the assembly hazard with the following requirement:

"10.1 Instructions must be provided with the products and shall be easy to read and understand. Assembly, maintenance, cleaning, operating, folding instructions, and warnings where applicable must be included. A means shall be provided to keep the instructions with the product."

Other product-related or miscellaneous problems ranged from complaints of undesirable paint/finish, to a sharp surface, to unspecified safety concerns. Eight injuries were reported under this category, including two deaths in which the children were found standing with their chin on the side rail. It is not clear how or what led both children to remain in a slumped position over the upper rail with no obvious (or reported) obstacle around to confine and keep them in the position found. This is especially puzzling considering that even the youngest (17 months old) was reportedly able to climb out of the play yard and had done so on several occasions. Health Sciences staff finds it very difficult to conclude that the products contributed to the death of the two children in the manner described in the IDIs in absence of other mitigating factors.⁵

6. Lack of Structural Integrity

The majority of the non-recall-related incidents attributable to poor structural integrity involved play yards with structural failure(s) of the corner brackets. Typical failure scenarios included, but were not limited to, rivets pulling through corner brackets, propagation of cracks under rivet heads, stress whitening, and the liberation of rivets and plastic pieces. The resulting hazards include sharp points and edges, pinching and finger entrapment, choking on small parts, and escape from the play yard enclosure.

Staff of LSM and ESME (the divisions of Laboratory Sciences Mechanical Engineering and Engineering Sciences Mechanical Engineering, respectively) determined that many of the incidents that related to corner post attachment failure were attributable to cyclic loading of the top side rails. This loading occurred when consumers inadvertently and repeatedly leaned on the

⁵ Communication July 21, 2011, with Dr. S. Wanna-Nakamura, CPSC Directorate for Health Sciences.

top side rails while accessing the occupant, or when a child repeatedly used the top side rails for support while standing. These scenarios each imparted a small cyclical twisting action⁶ to the top side rail corner post attachment joints.

A new performance requirement was developed and validated by LSM and ESME staff, which addressed the fatigue failures observed in corner post attachment joints. This test is now §8.30, *Top Rail to Corner Post Attachment Test*, in ASTM F 406-11. To pass this test, play yard corner brackets must not fail when a single significantly large twisting action (moment) is applied to the midpoint of the top side rails. The magnitude of this moment is 40 ft-lbs. Corner brackets of recalled products in the CPSC's possession failed this test with an applied moment of 20-24 ft-lbs. The 40 ft-lb (53 Nm) moment equates to a safety factor of 2 (2 x 20 ft-lbs = 40 ft-lbs). Products that meet this test are less likely to have weak corner brackets thereby reducing the number of injured children.

7. Mattress Pad/Floor Board

There were several reported injuries, including scrapes and bruises, created by a child rolling or falling into a pocket on the floor board where the mattress had been lifted upward. However, the significant foreseeable hazard associated with mattress displacement involves entrapment leading to strangulation and/or asphyxia. This is particularly dangerous for children 12 months old and younger, who have the cognitive ability and strength to pull up on the end of the mattress and maneuver their head and/or body between the mattress and the floor structure. Staff is aware of three incidents in which a child became entrapped in this manner. Fortunately, caregivers recognized quickly the potential for dangerous entrapment and removed children from the play yards promptly.

Staff examined 12 play yards and found that the two most common methods of attaching a play yard's mattress to its base are hook and loop ("Velcro") straps and patches. Testing showed that patches on these products, typically a 2-inch-square, separate when a mattress corner is pulled up with less than 4 lb of force. The remaining products staff studied, all had mattresses secured with hook and loop straps. The force required to lift these mattresses more than 5 inches high ranged from 11 to 25 lbf.

A new test requirement, developed by LSM staff and validated with the stakeholders, requires the mattress to be pulled up with 15 lbs of force. During the test, the mattress cannot lift more than 5.25 inches from its original position. This test was adopted by the ASTM play yard subcommittee in January 2011, and is now §8.28, *Mattress Vertical Displacement Test*, in F 406-11, and staff believes it is adequate to address the hazard.

8. Fabric- or Mesh-Related Issues

Staff reviewed this issue with samples that included problems with stitching that unraveled, fabric tears, mesh holes, and stitching that caught teeth and abrasive mesh material. Five injuries

⁶ In engineering terms, this would be described as a moment or torque being applied to the top rail corner post attachment points.

were reported in this category, but none required hospitalization. Therefore, the severity of the hazard is low. These issues are already addressed by three performance requirements in F 406-11:

- 7.6 Mesh Requirements Holes in the mesh cannot permit a ¹/₄-inch diameter (fingersized) probe to be forced in.
- 7.7 *Fabric Strength* Breaking and tear strength of fabrics are specified.
- 7.8 Mesh/Fabric Assembly Requirements Seams cannot be unraveled easily and must meet specified strength.

Staff determined that due to the low number of incidents relative to the large number of products in the field, and the low severity of the injuries, the hazard was addressed sufficiently by F 406- $11.^{7}$

9. Other Changes to the ASTM Voluntary Standard F 406

Table 2 summarizes three changes to the voluntary standard F 406-11 recommended by staff for inclusion in the mandatory rule. All of these changes have been balloted by ASTM for inclusion in F 406-11, approved by subcommittee members, and are expected to be published before the end of this year.

> Table 2. CPSC Staff Recommended Changes to ASTM F 406-11 (Strikeout indicates current language that is recommended to be removed. **Bold** indicates additional language recommended.)

| ASTM F 406 Section # | Sub-Section | Recommended Addition |
|-------------------------------------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.30 Top Rail to Corner Post Attachment Test | 8.30.3.1 | Mount a rigid and substantially horizontal moment arm weighing less than 5 lbm (2.2 kg) to the hinge/latching device at the longitudinal center of the top rail through 2×2 in. (50 \times 50 mm) two clamping surfaces, each 1 in ² – 4 in ² (6.5 cm ² - 26 cm ²) designed to firmly grasp the hinge/latching device. The moment arm shall be at least 24 in. (602 mm) long and extend towards the outside of the play yard. <i>Rationale: Clamp surface design – shape,</i> <i>materials, etc. – is intentionally not specified,</i> <i>and surface area is given as a range, to</i> <i>accommodate the expected wide variety of</i> <i>hinge/locking mechanism designs.</i> ⁸ |
| 8.12 Floor Strength Test for | 8.12.1 | Equipment - 2 Wood blocks, $6 \ge 6$ in. (150 ≥ 150 |

⁷ No changes to the three ASTM F 406 mesh and fabric performance requirements have been made in more than 10

years. ⁸ Rea, G. K.; Proposed change of section 8.30 and rationale from document "Proposed Language F406 Rev R.docx" dated April 13, 2011.

| | mm). |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Rationale: Clarification of the wording. |
| | |
| 8.12.2.1 | Remove cushions that are not part of the floor or mattress support. Place a 50-lb (23-kg) and a 30- lb (14-kg) weight each onto a 6 by 6-in. (150 by 150 mm) wood block spaced 6 6 ^{-†} /2 in. (150 6 13 mm) apart and maintain for 60 s. Perform the test in those locations deemed to be the weakest or the most likely to fail. Remove the load and check for structural failure. Place the wood blocks 6 +/- 1/2 inch (150 mm +/- 13 mm) apart. Place a 50-lb (23-kg) weight on one wood block and a 30-lb (14 kg) weight on the other wood block. Maintain for 60 s. Perform the test in those locations deemed to be the weakest or the most likely to fail. Remove the loads and check for structural failure. Rationale: Clarification of the wording by separating instructions into separate sentences. |
| | 8.12.2.1 |

E. Potential Small Business Impact (Tab C)

Typically, play yards are produced and/or marketed by juvenile product manufacturers and distributors. Currently, there are at least 23 manufacturers or importers supplying play yards to the U.S. market. Eleven are domestic manufacturers, 10 are domestic importers, and 2 are foreign firms. Based on U.S. Small Business Administration guidelines, 20 are small firms—10 domestic manufacturers and 10 domestic importers—likely to be affected by the staff-recommended proposed standard, as described in the Directorate for Economic Analysis memo (Tab C).

There should be little or no impact on the seven small manufacturers or the six small importers whose play yards meet the voluntary standard. Some product redesign could be required for the three small manufacturers whose play yards are not compliant with the voluntary standard. The actual costs of a redesign are unknown but will vary from play yard to play yard. Any changes necessary to meet ASTM 406-11 would be made regardless of whether the Commission approves the staff-recommended additions. However, a major redesign is unlikely to be necessary in most cases.

Importers of noncompliant play yards may need to discontinue their importation of these products if their existing supplier does not come into compliance, possibly replacing the noncompliant play yards with compliant play yards or other juvenile products. However, two of

these four importers specialize in the importation of products from a specific foreign company. For these firms, finding an alternative supply source is probably not an option. However, they could still respond to the rule by discontinuing the importation of their noncomplying play yards, possibly replacing them with other juvenile products.

IV. STAFF RECOMMENDATIONS

The requirements outlined in staff's draft proposed rule are the same as those in ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* with three modifications. These changes will strengthen the standard and reduce the risk of injury by ensuring that play yard testing is performed properly. The modifications to F 406-11, supported by CPSC staff, are:

- 1. Remove the size and shape restrictions from the clamping surface in the corner bracket structural integrity test in section 8.30.3.1.
- 2. Clarify wording in the *Equipment* subsection (8.12.1) of 8.12 Floor Strength Test for Mesh/Fabric Products.
- 3. Clarify wording in subsection 8.12.2.1 of 8.12 Floor Strength Test for Mesh/Fabric Products.

CPSC staff recommends that the Commission proceed with the rulemaking process for play yards by publishing a notice of proposed rulemaking, as drafted by the Office of the General Counsel (Tab D). CPSC staff also recommends an effective date of 6 months after publication of the final rule.

TAB A:

Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007–Present



Memorandum

Date: August 17, 2011

- TO : Gregory K. Rea Play Yards Project Manager Division of Mechanical Engineering Directorate for Laboratory Sciences
- THROUGH: Kathleen Stralka Associate Executive Director and Acting Division Director, Division of Hazard Analysis Directorate for Epidemiology
- FROM : Risana Chowdhury Division of Hazard Analysis Directorate for Epidemiology
- SUBJECT : Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007–Present⁹

I. INTRODUCTION

This memorandum characterizes the number of deaths and injuries and the types of hazards related to play yards (products coded as 1513 and occasionally as 1529) over a period of more than 3 years beginning in November 2007.¹⁰ These characterizations are based on incident reports received by CPSC staff between early November 2007 and early April 2011. The memorandum also presents national injury estimates from November 2007 through December 2010.¹¹

The ASTM voluntary standard (F 406 - 11) addresses safety issues related to play yards. According to the ASTM definition, a "play yard" is a framed enclosure with a floor made for the purpose of providing sleeping and playing accommodations for a child who cannot climb out and

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

⁹ This analysis was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.
¹⁰ Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this

¹⁰ Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather, to quantify the number of fatalities and injuries reported to CPSC staff and to provide national estimates of emergency department-treated injuries.

¹¹ National estimates of emergency department-treated injuries related to play yards are not currently available for 2011.

is less than 35 inches (890 mm) in height. The ASTM standard also covers bassinets, changing tables, and similar attachments. CPSC staff, however, has excluded from this analysis any bassinet, changing table, or similar attachment-related incidents in which the product failure involved the attachment rather than the play yard structure. Those failures are being addressed in other CPSC regulatory work. Furthermore, in this memo, CPSC staff limited the data to incidents reporting the user's age to be 3 years or younger, although there is no upper age limit of the user recommended by the ASTM standard.

CPSC staff has been closely monitoring incoming incident reports on play yards since late 2007, in a pilot project known as the Early Warning System (EWS). Each week, all data entered into the CPSC epidemiology databases during the previous week are drawn into EWS. It is important to note that the date of entry of the incident reports into the databases is different from the date of the actual incident. This analysis is based on all play yard-related incident data in the EWS with date of entry from November 1, 2007 through April 10, 2011. A search revealed that the year of incident associated with play yard-related reports in the EWS ranges from 1995 through 2011. However, only a small fraction of all play yard-related incidents that occurred prior to November 2007, were captured in the EWS because they preceded the start of the pilot project. Nevertheless, for the timeframe covered, EWS contained more than 2,100 incident reports related to play yards that have been reviewed and encoded carefully by the subject matter expert for failure modes. Thus, EWS served as the database of choice to support the play yard regulatory work. Due to the large number of injury reports received through emergency departments during this timeframe, the national estimates of emergency department-treated injuries associated with play yards are presented separately from the rest of the incident data.

II. INCIDENT DATA¹²

CPSC staff is aware of a total of 2,128 incidents involving 49 fatalities and 2,079 nonfatal incidents related to play yards that were reported from November 2007 through early April 2011. Reporting is ongoing. The number of reported fatalities, nonfatal injuries, and noninjury incidents may change in the future.

¹² The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the National Electronic Injury Surveillance System (NEISS). These reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to play yards.

Date of extraction for reported incident data on play yards was April 10, 2011. All data coded under product code 1513, and some coded under 1529 were extracted. Upon careful joint review with Laboratory Sciences (LS) and Engineering Sciences (ES) staff, some cases were considered out-of-scope for purposes of this memo. Products such as bassinets and changing tables that attach on top of play yards were excluded if it was clear that the failure was of the attachment and not of the play yard. With the exception of incidents occurring at U.S. military bases in foreign countries, all incidents occurring outside the United States have been excluded. Any case where the official report cited a natural cause of death, such as SIDS or pulmonary failure, for example, was excluded. Incidents where the involvement of the play yard was incidental (an infant, outside the play yard, got hurt on it, for example) were considered out of scope as well. However, all incidents reporting unsafe sleep environment in and around the play yard that resulted in fatalities, injuries, or near-injuries were retained.

A. Fatalities

A total of 49 play yard-related fatalities have been reported since late 2007. The age of the decedent was unknown for one child; of the remaining, 69 percent were 1-year-old or younger, while the rest were between 1 year and 3 years of age.

The majority of the deaths (37 out of 49, or 76 percent) were related to the environment in or around the play yard. The hazard scenarios in these deaths can be grouped into the following broad categories:

- Unsafe environment <u>within</u> the play yard: 27 deaths were related to the presence of soft or extra bedding in the play yard, prone placement of the infant, and/or the infant getting wedged between the side of the play yard and mattress or bedding.
- Unsafe environment <u>around</u> the play yard: 10 deaths were related to materials on or around the play yard. Examples of materials associated with the fatalities include: window blind cords or computer cords, and various improvised covers, such as wood, mesh gate, or crib tent placed atop play yard to prevent the child from climbing out.

Seven reported fatalities (14 percent) were product-related. An incident was classified as product-related if CPSC subject matter experts felt that a design change or standard modification could have mitigated the hazard. The seven reported incidents included:

- Two fatalities of unsupervised infants who climbed out of the play yard and drowned in a nearby pool.
- Two deaths occurred in a manner very similar to each other. In both cases, the children's' bodies were found reaching outside the play yard but suspended from the top rail. The fatalities were attributed to mechanical positional asphyxia/strangulation.
- One death resulted from a play yard collapse that entrapped the infant.
- One death resulted from strangulation of the infant in the play yard on a looped strap that was hanging below an accessory above the child in the play yard.
- One fatality was attributed to a tri-fold mattress pad that was incompletely unfolded. The child was found in the crease between the mattress pad and liner.

The remaining five fatality reports (10 percent) provided insufficient information to determine the associated hazard. Two incidents only report that a child was found unresponsive in a play yard. The remaining three incidents reported more information, but the hazard was still unknown.

B. Nonfatal Incidents

A total of 2,079 play yard-related nonfatal incidents have been reported since November, 2007. The majority (1,738 out of 2,079 or 84 percent) of the reports were submitted to the CPSC by retailers and manufacturers through the CPSC's "Retailer Reporting System." The remaining reports of nonfatal incidents were submitted to the CPSC through various sources, such as the hotline, Internet reports, newspaper clippings, and state/local authorities.

Among the 2,079 nonfatal incident reports, 165 reported an injury to an infant using the play yard at the time of the incident. There was no age information available for the victims in 60 of the injury reports; almost all of these reports were received from manufacturers or retailers. Among those with age information available, 86 percent of the injuries were reported to have been sustained by infants 1-year-old or younger. The rest were between 1 and 3 years of age.

There were four play yard-related injuries that reportedly required hospitalization. The most severe injury involved a 7-week old, who was left unattended for a few hours with his or her face buried in soft bedding; the child suffered brain damage. Two other incidents—one of a child falling out of the play yard—and one of a play yard collapsing on the child, reported head injuries requiring hospitalization. The fourth injury, a severe finger laceration, occurred when an infant got a finger caught as a caregiver attempted to set up the play yard. Among the rest of the injuries that did not require hospitalization, there were reports of three limb fractures and one broken nose. Examples of the remaining injuries include: bruises, contusions, abrasions, lacerations, and dental injuries.

The remaining 1,914 nonfatal incidents reported that no injury had occurred or provided no information about an injury. However, many of the descriptions indicated the potential for a serious injury or even death.

III. HAZARD PATTERN IDENTIFICATION

CPSC staff considered all 2,128 incidents (49 fatal and 2,079 nonfatal) to identify the hazard patterns associated with the play yard-related incidents. The incidents were grouped into three broad categories:

- Product-related issues
- Unsafe Environment issues
- Other issues

A. Product-Related Issues:

- Eighty-nine percent of the incident reports (1,902 out of 2,128)) were related to *side rail collapses.* Of these, 1,676 reports (88 percent), concerned predominately one model and were received from manufacturers and retailers, either shortly before or after the publication of a recall notice in January 2009. This category includes one fatality and 124 injuries, one a hospitalization for a concussion injury.
- Lack of *structural integrity*, which includes issues such as loose wheels, loose hardware, and broken and/or detached components leading to instability and/or collapse of the product, was the next most commonly reported issue. There were eight injuries reported in this category.
- Children *climbing/falling* out of the play yard, with two toddlers subsequently drowning in a pool. Five of the incidents were injuries, with one requiring

hospitalization for a serious head injury. Thus, this category included two deaths and five injuries.

- *Fabric or mesh*-related issues. These include problems with stitching that unraveled, tears in the fabric, mesh holes that were too large and caught the infant's teeth, and mesh material that was too abrasive. Five injuries were reported in this category.
- Problems with *floor board/pad*. Examples include failure of fasteners designed to keep floor pad in place and flimsy floor boards providing insufficient support. This category includes five injuries.
- *Impact-related injuries*. Four incidents reported injuries when a child inside a play yard fell and impacted the play yard.
- Problems with *accessories*. Examples include broken/detached components from a music box, tray, mirror, toy holder, and tent accessories, as well as hazards posed by dangling straps from changing table attachments. One fatality and two injuries are in this category.
- Assembly issues. Incidents reports consisted of complaints of difficulty in setting up the play yard or concerns about the product's structural integrity when set up following instructions. This category includes two injuries, including one that required hospitalization for a severe finger laceration. One fatality resulted when the tri-fold mattress pad was not unfolded completely.
- *Other product-related* problems included complaints of undesirable paint/finish, sharp surfaces, and other unspecified safety concerns. Eight injuries and two fatalities were reported under this category. The two fatalities resulted when the child asphyxiated as a result of hanging over the side or top rail of the play yard.

B. Unsafe Environment Issues

Most of the fatalities resulted from unsafe environments in or around the play yard. None of the incidents, however, can be directly related to any product failure or design flaw.

- *Within the play yard* : Hazards created by the presence of soft and/or extra bedding inside the play yard and prone placement of young infants predominated this category, which includes 27 fatalities and one severe injury that left the child brain damaged.
- *Around the play yard:* Hazardous surroundings that allowed easy access to various cords or plastic bags and placement of improvised covers to contain the infant in the play yard resulted in 10 reported fatalities.

C. Other issues

For the remaining incident reports, there was insufficient information available for CPSC staff to identify the hazard scenario. These include reports of five fatalities and one injury.

The distribution of the 2,128 incidents by the hazard patterns described in Sections A through C above are shown in Table 1 below.

| Issues | Issues Total Incidents Deaths | | | | Injuries | | |
|-----------------------|-------------------------------|------------|-------|------------|----------|------------|--|
| | Count | Percentage | Count | Percentage | Count | Percentage | |
| Product-Related | 2,083 | 98 | 7 | 14 | 163 | 99 | |
| Side Rail Collapse | 1,902 | 89 | 1 | 2 | 124 | 75 | |
| Structural Integrity | 72 | 3 | | | 8 | 5 | |
| Fabric/Mesh | 27 | 1 | | | 5 | 3 | |
| Floor Board/Pad | 24 | 1 | | | 5 | 3 | |
| Accessory | 13 | 1 | 1 | 2 | 2 | 1 | |
| Assembly | 12 | 1 | 1 | 2 | 2 | 1 | |
| Fall/Climb Out | 8 | <1 | 2 | 4 | 5 | 3 | |
| Impact on Play Yard | 5 | <1 | | | 4 | 2 | |
| Other Product-Related | 20 | 1 | 2 | 4 | 8 | 5 | |
| Unsafe Environment | 38 | 2 | 37 | 76 | 1 | <1 | |
| Within the Play Yard | 28 | 2 | 27 | 55 | 1 | 1 | |
| Around the Play Yard | 10 | < 1 | 10 | 20 | | | |
| | | | | | | | |
| | | | | | | | |
| Other | 7 | < 1 | 5 | 10 | 1 | <1 | |
| Total | 2,128 | 100 | 49 | 100 | 165 | 100 | |

| Table 1. | Distribution of Rep | ported Incidents | oy Hazard | Patterns | Associated | with Play | Yards | | |
|---------------------------------------------------|---------------------|------------------|-----------|----------|------------|-----------|-------|--|--|
| Reporting Period: November 1, 2007–April 10, 2011 | | | | | | | | | |

Source: U.S. Consumer Product Safety Commission's epidemiological databases IPII, INDP, and DTHS.

Note: The percentages have been rounded to the nearest integer. Subtotals do not necessarily add to heading totals.

IV. NATIONAL INJURY ESTIMATES¹³

There were an estimated total of 4,300 injuries (sample size=156, coefficient of variation=0.14) related to play yards that were treated in U.S. hospital emergency departments between November 2007 and December 2010. Partial estimates for 2011 are not available until NEISS data for 2011 is finalized in spring 2012. The injury estimates for individual years are not reportable because they fail to meet publication criteria.¹⁴ There was no statistically significant increase or decrease observed in the estimated injuries from one complete year to the next, nor

¹³ The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of hospitals selected as a probability sample of all the U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable the CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

All data coded under product code 1513 for patients aged 3 years and under was extracted. Certain records were considered outof-scope for the purposes of this memo. For example, an injury that occurred when the play yard fell on the child was excluded. Another example was of an infant playing with a friend inside the play yard and suffering an injury or a child getting an insect bite while in the play yard. These records were excluded prior to deriving the statistical injury estimates.

¹⁴ According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

was there any statistically significant trend observed over the timeframe from November 2007 through December 2010.

No deaths were reported through the NEISS. The data included children ranging in age from birth to 3 years old. Thirty-three percent of the injured were between 5 months old and 1-year-old; 62 percent were between 1 and 2 years old; and the rest were between 2 and 3 years of age. For the emergency department-treated injuries related to play yards, the following characteristics occurred most frequently:

- Hazard falls inside the play yard, out of the play yard, or unspecified. (83%).
- Injured body part head (37%), mouth (16%), and face (14%).
- Injury type internal organ injury (23%), soft tissue injury (22%), laceration (19%), and fracture (15%).
- Disposition treated and released (92%).

TAB B:

Proposed Change to ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, for Incorporation into Staff's Draft Proposed Rule



UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION BETHESDA, MD 20814

Memorandum

Date: August 17, 2011

- TO: Gregory K. Rea, Project Manager Division of Mechanical Engineering Directorate for Laboratory Sciences
- THROUGH: George A. Borlase Associate Executive Director Directorate for Engineering Sciences

Mark Kumagai, Director Division of Mechanical Engineering Directorate for Engineering Sciences

- FROM: Jacob J. Miller Division of Mechanical Engineering Directorate for Engineering Sciences
- SUBJECT: Proposed Change to ASTM F 406-11, *Standard Consumer Safety Specification* for Non-Full-Size Baby Cribs/Play Yards, for Incorporation into Staff's Draft Proposed Rule

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC) to assess the effectiveness of voluntary consumer product safety standards for durable infant and toddler products and to promulgate mandatory safety standards. Section 104 (b)(1)(B) states: "The Commission shall . . . promulgate consumer product safety standards that -- (i) are substantially the same as voluntary standards; or (ii) are more stringent than such voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products."

This memorandum assesses the effectiveness of ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs and Play Yards*, and it recommends changes to that standard for inclusion in the mandatory rule on play yards.

The ASTM defines a "play yard" as:

play yard (aka playpen), n- a framed enclosure that includes a floor and has mesh or fabric sided panels primarily intended to provide a play or sleeping environment for children. It may fold for storage or travel.

Figure 1-A is a typical play yard with mesh/fabric sides that fold for storage or travel. A non-full-size (NFS) crib (Figure 1-B) is a product with rigid sides that is either larger or smaller than a full-size (FS) crib. A FS crib (Figure 1-C) is also an infant sleeping product and has regulated interior dimensions.



Figure 1. Infant Sleeping Products

It is important to note that ASTM has combined requirements for NFS cribs and play yards into one ASTM voluntary standard, F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs and Play Yards*. The CPSC published mandatory rules for NFS cribs, 16 CFR part 1220, by specifying applicable sections of ASTM F406. Similarly, CPSC staff is recommending adopting applicable sections of F 406 for a mandatory rule for play yards.

ASTM F 406 - History/Background

ASTM first published a standard for play yards, ASTM F 406, *Standard Consumer Safety Specification for Play Yards*, in 1977, to address incidents associated with mesh/fabric cribs or play yards.

In 1997, F406-97 was published with requirements for play yards with a top rail central hinge as shown in figure 1A. The requirements were intended to address play yards incidents associated with collapsing center hinges that entrapped and strangled infants. The standard stated that these play yards, "... shall have a locking device that automatically engages when placed in a manufacturer's recommended use position. No top rail shall give the appearance of being in the manufacture's recommended use position unless the locking device is fully engaged."

In 1999, ASTM published F406-99. This revision required the top rail locking mechanisms of play yards with central hinges to withstand a 100 lb diagonal force without breaking or

disengaging. This requirement was intended to address play yards incidents more effectively that were associated with collapsing center hinges that entrapped and strangled infants.

In 2002, ASTM published F406-02, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*. This revision included requirements to address incidents of hazardous protrusions that entangled a child's clothing and resulted in strangulation.

In 2005, the standard was revised to include testing requirements to address entrapment in play yard accessories.

Since 2005, ASTM F 406 has been revised several times. The F 406-08 revision (March 2008) added a requirement for toy attachments and a requirement for straps that hang from an attachment that form a loop inside the enclosure. Also, the labeling and warnings section was reorganized for clarity. Later that year, the F 406-08a revision (October 2008) incorporated text clarifications and the definition of a "strap." In the August 2009 release of F 406-09, ASTM inserted a test procedure to check for a false latch condition for a portable NFS crib folding side.

ASTM approved the most substantial revision, F 406-10, on June 1, 2010; the revision modified the previous version of the standard in response to the crib notice of proposed rulemaking (NPR) as follows:

- 1) Added a limitation on movable components (drop-sides);
- 2) Added Health Canada's cyclic side shake test to simulate a lifetime of shaking;
- 3) Added the spindle/slat strength test;
- 4) Added requirements to prevent loosening of wood screw and other fasteners;
- 5) Added a requirement to help prevent misassembly of key components; and
- 6) Revised the slat strength requirement to be more stringent.

In addition to the substantial changes listed above, the 2010 version also included several minor and editorial changes. Many of these were added to make the NFS crib standard more consistent with the FS crib standard. This work to align NFS crib requirements with FS crib requirements continued throughout 2010, in revisions F 406-10a and F 406-10b. With the publication of the latter, NFS cribs and FS cribs became subject to the same ASTM performance requirements and were both aligned with the crib NPR, with one exception, removal of the fastener retightening allowance between tests. The additions included:

<u>F 406-10a</u>

- 1) A new requirement, Mattress Support System Vertical Impact Test;
- 2) Revised Crib Side testing requirements;
- 3) Procedure for moveable side latch tests; and
- 4) Various editorial changes.

<u>F 406-10b</u>

- 1) Spindle/Slat strength test procedure amended to clearly define testing procedures for NFS cribs with folding, segmented sides; and
- 2) Warning clarification related to netting.

The last and most recent revision, F 406-11, was published in June 2011, and included several new requirements developed jointly by CPSC staff and the ASTM play yard task group. This memorandum assesses the effectiveness of ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, and it recommends changes to that standard for inclusion in a draft proposed mandatory rule on play yards.

II. INCIDENT HAZARD REVIEW

According to the Directorate for Epidemiology¹⁵ staff, there were a total of 2,128 incidents involving 49 fatalities and 2079 nonfatal incidents related to play yards reported from November 2007 through April 2011. Thirty-seven of the 49 fatalities were associated with an unsafe environment, unrelated to any structural failure or physical design flaw of the play yard. Twenty-seven of these 37 fatalities were caused by an unsafe environment within the play yards and involved death by asphyxiation due to the presence of soft or extra bedding in the play yard, prone placement of the infant, and/or the infant becoming wedged between the side of the play yard and extra or ill-fitting mattresses or bedding. The remaining10 fatalities were caused by an unsafe environment around play yards, unrelated to any structural failure of the play yard, and included 10 deaths involving the proximity of the play yard to hazardous surroundings, such as window blind cords.

The 2,128 incidents reported from November 2007 to April 2011, were grouped into three categories: product-related issues, unsafe environment issues, and other issues. Because the purpose of this memo is to assess the adequacy of the performance requirements of the current voluntary standard, only the product-related incidents or incidents caused by the design or construction of the play yard are reviewed in detail.

<u>Side Rail Collapse</u> – Approximately 89 percent or 1,902 out of the 2,128 incidents were related to side rail collapse including one fatality. Manufacturers and retailers submitted the majority of the incident reports, and the reports relate to a play yard recall that was announced in January 2009. (The fatality is not related to these recalls.) The majority of these incidents involved a child who fell when a side rail latch collapsed. CPSC staff reviewed these incidents in detail and determined that the current False Latch requirement in F 406-11 addresses this hazard scenario.

<u>Insufficient structural integrity</u> – After side rail collapse, the highest number of incidents involved structural integrity issues. This included issues such as loose hardware and broken and/or detached components that led to instability and/or collapse of the product. There were eight injuries reported in this category, including bruises and cuts to the face and head.

<u>Floor board/mattress displacement</u> – The next highest number of incidents for product-related issues involved floor board/mattress displacement. Incidents included failure of fasteners and straps designed to restrain play yard floor boards and mattresses. Very few injuries related to

¹⁵ Memorandum from Risana Chowdhury to Gregory K. Rea, "Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between Nov, 2007 to Present," August 17, 2011.

mattress displacement were reported; however, many near-miss entrapment scenarios were reported that involved children younger than 12 months old crawling underneath the play yard and becoming entrapped under the play yard's mattress.

<u>Fabric or mesh-related issues</u> – Examples of this issue included: unraveled stitching, fabric tears, enlarged mesh holes, and abrasive mesh material. Five injuries were reported in this category.

<u>Accessories</u> – Examples of accessory issues included broken/detached components from a music box, tray, mirror, toy holder, and tent accessories and hazards posed by dangling straps from changing table attachments. This category included one fatality and two injuries.

<u>Assembly instructions/other product-related issues</u> – There was one death involving a misassembled mattress pad that was not attached to the play yard floor panel. A 3-month-old was able to create a gap large enough to become entrapped face down between the side of the play yard and the displaced mattress pad. Several incident reports included complaints by consumers who had difficulty setting up play yards. Other problems included: complaints of undesirable paint/finish, sharp surfaces, and other unspecified safety concerns. This category included 10 reports of injury.

III. ADEQUACY OF THE CURRENT ASTM F 406-11 REQUIREMENTS

The following is a listing of the hazard patterns identified, starting with those with the most fatalities, followed by those with no fatal incidents but indicated in order of the potential severity of the hazard (bold font indicating a hazard where fatalities have been reported). Following the list is a discussion regarding each hazard and how it relates to the current voluntary standard F 406-11.

- 1. Unsafe sleep environment and other non-product-related issues
- 2. Climbing/Falling out
- 3. Side rail collapse
- 4. Accessories
- 5. Assembly/Other product-related problems
- 6. Lack of structural integrity
- 7. Mattress pad/floor board
- 8. Fabric- or mesh-related issues
- 9. Other changes to ASTM voluntary standard F 406

1. Unsafe Sleep Environment and Other Non-Product-Related Issues

The greatest hazard found in the fatality data was unsafe sleep environments. This category included incidents where children were put to sleep on their stomachs, resulting in positional asphyxia; the addition of extra bedding, such as pillows or comforters to the play yards in combination with the prone sleep position may have contributed to the positional asphyxia

hazard. This hazard is associated with caregiver action and is not due to the design or construction of the play yard; there are no performance requirements that can address this hazard adequately. ASTM F 406-11 already contains labeling requirements that point out how deadly this hazard can be. Staff is not making any recommended changes to the voluntary standard to attempt to address unsafe sleep environment issues any further. Staff believes that a strong education and information campaign is a more effective way to address the issue of safe sleep environment for infants.

There were ten other fatalities associated with non-product-related issues. These included hazardous surroundings, such as window blind and computer cords in or near a play yard resulting in strangulations. With the exception of warning labels, these issues are also not addressable in a play yard standard and are addressed more effectively with an education and information program.

2. Climbing /Falling Out¹⁶

Some play yard escapes may be performed without injury, but it is reasonable to expect falls and injuries to occur. A play yard designer faces limited options for preventing children from climbing out. The play yard is basically a lidless box. Play yards that prevent climbing out would require either higher sides or lids to be effective. Both designs would introduce other problems that are potentially of more concern than the problem of climbing out. For instance, making the sides higher increases the difficulty caregivers have placing their children, especially the youngest ones, into the play yards or lifting them out. This could increase the use of alternative sleeping arrangements, such as allowing children to sleep in adult beds, which have serious hazards associated with them. Introducing a lid or some other kind of cover to a play yard creates more movable parts, with more possibilities for mechanical failures, which could lead to entrapment, entanglement, or strangulation.

Staff has been unable to identify a performance criterion for inclusion in the play yard standard that would effectively reduce incidents of children climbing out of play yards without simultaneously introducing other potential hazards. The warnings in the play yard standard F 406-11 are placed in an optimal order in the warning lists required for that product.

3. Side Rail Collapse

The highest number of incidents (89 percent, or 1,903 out of the 2,128) pertained to side rail collapse. These incidents almost universally involved a child who fell when a side rail latch collapsed. Most of these incident reports involved recalled products and were received from manufacturers and retailers. These recalls led to the addition of a new test procedure in ASTM F 406-09 to test for a false latching situation. CPSC staff reviewed these incidents in detail and determined that the current ASTM standard adequately addresses this hazard scenario.

¹⁶ Based on crib fall out discussion from: Midgett, Jonathan "Human Factors Analysis of Children Climbing Out of Cribs and Getting Limbs Caught Between Slats," Full-Size Crib NPR Briefing Package; June 3, 2010.

Additionally, ASTM F 406-11 includes a performance requirement and test method that addresses a side rail collapse issue that was a problem in the past but was never adequately addressed in past editions of the ASTM play yard standard. In brief, when folding play yards were relatively new products in the 1990s, some products did not include features designed to prevent unintentional collapse of the side rails. Some play yards collapsed into a V-shape. If a child's neck is caught in the V-shape, the child could suffocate. Most producers of play yards chose to stop designing products that could form a V-shape when the side rails collapsed. The ASTM standard, however, was not revised to ban this design.

According to CPSC Press Release # 98-128, there were 12 deaths from 1990 through May 1998, due to play yard side rail collapses that resulted in the formation of a V-shape. Danny Keysar, who CPSIA section 104 was named after, is one of the 12 infant/toddlers killed. These deaths led to the recall of 1.5 million play yards in 1998. (These fatalities are not included in the list of incident data referenced throughout this document because they pre-date the creation of the Early Warning System database [the database used to support the regulatory work here]).

Two other noninjury incidents were reported in the last three years related to a child becoming entrapped at the neck on a collapsed side. In one incident, IDI 081104CCC2093, the child was standing when the side collapsed, entrapping the child at the neck. A grandparent heard the side collapse and promptly removed the child from the collapsed side. In another incident, a consumer stated that a V-shaped configuration was created when the side inadvertently collapsed with the child out of the play yard. Both of these incidents occurred on a play yard previously recalled for side collapse.

The recent revision ASTM F406-11 added new requirements to prevent the formation of a sharp V shape when the play yard is partially folded. This requirement should result in a wider opening that is less likely to entrap the head and neck of a play yard occupant if the rail should collapse.

For play yards bearing rigid top rails with a double hinge/latching device, the product is placed in the manufacturer's recommended use position with the first segment of one top rail assembly intentionally unlocked and the second locked as shown in figure 2.



Figure 2. Double Hinge Device

The angle created within 3 inches of the point at which the rail segment and hinge/latch device meet is then measured. The product fails if the angle measures less than 75 degrees. Seventy-five degrees is based on the included angle incorporated on Test Template B for identifying

dangerous gaps on gates in ASTM F 1004-09, *Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures*.

For play yards in which the uppermost edge is a nonrigid member, such as stiff elastic cord, a visual inspection is required to determine if contact failure has occurred when a 30 lbf is applied vertically downwards with Test Template B from ASTM F 1004-09.

While the 100 lb load requirement on the latch/hinge and the false latching requirements added to F 406-09 are intended to prevent a hinge collapse, the wide angle hinge requirement for a single unlocked hinge should also be an added safety factor if a hinge/latch fails. These combined requirements should be an effective deterrent against head entrapment in a collapsed side rail.

Staff believes all of these top rail and hinge requirements adequately address the entrapment hazard and should further reduce associated injuries.

4. Accessories

One death resulted from strangulation of an infant in a play yard on a looped strap that hung below an accessory into the occupant's play/sleep area. This occurred in May 2007, and it led directly to the addition of a new requirement in F 406-08a, prohibiting hazardous loops from being formed by straps that hang from an attachment inside the play yard enclosure. Staff believes this requirement is adequate and is not recommending any new requirements to address this hazard at this time.

5. Assembly Difficulties/Other Product-related Problems

There were 12 incidents in this category, with one fatality and two injuries, one of which was severe. The death involved a mattress pad that had not been attached to the play yard floor panel. In IDI 080205CCC2418, a 3-month-old died of asphyxiation when placed in a prone position in a play yard, with a ¹/₂-inch trifold mattress pad. The infant was able to push the mattress pad away from the side of the play yard approximately 2 ¹/₂ inches. The infant was discovered face down in the 2¹/₂-inch gap. Staff reviewed the incident and concluded that the Velcro straps were not attached to the floor panel. Staff believes that had the mattress straps been correctly assembled to the floor panel, this death could have been avoided.

The one injury that required hospitalization, a finger laceration closed with eight stitches, occurred when the victim's finger got caught in the gap between the corner bracket and side rail as the side rail was lifted and latched. Although the finger laceration injury was severe, staff's hazard analysis indicated that this scenario was neither an emerging nor established trend.

The voluntary standard addresses the assembly instruction hazard with the following requirement:

"10.1 Instructions must be provided with the products and shall be easy to read and understand. Assembly, maintenance, cleaning, operating, folding instructions, and warnings where

applicable must be included. A means shall be provided to keep the instructions with the product."

Other product-related or miscellaneous problems included complaints of undesirable paint/finish, sharp surfaces, and other unspecified safety concerns. Ten injuries were reported under this category, including two deaths. Staff reviewed each of the In Depth Investigation reports (IDI) related to these deaths, IDI 110222HAA3437 and IDI 080910CBB2998.

In IDI 110222HAA3437, a 17-month-boy was found dead in an upright position in a play yard at a child care facility. The child was found with his head/chin resting on the upper railing of the play yard with his arms hanging out of it. According to the day care provider, the child was able to climb out of the play yard. The interior distance from the floor of the play yard to the top rail is 22 inches. The child was 31-inches-tall and weighed 30 lbs. The medical examiner determined the cause of death was possible asphyxia.

In IDI 080910CBB2998, a 23-month-old boy was placed to sleep in the product with a "sippy cup," two blankets, and a pillow. The play yard was covered by a fitted sheet to block the light. The child was found dead in an upright, standing position, with his chin resting on the upper railing and his arms hanging outside the play yard. The interior distance from the floor of the play yard to the top rail is 21 inches. The child was 36-inches-tall and weighed between 25 to 30 lbs. The autopsy revealed the cause of death was mechanical positional asphyxia.

Staff concluded it was not clear how or what led both children to remain in a slumped position over the upper rail with no obvious (or reported) obstacle around to confine and keep them in the position found. This is especially puzzling considering that even the youngest child (17 months old) was reportedly able to climb out of the play yard and had done so on several occasions. Staff finds it very difficult to conclude that the products contributed to the death of the two children in the manner described in the IDIs in absence of other mitigating factors.

6. Lack of Structural Integrity

The majority of the non-recall-related incidents attributable to poor structural integrity involved play yards with structural failure(s) of the corner brackets. Typical failure scenarios included, but were not limited to, rivets pulling through corner brackets, propagation of cracks under rivet heads, stress whitening, and the liberation of rivets and plastic pieces. Figure 3 includes photos of typical corner bracket failures. For example, in IDI 100325CWE2014, a changing table attached to a play yard collapsed when a rivet pulled through the corner plastic bracket while a 4-month-old was on the changing table. In another incident, IDI 100519HCC1742, the rivets pulled completely through two corner post brackets, causing the side to partially collapse when the consumer leaned over the front of the play yard to remove the occupant. In a third incident, IDI 090116HCC3259, a 10-month-old was standing inside his play yard and holding onto the top side rail, when the corner of the play yard suddenly collapsed and entrapped him in a corner. He sustained a bruise, bump, and abrasion to his forehead. The play yard collapsed when a plastic corner piece fractured and liberated at the corner post where a vertical strut connects to the top rail.


Figure 3. Typical Failure Modes of Plastic Corner Brackets

Staff of ESME and LSM(Engineering Sciences Mechanical Engineering and Laboratory Sciences Mechanical Engineering divisions, respectively) determined that many of the incidents involving corner post attachment failure were attributable to cyclic loading of the top side rails. This loading occurred when consumers inadvertently and repeatedly leaned on the top side rails while accessing the occupant, or when child repeatedly used the top side rails for support while standing. These scenarios each imparted a small cyclical twisting action¹⁷ to the top side rail corner post attachment joints.

A new performance requirement was developed and validated by LSM and ESME staff, which addressed the fatigue failures observed in corner post attachment joints. To meet staff's new *Top*

¹⁷ In engineering terms, this would be described as a moment or torque being applied to the top rail corner post attachment points.

Rail to Corner Post Attachment Test, ¹⁸ play yard corner brackets must not fail when a single significantly large twisting action (moment) is applied to the midpoint of the top side rails. The magnitude of this moment is 40 ft-lbs. Corner brackets of recalled products in the CPSC's possession failed this test with an applied moment of 20 to 24 ft-lbs. The 40 ft-lb (53 Nm) moment equates to a safety factor of 2 (2 x 20 ft-lbs = 40 ft-lbs).

Failure of the *Top Rail to Corner Post Attachment Test* is defined as any crack in the corner brackets, fasteners pulling completely through a bracket wall, or fasteners or fastener pieces becoming liberated, similar to the failure modes observed on incident play yard corner posts. Audible indications during testing do not constitute evidence of failure. Due to the severity of this test, the requirements in F 406-11 section 5.8 for Latching and Locking Mechanisms do not apply after completion of this test.

7. Mattress Pad/Floor Board

There were several reported injuries, including scrapes and bruises, created by a child rolling or falling into a pocket on the floor board where the mattress had been lifted upward. However, the significant foreseeable hazard related to mattress displacement involves entrapment that leads to asphyxiation. This is specifically dangerous for children 12 months old and younger, who have the cognitive ability and strength to pull up on the end of the mattress and maneuver their head and/or bodies between the mattress and the floor structure. Staff is aware of three incidents in which a child became entrapped in this manner. In IDI 08121HCC1245 an 8-month-old was able to crawl underneath the mattress of the play yard and became entrapped at the neck. Similarly, in 081128CBB1217 and 090327HCC3457, a 14-month-old and 11-month-old, respectively, crawled under a mattress secured only by Velcro patches and became entrapped. In all three incidents, a caregiver quickly recognized the potentially dangerous entrapment and promptly removed the child from the play yard.

The two most common methods of attaching a play yard's mattress to its base are hook and loop Velcro straps and patches. Staff tested several play yards involved in mattress detachment incidents and discovered that patches separate when a mattress corner is pulled up with less than 4 lbs of force. Likewise, staff discovered the force required to lift a mattress attached with hook and loop straps more than 5 in ranged from 11 to 25 lbf.

A new test requirement, developed by staff and validated with the stakeholders, requires the mattress to be pulled up with 15 pounds of force. Fifteen pounds has been selected based on successful precedent set by similar tests in the play yard and other juvenile product standards. For example, the tension test for the removal of protective components and the test for warning label permanency both require a 15 lb pull force. During this test, the mattress may not lift more than 5.25 inches from its original position. In addition, the new ASTM requirement allows the tester to select any location that seems likely to fail along the edge of the mattress that is parallel to the mattress folds. In practice, this would probably only necessitate three or four pulls of the mattress, namely at both corners and in or near the middle of the edge. Most folding mattresses only fold in one direction, but if a design includes folds in other directions, the test can accommodate this without difficulty. Other juvenile product standards typically allow testers to

¹⁸ This test is now section 8.30, *Top Rail to Corner Post Attachment Test,* in ASTM F 406-11.

select positions that are considered "most onerous" or "most likely to result in failure" if the determination of such a location is generally obvious, as in this case.

This test was adopted by the ASTM play yard subcommittee in January 2011, and is now 8.28, *Mattress Vertical Displacement Test*, in F 406-11, and staff believes that it is adequate to address the hazard.

8. Fabric or Mesh-Related Issues

Staff reviewed this issue with samples that included problems with stitching that unraveled, fabric tears, mesh holes, stitching that caught teeth and abrasive mesh material. Five injuries were reported in this category, but none required hospitalization. Therefore, the severity of the hazard is low. These issues are already addressed by three performance requirements in F 406-11:

- <u>7.6 Mesh Requirements</u> Holes in the mesh cannot permit a 1/4 inch diameter (finger- sized) probe to be forced in.
- <u>7.7 Fabric Strength</u> Breaking and tear strength of fabrics are specified.
- <u>7.8 Mesh/Fabric Assembly Requirements</u> Seams cannot be unraveled easily and must meet specified strength.

Staff determined that—due to the low number of incidents relative to the large number of products in the field, and the low severity of the injuries—the hazard was addressed sufficiently by F 406-11.¹⁹

9. Compliance with General Requirements Post Testing and Testing Order

Prior to F 406-11, the standard did not explicitly state that each of the General Requirements listed in section 5, such as the requirements for Corner Posts, Scissoring, Shearing, or Pinching, Latching and Locking Mechanisms, and Openings, must be met both before <u>and</u> after all of the performance requirements have been completed. There appears to have been an implicit understanding among industry that this has been the case. The addition of this language in section 7.1, *The product shall comply with the requirements of Section 5 before and after all testing in this section unless noted otherwise*, codifies and clarifies this requirement.

Similarly, each performance requirement must be conducted in the order listed in section 7 of F 406-11. CPSC staff believes that the testing sequence can influence results and notes that in other juvenile standards, such as the standard for non-full-size and full-size cribs, a specified order is provided. Typically, the most stringent order (one to result most likely in the failure of the product) is used. Thus, the most severe test, *7.11 Top Rail to Corner Post Attachment*, a potentially destructive test, is the last test listed.

¹⁹ No changes to the three ASTM F 406 mesh and fabric performance requirements have been made in more than 10 years.

IV. OTHER STANDARDS

CPSC staff compared the performance requirements of ASTM F 406-11 to the performance requirements of other standards for play yards. Table 2 of the Appendix depicts a summary of this review.

The European (EN) standards and Australian/New Zealand (AS/NZ), EN 12227, and AS/NZS 2195, respectively, influenced the development of ASTM F 406-11. For example, discussions with staff's European counterparts provided insight into the 300 cycle fatigue test, initially considered for inclusion in F 406-11 section 8.30, *Top Rail to Corner Post Attachment Test*, to evaluate corner bracket structural integrity. CPSC staff learned that the true intent of this cyclic test was to test the integrity of the side rail locking devices. The incidents that related to top rail and corner post attachment included reports of rivets pulling through corner brackets and cracked plastic corner posts. Therefore, staff concluded that the cyclic test in EN 12227 would not effectively identify top side rails susceptible to corner post attachment failure. In addition, the EN test required about 5 hours to complete by one technician, whereas the CPSC's proposed *Top Rail to Corner Post Attachment Test* takes one technician only about 15 minutes to complete.

The top rail configuration requirements of F 406-11 section 8.29.1 are an evolution of the requirements in AS/NZS2195. 2010 section 8.4.2. The AS/NZS voluntary standard requires a minimum 80 mm (3inch) gap between the folding sides of the top rail, which simulates failure of two locking devices. In addition, the AS/NZS standard requires an angle of no less than 90 degrees between the sides of the play yard, with failure of one locking device. A neck entrapment requirement, widely accepted by CPSC staff and the stakeholders, already exists in the ASTM standard F 1004-09, *Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures*. Staff decided to use the hinge width, 38 millimeters, and included angle, 75 degrees, incorporated on Test Template B for identifying dangerous gaps on gates from this standard.

Only the EN standard included a performance requirement for mattress displacement. The requirement in EN 12227 ensures that the mattress does not detach when a horizontal force is applied to a mass placed on the mattress. CPSC staff decided that measurement of the horizontal distance between the mattress and the sides of the product would be more difficult to obtain, due to the varying flexibility of the side walls commonly found on play yards. Greater certainty is achieved measuring the vertical distance that a mattress can be raised. Therefore, measurement of the vertical distance that a mattress can be raised to determine if a hazard is present because this is the more reliable and repeatable of the two measurements.

Other differences remain between what CPSC staff is recommending for a proposed rule and these other play yard standards. These have been reviewed and evaluated, and staff believes that the requirements already found in ASTM F 406-11, plus the staff recommended changes, are either the most stringent requirements among all the standards or are considered adequate to address the incidents seen in the data and reduce the risk of injury to children in play yards.

V. PROPOSED SAFETY STANDARD FOR PLAY YARDS

Late in the process of approving F 406-11, a new issue arose regarding the size and shape of the clamp faces used in the *Top Rail to Corner Post Attachment Test*. CPSC technical staff and the ASTM play yard task group developed and approved a change to the requirement published in F 406-11. This technical change provides a clamping surface area range to accommodate the wide variety of hinge/locking mechanism designs on the market. Previously, a specific clamping surfaces from 1 in² to 4 in,² without specifying the shape that would grasp the hinge/latching device best. The exact wording of this change is listed in Table 1. This language went out to ballot in June 2011 via the ASTM balloting procedures, and if approved, will be included in the next iteration of the ASTM standard, F 406-11a. CPSC staff agrees with the revised language and recommends its inclusion in staff's proposed rule.

Additionally, staff is recommending two technical clarification changes concerning play yards. These changes are also included in recent ASTM ballots. These technical changes were added to clarify the test procedure in section 8.12, *Floor Strength Test for Mesh/Fabric Products*. Table 1 lists the exact wording of this change to be included in F 406-11a and staff's proposed rule.

| ASTM F 406 Section # | Sub-Section | Recommended Addition |
|-------------------------------------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.30 Top Rail to Corner Post Attachment Test | 8.30.3.1 | Mount a rigid and substantially horizontal moment arm weighing less than 5 lbm (2.2 kg) to the hinge/latching device at the longitudinal center of the top rail through 2×2 in. (50 \times 50 mm) two clamping surfaces, each 1 in ² – 4 in ² (6.5 cm ² - 26 cm ²) designed to firmly grasp the hinge/latching device. The moment arm shall be at least 24 in. (602 mm) long and extend towards the outside of the play yard. |
| 8.12 Floor Strength Test for Mesh/Fabric Products: | 8.12.1 | <i>Equipment</i> - 2 Wood block s , 6 by 6 in. (150 by 150 mm). |
| 8.12.2 Test Method: | 8.12.2.1 | Remove cushions that are not part of the floor or mattress support. Place a 50-lb (23-kg) and a 30-lb (14-kg) weight each onto a 6 by 6-in. (150 by 150- mm) wood block spaced 6 6 ⁻¹ /Aace a 50-lb (23-kg) and a 30-lb (14-kg) weight each onto a 6 by 6 in. (150 by 150 mm) wood block spaced 6 6 device at the longitudinal center o the load and check for |

Table 1. CPSC Staff-Recommended Changes to ASTM F 406-11

| (Strikeout indicates current language that is recommended to be removed. | Bold indicates |
|--------------------------------------------------------------------------|-----------------------|
| additional language recommended.) | |

| structural failure. |
|--------------------------------------------------|
| Place the wood blocks 6 +/- 1/2 inch (150 mm |
| +/- 13 mm) apart. Place a 50-lb (23 -kg) weight |
| on one wood block and a 30 lb (14 kg) weight on |
| the other wood block. Maintain for 60 s. |
| Perform the test in those locations deemed to be |
| the weakest or the most likely to fail. Remove |
| the loads and check for structural failure. |

VI. CONCLUSIONS

ES staff recommends adopting the requirements that apply to play yards specified in ASTM F 406-11 as the draft proposed mandatory standard for play yards, including one substantial change and two editorial changes. Staff and the ASTM subcommittee on Play Yards agree on revising section 8.30, *Top Rail to Corner Post Attachment Test*, to accommodate a range of clamping surfaces for the wide variety of hinge/locking mechanism designs. In addition, staff and ASTM agree on an editorial change to clarify the test procedure for the section 8.12, *Floor Strength Test for Mesh/Fabric Products*. In conclusion, ES staff reviewed the incidents and feels that the current voluntary standard and proposed requirements adequately address the reported hazards.

APPENDIX

Table 2. Summary of Other Play Yard Standards and the ASTM Play Yard/NFS Standard

| Test | ASTM F 406-11 | Health Canada -C.R.C., c. 932 | EN 12227-1 & 2:1999 | AS/NZS S2195.2010 |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Side Height | Height of sides of a unit shall be at least 20 in. | (Test not in standard) | Height of sides of a unit shall be at least 24 in. | (Test not in standard) |
| Side Deflection and Strength | 50 lbf vertically downward on top rail; 30 lbf vertically downward on floor; 100 lbf at 45 and 90 degrees on top rail | (Test not in standard.) | 67 lbf vertically downward on top rail | 112 lbf vertically downward on top rail |
| Floor Strength | 50 lbf and 30 lbf on weakest portion of floor; 30 lbm weight dropped 50 times | 50 lbf on weakest portion of floor | 22 lbm weight dropped 1000 times at: 1) center of one side 2) center of one end 3) center of the base 4) near an attachment point | 22 lbm weight dropped 1000 times |
| Top Rail Covering Material | Top rail vinyl cover minimum thickness 0.011 in. | (Test not in standard) | (Test not in standard) | (Test not in standard) |
| Mesh Requirements | No openings larger than 0.25 in. with 5 lbf; 20 lbf ten cycles at geometric center, near top rail, and near bottom of each side | No openings larger than 0.25 in. with 5 lbf; 20 lbf ten cycles at geometric center, near top rail, and near bottom of each side | (Test not in standard) | No openings larger than 0.25 in. with 6.7 lbf |
| Fabric Material Requirements | 50 lbf fabric breaking strength | (Test not in standard) | 56.2 lbf fabric breaking strength | (Test not in standard) |
| Mesh/Fabric Assembly Requirements | 30 lbf seam strength | (Test not in standard) | (Test not in standard) | (Test not in standard) |
| Mattress Vertical Displacement | Mattress must not vertically displace more than 5.25 in with 15 lbf | (Test not in standard) | Mattress must not horizontally displace with 11.2 lbf | (Test not in standard) |
| Top Rail Configuration | Minimum 38 mm hinge width and 75 degrees | (Test not in standard) | (Test not in standard) | Minimum 80 mm hinge width and 90 degrees |
| Top Rail to Corner Post Attachment | 40 ft-lb, upward and downward, at the midpoint of each top rail | (Test not in standard) | 22.5 lbf at four points applied horizontally on the corners, 4000 cycles | 22.5 lbf at four points applied horizontally on the corners, 2000 cycles |

TAB C:

Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Play Yards



UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION BETHESDA, MD 20814

Memorandum

Date: August 17, 2011

| TO : | Gregory K. Rea Project Manager, Play Yards Directorate for Laboratory Sciences |
|-----------|------------------------------------------------------------------------------------------------|
| THROUGH: | Gregory B. Rodgers, Ph.D. Associate Executive Director Directorate for Economic Analysis |
| | Deborah V. Aiken, Ph.D. Senior Staff Coordinator Directorate for Economic Analysis |
| FROM : | Jill L. Jenkins, Ph.D. Economist Directorate for Economic Analysis |
| SUBJECT : | Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed |

I. INTRODUCTION

Standard for Play Yards

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104 of the CPSIA requires that the U.S. Consumer Product Safety Commission (CPSC) examine and assess the effectiveness of the currently existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. Play yards are among the durable products specifically named in section 104. CPSC staff worked closely with ASTM International (formerly known as the American Society for Testing and Materials) to incorporate three new requirements and test procedures into the most recent voluntary ASTM standard for non-full-size baby cribs/play yards (F 406-11). Upon review, CPSC staff recommends that the Commission adopt the relevant sections²⁰ of F 406-11, with a few modifications that staff anticipates will be included in the next version of the voluntary standard.

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA requires that CPSC staff prepares an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is published. The initial

²⁰ Since ASTM F 406-11 covers both non-full-size cribs and play yards, some requirements are applicable only to play yards or non-full-size cribs, while others are applicable to both products.

regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

- 1. a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- 2. a description of the reasons why action by the agency is being considered;
- 3. a succinct statement of the objectives of, and legal basis for, the proposed rule;
- 4. a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- 5. an identification, to the extent possible, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

II. THE PRODUCT 21

Play yards, also known as playpens, are made of mesh or fabric side panels that attach to a rigid frame structure, including a floor. They are primarily intended to provide play and/or sleeping environments for children who cannot climb out. Some are foldable for storage or travel purposes. Inflatable products are not included in the definition of "play yard."

Many accessories that come with play yards are also covered by the staff-recommended proposed rule. Those accessories must comply with the relevant ASTM standard as well (*i.e.*, a bassinet accessory attached to a play yard must comply with the play yard standard, as well as the bassinets/cradles standard). Exceptions include accessories that hang outside the occupant area or attach only to another accessory.

III. THE MARKET FOR PLAY YARDS

Play yards are typically produced and/or marketed by juvenile product manufacturers and distributors. CPSC staff believes that there are currently at least 23 manufacturers or importers supplying play yards to the U.S. market. Two are foreign importers (*i.e.*, import from foreign companies and distribute from outside of the United States). Eleven firms are domestic manufacturers, and 10 are domestic importers.²² Play yards from 11 of the 23 firms have been certified as compliant with the ASTM voluntary standard by the Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers. Three additional firms claim compliance with the voluntary standard, and, in some cases, provide test results online.

²¹ ASTM F 406-11.

²² Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

According to a 2005 survey conducted by the American Baby Group (2006 Baby Products Tracking Study),²³ 76 percent of new mothers own at least one play yard—74 percent own portable play yards, and 28 percent own full-size play yards.²⁴ Approximately 35 percent of portable play yards and 17 percent of full-size play yards were handed down or purchased secondhand.²⁵ Thus, about 65 percent of portable play yards and 83 percent of full-size play yards were acquired new. This suggests annual sales of about 2.9 million play yards to households (.74 x .65 x 4.1 million births per year + .28 x .83 x 4.1 million births per year).²⁶

IV. REASON FOR AGENCY ACTION AND LEGAL BASIS FOR THE DRAFT PROPOSED RULE

Section 104 of the CPSIA requires the CPSC to promulgate a mandatory standard for play yards that is substantially the same as, or more stringent than, the voluntary standard. CPSC staff worked closely with ASTM to develop the three requirements and test procedures new to ASTM F 406-11. These new requirements address several known hazard patterns and will help to reduce injuries and deaths in play yards.²⁷ CPSC staff is recommending a few modifications to F 406-11, primarily to clarify test procedures. Their inclusion is anticipated in the next iteration of the voluntary standard as well.

V. COMPLIANCE REQUIREMENTS OF THE DRAFT PROPOSED RULE

CPSC staff recommends adopting the voluntary ASTM standard for play yards (F 406-11) (excluding parts that relate solely to non-full-size cribs) with a few modifications. Some of the more significant requirements of the current voluntary standard (ASTM F 406-11) as they relate to play yards are listed below. New requirements for the 2011 standard are italicized.

²³ The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, since the most recent survey information is from 2005, it may not reflect the current market. In particular, it is possible that the mandatory crib standards approved by the Commission in December 2010 could change the demand for play yards. However, since the number of play yards sold could either increase or decrease as a result of the crib standards, the estimate presented here is the most reasonable based on the data available.

²⁴ Neither full-size nor portable play yards were defined for Baby Products Tracking Study respondents, many of whom appear to own more than one type of play yard. However, it seems likely that respondents considered portable play yards to be those smaller than other play yards and more easily transported to other locations. While there is no one standard size of play yards, staff is aware of two common sizes, approximately 40 inches and 30 inches in length. These may be considered by the survey's respondents to be full-size and portable play yards, respectively.

²⁵ The data on secondhand products for new moms was not available. Instead, data for new moms and expectant moms was combined and broken out into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage of play yards that were handed down or purchased secondhand. Additionally, play yard categories have been collapsed for simplicity. ²⁶ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National

Center for Health Statistics, National Vital Statistics System, "Births: Preliminary Data for 2009," *National Vital Statistics Reports* Volume 59, Number 3 (December 21, 2010): Table 1. Number of births in 2009 is rounded from 4,131,019.

²⁷ Chowdhury, 2011 and memorandum from Jacob J. Miller, Division of Mechanical Engineering, Directorate for Engineering Sciences, dated August 17, 2011, Subject: Proposed Change to ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, for Incorporation in Staff's Draft Proposed Rule.

- Corner post and protrusion requirements—intended to address strangulation hazards that could result when various children's items catch on posts or protrusions.
- Latching mechanism tests—intended to ensure that latching and locking mechanisms work as intended and prevent unintended folding while in use.
- Stability test—intended to prevent play yards from tipping over.
- Entrapment test for play yard attachments—intended to prevent a child's head from becoming entrapped while the accessory (*e.g.*, bassinet, changing table, etc.) is attached, but not necessarily in use.
- Side deflection and strength tests—intended to prevent play yard sides from breaking, folding, etc. when subjected to static weights. Also limit how much a static weight can lower the side height.
- Floor strength tests—intended to ensure structural integrity when the play yard is exposed to both static and dynamic loads.
- Mesh/fabric requirements—intended to ensure the mesh and/or fabric's strength, as well as the strength of its attachment to the play yard structure. Also address the entrapment of children's fingers and toes in mesh and the tearing of seams and stitching.
- Minimum side height requirements—intended to prevent children from getting out of the play yard on their own.
- Mattress vertical displacement test—a new requirement for the 2011 standard, intended to prevent floor entrapment hazards that are present when a child is able to pull up the mattress pad or removable floor structure and get their head between it and the side of the play yard and then under the mattress pad.
- Top-rail configuration test—a new requirement for the 2011 standard, intended to prevent play yards from using hinge/latch designs that create a V- or diamond shape when folded. In the past, these have resulted in head/neck entrapments.
- Top rail to corner post attachment requirements—a new requirement for the 2011 standard, intended to prevent broken corner brackets, loosened fasteners, etc. that have occurred in the market. The test method checks the robustness of the connection points between the top rails and corner brackets.

The voluntary standard also includes: (1) torque and tension tests to assure that protective components cannot be removed; (2) requirements for several play yard features to prevent entrapment and cuts (minimum and maximum opening size, small parts, exposed coil springs, protective components, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) mattress requirements; (5) a vinyl thickness requirement when used to cover a play yard's top rail; (6) requirements for instructional literature; and (7) limits on the length of flexible cords and straps intended to prevent strangulations.

Staff recommends including modifications to ASTM F 406-11 in the proposed rule that mirror the balloted changes recently approved by the ASTM subcommittee. They are expected to have no impact on play yard manufacturers. These modifications are:²⁸

²⁸ Miller, 2011.

- 1. A clarification in the top rail to corner post attachment test. It is intended to accommodate a range of clamping surfaces and is not expected to changes test results.
- 2. Two editorial changes to the floor strength test that leaves the content of the test unaltered.

VI. OTHER FEDERAL OR STATE RULES

The Commission is in the process of implementing Sections 14(a)(1) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. Section 14(a)(1) requires every manufacturer of a product that is subject to a product safety rule to certify that the product complies with all applicable safety rules. Section 14(d)(2)(A) requires the Commission to establish protocols and standards (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Since play yards now will be subject to a mandatory standard, they will be subject to the certification requirements of Section 14(a)(1) when that rule becomes final. Moreover, play yards are children's products and will eventually be subject to the third-party testing requirements of Section 14(d)(2)(A).

VII. IMPACT ON SMALL BUSINESSES

There are approximately 23 firms currently known to be producing or selling play yards in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of play yards is a small business if it has 500 or fewer employees, and an importer is considered a small business if it has 100 or fewer employees. Based on these guidelines, 20 are small firms—10 domestic manufacturers and 10 domestic importers. The remaining firms are a large domestic manufacturer and two foreign importers. There may be additional unknown small manufacturers and importers operating in the U.S. market.

A. Small Manufacturers

We assume that firms whose play yards meet the voluntary standard will continue to do so in the future. This means that firms that meet ASTM F 406-10 would adapt their products to meet F 406-11 within 6 months after the standard is published. This is the amount of time JPMA typically allows for products in their certification program to shift to a new standard, although manufacturers can do so earlier. ASTM F 406-11 was published in July 2011, putting the approximate date when play yards will have become compliant with it to February 2012. The mandatory standard for play yards would be effective no earlier than mid-year 2012.

The impact of the staff-recommended proposed standard on small manufacturers will differ based on whether their play yards are compliant with ASTM F 406-11. For manufacturers whose play yards meet the requirements of ASTM F 406-11 (7 of 10 firms), there will be little or no impact.

Meeting ASTM 406-11's requirements could necessitate some product redesign for one or more play yards not believed to be compliant with the voluntary standard. The redesign would be minor if most of the changes involve adding straps or using different mesh or fabric, but it could be more significant if changes to the frame are required. Consequently, the staffrecommended rule could potentially have a significant impact on one or more of the three manufacturers of play yards whose products do not conform to the voluntary standard. However, any impact may be mitigated if costs are treated as new product expenses that can be amortized. It should be noted, however, that these firms would incur most of these expenses whether or not the Commission approves the staff-recommended additions.

The scenario described above assumes that only firms that produce play yards certified by JPMA or that claim compliance with the voluntary standard will pass F 406-11's requirements within 6 months after publication. This is not necessarily the case. CPSC staff has identified many cases in which products not certified by JPMA are actually compliant with the relevant ASTM standard. To the extent that this is true, the impact of the staff-recommended proposed rule will be less significant than described.

B. Small Importers

Importers of play yards would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the staff-recommended proposed standard. The wholesale cost of compliant play yards could increase, and importers, in turn, could pass on some of those increased costs to consumers.²⁹ Some importers could respond to the rule by discontinuing the import of their non-complying play yards. However, the impact of such a decision may be mitigated by replacing the noncompliant play yards with compliant play yards or another juvenile product. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue. This might be necessary for the four importers who staff assumes will not be compliant with ASTM F 406-11; staff does not believe that the six importers of compliant play yards will require any modifications to meet the staff-recommended proposed standard.

Two of the four small importers of non-compliant play yards specialize in the importation of products from a specific foreign company. For these firms, finding an alternative supply source is probably not an option. However, they could respond to the rule by discontinuing the import of their non-complying play yards, possibly replacing them with other juvenile products.

²⁹ These products would also be expected to be of higher quality given the additional safety requirements.

VIII. ALTERNATIVES

Since staff believes that there are few or no costs associated with the staff-recommended changes to ASTM 406-11, adopting the voluntary standard—without modifications—will not reduce the impact on small firms. Firms whose play yards do not comply with the current voluntary standard (and, it is therefore assumed, will not comply with ASTM F 406-11 either) could still require substantial product changes in order to meet F 406-11. On the other hand, firms with compliant play yards would have few or no costs under either scenario.

Setting an effective date later than the staff-recommended 6-month-period, however, would reduce the impact on firms whose play yards are not expected to meet ASTM F 406-11. This would allow suppliers additional time to modify and/or develop compliant play yards and spread the associated costs over a longer period of time.

TAB D:

Federal Register Notice of Proposed Rulemaking to establish a Safety Standard for Play Yards

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1221

CPSC Docket No. CPSC-2011-

RIN 3041-____

Safety Standard for Play Yards

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") requires the United States Consumer Product Safety Commission ("Commission," "CPSC," or "we") to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for play yards in response to the direction under Section 104(b) of the CPSIA.

DATES: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2011-____, may be submitted electronically or in writing:

<u>Electronic Submissions:</u> Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer directly accepting comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

<u>Written Submissions:</u> Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

<u>Instructions:</u> All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <u>http://www.regulations.gov</u>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

<u>Docket:</u> For access to the docket to read background documents or comments received, go to <u>http://www.regulations.gov</u>, and insert the docket number, CPSC 2011-____, into the "Search" box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Gregory K. Rea, Project Manager, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email GRea@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008, ("CPSIA," Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA requires the Commission to promulgate consumer product safety standards for durable infant and toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The term "durable infant or toddler product" is defined in section 104(f)(1) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. Play yards are one of the products specifically identified in section 104(f)(2)(F) as a durable infant or toddler product.

In this document, the Commission proposes a safety standard for play yards. The proposed standard is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F 406-11, "Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards" ("ASTM F 406-11"). The ASTM standard is copyrighted but can be viewed as a read-only document, only during the comment period on this proposal, at <u>http://www.astm.org</u>, by permission of ASTM.

B. The Product

1. Definition

ASTM F 406-11 defines a "play yard" as a "framed enclosure that includes a floor and has mesh or fabric sided panels primarily intended to provide a play or sleeping environment for children. It may fold for storage or travel." Play yards are intended for children who are less than 35 inches tall who cannot climb out of the product. Play yards are convenient because they usually fold for storage or travel. Some play yards include accessory items that attach to the product, including mobiles, toy bars, canopies, bassinets, and changing tables. The accessory item(s) usually attaches to the side rails or corner brackets of the play yard.

2. The Market

Based on a 2005 survey conducted by American Baby Group titled, "2006 Baby Products Tracking Study," we estimate that approximately 2.9 million play yards are sold in the United States each year. We estimate that there are 23 manufacturers or importers supplying play yards to the U.S. market. Eleven firms are domestic manufacturers, and 10 firms are domestic importers. Two firms are foreign importers.

Play yards from 11 of the 23 firms have been certified as compliant with the ASTM voluntary play yard standard by the Juvenile Products Manufacturers Association ("JPMA"), the major U.S. trade association that represents juvenile product manufacturers and importers. In addition, three other firms claim compliance with the ASTM voluntary play yard standard and, in some cases, provide test results publicly.

C. Incident Data

The CPSC's Directorate for Epidemiology reports that there have been 2,128 incidents reported to the Commission regarding play yards from early November 2007 until early April

2011. Of the 2,128 reported incidents, there were 49 fatalities, 165 nonfatal injuries, and 1,914 noninjury incidents. The data is drawn from the CPSC's "Early Warning System" ("EWS"), a database created in late 2007, which allows the Commission to monitor incoming incident data closely. Once an incident report is entered into EWS, it is carefully reviewed by a subject matter expert. Thus, EWS contains the best data to support the play yard regulatory work.

1. Fatalities

From early November 2007 through early April 2011, there were 49 fatalities associated with play yards. Twenty-seven deaths are attributable to unsafe sleep environments within the play yard, such as the presence of soft or extra bedding, or unsafe sleep practices, such as putting infants to sleep on their stomach instead of their back.

Ten suffocation deaths were caused by unsafe environments around the play yard. Examples of hazardous surroundings include: window blind cords or computer cords that fell into the play yard where the cords formed dangerous loops and resulted in strangulation fatalities. Other deaths were caused when items were placed on top of the play yard to prevent the child from climbing out. These items, such as wood, mesh gates, or crib tents, caused suffocation deaths when children tried to crawl out of the product and became stuck between the side rail and the item placed on top of the play yard.

The remainder of the fatal incidents include:

- Two children were killed in separate incidents when they were able to climb out of a play yard and gain access to a pool. Both children drowned in the pool.
- Two toddlers were killed in separate incidents while standing up in a play yard. It is believed that they leaned forward against the side rail (possibly to reach an object that the

child had thrown outside the play yard), lost consciousness, and suffocated when the pressure from the side rail compressed the airway.

- One toddler was killed when the play yard collapsed unexpectedly. The child was trapped and suffocated.
- One death was caused by a looped strap hanging from a changing table accessory. The changing table was supported by the side rails of the play yard. The looped strap fell into the play yard space occupied by the child and resulted in the child's strangulation.
- One death was caused by an assembly error that occurred when the mattress pad was not secured completely to the bottom of the play yard. The child suffocated in the pocket created between the unsecured mattress pad and the floor of the play yard.
- Five other deaths are associated with play yards, but there was insufficient information to determine the cause.

2. Nonfatal Injuries

From early November 2007 through early April 2011, there were 2,079 nonfatal incident reports. Of those, 165 incidents involved an injury, and four of those required hospitalization. Although the remaining 1,914 nonfatal incident reports did not result in an injury, many of the descriptions indicate the potential for serious injury or death.

The largest number of nonfatal incident reports were attributable to the unexpected collapse of the side rail of a play yard. Of the 2,079 nonfatal incident reports, 1,902 involved the collapse of one or more sides of a play yard. Of the 165 incidents involving an injury, 124 were the result of a play yard side rail collapse. Of the 124 injuries, there was one hospitalization for a concussion that was caused by the collapse of a side rail.

The remainder of the nonfatal injury incidents included:

- Eight injuries caused by broken or detached component parts, such as loose wheels or loose hardware, which resulted in instability or collapse of the product.
- Eight injuries caused by various product-related problems, including sharp surfaces.
- Five injuries related to the mesh or fabric sides of the play yard, such as stitching that unraveled, tears in the fabric, mesh holes that were too large, and mesh material that was too abrasive.
- Five injuries related to the mattress pad or the floor of the play yard. Examples of injuries in this category included: mattresses or pads that were insufficiently fastened to the play yard floor, resulting in toddlers becoming trapped under the mattress or pad.
- Five injures related to toddlers climbing out or falling out of the play yard. This category included one toddler who was hospitalized for a serious head injury after climbing or falling out of the play yard.
- Four injuries resulted when children were standing in the play yard, lost their balance, and fell.
- Two injuries caused by broken or hazardous accessories, such as dangling straps from changing tables. Other examples of hazardous accessories included: broken or detached components from music boxes, trays, mirrors, and toy holders.
- Two injuries related to assembly errors, including one child who was hospitalized with a severe finger laceration after getting his or her finger caught in the play yard as it was being assembled.

- One injury that resulted in a hospitalization was caused by the presence of soft bedding in the play yard. This was a severe injury to a 7-week-old infant who suffered brain damage.
- One other injury is associated with play yards, but there was insufficient information to determine the cause.

D. Play Yard International Standards and the ASTM Voluntary Standard

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of "consumer groups, juvenile product manufacturers, and independent child product engineers and experts" to "examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products." Through the ASTM process, we consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. Most of the consultation involved assessing and reviewing the ASTM standard, which is the primary play yard standard in effect in the United States. Significantly, in 2010, in consultation with ASTM, we identified three hazards that were not addressed in the ASTM play yard standard. Those three hazards are now addressed in ASTM 406-11 and include new requirements to address side rails that collapse into a dangerous V-shape (discussed in section E.5 below); new requirements to address structural failures related to corner brackets (discussed in section E.8 below); and new requirements to address mattress displacement (discussed in section E.10 below).

In addition to reviewing the ASTM standard, we reviewed several international standards.

1. International Standards

We reviewed several international standards when working with ASTM to create ASTM 406-11, including:

- the European Standard, BS EN 12227-1 & 2: 2010, "Playpens for domestic use";
- the Australian and New Zealand Standard, AS/NZ S2195: 2010, "Folding cots Safety Requirements"; and

• the Canadian standard, C.R.C., c. 932, "Playpen Regulations."

We considered the Australian and New Zealand Standard when we, in consultation with ASTM, devised the performance requirement and test method to address V-shape side rail collapses. Ultimately however, CPSC and ASTM chose to use a test method meant to prevent neck entrapment in expansion gates that exists in ASTM F 1004-09, "Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures."

We considered the European Standard when we, in consultation with ASTM, devised the performance requirement and test method to address structural failures in corner brackets. Ultimately, the test method found in the European Standard was rejected because its main purpose is to test latch durability, rather than corner post durability. The requirements currently found in ASTM F 406-11 to address this hazard were developed by CPSC staff and are better suited than the requirements in the European Standard to test corner post durability.

We also considered the European Standard when we, in consultation with ASTM, created the mattress displacement performance requirement and test method. While the requirements in ASTM F 406-11 are similar to those in the European Standard, we, in consultation with ASTM staff, made changes that will result in more reliable and repeatable results.

2. The ASTM Voluntary Standard

ASTM F 406 was first approved and published in 1977. ASTM has revised the standard several times since then, with the most current version, ASTM F 406-11, published on May 15, 2011. Historically, one of the most significant changes occurred in ASTM F 406-02, published in June 2002, when the standard for non-full-size cribs merged with the play yard standard to group products with similar uses, and took on its current name, "Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards."

The proposed rule would only pertain to play yards. In the *Federal Register* of December 28, 2010 (75 FR 81766), we issued a final rule on safety standards for non-full-size cribs. Thus, the proposed rule would exclude provisions of ASTM F406-11 that apply to non-full-size cribs. The proposed rule would exclude from the play yard standard sections 5.17, 5.19, 5.20, the entirety of section 6, section 8.1 through 8.10.5, and section 10.1.1.1 of ASTM F 406-11. In addition, for section 9.4.2.10 of ASTM F 406-11, we propose to include only the first section, which is a labeling requirement meant to inform consumers that only the mattress or pad provided by the manufacturer should be used. The remainder of section 9.4.2.10 of ASTM F 406-11 is applicable to non-full-size cribs and would be excluded from the play yard standard.

Many play yards include accessory items, such as bassinets or changing tables that attach to the side of the play yard rails. While ASTM F 406-11 contains requirements to address entrapment of children in accessories, such as requirements designed to prevent changing table straps from forming loops that enter the play yard space and could cause strangulation, the specific requirements for accessories will be addressed in separate rulemakings. For example, ASTM F 406-11 addresses possible entrapment in bassinet attachments, but the performance

requirements, test methods, and warning provisions for the bassinet itself will be handled in a separate rulemaking.

The key provisions of the current ASTM play yard standard include: definitions; general requirements; performance requirements; specific test methods; and requirements for marking, labeling, and instructional literature.

<u>Definitions.</u> The definition of "play yard (aka playpen)" is a "framed enclosure that includes a floor and has mesh or fabric- sided panels, primarily intended to provide a play or sleeping environment for children. It may fold for storage or travel."

<u>General Requirements and Specific Test Methods.</u> The play yard standard contains general requirements that the product must meet, as well as mandated test methods that must be used to ensure that the product meets those requirements, including:

- requirements for corner posts;
- restrictions on sharp points and edges (as well as their protective caps), small parts, lead paint, and flammable solids;
- specifications to prevent scissoring, shearing, and pinching;
- requirements for toy accessory items;
- specifications on latching and locking mechanisms;
- specifications on openings (intended to prevent finger and toe entrapment),
 labeling (intended to prevent labels from being removed and ingested or aspirated on), coil springs and protrusions;
- requirements that the play yard be stable;
- requirements meant to protect a child from entrapment in accessory items, such as a bassinet or changing table, as well as requirements to protect a child from being

strangled in a cord or strap that accompanies the product or an accessory item (such as the restraint straps on a changing table); and

• specifications for the mattress in a play yard.

<u>Performance Requirements and Specific Test Methods.</u> The play yard standard provides performance requirements that the product must meet, as well as mandated test methods that must be used to ensure that the product meets the performance requirements, including:

- a side height requirement (the side of the play yard must be, at least, 20 inches from the top of the noncompressed mattress pad to the top of the side rail);
- side deflection and strength requirements (the play yard must be able to withstand testing without collapsing, and the hinge and latch mechanisms must remain operational);
- floor strength requirements;
- requirements to address the material that covers the top rail, as well as specifications for the mesh or fabric used in play yards;
- requirements addressing mattress displacement;
- requirements to eliminate the risk that the side rails will form a dangerous V-shape when collapsed; and
- requirements addressing corner bracket failures.

Order of Testing. ASTM F 406-11 also addresses the order of testing. ASTM F 406-11 clarifies that the general requirements, such as restrictions on corner posts, must be met both before and after the performance requirement test methods have been completed.

Additionally, ASTM F 406-11 indicates that the tests to determine compliance with the performance requirements must be conducted in the order specified in the standard because the

testing sequence can influence the test results. Therefore, the standard lists tests in a way such that the most potentially destructive tests are performed last.

<u>Marking, Labeling, and Instructional Literature.</u> ASTM F 406-11 has requirements for marking, labeling, and instructions that must accompany a play yard, including warnings regarding proper use of accessory attachment items, and warnings regarding suffocation hazards that may arise if soft bedding is added to the product.

E. Assessment of Voluntary Standard ASTM F 406-11

We considered the fatalities, injuries, and noninjury incidents associated with play yards, and we evaluated the voluntary standard to determine whether ASTM F 406-11 addresses the incident or whether more stringent standards are required that would further reduce the risk of injury associated with the products. We discuss our assessment in this section, but our assessment does not include deaths and injuries associated with play yards where there was insufficient evidence to determine the cause.

1. Unsafe Sleep Environment and Unsafe Sleep Practices

Unsafe sleep environments, such as sleep environments that contain additional or soft bedding, and unsafe sleep practices, such as placing infants to sleep on their stomach instead of their back, resulted in 27 fatalities and one very serious injury that required hospitalization and resulted in brain damage to the child. Unsafe sleep environments and unsafe sleep practices are not attributable to the design or construction of play yards. ASTM F 406-11 includes product warnings that address the hazards of soft bedding and the hazards associated with placing a child to sleep on their stomach. We do not believe that there are additional requirements that can be put in place in the standard to address unsafe sleep environments and unsafe sleep practices.

2. Hazardous Surroundings

Ten suffocation deaths were attributable to unsafe environments around the play yard. Examples of hazardous surroundings include: window blind cords and computer cords that fall into a play yard, forming a loop, and causing strangulations. Other deaths were caused when caregivers placed an object on top of the play yard to keep the child in the play yard, and fatalities resulted when children tried to climb out of the play yard and became trapped between the cover and the side rail. Risks due to hazardous surroundings are not attributable to the design or construction of play yards. ASTM F 406-11 includes product warnings that address the dangers of placing a product near windows where cords can cause strangulation. ASTM F 406-11 also includes a warning about the dangers of using improvised netting or covers over play yards. We do not believe that there are additional requirements that can be put in place in the standard to address this issue.

3. Risks associated with children climbing out or falling out of a play yard

Two children were killed when they were able to climb out or they fell out of their play yard and accessed a pool. Both children drowned. Additionally, five children were injured after climbing or falling out of their play yard, including one injury that resulted in a serious head injury and required hospitalization.

We considered alternatives that might make it less likely that a child could climb or fall out of a play yard. For example, play yards could be mandated to have higher sides, or manufacturers could provide a "lid" or cover to the play yard. However, in both cases, we felt that these solutions might create additional hazards. Higher sides might make it more difficult for a caregiver to put the child inside the play yard and might increase the chance that caregivers will find alternative, but less safe, sleep environments (such as allowing infants to sleep in adult

beds). Requiring a lid or cover increases the chances that the lid or cover will fail in some way, allowing children to attempt to climb out of the product, only to become stuck between the lid and the side rail, which could cause suffocation.

Therefore, we determined that warnings are the most appropriate way to address climbout and fall-out hazards. ASTM F 406-11 includes product warnings indicating that play yards are designed for children who are not able to climb out of the play yard. There are additional warning requirements regarding removing any object that can serve as a step that would enable a child to climb out of the play yard. We do not believe that there are additional requirements that can be put in place in the standard to address this issue.

4. Standing/Choking Deaths

Two toddlers were killed in a similar, but currently unexplained, manner. In both situations, the toddler stood up in the play yard and placed his or her neck against the side rail. In both situations, it is believed that they leaned forward against the side rail (possibly to reach an object that the child had thrown outside the play yard), lost consciousness, and suffocated when the pressure from the side rail compressed the airway. We have investigated both deaths and believe that further review by CPSC staff is warranted to determine if the design or construction of the play yard contributed to the deaths. If we conclude that the design or construction of the play yard did contribute to these deaths, we will determine whether additional requirements are necessary. Because the causation of these incidents is unclear, we are not proposing additional requirements in the standard to address the possibility of standing/choking deaths at this time.

5. Side Rail Collapse

One child was killed when a play yard's side rails collapsed, trapping the child and resulting in suffocation. Additionally, 124 of the 165 nonfatal injury reports are attributable to side rail collapse. One injury required hospitalization for a concussion. The largest number of nonfatal incident reports (1,902 out of 2,079 reports) are attributable to play yard side rail collapse. We reviewed these incidents and have determined that the majority are caused by failure of the side rail latch that keeps the side rail locked and in place.

Side collapse issues were addressed significantly in 1997, in ASTM F 406-97, which required the side rails of play yards to have a locking device in order to prevent the center hinge from collapsing and causing the side rail to fall. In 1999, ASTM added a test method that required the locking mechanism on the side rail hinges to withstand a force of 100 pounds, applied diagonally, without breaking or disengaging.

In August 2009, after a significant number of recalls involving side collapse issues, ASTM published ASTM F 406-09, which included, for the first time, a false latch test in the ASTM play yard standard. The addition of the false latch test was designed to ensure that the top rail does not give the appearance of being locked, when, in fact, the locking device is not engaged completely.

The recalls related to side collapse, which prompted the change in the 2009 ASTM standard include:

- A January 2009 recall of 200,000 play yards. The CPSC press release can be found here: http://www.cpsc.gov/cpscpub/prerel/prhtml09/09098.html.
- An April 2009 recall of 25,000 play yards. The CPSC press release can be found here: <u>http://www.cpsc.gov/cpscpub/prerel/prhtml09/09187.html</u>

• A July 2009 recall of about 1 million play yards. The CPSC press release can be found here: <u>http://www.cpsc.gov/cpscpub/prerel/prhtml09/09265.html</u>.

Additionally, ASTM F 406-11 includes a performance requirement and test method that addresses a side rail collapse issue that was a problem in the past but was never adequately addressed in past editions of the ASTM play yard standard. In brief, when folding play yards were relatively new products in the 1990s, some products did not include features designed to prevent unintentional collapse of the side rails. Some play yards collapsed into a V-shape. If a child's neck is caught in the V-shape, the child could suffocate. Most producers of play yards chose to stop designing products that could form a V-shape when the side rails collapsed. The ASTM standard, however, was not revised to ban this design. According to a CPSC press release, originally issued on August 21, 1998, and last revised on May 10, 2004, 13 children died from suffocation in play yards where the side rail collapsed into a V-shape. (These fatalities are not included in the list of incident data referenced throughout this document because they predate the creation of the Early Warning System database [the database used to support the regulatory work here]). The press release also mentioned that more than 1.5 million play yards with this dangerous design flaw have been recalled in past years. The press release can be found at: http://www.cpsc.gov/cpscpub/prerel/prhtml98/98156.html.

Thus, after a review of the incidents, as well as an assessment of the locking and latching provisions, the false latch provision, and the new provisions meant to prevent a side collapse that results in a V-shape, we determined that these performance requirements and test methods are sufficient to address play yard side rail collapse issues. Thus, we are not proposing additional requirements at this time.

6. Hazards Related to Accessories

Play yards often are sold with accessory items, such as changing tables and bassinets, which are meant to attach to the side rails of the play yard. One child was killed when a dangling strap from a changing table accessory formed a loop inside the occupant area of the play yard, resulting in the child's strangulation. The play yard involved in the fatality prompted a recall of 425,000 play yards. That recall was issued on September 27, 2007. The CPSC press release for the recall can be viewed at:

<u>http://www.cpsc.gov/cpscpub/prerel/prhtml07/07315.html</u>. Additionally, there were two injuries caused by broken or hazardous accessories.

In 2005, ASTM published ASTM F 406-05a, which included a section to address entrapment in accessories. The requirement and the accompanying test method were designed to ensure that accessories cannot create openings that can entrap a child's head. In 2008, ASTM published ASTM F 406-08, which included a provision that prohibits the use on an accessory of cords and straps that are capable of forming a loop that could strangle a child. The 2008 ASTM standard also added requirements for toy attachments intended to address incidents related to broken or detached components from music boxes, mirrors, and toy holders.

We believe that these requirements are sufficient to address these hazards, and we are not proposing additional requirements at this time.

7. Assembly Errors

One fatality and two injuries are attributable to assembly errors. The death occurred when the mattress pad of the play yard was not completely secured to the floor of the play yard. The child suffocated in the pocket created between the unsecured pad and the floor of the product. An assembly error was the cause of one very serious injury, which required a hospitalization and occurred when a child got his or her finger caught in the gap between the corner bracket and the side rail of the play yard as it was being assembled. The child suffered a severe laceration that required medical attention.

ASTM F 406-11 contains provisions requiring clear, easy-to-read assembly instructions. We believe that these requirements are sufficient to address these hazards, and we are not proposing additional requirements at this time.

8. Broken or Detached Component Parts leading to Structural Failures

Eight injuries, including bruises and cuts, were caused by broken or detached component parts, such as loose wheels or loose hardware, which led lead to the product becoming unstable or collapsing. Most incidents involved structural failure at the corner brackets of the play yard, resulting in rivets pulling through the corner brackets, cracking of the plastic under the rivets' heads, and rivets and plastic pieces falling out of the corner bracket. This causes the play yard to collapse.

We believe corner post failures are caused by repeated loading of the side rails by one of the following methods:

- caregivers inadvertently and repeatedly leaning on the side rails to reach the child or to use the bassinet or changing table accessory;
- children who use the side rails for support while standing; and/or
- accessories that are attached to and removed repeatedly from the side rails and corner posts.

In 2010, CPSC staff recommended a new performance requirement and test method to address this hazard, which was included for the first time in ASTM F 406-11. We believe that

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION. these requirements are sufficient to address these hazards, and we are not proposing additional requirements at this time.

9. Mesh and Fabric Sides

Five injuries are related to the mesh or fabric sides of the play yard, such as stitching that unraveled, tears in the fabric, mesh holes that were too large and caught an infant's tooth, and mesh material that was too abrasive.

ASTM F 406-11 contains several performance requirements and test methods to address hazards caused by mesh or fabric. We believe that these requirements are sufficient to address the associated hazards, and we are not proposing additional requirements at this time.

10. Mattress Pad or Play Yard Floor Hazards

Five injuries are attributable to problems with the mattress pad or floor of the play yard. Most of these incidents are related to mattress displacement, which occurs when children are able to pull up the mattress and become trapped between the floor of the play yard and the mattress. The mattress of most play yards is attached to the product by hook and loop straps, commonly referred to as "Velcro" straps. The other commonly used method is a "Velcro" patch.

ASTM F 406-11 includes a performance requirement and a test method that would require a play yard mattress to be able to withstand a certain amount of force before it can be lifted high enough to allow a child to become trapped between the mattress and the play yard floor. We believe that these requirements are sufficient to address these hazards, and we are not proposing additional requirements at this time.

11. Impact on Play Yard

There were four injuries that occurred in play yards because children were standing up in a play yard, lost their balance, and fell. ASTM F 406-11 does include product warnings that
address the need to provide supervision, as necessary, when the child is in the product, particularly when the child is playing in the play yard. We believe that these requirements are sufficient, and we are not proposing additional requirements at this time.

12. Other Product-Related Concerns

Eight injuries were caused by other product-related problems, such as sharp surfaces. For the incidents where we could determine the problem's cause, we believe that the current requirements are sufficient to address these hazards, and we are not proposing additional requirements at this time.

F. Description of Proposed Changes to ASTM Standard

The proposed rule would create a new part 1221 titled, "Safety Standard for Play Yards." The proposal would establish ASTM F 406-11, "Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards," as a consumer product safety standard, but with certain changes. We are proposing three changes to ASTM F 406-11, as it applies to play yards. The provisions of ASTM 406-11 that apply to non-full-size cribs have been excluded because those products are addressed in a separate rulemaking.

Two of the three proposed changes would clarify the existing provisions. Clarification will reduce potential misinterpretations that could result in improper testing. Thus, these clarifications will strengthen the standard and reduce the risk of injury by ensuring that play yard testing is performed properly.

The last proposed change would affect the test method for determining the strength of corner brackets. The method in ASTM F406-11 currently requires the tester to use a specific size clamp. The proposed change would allow the tester some flexibility, within a carefully selected range, in choosing the clamp to account for play yards with hinges that vary in size. By

allowing the tester to choose the most appropriate clamp, we are strengthening the standard and reducing the risk of injury by ensuring that the appropriate testing equipment is used. Using the most appropriate testing equipment will ensure that the test is performed properly and that only the safest play yards will pass laboratory testing and enter the market.

We describe these proposed changes immediately below:

1. Clarifying the equipment needed to perform the floor strength test (Section 8.12.1)

Currently, ASTM F 406-11 contains a performance standard to measure the floor strength of a play yard. Section 8.12.1 of ASTM F 406-11 specifies the use of a "Wood block, 6 by 6 in. (150 by 150 mm)." However, the test method in ASTM F 406-11 requires the use of two wood blocks to test the floor strength of the play yard. The proposed rule, therefore, would clarify that "2 Wood blocks" are needed.

2. Clarifying the floor strength test method (Section 8.12.2.1)

The current text of the test method for measuring the floor strength of play yards states that the tester must "(p)lace a 50-lb (23-kg) and a 30-lb (14-kg) weight each onto a 6 by 6-in. (150 by 150-mm) wood block spaced 6 +/- $\frac{1}{2}$ in. (150 +\- 13 mm) apart and maintain for 60s." The proposed rule would simplify this sentence by dividing it into three sentences by replacing it with the following: "Place the wood blocks 6 +/- $\frac{1}{2}$ inch (150 mm +/- 13 mm) apart. Place 50-lb (23-kg) weight on one wood block and a 30 lb (24 kg) weight on the other wood block. Maintain for 60 s." This revision also clarifies that the wood blocks should be put into position before the weight is applied.

3. The shape and area of the clamping surface for the "Top Rail to Corner Post Attachment Test" (Section 8.30.3.1)

Currently, ASTM F 406-11 contains a performance standard to address the structural failure of corner brackets of play yards. The test method directs the tester to use clamps to apply a twisting motion to the rail, which strains the corner brackets. The product will fail the test if, for example, there is cracking of the corner brackets. The current test method specifies the shape and area of the clamping surfaces (2 by 2 in.). The proposed rule would allow the tester to choose the shape and area of the clamping surface, within a specified range (1-square-inch to 4 square inches) to accommodate the variety of hinge latching devices in different models of play yards.

4. Exclusion of ASTM F 406-11 sections that are applicable to non-full-size cribs

The proposed rule would pertain only to play yards. In the *Federal Register* of December 28, 2010 (75 FR 81766), we issued a final rule on safety standards for non-full-size cribs. Thus, the proposed rule would exclude the provisions of ASTM F406-11 that apply to non-full-size cribs. Specifically, the proposal would exclude sections 5.17, 5.19, 5.20, the entirety of section 6, section 8.1 through 8.10.5, and section 10.1.1.1 of ASTM F 406-11. In addition, for section 9.4.2.10 of ASTM F 406-11, the proposal would include only the first section, which is a labeling requirement meant to inform consumers that only the mattress or pad provided by the manufacturer should be used. The remainder of section 9.4.2.10 of ASTM F 406-11 is applicable to non-full-size cribs, and it would be excluded from the play yard standard.

G. Effective Date

The Administrative Procedure Act ("APA") generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. § 553(d). To allow time

for play yards to come into compliance, we intend for the standard to become effective 6 months after the publication of the final rule in the *Federal Register*. We invite comment on how long it will take play yard manufacturers to come into compliance.

H. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601–612, requires agencies to consider the impact of proposed rules on small entities, including small businesses. Section 603 of the RFA requires that we prepare an initial regulatory flexibility analysis and make it available to the public for comment when the notice of proposed

rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of the reasons why action by the agency is being considered;
- A succinct statement of the objectives of, and legal basis for, the proposed rule;
- A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

In addition, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule that would accomplish the stated objectives of the proposed rule and, at the same time, reduce the economic impact on small businesses.

2. The Market

Based on a 2005 survey conducted by American Baby Group titled, "2006 Baby Products Tracking Study" and Centers for Disease Control and Prevention birth data, we estimate that approximately 2.9 million play yards are sold in the United States each year. We estimate that there are at least 23 manufacturers or importers supplying play yards to the United States market. Eleven of these firms are domestic manufacturers, and 10 of these firms are domestic importers. Two of the firms are foreign importers.

Under the U.S. Small Business Administration ("SBA") guidelines, a manufacturer of play yards is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, 10 domestic manufacturers and all 10 of the domestic importers known to supply play yards to the U.S. market are small businesses. The remaining entities include a large domestic manufacturer and two foreign importers. There may be additional unknown small manufacturers and importers operating in the U.S. market.

The Juvenile Product Manufacturers Association ("JPMA") runs a voluntary certification program for juvenile products. Certification under the JPMA program is based on the ASTM voluntary play yard standard. Eleven of the 23 manufacturers or importers have been certified as compliant with the ASTM voluntary play yard standard by the JPMA. Three additional manufacturers or importers claim to comply with the ASTM voluntary play yard standard, but they do not participate in the JPMA certification program. In some cases, these three manufacturers or importers may provide test results on-line. Seven small domestic

manufacturers supplying play yards to the U.S. market claim to comply with the ASTM voluntary play yard standard. Of the importers, six claim to comply with the ASTM voluntary play yard standard.

3. Impact of the Proposal on Small Business

Section 104 of the CPSIA requires the CPSC to promulgate standards for durable infant or toddler products, including play yards. The impact of this rulemaking, if finalized, on the 20 small domestic entities could be significant. However, the impact of the proposed standard on small manufacturers and importers will differ, based on whether their products are already in compliance with the ASTM voluntary play yard standard.

Of the 10 small domestic manufacturers, seven produce play yards that are certified as compliant by JPMA or claim to be in compliance with the voluntary standard. The three noncompliant manufacturers may need to modify their product substantially to meet the ASTM standard. The costs associated with these modifications might include product redesign. The redesign could be minor if, for example, the manufacturer needs to use additional or different fabric or mesh. However, the changes could be more significant if a redesign of the product frame is required. The impact of these costs may be mitigated if they are treated as new product expenses and amortized.

Of the 10 small domestic importers, six import play yards that are certified as compliant by JPMA or claim to be in compliance with the voluntary standard. The four noncompliant importers may need to find an alternative source if their existing supplier does not modify their play yards to comply with the standard. However, the impact of that decision could be mitigated by replacing the noncompliant product with a compliant product made by a different

manufacturer. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue.

Two of the noncompliant importers import products from a specific foreign country. For these entities, finding an alternative supply source may not be an option. However, they could stop importing noncompliant play yards and replace them with other juvenile products.

The information in this section assumes that three domestic manufacturers and four domestic importers do not comply with the voluntary standard. This may not be the case. We have identified many cases where products that are not certified by JPMA, or do not otherwise claim compliance with the voluntary standard, actually meet the relevant standard. To the extent that this is true, the impact of the proposed rule will be less significant than described.

4. Alternatives

For the 13 small domestic entities that already comply with the voluntary standard, there are few or no costs associated with the three minor changes being proposed. For the seven small domestic entities that are not compliant (or where it is unknown if they are compliant) the adoption of the voluntary standard as a mandatory consumer product safety standard could result in substantial costs.

For these entities, setting an effective date longer than 6 months could reduce the impact. This would allow small manufacturers additional time to make necessary changes to their product, and it would allow small importers to find alternative sources. It would also allow entities to spread costs over a longer period of time.

5. Conclusion of Initial Regulatory Flexibility Analysis

It is possible that the proposed standard, if finalized, could have a significant impact on some small businesses. The extent of these costs is unknown. For manufacturers, product

redesign might be necessary, and it is possible that the costs could be large for some entities. Importers may need to find alternative sources of play yards. Additionally, all manufacturers and importers will eventually be subject to third party testing and certification requirements, as discussed in section L below. There will likely be some additional costs associated with third party testing and certification.

At least some costs are expected to be passed on to consumers. We invite comment on what these costs may be, whether they may be passed on to the consumer, and how these costs will impact small businesses.

I. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has "little or no potential for affecting the human environment" it will be categorically exempted from this requirement. 16 CFR § 1021.5(c)(1). The proposed rule falls within the categorical exemption.

J. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget ("OMB") under the Paperwork Reduction Act of 1995 (44 U.S.C. §§ 3501–3521). In this document, pursuant to 44 U.S.C. § 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;

- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Play Yards

Description: The proposed rule would require each play yard to comply with ASTM F

406-11, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards.

Sections 9 and 10 of ASTM F 406-11 contain requirements for marking, labeling, and

instructional literature. These requirements fall within the definition of "collection of

information," as defined in 44 U.S.C. § 3502(3).

Description of Respondents: Persons who manufacture or import play yards.

Estimated Burden: We estimate the burden of this collection of information as follows:

| Table 1 - Estimated Annual Reporting Burder |
|---------------------------------------------|
|---------------------------------------------|

| 16 CFR | Number of | Frequency | Total | Hours per | Total |
|-----------|-------------|-----------|-----------|-----------|--------|
| Section | Respondents | of | Annual | Response | Burden |
| | _ | Responses | Responses | _ | Hours |
| 1221.2(a) | 9 | 3 | 27 | 1 | 27 |
| | | | | | |

Our estimates are based on the following:

Section 9.1.1.1 of ASTM F 406-11 requires that the name and the place of business (city, state, mailing address, including zip code, or telephone number) of the manufacturer, distributor, or seller be marked clearly and legibly on each product and its retail package. Section 9.1.1.2 of ASTM F 406-11 requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

There are 23 known entities supplying play yards to the U.S. market. Fourteen entities produce labels that comply with the standard. Thus, there would be no additional burden on these entities. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because these 14 entities already produce labels that comply with the standard, we tentatively estimate that there are no burden hours associated with Sections 9.1.1.1 and 9.1.1.2 of ASTM F 406-11 because any burden associated with supplying these labels would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

We assume that the remaining nine entities use labels on their products and their packaging but might need to modify their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies an average of three different models of play yards; therefore, the estimated burden hours associated with labels is 1 hour per model x 9 entities x 3 models per entity = 27 hours.

We estimate that the hourly compensation for the time required to create and update labels is \$27.98. This is based on data from March 2011, provided by the U.S. Bureau of Labor Statistics. The information is available at: <u>http://www.bls.gov/news.release/pdf/ecec/pdf</u> in Table 9, under the heading "all workers, goods-producing industries" and the subheading "sales and office." Therefore, the estimated annual cost to industry associated with the proposed labeling requirements is \$755.46 (\$27.98 per hour x 27 hours = \$755.46).

Section 10.1 of ASTM F 406-11 requires instructions to be supplied with the product. Play yards are products that generally require assembly, and products sold without such information would not be able to compete successfully with products supplying this information. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because we are unaware of play yards that generally require some installation, but lack any instructions to the user about such installation, we tentatively estimate that there are no burden hours associated with section 10.1 of ASTM F 406-11 because any burden associated with supplying instructions with play yards would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

Based on this analysis, the proposed standard for play yards would impose a burden to industry of 27 hours at a cost of \$755.46 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. § 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. § 3506(c)(2)(A), we invite comments on:

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

K. Preemption

Section 26(a) of the CPSA, 15 U.S.C. § 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as "consumer product safety rules," thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

L. Certification

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSCenforced requirements. 15 U.S.C. § 2063(a). Such certification must be based on a test of each product or on a reasonable testing program or, for children's products, on tests on a sufficient

number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable requirements. As discussed in section A of this preamble, section 104(b)(1)(B) of the CPSIA refers to standards issued under this section as "consumer product safety standards." Similarly, such standards also would be subject to section 14 of the CPSA. Therefore, any such standard would be considered a "consumer product safety rule" to which products subject to the rule must be certified.

Because play yards are children's products, they must be tested by a third party conformity assessment body whose accreditation is accepted by the Commission. In the future, the Commission will issue a notice of requirements to explain how laboratories can become accredited as third party conformity assessment bodies to test play yards to the new safety standard. (Play yards also must comply with all other applicable CPSC requirements, such as the lead content and phthalate content requirements in section 101 and 108 of CPSIA respectively; the tracking label requirement in section 14(a)(5) of the CPSA; and the consumer registration form requirements in section 104 of the CPSIA.)

M. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for play yards. We invite all interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects in 16 CFR Part 1221

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys. Therefore, the Commission proposes to amend Title 16 of the Code of Federal Regulations by adding a new part 1221 to read as follows:

PART 1221-SAFETY STANDARD FOR PLAY YARDS

Sec.

1221.1 Scope.

1221.2 Requirements for play yards.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008).

§ 1221.1 Scope.

This part establishes a consumer product safety standard for play yards.

§ 1221.2 Requirements for Play Yards.

(a) Except as provided in paragraph (b) of this section, each play yard must comply with all applicable provisions of ASTM F 406-11, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards, approved on May 15, 2011. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. § 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <u>http://www.astm.org</u>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) Comply with the ASTM F 406-11 standard with the following additions or exclusions:

(1) Do not comply with section 5.17 of ASTM F 406-11.

(2) Do not comply with section 5.19 of ASTM F 406-11.

(4) Do not comply with section 5.20 of ASTM F 406-11.

(5) Do not comply with section 6, Performance Requirements for Rigid Sided Products, of ASTM F 406-11, in its entirety.

(6) Do not comply with sections 8.1 through 8.10.5 of ASTM F 406-11.

(7) Instead of complying with section 8.12.1 of ASTM F406-11, comply with the following:

(i) 8.12.1 *Equipment* – 2 Wood blocks, 6 by 6 in. (150 by 150 mm).

(8) Instead of complying with section 8.12.2.1 of ASTM F 406-11, comply with the following:

(i) 8.12.2.1 Remove cushions that are not part of the floor or mattress support. Place the wood blocks $6 +/- \frac{1}{2}$ inch (150 mm +/- 13 mm) apart. Place 50-lb (23-kg) weight on one wood block and a 30 lb (24 kg) weight on the other wood block. Maintain for 60 s. Perform the test in those locations deemed to be the weakest or the most likely to fail. Remove the load and check for structural failure.

(9) Instead of complying with section 8.30.3.1 of ASTM F406-11, comply with the following:

(i) 8.30.3.1 Mount a rigid and substantially horizontal moment arm weighing less than 5 lbm (2.2 kg) to the hinge/latching device at the longitudinal center of the top rail through two clamping surfaces, each 1 in² - 4 in² (6.5 cm² - 26 cm²) designed to firmly grasp the hinge

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION. latching device. The moment arm shall be at least 24 in (603 mm) long and extend towards the outside of the play yard.

(10) Instead of complying with section 9.4.2.10 of ASTM F 406-11, comply with only the following:

(i) 9.4.2.10 For products that have a separate mattress that is not permanently fixed in place:

Use ONLY mattress/pad provided by manufacturer.

(11) Do not comply with section 10.1.1.1 of ASTM F 406-11.

Dated: _____.

Todd A. Stevenson, Secretary, Consumer Product Safety Commission