The contents of this document will be discussed at the Commission Meeting (briefing) scheduled for June 13, 2012.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: JUNE 27, 2012

June 6, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: Hyun S. Kim, Acting Assistant General Counsel
Leah Wade, General Attorney

SUBJECT: Final Rule: Safety Standard for Play Yards

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice on a final rule on a safety standard for play yards.

Please indicate your vote on the following options.

I. Approve publication of the draft notice in the *Federal Register,* without changes.

_____ _____
(Signature) (Date)

II. Approve publication of the draft notice in the *Federal Register,* with changes. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve publication of the draft notice in the *Federal Register.*

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachments:

Draft *Federal Register* Notice–Safety Standard for Play Yards: Final Rule

Staff Briefing Package: Final Standard for Play Yards

Staff Briefing Package

Section 104(b) of the Consumer Product Safety Improvement Act of 2008:
Safety Standard for Play Yards
Final Rule

June 6, 2012

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically approved and signed.

Memorandum

Date: June 6, 2012

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM : DeWane Ray
Assistant Executive Director for Hazard Identification and Reduction

Gregory K. Rea
Project Manager, Play Yards
Division of Mechanical Engineering
Directorate for Laboratory Sciences

SUBJECT : Final Rule for Safety Standards for Play Yards

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) 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 play yards. The Commission is charged with examining and assessing the effectiveness of any voluntary consumer product safety standards and 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 began in early 2010.

On September 20, 2011, the Commission issued a notice of proposed rulemaking (NPR) to establish a safety standard for play yards.[1] The NPR proposed incorporating by reference the requirements for play yards in the ASTM International voluntary standard ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards,* with certain

[1] 76 Fed. Reg. 58167 (Sept. 20, 2011).

changes to specific provisions in the voluntary standards in order to strengthen the proposed rule. This briefing package provides staff's responses to the comments on the NPR, as well as staff's recommendations regarding the final rule, and presents a final regulatory flexibility analysis to evaluate the possible economic impact of the staff-recommended final rule on small businesses.

II. INCIDENT DATA (TAB A)

The briefing package prepared by staff accompanying the NPR[2] provided a comprehensive and detailed review of the incident data associated with play yards. This data was developed using the Early Warning System (EWS) database, which has been a pilot program at the CPSC since November 2007. As of April 10, 2011, the EWS contained a total of 2,128 incident reports related to play yards. From April 11, 2011 through December 31, 2011, the period of time covered by the update in Tab A, the CPSC epidemiological databases contained 41 additional reported incidents. Of these, 15 were fatal; eight of the 26 nonfatal incidents resulted in injuries. A brief overview of the data is provided below. For more details, please refer to Tab A.

Fatalities

There were 15 fatalities reported to CPSC staff between April 11, 2011 and December 31, 2011, associated with play yards, three of which were product-related.

Nonfatal Injuries

A total of eight incidents involving a play yard-related injury were reported to CPSC staff between April 11, 2011 and December 31, 2011. None of the injuries was serious enough to require hospitalization.

Noninjury Incidents

Eighteen of the 41 incidents did not have any reported injuries associated with them. These incidents ranged from those that potentially could have resulted in an injury or fatality, to general complaints or comments from consumers with regard to their play yards.

III. STAFF'S RECOMMENDED CHANGES TO THE PROPOSED STANDARD

The proposed rule for play yards referenced ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards,* with three modifications. These proposed modifications to the ASTM standard were:

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] Rea, G. K., Wade, L., *et. al.*, *"Section 104(b) of the Consumer Product Safety Improvement Act of 2008: Safety Standard for Play Yards Notice of Proposed Rulemaking,"* U.S. CPSC, August 17, 2012.

2. Clarify wording in the *Equipment* subsection (8.12.1) of the Floor Strength Test for Mesh/Fabric Products.
3. Clarify wording in subsection 8.12.2.1 of the Floor Strength Test for Mesh/Fabric Products.

In August 2011, around the time the NPR briefing package was submitted to the Commission, ASTM balloted and approved several items pertaining to F 406-11. On September 15, 2011, ASTM approved a revised standard, F 406-11b, which contains these balloted changes. Included in the changes are new or revised sections, intended to match the three modifications specified in the NPR. Although some of the wording is different from what the Commission proposed in the NPR, the intent is the same. Staff believes that the wording in the revised ASTM standard (F 406-11b) is either substantially equivalent to, or provides better clarity than, the NPR language.

ASTM issued another ballot on November 30, 2011, which contained two additional items affecting the play yard portion of the standard. The balloted items:

1. Improved the clarity of the side rail structural integrity ("twist") test procedure in §8.30.3.1, and Figures A1.36 and A1.37; and
2. Added a preload to the mattress displacement test procedure in §8.28.2, which improved test repeatability.

These balloted items were approved in January 2012, and published in ASTM F 406-12 during February 2012.

In response to staff's concerns and those of a commenter to the NPR, a new change to the standard was published on May 23, 2012, in F 406-12a. It modified the Top Rail Configuration requirements of §7.10. The language of this section clarifies that the intent of the requirement is to address entrapment hazards associated with play yards whose top rails create a downward-pointing V-shape when folded. Incident data and staff hazard analysis expertise affirm that upward-folding side rails are not a hazard. The published F 406-12a language in §7.10 (<u>underlined</u> text is new) is:

> 7.10 *Top Rail Configuration:*
>
> Play yards containing one or more rigid top rails that contain a <u>central</u> hinge/latching device(s) to lock the top rail in the use position <u>and move vertically downward from the use position when unlocked</u> (see Fig. A1.3) must meet the requirements detailed in 7.10.1 and, if applicable, 7.10.2. Non-rigid top rails must meet the requirements specified in 7.10.3.
>
> Title of Figure A1.3: Top Rail Assembly with Central Hinge(s) <u>that move vertically downward.</u>

Rationale: The requirements in 7.10 for Top Rail Configuration are intended to address entrapment hazards associated with frames folding and creating a "V" shape when in their use position.

Staff recommends that the Commission approve incorporating by reference ASTM F 406-12a as the mandatory safety standard for play yards, with an additional performance requirement to address misassembly. This requirement was prompted by a product-related fatality in a bassinet accessory of a play yard that had been assembled and used without an important structural component. It became clear to staff that bassinet or cradle accessory misassembly may not be initially visually evident to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the misassembled accessory and inadvertently place a child in danger.

Staff worked with the ASTM Play Yard subcommittee in 2012 to develop language to address this hazard. The ASTM task group that undertook this effort met six times from January through April 2012, and was comprised of all major stakeholders including manufacturers, third party test laboratories, consumer advocates, and CPSC staff. The result of this effort is the language presented below, which staff expects to be balloted by the ASTM subcommittee in summer 2012. It contains language addressing misassembly of bassinet and cradle attachments to play yards with missing support and/or attachment pieces. This language would replace the existing §5.19 and move the previous language of §5.19, which applied only to non-full-size cribs, to §6.18.[3] A new test procedure was developed and placed in §8.31. Clarity of meaning was enhanced by adding a definition of "bassinet/cradle accessory" and modifying the definition of "key structural elements" in §3.1.9. The language being proposed for ballot (underlined language is new) is:

Additional equipment needed:

2.5 *Other References:* CAMI Newborn Dummy (See Fig. A)[α]

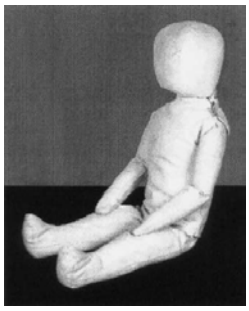


Figure A. CAMI Newborn Dummy (7.5 lb, 3.4 kg)

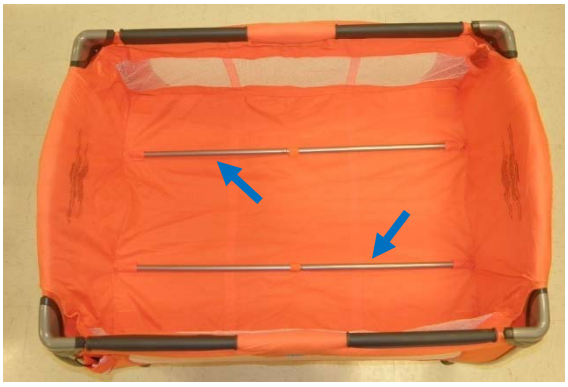
[α] Department of Transportation, Federal Aviation Administration, Drawing No.SA-1001.

[3] No changes were made to the misassembly requirement for non-full-size cribs. The provision was merely moved to a different location in the standard.

Modified definition:

3.1.9 *key structural elements*, n – side assemblies, end assemblies, mattress supports, or stabilizing bars that create the occupant retention area, or the components that provide the supporting frame and/or means of attachment for a bassinet/cradle accessory (see Figure B).

(a)



(b)

Figure B. Examples of bassinet/cradle accessory key structural elements: (a) mattress pad support bars, and (b) accessory end panel attachment bar.

New definition:

3.1.X *bassinet/cradle accessory* , n – a supported sleep surface that attaches to a non-full-size crib or play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (nonrocking) position.

New general requirement:

5.19 *Bassinet/Cradle Accessories Missing Key Structural Elements*:

5.19.1 Bassinet/cradle accessories that have all key structural elements permanently attached to the bassinet/cradle accessory, or by any permanent means prohibiting their removal from the bassinet/cradle accessory, are exempt from the following key structural

element requirements. For the purpose of this section, a mattress pad without key structural elements permanently attached is not considered a key structural element.

5.19.2 Bassinet/cradle accessories that require consumer assembly of key structural element(s), and can be assembled and attached to the product with any key structural element(s) missing, shall meet either 5.19.2.1, or 5.19.2.2 when each key structural element not permanently attached is removed. For the purpose of this section, a mattress pad without key structural elements permanently attached is not considered a key structural element.

5.19.2.1 The bassinet/cradle accessory shall collapse, such that any part of the mattress pad contacts the bottom floor of the play yard, or is not able to support the newborn CAMI dummy when tested to 8.31.

5.19.2.2 The bassinet/cradle accessory sleep surface shall tilt by more than 30 degrees when tested to 8.31.

Rationale: The bassinet/cradle missing key structural elements requirements were included to address IDI 110825CAA2853. Bassinet or cradle accessory misassembly may not be initially visually evident to the consumer. If the accessory with omitted component(s) supports the 7 lbm. newborn CAMI dummy without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the accessory and inadvertently place a child in danger.

New performance test:

8.31 Bassinet and Cradle Accessory Sleep Surface Collapse/Tilt

8.31.1 Determine the number of removable (*i.e.*, not permanently attached to the accessory) key structural elements used in the assembly of the bassinet/cradle accessory, and number them 1 through *n*, until all removable elements are numbered.

8.31.2 Assemble the bassinet/cradle accessory to the product according to manufacturer's instructions.

8.31.3 Establish a horizontal reference plane by placing an inclinometer on the floor of the testing area, and then zero the inclinometer.

8.31.4 Remove key structural element #1 used in the assembly of the bassinet/cradle accessory and attempt to assemble the accessory back onto the product.

8.31.4.1 If the accessory can be assembled onto the product without element #1, proceed to 8.31.5.

8.31.4.2 If the accessory cannot be assembled onto the product without element #1, the accessory shall be considered to meet 5.19.2. Proceed to 8.31.7.

8.31.5 Place a newborn CAMI dummy in the center of the sleep surface, oriented parallel with the longest side of the bassinet/cradle accessory (see figure C). Visually determine if the bassinet/cradle accessory collapses or it no longer supports the newborn CAMI within 2 sec.

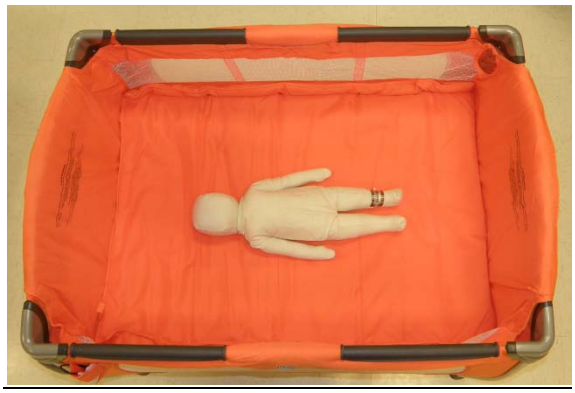


Figure C. Infant CAMI dummy positioned for bassinet/cradle accessory sleep surface test.

8.31.6 If collapse does not occur, measure the sleep surface's angle of incline relative to the horizontal plane established in 8.31.3 at the location(s) most likely to meet the angle requirement in 5.19.2.2. Record this angle (figure D).

Figure D. Bassinet/cradle accessory sleep surface test angle measurement.

8.31.7 Replace the removed key structural element.

8.31.8 Repeat 8.31.4 – 8.31.7 removing and replacing each key structural element (identified in 8.31.1) one at a time, starting with #2 through *n* and evaluating the resulting condition.

In summary, staff recommends that the Commission adopt ASTM F 406-12a as the play yard mandatory rule with the following substantial modification:

1) Add language from ASTM play yard task group which addresses the fatal hazard posed by assembling bassinet/cradle accessory attachments to play yards with missing key structural elements.

IV. EFFECTIVE DATE

The NPR proposed a 6-month effective date for the play yard standard, but it requested comments on the impact of such an effective date. We received several comments regarding when the mandatory standard should become effective. We considered each comment that addressed the issue. We also carefully considered how the new misassembly requirement should affect staff's recommendation regarding the effective date.

Staff participated in public ASTM Play Yard Task Group conference call meetings on January 11, January 30, March 21, April 4, April 12 and April 27, 2012, and the F15.18 Subcommittee meeting at ASTM headquarters on April 17, 2012. During the latter two meetings, manufacturers' concerns regarding the effective date were raised. On May 7, 2012, a group of play yard manufacturers submitted a letter[4] to CPSC staff through their trade group, the Juvenile Products Manufacturers Association (JPMA), detailing the efforts required by their members to comply with the misassembly requirement (see Tab B, Appendix B). These manufacturers requested a 12-month effective date. Staff agrees that the impact of the new misassembly requirement on existing designs could be significant. We also appreciate that the length of time for product redesign or changes to the manufacturing process are approximately one year. Therefore, staff recommends a 12-month effective date for the final rule.

V. FINAL REGULATORY FLEXIBILITY ANALYSIS (TAB B)

Play yards are typically produced and/or marketed by juvenile product manufacturers and distributors. CPSC staff estimates that there are currently at least 21 domestic manufacturers or importers supplying play yards to the U.S. market: ten are domestic manufacturers and 11 are domestic importers. In addition, three foreign firms supply the U.S. market: one is a manufacturer and the others are importers who import from foreign companies and distribute from outside of the United States. Based on U.S. Small Business Administration guidelines, 19 are small firms—9 domestic manufacturers and 10 domestic importers—likely to be affected by the staff-recommended final standard, as described in the Directorate for Economic Analysis memo (Tab B).

[4] Dwyer, M., JPMA Executive Director, *JPMA Letter to CPSC Requesting an Extended Play Yard Final Rule Effective Date*, May 7, 2012. See Tab B, Appendix B.

There could be a significant direct impact on the costs of producing play yards for a few of the six small manufacturers or the four small importers whose play yards meet the current voluntary standard if their products require redesign to meet the staff-recommended misassembly requirement. There could also potentially be a significant direct impact for the three small manufacturers whose play yards are not compliant with the current voluntary standard and might require a redesign of the product.

Importers of noncompliant play yards may need to discontinue their import if their existing supplier does not come into compliance, possibly replacing the noncompliant play yard with a compliant play yard or another juvenile product. However, two of these six 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, but they could still respond to the rule by discontinuing the import of their noncomplying play yards, possibly replacing them with other juvenile products.

In addition to the direct costs of the staff-recommended final play yard standard, there are indirect testing and certification costs that do not arise directly as a consequence of the play yard rule's requirements. Rather, once the final rule becomes effective and the notice of requirements is in effect, play yards will become subject to additional costs associated with the third party testing and certification. These indirect costs could be significant for small manufacturers. They could also be significant for small importers if their suppliers do not perform third party testing.

VI. STAFF RESPONSES TO PUBLIC COMMENTS (TABS B, C, AND D)

The CPSC received 23 comments regarding the notice of proposed rulemaking for play yards (Docket No. CPSC–2011–0064).

Table 1: Public Comments to Play Yard Proposed Rule (Docket No. CPSC-2011-0064)

Docket #: CPSC-2010-0075		
Comment #	**Name**	**Organization/Affiliation**
1	Augusta Johnson	(none given)
2	Oscar Moreno	(none given)
3	Jeremy Marshall	(none given)
4	David Doe	(none given)
5	Kristen Eady	(none given)
6	Eugene Levin	(none given)
7	J.H. Uhm	New York University School of Law
8	Stefanos Touzos	New York University School of Law
9	Minyoung Ko	New York University School of Law
10	Rebekah Soule	New York University School of Law
11	Allison Kahl	New York University School of Law
12	Carey Shenkman	New York University School of Law
13	Tim Andree	New York University School of Law

14	Eugene Levin	(none given)
15	Jennifer Kirsch	(none given)
16	Malin Henrikson	BabyBjörn AB
17	Niklas Gerborg	BabySwede LLC
18	James Buskell	(none given)
19	Dion Martinez	(none given)
20	Lisa Olney	(none given)
21	Ann-Katherine Hailey	University of Memphis
22	Nancy Cowles (submitter) Rachel Weintraub (co-signee) Donald L. Mays (co-signee)	Kids In Danger, Consumer Federation of America, Consumers Union (joint comment)
23	Lauren Pfeiffer (submitter) Robert B. Waller, President (signee)	Juvenile Products Manufacturing Association (JPMA)

Table 1 lists the commenters and comment numbers. For a full copy of all comments visit: www.regulations.gov, and review the Public Submissions for Docket No. CPSC-2011-0064.

The comments regarding economic impact and the effective date are addressed in Tab B of this briefing package. Technical comments regarding the proposed rule and the ASTM standards are addressed in Tab C. Comments that involved human factors issues and all other general comments, including the comment which prompted the new requirement regarding bassinet accessory assembly with missing components, are addressed in Tab D of this briefing package.

Most comments supported the proposed rule, including the proposed modifications to the ASTM standard. The comments raise a variety of issues that staff has addressed in its response memoranda. A listing of these issues and where to find staff's responses are outlined below:

Economic Issues (Tab B, Appendix A)

1. Small Business Impact (Commenter 7)
2. Effective Date (Commenters 7, 8, 16 & 17, 22 & 23)
3. American Baby Group Data (Commenter 8)

Technical Comments (Tab C)

1. Play Yards with Upward Folding Side Rails (Commenters 16 & 17)
2. Hazards Related to Accessories (Fatigue Testing on the Attachment Points of Accessories) (Commenter 22)
3. Impact on the Play Yard (Suction Cups for Stability) (Commenter 1)

Human Factors Related and Other General Comments (Tab D)

1. Generally Unsupportive of Regulations (Commenter 4)
2. The Definition of "Play Yard" (Commenter 7)
3. ASTM Voluntary Standard F 406 as the Basis for the Mandatory Standard (Commenters 6, 10 & 11, 14)

4. Adequacy of Testing (Commenter 10)
5. Injury Rates (Commenters 6 & 14)
6. International Standards (Commenters 9 & 10)
7. Quality Control (Commenter 18)
8. Bassinet and Cradle Accessory Misassembly with Missing Parts (Commenter 22)
9. Unsafe Sleep Environment (Commenters 1, 6, 11,14, 19, 22)
10. Clearance Around Play Yards (Commenter 1)
11. Play Yard Covers (Commenters 6 & 14)
12. Risks Associated with Children Climbing Out of Play Yards (Commenter 19)
13. Standing/Choking Deaths (Commenter 22)
14. Hazards Related to Accessories (Changing Tables; Head and Neck Entrapment in Accessories)(Commenters 2 & 20)
15. Mattress Vertical Displacement Test Repeatability (Commenter 23)
16. Warning Statements (Commenters 12 & 20)
17. Package and Product Marking to Indicate Compliance with the Mandatory Rule (Commenter 22)

VII. STAFF RECOMMENDATIONS

Staff recommends that ASTM F 406-12a be incorporated by reference into the mandatory play yard standard with the addition of a bassinet/cradle accessory misassembly provision, which makes the mandatory standard more stringent than the voluntary standard in order to reduce further the risk of injury associated with play yards. Finally, staff recommends a 12-month effective date.

TAB A:

Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between April 10, 2011 and December 31, 2011

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: February 8, 2012

TO : Gregory K. Rea
Play Yards Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Risana T. Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between April 10, 2011 and December 31, 2011

This memorandum updates, and is supplemental to, the data presented in the Play Yard NPR briefing package presented to the Commission in September 2011. The staff-recommended final rule is based on the data provided in the September 2011 briefing package, in addition to the updated incident data. The date of extraction for the earlier data was April 10, 2011. This memorandum includes play yard-related incident data reported to CPSC staff from April 10, 2011 through December 31, 2011. However, because the 2011 data from CPSC's National Electronic Injury Surveillance System (NEISS) database will not be finalized until spring 2012, any national injury estimate update, to include 2011, was not possible.

Incident Data[5]

A search of the CPSC epidemiological databases showed that there were 41 new play yard-related incidents reported between April 10, 2011 and December 31, 2011. Almost all were reported to have occurred between 2009 and 2011. Fifteen of the 41 incidents were fatal and 26 were nonfatal; eight of the nonfatal incidents resulted in injuries.

Fatalities

Among the 15 fatalities, 13 were 1-year-old or younger, while the remaining two were between 1 year and 2 years of age. Unsafe environment within the play yard was responsible for 11 of the 15 fatalities. This included 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 extra mattress placed inside. There were three fatalities that were product-related: one decedent, while trying to climb out of the play yard, grabbed hold of a nearby bassinet when the canopy of the bassinet fell forward and caught him at the neck; the second decedent was asphyxiated when his head got stuck in a torn opening between the floor and the mesh side of the play yard; the third decedent slid to a corner of an unlevel bassinet attachment that was incorrectly assembled. Very little is known about the circumstances of the fifteenth fatality.

Nonfatal Incidents

There were eight injuries reported among the 26 nonfatal incidents. No age information was available for three of the injured victims; among the remaining five, four were under 1 year of age and one was 16 months of age. The injuries, while not serious enough to require hospitalization, included bruises, cuts, and dental injuries. All of the injuries were related to various product-related issues, such as structural integrity, fabric/mesh, or accessories, for example.

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[5] The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, and the Death Certificate (DTHS) file. These reported deaths and incidents are neither a complete count of all that occurred during this time period nor a sample of known probability of selection. 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 January 3, 2012. All data coded under product code 1513, and some coded under 1529 was 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 bassinet or changing table 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.

Hazard Pattern Identification

The hazard patterns identified among the 41 new incident reports were similar to the hazard patterns that were identified among the incidents considered for the NPR and are grouped as follows (in descending order of frequency of incidents):

A. **Product-Related Issues:**

- *Structural integrity*: There were 10 incidents involving lack of structural integrity of the play yard. Examples include broken/detached components leading to instability or collapse of the product, loose hardware, and loose wheels. There were three injuries reported in this category.

- *Fabric or mesh-related issues:* There were five incidents, including one fatality and two injuries, due to problems such as tears in the fabric, unraveled stitching, and mesh holes that were too large and caught the infant's teeth.

- *Accessory issues:* There were four incidents, including one injury, which reported broken/detached components from mobile or tent accessories.

- *Floor board/pad issues:* There were three incidents reporting failures of fasteners designed to keep the floor pad in place and flimsy floor boards providing insufficient support. There were no injuries reported in this category.

- *Side rail collapse:* There were three incidents that reported problems with the side rails collapsing. None of the incidents reported any injuries.

- *Climbing/falling issues*: There were two incidents reported in this category. One of the incidents was a fatality where the infant, who was attempting to climb out by grabbing onto a nearby separate bassinet, was caught behind the neck by the canopy of the bassinet which fell forward. In the second incident, the infant suffered a bruise when she fell out of the play yard while leaning over the rail.

- *Assembly issues:* There was one fatality that resulted from the misassembly of the bassinet attachment to the frame of the play yard. The bassinet ended up with a decline at one corner where the 3-month-old was found prone and unresponsive.

- *Other product-related issues:* There was one report of an infant nearly choking on a sticker that was a component of the play yard.

B. Unsafe Environment Issues

- *Unsafe environment within the play yard:* There were 11 incidents, all fatalities, resulting from hazards created by the presence of soft and/or extra bedding, prone placement of young infants, and/or the infant getting wedged between the side of the play yard and extra mattress placed inside.

C. Other Issues

- *Other Issues*: One report of a fatality provided very little product- or scenario-specific information to determine the hazard.

TAB B:

Final Regulatory Flexibility Analysis of Staff-Recommended Final Standard for Play Yards

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: April 30, 2012

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 : Final Regulatory Flexibility Analysis of Staff-Recommended Final Rule for Play Yards

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104 of the CPSIA requires the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") to evaluate the 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.

The notice of proposed rulemaking (NPR) for play yards, approved by the Commission for publication in September 2011, was based upon the relevant sections of the voluntary ASTM International (formerly known as the American Society for Testing and Materials) standard for non-full-size baby cribs/play yards (F 406-11).[6] The Commission proposed a few modifications to F 406-11 at that time: (1) a clarification to the top rail to corner post attachment test; and (2) two editorial changes to the floor strength test. These modifications were incorporated into an updated standard F 406-11b, which ASTM published in September 2011; the changes are also

[6] Since ASTM F 406 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.

included in F 406-12 (published February 2012) and F 406-12a (published May 23, 2012). For F 406-12, ASTM added a preload component to the mattress vertical displacement test and clarified the wording and figures associated with the top rail to corner post attachment test. In response to public comments generated by the NPR, F 406-12a incorporates a clarification that the neck entrapment requirements apply only to products with top rails that fold downward, because products without this feature do not create the hazard the requirement addresses. F 406-12 will go into effect, for Juvenile Products Manufacturers Association (JPMA) certification purposes, in August 2012, while F 406-12a will go into effect in December 2012.

CPSC staff now recommends that the Commission adopt F 406-12a as a final rule with one new requirement: bassinet/cradle accessories shall either have key structural elements permanently attached *or* the accessory should be obviously unusable when any one key structural element is left out. This new requirement was developed in consultation with ASTM and will go out for a ballot vote to the ASTM members.

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis when the Commission promulgates a final rule. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. a succinct statement of the objectives of, and legal basis for, the rule;
2. a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the 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. a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

The Product[7]

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.

Many accessories that come with play yards are also covered by the staff-recommended proposed rule. Those accessories would need to comply with the relevant ASTM standard as well (*i.e.*, a bassinet attachment sold with 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.

The Market for Play Yards

Play yards are typically produced and/or marketed by juvenile product manufacturers and distributors. CPSC staff estimates that there are currently at least 21 domestic manufacturers or importers supplying play yards to the U.S. market; ten are domestic manufacturers and 11 are domestic importers. In addition, three foreign firms supply the U.S. market: one is a manufacturer, and the others are importers that import from foreign companies and distribute from outside of the United States.[8] Play yards from 10 of the 24 firms have been certified as compliant with the ASTM voluntary standard F 406-11b by the JPMA, the major U.S. trade association that represents juvenile product manufacturers and importers.[9] One additional firm claims compliance with F 406-11b.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*),[10] 74 percent of new mothers own portable play yards, and 28 percent own full-size play yards. Approximately 35 percent of portable play yards, and 17 percent of full-size

[7] ASTM F 406-12a.

[8] Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites. Since the September 2011 NPR, several firms have stopped or started supplying play yards to the U.S. market.

[9] JPMA typically allows 6 months for products in their certification program to shift to a new standard once it is published. F 406-12 will become effective for JPMA certification purposes in August 2012 and F 406-12a, the voluntary standard upon which the proposed final rule is based, will become effective in December 2012.

[10] 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 standard that went into effect for manufacturers, importers, and retailers on June 28, 2011 could have changed the demand for play yards.

play yards were handed down or purchased second-hand.[11] Thus, about 65 percent of portable play yards and 83 percent of full-size play yards were acquired new. This suggests sales of roughly 2.9 million play yards to households annually (.74 x .65 x 4.1 million births per year + .28 x .83 x 4.1 million births per year).[12] Staff has no specific information on play yard lifecycles, but it seems likely that many are used for more than one child. Given that play yards are relatively inexpensive and new designs are introduced frequently, an assumption of a 4–5 year life cycle for play yards does not seem unreasonable. If so, approximately 11.6-14.5 million play yards might be available for use in U.S. households in any given year.

According to Epidemiology (EPI) staff, there were an estimated 2,300 emergency department-treated injuries to children under age 5 related to play yards in 2010.[13] Assuming an estimated 11.6–14.5 million play yards available for use in U.S. households during 2010, there would have been about 1.6–2.0 emergency department-treated injuries annually for every 10,000 play yards available for use.

Reason for Agency Action and Legal Basis for the Draft Final 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 new requirements and test procedures that have been added to the voluntary standard since 2010. These new requirements address several known hazard patterns and will help to reduce injuries and deaths in play yards,[14] and they have resulted in the current voluntary standard F 406-12a, upon which the staff-recommended final rule is based. However, CPSC staff recommends adding a new requirement to F 406-12a that would ensure that play yard bassinet accessories either: (1) have all key structural components permanently attached; or (2) are obviously unusable when a key structural component is left out.

[11] The data on secondhand products for new mothers were not available. Instead, data for new mothers and expectant mothers were combined and broken into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage that was handed down or purchased secondhand. Additionally, play yard categories have been collapsed for simplicity.

[12] 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: Final Data for 2009," *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. Number of births in 2009 is rounded from 4,130,665.

[13] Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, Nursery Product-Related Injuries and Deaths Among Children Under Age Five (December 2011).

[14] Memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated August 17, 2011, Subject: Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007-Present; Memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated February 8, 2012, Subject: Play Yard-Related Deaths, Injuries, and Potential Injuries Reported Between April 10, 2011 and December 31, 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.

This requirement would address a recent death,[15] as well as a safety concern mentioned in one of the NPR comments.

Requirements of the Draft Final Rule

CPSC staff recommends adopting the voluntary ASTM standard for play yards, F 406-12a (excluding parts that relate solely to non-full-size cribs), with the addition of the bassinet/cradle key structural elements requirement mentioned above. Some of the more significant requirements of ASTM F 406-12a, as it relates to play yards, are listed below. The requirements that have been added since the NPR are in italics.

- Corner post and protrusion requirements—intended to address choking 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 tip over.
- Entrapment test for attachments—intended to prevent a child's head from becoming entrapped while the accessory (*e.g.*, bassinet or changing table) 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 limits how much a static weight can lower the side height.
- Floor strength tests—intended to ensure structural integrity when play yard is exposed to both static and dynamic loads. *This was modified in F 406-11b to clarify the test procedure, as proposed by the Commission in the September 2011 NPR.*
- Mesh/fabric requirements—intended to ensure its strength, as well as the strength of its attachment to the play yard structure. Also addresses 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—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. *The test procedure was modified in F 406-12 to include a preload intended to remove any slack prior to testing.*
- Top-rail configuration test—intended to prevent play yards from using hinge/latch designs that create a V- or diamond shape when folded. In the past, these have

[15] Chowdhury 2012.

resulted in head/neck entrapments. *Based on one of the comments received in response to the September 2011 NPR, this requirement was modified in F 406-12a to only apply to play yards whose top rails fold downward, thereby potentially creating a hazardous V- or diamond-shaped opening.*[16]

- Top rail to corner post attachment requirements—intended to prevent broken corner brackets, loosened fasteners, etc. that have occurred in the market and resulted in recalls. The test method checks the robustness of the connection points between the top rails and corner brackets. *The test clamps required for the test procedure can vary to accommodate diverse hinge types. This was a change proposed by the Commission in the September 2011 NPR and included as part of F 406-11b. The test procedure was modified further for F 406-12 to clarify the wording and associated figures.*

The voluntary standard also includes: (1) torque and tension tests to ensure 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.

As noted above, CPSC staff recommends adding a new requirement to the final rule that would address hazards associated with misassembled bassinet attachments. This requirement was prompted by a product-related fatality in a bassinet accessory of a play yard that had been assembled and used without an important structural component. It became clear to staff that bassinet or cradle accessory misassembly may not be initially visually evident to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the accessory and inadvertently place a child in danger. This hazard was mentioned in one of the comments received in response to the September 2011 NPR. CPSC staff has worked with the ASTM task group to develop this new requirement, and it is expected to go out to ballot soon.

Under the new requirement, bassinet/cradle accessories that require consumer assembly of key structural elements and that can be assembled and attached to the play yard with any of those elements missing must either:

[16] Memorandum from Jacob J. Miller, Division of Mechanical Engineering, Directorate for Engineering Sciences, dated February 29, 2012, Subject: Staff Responses to Technical Comments on the Notice of Proposed Rulemaking for Play Yards, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).

1. Have all key structural elements permanently attached to the accessory; or
2. Be obviously unusable when attached to the play yard with any key structural element removed.[17]

It is likely that most manufacturers will respond to the new requirement by permanently attaching key structural elements to the bassinet/cradle accessory. CPSC staff and ASTM task group members have already identified several methods to accomplish this and determined that doing so will not increase the packaging size, which could have increased the costs of compliance significantly. The actual cost to manufacturers who elect to permanently attach the key structural elements to the accessory should be minimal, primarily involving additional stitching, rivets, and other methods of attachment. However, one firm has expressed their concern about the significant costs that would be involved in product redevelopment, including the possible need for larger packaging, to ensure that their products "fail" via the second option listed above. Product redevelopment could involve significant costs, particularly as no possible design has been identified by manufacturers in the ASTM task group that might succeed in failing visibly when each and every structural element is removed individually. Therefore, in the short run, it is highly probable that, where possible, most suppliers will attach all key structural elements to the accessories.

While the bassinet accessory misassembly requirement developed naturally from the NPR and the comments received, it is a new requirement, and staff believes that additional time may be required for manufacturers to review the requirement, evaluate their products, and develop a method to meet the missing key structural elements requirement for bassinet/cradle accessories. Therefore staff is recommending a 12-month effective date for the final rule. This is consistent with the effective date requested by JPMA (see Appendix B).

Issues Raised by Public Comments

There were several issues raised by public comment in response to the initial regulatory flexibility analysis. These include concerns about the market data used, how well the analysis complied with the requirements of the RFA, and the appropriate effective date. These comments and their responses are presented in their entirety in Appendix A.

Additionally, there was one comment that resulted in a change to the ASTM standard F 406-12a. Specifically, the commenter pointed out that play yards whose top rails only fold upward

[17] Memorandum from Gregory K. Rea, Project Manager, Play Yards, Division of Mechanical Engineering, Directorate for Engineering Sciences, and Leah J. Wade, General Attorney, Regulatory Affairs Division, Office of the General Counsel, dated May 18, 2012, Subject: Staff Responses to General Comments on the Notice of Proposed Rulemaking for Play Yards, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).

are not at risk of creating a hazardous V- or diamond shape that has been associated with head and neck entrapments. Another commenter suggested changes to the mattress vertical displacement test that was added to the voluntary standard for version F 406-12. In recommending that the Commission adopt F 406-12a, staff is agreeing with both of these comments and recommends including the exception to the top-rail configuration test and the changes to the mattress vertical displacement test in the staff-recommended final rule.

Finally, one comment pointed out the hazards associated with products that appear to be fully operational, even when misassembled. Staff agrees with this comment and has included a missing key structural elements requirement in the draft final rule to address it and a recent death that highlights this hazard.

Other Federal or State Rules

The Commission is in the process of implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a children's product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(i)(2) of the CPSA 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 representative 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.

Because play yards will be subject to a mandatory standard, they will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA when the mandatory standard and the notice of requirements become effective.

Impact on Small Businesses

As noted earlier, there are approximately 21 domestic 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 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, 19 are small firms—nine domestic manufacturers and 10 domestic importers. The remaining domestic firms are a large manufacturer and a large importer. There may be additional unknown small domestic manufacturers and importers operating in the U.S. market.

Small Manufacturers

The expected impact of the staff-recommended proposed standard on small manufacturers will differ based on whether their play yards are compliant with ASTM F 406-11b. Firms whose play yards meet the requirements of F 406-11b are generally expected to continue to do so as new versions are published, typically within 6 months, which is the amount of time JPMA allows for products in their certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. Therefore, it is likely that firms supplying play yards that comply with ASTM F 406-11b (which went into effect for JPMA certification purposes in March 2012) would also comply with F 406-12a by December 2012, even in the absence of a mandatory standard.

Despite the additional staff-recommended requirements pertaining to misassembly, there should be little direct impact on the costs of producing play yards for most manufacturers whose products are likely to meet the requirements of ASTM F 406-12a (6 of 9 firms). The play yards of one firm are already in compliance with the staff-recommended new requirement. While it is possible that the other firms might opt to redesign their products, it is more likely that they will either discontinue supplying bassinet attachments with their play yards or permanently attach the structural elements to the bassinet. Either of these options would probably be easier and less costly. In fact, several of these firms have been involved in the language development for the new requirement and have indicated that they are moving toward permanently attached key structural elements. However, some firms may need (or opt) to redevelop their play yards, and the direct impact on these firms could be significant. One manufacturer estimated that a complete play yard redesign, including engineering time, prototype development, tooling, and other incidental expenses, would cost approximately $500,000.

Meeting ASTM 406-12a's requirements could necessitate product redesign for some play yards not believed to be compliant with F 406-11b. The redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric; but the redesign could be more significant if changes to the frame are required. Consequently, the staff-recommended rule could potentially have a significant direct impact on the three small manufacturers of play yards that have not conformed to F 406-11b, regardless of how they choose to meet the staff-recommended requirement for key structural elements. However, any direct impact may be mitigated if costs are treated as new product expenses that can be amortized.

It is possible that some firms whose play yards are neither certified as compliant nor claim compliance with F 406-11b are, in fact, compliant with the standard. CPSC staff has identified many such cases with other products. To the extent that some of these firms may supply compliant play yards and have developed a pattern of compliance with the voluntary standard, the direct impact of the staff-recommended final rule will be less significant than described above.

Although the direct impact of the staff-recommended final rule should not be significant for most small manufacturers, there are indirect impacts as well. These impacts are considered indirect because they do not arise directly as a consequence of the play yard rule's requirements. Nonetheless, they could be significant. Once the final rule becomes effective and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include lead and phthalates testing, in addition to the physical and mechanical test requirements specified in the staff-recommended final rule. Based on information provided by a play yard manufacturer, additional industry input, and confidential business information obtained when staff was developing the third party testing rule, total third party testing costs for play yards could amount to $3,520–$8,670 per sample, depending primarily upon the number of accessible components. If lead content can be tested using X-ray fluorescence (XRF) technology (rather than "wet chemistry," which is significantly more expensive), the cost per sample could fall to $1,710–$2,270. Testing overseas could potentially reduce some third party testing costs, but that may not always be practical.

On average, each small domestic play yard manufacturer supplies 14 models of play yards to the U.S. market annually. Therefore, if third party testing was conducted every year, third party testing costs for each manufacturer could range from $49,300 to $121,300 annually. Based on a review of firm revenues, the impact of third party testing could be significant for some small manufacturers, even if only one play yard sample per model is required for testing. If more than one sample per model would be needed to meet the testing requirements, third party testing costs could have a significant impact on many of the manufacturers.

Small Importers

Staff does not believe that many of the four importers of play yards currently in compliance with F 406-11b will experience significant direct impacts as a result of the draft final rule. Similar to domestic manufacturers, in the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves. However, any increase in production costs experienced by their suppliers may be passed on to them.

However, 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 final rule, which may be the case with the six importers of play yards not believed to be in compliance with F 406-11b. Some could respond to the rule by discontinuing the import of their non-complying play yards, possibly discontinuing the product line altogether as one importer plans. However, the impact of such a decision could be mitigated by replacing the non-compliant play yard with a compliant play yard. This would not be an option for two of the six importers whose play yards are not believed to comply with F 406-11b. These firms specialize in the importation of products from a specific foreign company, and, therefore, finding an alternative supply source is probably not an option. However, they could respond to the rule by replacing their non-complying play yards with other juvenile products. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue.

As in the case with manufacturers, all importers will also be subject to third-party testing and certification requirements, and consequently, will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third-party testing. The resulting costs could have a significant impact on some small importers that must perform the testing themselves.

Alternatives

Aside from the third party testing costs, which will become applicable when the final rule becomes effective and the notice of requirements goes into effect, there should not be significant costs associated with the staff-recommended change to ASTM F 406-12a if suppliers opt to permanently attach key structural elements to their bassinet/cradle accessories. However, it is possible that some firms may need to redesign their play yards to meet the staff-recommended play yard standard. Therefore, adopting the voluntary standard without modifications could significantly reduce the impact on a few small firms.

Staff recommends an effective date of 12 months for the final rule. CPSC staff generally considers 6 months sufficient time for suppliers to come into compliance with a mandatory standard. But, in this case, we believe that additional time is needed to allow suppliers to come into compliance with the new requirement that addresses misassembly in bassinet accessories.

Setting an effective date later than the staff-recommended 12 months could, however, further reduce the direct impact on firms whose play yards are not expected to meet ASTM F 406-12a in the absence of a mandatory standard. 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. However, the trade association that represents most juvenile product manufacturers felt that 12

months was a sufficient amount of time for play yard suppliers to come into compliance with the mandatory standard that includes the new requirement for bassinet accessories. Thus, we recommend a 12-month effective date for the play yard mandatory standard.

Appendix A:
Response to Public Comments

Presented below are the responses to comments directed toward the initial regulatory flexibility analysis for play yards.

1. Small Business Impact

   Comment - One commenter expressed concerns about how effectively the CPSC complied with the requirements of the Regulatory Flexibility Act (RFA). The commenter believes that "the economic impact" of the proposed rule will "be significant" because "most manufacturers and importers of play yards would qualify as small" businesses. In support of this point, the commenter states: "…the required tasks of product redesign, finding alternative suppliers, etc., involve major business decisions based on thorough analyses of product designs (even for minor changes), potential suppliers, alternative products to be imported, etc." The commenter believes that "the economic impact…should be minimized for substantially all of the market players."

   Staff Response - The commenter asserts that the proposed rule will have a significant impact on all small firms. However, the proposed final rule is largely equivalent to F 406-11b (with a few low or no cost changes) which is already in effect. Several firms have a history of making adjustments to their play yards to remain in compliance with the ASTM standard, and they would likely continue to comply in the absence of a mandatory standard. Firms with a history of voluntary compliance will have few, if any, costs associated with the proposed rule, regardless of their size. Therefore, seven out of 10 small manufacturers and six of the 10 small importers in the initial regulatory flexibility analysis would *not* likely be affected significantly by the proposed rule.

   The commenter believes that product redesign will have a significant impact "even for minor changes." Based upon CPSC staff's conversations with manufacturers, the type of modification is the relevant driver of costs. Specifically, changes that involve making new molds (such as changes to the frame) would have a more significant impact on firms than changes involving soft parts (such as the straps, fabric, and mesh). The initial regulatory flexibility analysis specifically took this information into account.

   The commenter also implies that "finding alternative suppliers" will involve "thorough analyses of …potential suppliers [and] alternative product to be imported" and will, therefore, impose significant costs on importers. While there are costs associated with finding suppliers and products, the costs of doing so as a result of this rule should not be

significant for firms that routinely undertake this type of activity. Each firm likely has established relationships with one or more suppliers and is familiar with their product lines.

The initial regulatory flexibility analysis recognized that the impact on firms supplying non-ASTM compliant play yards to the U.S. market (3 of 10 manufacturers and 4 of 10 importers) could potentially be significant. However, because the CPSIA requires the CPSC to promulgate a mandatory standard that is substantially the same as, or more stringent than, the voluntary standard, the CPSC is limited in how it can minimize the economic impact on small firms. For the final rule, CPSC staff recommends adopting F 406-12a with one addition, which will most likely result in suppliers permanently attaching key structural elements to bassinet/cradle attachments. For the most part, this will involve additional stitching, rivets, and other methods of attachment that are generally low-cost changes. Staff is also recommending a 12-month effective date to reduce the burden on firms that may require additional time to meet the new bassinet/cradle accessory missing key structural elements requirement.

2. Effective Date

Comment - Several commenters weighed in on the appropriate effective date for the proposed rule. One commenter, representing numerous juvenile product manufacturers, supported the proposed 6-month effective date; while another manufacturer said: "from an industrial point of view, 6 months of fulfilling a new legislation is very short" and suggested "at least 12 month transition period." Two other commenters also felt that the effective date should be longer. One suggested that it was "doubtful that a six month grace period would provide sufficient protection for the small businesses that the RFA intends to protect," while the other said that an effective date "6 months after publication of the final rule" was "seemingly arbitrary" and that other alternatives "may encourage more compliance."

One commenter, representing several consumer advocacy groups, recommended "an effective date of 90 days after publication in the Federal Register." Their rationale is twofold. First, "the changes to the voluntary standard proposed by CPSC are minor." Second, "it affects only product manufactured after that date, not sold by that date"; and "manufacturers and retailers have large inventories of children's products and will be able to sell noncompliant product for years after the effective date. The sooner new products meet the standard, the better for the infants and toddlers who will be using them." However, the commenter indicated that they would support a 6-month effective date if additional requirements (such as the staff-recommended bassinet/cradle accessory missing key structural elements requirement) were added.

Staff Response - To ensure that all play yard suppliers have sufficient time to address the new staff-recommended "bassinet/cradle accessory missing key structural elements" requirement, staff is recommending a 12-month effective date for the final rule. CPSC staff shares concerns about noncompliant products being available for years beyond the effective date. However, ongoing compliance activities would still be used to pull unsafe play yards from the market.

3. American Baby Group Data Is Outdated

Comment - One commenter said: the "record demonstrates that the Commission relies solely upon information provided by a 2005 survey by American Baby Group for all market data," and added: "affected parties may challenge the rule by claiming that the Commission's actions are based on old, inaccurate data."

Staff Response - The commenter is incorrect in their assumption that the 2005 American Baby Group survey (*2006 Baby Products Tracking Study*) was the only source of market information considered by the Commission in the rulemaking process. The *Baby Products Tracking Study* was used to provide an estimate of the magnitude of the play yard market. The initial regulatory flexibility analysis recognized the limitations of this data, both for its age and its potentially biased sampling methods.

However, the regulatory flexibility analysis also used market research conducted independently by staff. This research provided information on the number of firms supplying play yards to the U.S. market, their type, their size, and their location. It also generated information on the number of products supplied by each firm, their compliance with the voluntary standard, and details about accessories. It is this information, along with input from engineering staff and manufacturers, which led to the conclusions of the initial regulatory flexibility analysis.

Appendix B:
JPMA Letter to CPSC Requesting an Extended Play Yard Final Rule Effective Date

May 7, 2012

Mr. Gregory K. Rea
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

RE: Notice of Proposed Rulemaking Safety Standard for Play yards effective date

Dear Mr. Rea:

Manufacturers who have participated in the voluntary standards process for ASTM F 406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* have been planning to meet the draft requirements set forth in the Notice of Proposed Rulemaking (NPR). They have already invested time and resources to develop working solutions to those requirements provided in the NPR. However, the CPSC has recently furnished IDI 110825CAA2853 to the ASTM task group and has subsequently communicated an additional concern associated with missing components for bassinet accessories used in play yards. As participants within the ASTM process, manufacturers have responded quickly to analyze the details associated with the IDI provided and they have also assisted in the development of a draft requirement to address this recently discovered concern. The requirement has undergone several revisions in a short time thus demonstrating; the difficulty in creating the language necessary to address the concern, and the measure to which the task group has diligently supported the effort by supplying comments and recommendations for improvement.

Although the draft language is near finalization, manufacturers are only beginning to comprehend the options available for compliance in a manner in which design solutions may be developed. Consequently the addition of this late requirement has manufacturers very concerned over the staff's original recommended effective date of 6 months from publication of final rule.

Manufactures concur with the staff's point under Section *VIII Alternatives* of the NPR, that establishing an effective date later than the staff-recommended 6-month-period, 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. To add specifics to this point, manufacturers are faced with the many additional challenges including but not limited to: *(1) Training staff on new requirements, (2) Innovating solutions that have the capability of being manufactured, (3) addressing products that are midway through the development process, (4) Addressing products that are presently in the market, (5) Assessing the retailers reaction to the changes and addressing those accordingly.* All of these points require consideration to ensure a safe and compliant product is produced.

Juvenile Products Manufacturers Association, Inc.
15000 Commerce Parkway, Suite C • Mt. Laurel, NJ 08054 • 856.638.0420 • 856.439.0525
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Deviation or compression of the schedules brings added risk, cost and potentially inferior products.
For these reasons, **manufacturers within the task group are requesting that the CPSC staff recommendation for the Final Rule be 12 months from publication in the federal register and that it be applicable to product manufactured after such date.** This timeframe recommendation is in line with the CPSC allowance for many established regulations.

We are eager to continue to work with developing and solidifying the final requirements using the ASTM process but find this to be a major area of importance and we are seeking your support with the recommendation. We urge you to consider this recommendation in order to appropriately establish a reasonable effective date for the Play Yard Final Rule.

Sincerely,

Michael R. Dwyer, CAE
Executive Director

Juvenile Products Manufacturers Association, Inc.
15000 Commerce Parkway, Suite C • Mt. Laurel, NJ 08054 • 856.638.0420 • 856.439.0525
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TAB C:

Staff Responses to Technical Comments on the Notice of Proposed Rulemaking for Play Yards

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: February 29, 2012

TO: Gregory K. Rea
Project Manager, Play Yards
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: George A. Borlase, Ph.D., P.E.
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 : Staff Responses to Technical Comments on the Notice of Proposed Rulemaking for Play Yards, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)

I. INTRODUCTION

This memorandum provides a summary of the technical comments received on the notice of proposed rulemaking (NPR), [18] published on September 20, 2011, staff's responses to those comments, and a summary of staff's recommended changes to the NPR for the final play yard standard. The NPR proposed a safety standard for play yards under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).

II. STAFF'S RESPONSES TO COMMENTS

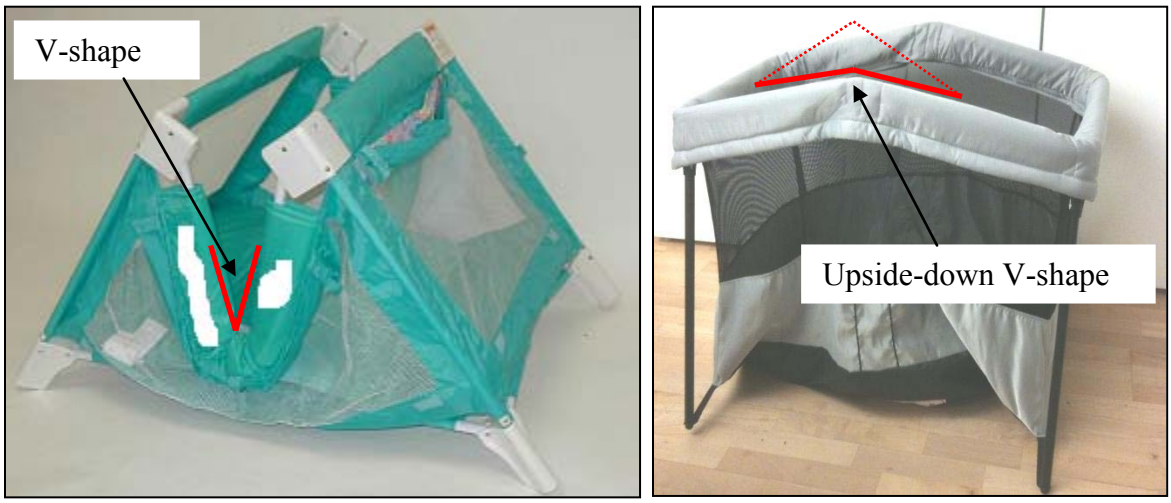
The CPSC received 23 comments on the NPR. Three of those comments related to the proposed physical requirements and were reviewed by mechanical engineering (ESME) staff. The issues

[18] 76 Fed. Reg. 58167 (Sept. 20, 2011).

include: (1) excluding play yards with side rails that fold upward from the top rail configuration assessment; (2) adding a cyclic test for side rails to assess attachment points of accessories; and (3) providing suction cups on play yards to address concerns about children falling in the play yard. These comments are discussed separately below.

1. Play Yards with Upward Folding Side Rails

Comment - One commenter, a play yard manufacturer, stated that play yards with side rails that fold upward should be excluded from the proposed top rail configuration requirement. The commenter noted that a "typical" play yard, shown in figure 1(a) below, could form a dangerous V-shape if the side rail latch mechanisms are not locked properly. The commenter stated that his firm's play yard, shown in figure 1(b), is designed differently than the "typical" play yard, in that the top rail folds upward, which instead forms a nondangerous upside down V-shape. If a child were to put their weight on the top rail by leaning on it, their weight would actually further lock the top side rail, rather than unlock it. The commenter requested that ASTM F 406-11b §7.10 exclude play yards that fold upward because they will not expose a child to a dangerous V-shape.



(a) Typical Play Yard (b) Commenter's Play Yard

Figure 1

Staff Response - CPSC staff and ASTM task group members agree with the commenter. The requirements of §7.10 for Top Rail Configuration are intended to address entrapment hazards associated with side rails folding and creating a V-shape which could entrap a child's neck. Staff and industry agree with the commenter that the entrapment danger does not exist on a play yard with side rails that fold upward from the use position as shown in Figure 1(b). CPSC staff and task group members worked cooperatively in refining the commenter's suggested wording and proposed a revision to §7.10. The exact wording of this change was approved for inclusion in the ASTM standard on May 1, 2012, and it was published in ASTM F 406-12a on May 23, 2012.

Table 1: Changes to ASTM F 406-12, § 7.10, published in ASTM F 406-12a
(~~Strikeout~~ indicates language that was removed. ***Bold italics*** indicate new language.)

ASTM F 406 12 Title and Sub-Section	**Recommended Changes**
7.10 Top Rail Configuration	7.10 *Top Rail Configuration:* Play yards containing one or more rigid top rails that contain a ***central*** hinge/latching device(s) to lock the top rail in the use position ***and move vertically downward from the use position when unlocked*** (see Fig. A1.3) must meet the requirements detailed in 7.10.1 and, if applicable, 7.10.2. Non-rigid top rails must meet the requirements specified in 7.10.3.
Figure A1.3	Top Rail Assembly with Central Hinge(s) ***that move vertically downward***
7.10.2	7.10.2 The included (inside) angle between play yard top rail segments when one side of the hinge/latching device is locked shall be at least 75º within 3 in. of the hinge/latching device when tested in accordance with 8.29.2. Products which do not allow top rail segments to be locked separately are exempt from this requirement.
7.10.3	The play yard shall not allow simultaneous contact of surface or corners as defined in Table 1 using Test Template B when tested in accordance with 8.29.3.
	Note 5 - Rationale: The requirements in 7.10 for Top Rail Configuration are intended to address entrapment hazards associated with frames folding and creating a "V" shape when in their use position.

2. Hazards Related to Accessories (Fatigue Testing on the Attachment Points of Accessories)

One commenter stated that the cyclic testing required for rigid-sided products, contained in §8.5 of ASTM F-406, should be required for mesh-sided products, such as play yards. The commenter stated that a cyclic test would assess better the integrity of play yard accessory attachment points used to secure bassinets and changing tables to the side rails of play yards. The commenter recommends that the cyclic testing in §8.5 of the ASTM standard be repeated with and without the attachments installed. The commenter stated that it appears that many incidents reported by the CPSC occur when the accessory came unattached at one or more attachment points and that additional durability testing will ensure that the attachments points will hold through a lifetime of use.

Staff's Response

The purpose of the cyclic testing requirement found in §8.5 is to evaluate the attachment security of threaded fasteners, such as screws, used in rigid-sided products, specifically full- and non-full-size cribs. The vast majority of play yard bassinet accessories known to staff are structureless, fabric shells that attach to the top rails of play yards. Since they have no structure of their own, they will be substantially unaffected by this kind of cyclic testing. The attachment components in play yards typically consist of plastic clips, hook-and-loop (Velcro) straps, or snaps sewn into soft material around the inner perimeter of the play yard. These attachment means are substantially different than the threaded fasteners this test is intended to evaluate. Thus, we feel that the test would not adequately test the durability of attachment points in play yard accessories.

Of the accessories mentioned by the commenter, bassinet/cradle play yard accessories are of the greatest concern because they are intended to be used while an infant is sleeping unsupervised. Staff identified five incidents where the attachment points of a play yard bassinet accessory failed. None of the incidents resulted in an injury to the child. Three incidents were caused by weak fabric or poor stitching. These hazards are addressed in the ASTM standard for play yards at §7.7 and §7.8, respectively, which address the durability of fabric and the strength of seams. The other two incidents were caused by separated hook-and-loop (Velcro) closures. On one, the closure failed to secure during the consumer's first use of the product and permitted the sleep surface to tilt slightly. The consumer immediately noticed the problem, which is most likely due to poor quality control in the manufacturing process. In the other incident, the hook-and-loop closure, used as a back-up means of attachment, wore out over time. The concern is that if the primary attachment were to fail, the worn hook-and-loop closure might permit the sleep surface to tilt. However, in this case, because the hook-and-loop closure was a secondary means of attachment, the product did not cause an injury or incident. Staff shares the commenter's concern about the robustness of bassinet/cradle attachments, but we do not agree that requiring cyclic testing for the attachment points will address those concerns. At this point, we cannot recommend a performance requirement and test method that would reduce the risk of injury associated with this hazard. Incoming data will be monitored to ensure that any emerging trends will be identified.

3. Impact on the Play Yard (Suction Cups for Stability)

Comment - One commenter stated that small children have wobbly legs and can fall down and sustain an injury because the play yard is not firmly secured to the floor, or it might be placed on an unlevel floor. The commenter states one idea for securing play yards to hard surface floors is to require suction cups on the legs.

Staff Response – Our incident data suggest that most children who are injured by falling in a play yard simply lose their balance. Thus, we disagree that children fall in play yards because the products are not firmly secured to the floor. However, even if that were the case, staff disagrees that suction cups will provide an improved means of attaching the legs of play yards to hard surfaces. The length of time for which the suction effect can be maintained depends significantly on the porosity, flatness, and cleanliness of the floor surface. Furthermore, play yards are typically set up and taken down multiple times and are used on a multitude of indoor surfaces including carpet, hardwood, and tile, as well as outdoor surfaces, such as grass and dirt. A consumer would not only have to inspect the suction cups for cleanliness and physical deformation before each use, but they also must remember to remove and install suction cups, as needed, depending on floor surface. Therefore, staff feels requiring suction cups is not an adequate means of preventing injuries of children falling in play yards.

III. SUMMARY OF STAFF'S RECOMMENDED CHANGES TO THE PROPOSED PLAY YARD RULE

The NPR for play yards proposed incorporating by reference ASTM F 406-11 *Standard Consumer Safety Specification for Non-Full-Size/Play Yards* and included three changes: one substantial change related to the §8.30 Top Rail to Corner Post Attachment Test, and two editorial changes for §8.12 *Floor Strength Test for Mesh/Fabric Products*. These three changes were approved by ASTM and were included in ASTM F 406-11b, published on September 15, 2011.

The November 2011 ballot included two changes to the ASTM play yard standard. Staff and stakeholders agreed to make changes to §8.28 *Mattress Vertical Displacement Test* and to clarify language of §8.30 *Top Rail to Corner Post Attachment Test*. The changes to §8.28 improve testing consistency for vertical mattress displacement by assuring that free movement of fabric is accounted for before establishing the reference point of the initial clamp position. The changes to §8.30 are editorial and clarify the test procedure. These changes were included in ASTM F 406-12 published in February 2012.

One commenter to the NPR suggested an exclusion be added for play yards with top rails which fold upward from the manufacturer's use position. This change was approved by ASTM and included in ASTM F 406-12a published on May 23, 2012.

IV. CONCLUSIONS

In conclusion, staff is recommending that the Commission adopt the ASTM voluntary standard F 406-12a for play yards, which includes the exclusion in §7.10 Top Rail Configuration for play

yards with top rails that move upward from the manufacturer's use position. Staff and industry agree that the entrapment danger does not exist on a play yard with side rails that fold upward from the use position.

TAB D:

Staff Response to General Comments on Notice of Proposed Rulemaking for Play Yards

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: May 18, 2012

TO: Briefing Package

THROUGH: Robert J. Howell, Deputy Executive Director for Safety Operations,
Office of the Executive Director

Andrew J. Stadnik, P.E., Associate Executive Director,
Directorate for Laboratory Sciences

James C. Hyatt, P.E., Director,
Division of Mechanical Engineering
Directorate for Laboratory Sciences

FROM: Gregory K. Rea, Project Manager, Play Yards
Directorate for Laboratory Sciences
Division of Mechanical Engineering

Leah J. Wade, General Attorney
Regulatory Affairs Division
Office of the General Counsel

SUBJECT: Staff Response to General Comments on the Notice of Proposed Rulemaking for Play Yards, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)

I. INTRODUCTION

The U.S. Consumer Product Safety Commission (CPSC) received 23 comments regarding the notice of proposed rulemaking (NPR)[19] for Play Yards (Docket No. CPSC–2011–0064). This memorandum provides an overview of all the general or nontechnical comments that were received and provides staff's responses to those comments. Responses to other comments not covered in this memorandum can be found in the other staff memos. Section VI of the briefing package cover memo lists a summary of comments and where they are addressed.

[19] 76 Fed. Reg. 58167 (Sept. 20, 2011).

II . GENERAL COMMENTS AND STAFF RESPONSES

1. Generally Unsupportive of Regulations

   Comment – The commenter does not support government regulation of this or any consumer product, and believes that a free market will "weed out those manufacturers of unsafe products."

   Staff Response – The Consumer Product Safety Improvement Act of 2008 requires the CPSC to promulgate mandatory regulations for durable infant and toddler products, including play yards. This final rule fulfills a statutory obligation given to the CPSC by Congress. Accordingly, issuance of a play yard mandatory regulation is consistent with the statutory requirements of the CPSIA.

2. The Definition of "Play Yard"

   Comment – One commenter perceived a possible loophole in the ASTM F 406 definition of "play yard," noting that materials other than mesh or fabric could be used to form the walls. The commenter feels that this would allow the manufacturer to circumvent the mandatory play yard rule.

   Staff Response – Play yards with sides made of materials that are not flexible would be considered rigid-sided products and would be classified as full-size- or non-full-size cribs subject to more severe requirements under 16 CFR part 1219 (full-size cribs) and 16 CFR part 1220 (non-full-size cribs). Therefore, it would be less burdensome to produce a mesh- or fabric-sided product. Accordingly, staff does not believe that a play yard manufacturer would attempt to evade the play yard standard requirements by making a rigid-sided product.

3. ASTM Voluntary Standard F 406 as the Basis for the Mandatory Standard

   Comment – Three commenters noted that the ASTM standard might not be the best basis for the mandatory play yard rule. Each commenter felt that because we do not have data to indicate whether the fatalities and injuries were caused by play yards that are not in compliance with the current ASTM standard, we cannot be sure that incorporating by reference the ASTM standard will result in safer play yards.

   Staff Response –The CPSIA requires that we base our mandatory standard for play yards on a voluntary standard. We chose the ASTM standard because it is the most widely used play yard standard in the United States. The ASTM committees that produce the standards

represent a cross-section of stakeholders, including manufacturers, retailers, testing laboratories, independent consultants, representatives from consumer advocacy groups, representatives from Health Canada, as well as CPSC staff. The creation of the standard involves analyzing CPSC incident data in detail, assessing other standards (including international standards), and testing products. The ASTM standard upon which we are basing the mandatory play yard regulation addresses the hazards known to staff. Staff's evaluation showed that the ASTM standard is the most stringent standard available; therefore, we believe that it is appropriate as the basis for the play yard mandatory rule.

4. Adequacy of Testing

Comment – A commenter stated that the proposed test methods for play yards, which do not include any cyclic tests (tests that involve hundreds or thousands of testing cycles in order to evaluate a product's durability), are insufficient because play yards are put up and taken down more often than cribs.

Staff Response – Cyclic testing is time-consuming and expensive. For play yards, we have found that using very heavy loads applied for one testing cycle (instead of cyclic testing, which would require relatively lighter loads and testing cycles that are repeated hundreds or thousands of times) can simulate a lifetime of use. The tests found in the play yard standard have been developed over time and have been found to be reliable indicators of when a play yard could present a hazard.

5. Injury Rates

Comment – One commenter indicated that "the extremely low incidence of injury puts into question the need for regulation at all, outside of the CPSIA mandate, as there probably is no heinous market failure."

Staff Response –The standard is based on careful analysis of incidents, injuries, and fatalities associated with play yards. Injury rates, when available, are an important part of that analysis. In this case, however, even if we agreed with the commenter that the injury rate is too low, that does not negate the requirement for the issuance of a play yard mandatory standard, which fulfills a statutory obligation given to the CPSC by Congress. However, we disagree with the commenter and believe that the incidents, injuries, and fatalities justify the issuance of a play yard mandatory standard.

6. International Standards

Comment – We received two comments regarding international play yard standards. One commenter expressed concern that our play yard mandatory standard could impact trade

agreements and emphasized the importance of standard harmonization as a way to avoid this. Another commenter stated that international harmonization should be a priority.

Staff Response – When drafting our proposed rule for play yards, we reviewed, compared, and considered a variety of play yard standards, including the Canadian standard, the European standard, and the Australian/New Zealand standard. There are differences between all the international standards. Thus, even if we adopted part or all of one of the standards listed here, we still would not have complete international harmonization. We are aware of the utility of having harmonized standards in a global marketplace, and we will continue to strive to achieve this harmonization whenever possible.

7. Quality Control

Comment – One commenter stated that the CPSC should establish a mandatory set of production and manufacturing inspection standards for the industry.

Staff Response – The CPSC's role is to monitor the results of the manufacturing process, not participate in the process itself. We do this in several ways. First, we are able to act preventatively by issuing mandatory standards and requiring children's products to be third party tested by an accredited laboratory. Second, we have the ability to act if the manufacturing process fails and a product is sold that does not meet a mandatory standard or is defective and presents a substantial risk of injury to the public.

8. Bassinet and Cradle Accessory Assembly With Missing Parts

Comment – One commenter stated that incidents arise from products that appear to be set up correctly but are actually misassembled. The commenter recommends that the CPSC add language to the mandatory play yard standard to address this hazard by requiring products with consumer-assembled components to be designed to prevent misassembly. If that is not possible, the commenter suggested that clear visual indicators be included that will alert consumers that the accessory has not been assembled correctly.

Staff Response – Staff agrees with the commenter that play yard bassinet misassembly poses a serious hazard to young children. If a bassinet accessory of a play yard has been assembled and used without important structural components, the misassembly may not be initially visually evident to the consumer. If the misassembled accessory supports an infant without demonstrating a catastrophic and obvious change to the sleep surface, a consumer may continue to use the accessory and inadvertently place a child in danger.

Staff worked with the ASTM Play Yard subcommittee in 2012 to develop a requirement which addresses this hazard. The ASTM task group that undertook this effort met six times from January through April, 2012, and was comprised of all major stakeholders, including manufacturers, third party test laboratories, consumer advocates, and CPSC staff.

The bassinet misassembly requirement offers two avenues for compliance. First, the bassinet accessory meets the requirement if all key structural elements are permanently attached to the bassinet accessory. Thus, manufacturers who permanently sew the support rods, tubes, bars, hooks, etc. into the bassinet shell would not need to have their product tested to this requirement. If the manufacturer chooses not to permanently attach key structural elements, the product must be tested by removing each key structural element and numbering them from 1 through *n*. Key structural element #1 is then removed from the bassinet. In order to pass the test, the product must: (1) completely collapse, or (2) tilt more than 30°. The angle of 30° represents a safety factor of three times over the 10° maximum safe sleep surface angle of incline determined by CPSC Human Factors staff. The test continues until each key structural element has been tested.

The requirement is meant to ensure that the omission of a key structural element is so visually obvious that the consumer will not use the product, inadvertently placing the child in danger. It should be noted that in order to *pass* this test, the item must *fail catastrophically* when a key structural element is omitted.

Staff recommends adopting the play yard bassinet misassembly language presented in Section III of this briefing package's cover memorandum, "Consumer Product Safety Improvement Act of 2008 (CPSIA), Final Rule for Safety Standards for Play Yards."

Comment – We received an e-mail on April 12, 2012, from a manufacturer who found a patent application that the commenter believes will preclude other play yard manufacturers from complying with the proposed bassinet misassembly requirement. The e-mail has been added to the "Supporting and Related Materials" on www.regulations.gov and can be viewed by searching under the docket number for this rulemaking, CPSC-2011-0064.

Staff Response – We reviewed U.S. Patent Application US 2011/0283457 A1, published on November 24, 2011, and filed on May 21, 2011, by Graco Children's Products, Inc. The application details 10 different methods to stiffen a play yard mattress pad before it is used in a play yard bassinet accessory. The methods in the patent application include attaching rods, tubes, bars and boards to the pad. Two of the stiffening methods depicted show rods or bars permanently attached to the mattress pad. In addition to the designs that stiffen the mattress pad, one method stiffens the shell of the play yard bassinet by inserting two long removable boards.

We are not aware of any products on the market today that would be impacted by this patent application. Staff believes that play yard manufacturers have numerous avenues for compliance with the proposed rule, regardless of whether the patent application is approved. For example, a majority of play yard bassinet accessories on the market add tubes or rods to the floor of the bassinet shell to provide a stable mattress pad platform. These manufacturers can continue to use their existing design, but can modify the product by permanently attaching key structural elements to the shell. Therefore, the patent application does not affect staff's recommendation regarding the misassembly language presented above.

Comment – On May 14, 2012, we received a letter from a play yard manufacturer who has several concerns about the proposed bassinet misassembly requirement. The letter has been added to the "Supporting and Related Materials" on www.regulations.gov, and it can be viewed by searching under the docket number for this rulemaking, CPSC-2011-0064.

First, the commenter expressed doubt regarding the causation of the underlying fatality that resulted in the proposed misassembly requirement. After reviewing the redacted In-Depth Investigation report (the "IDI"), which was supplied to the ASTM Subcommittee in October 2011, the commenter feels that the incident was caused by the detachment of a plastic clip that secures the bassinet shell to the side rails of the play yard. Second, the commenter is concerned about the costs associated with the proposed requirement. Third, the commenter feels that the development of the requirement and the test method were rushed and that insufficient time was allotted to research the implications of the proposal.

Staff Response – In addition to reviewing the IDI, staff tested an exemplar model of the bassinet accessory and play yard involved in the fatality and concluded that the incident was caused by the omission of key structural elements. As the commenter states, the bassinet did have plastic clips attached to the shell that secure the shell to the side rails of the play yard. Sometime after the child was placed in the bassinet accessory, one of the plastic clips detached. However, our testing indicates that detachment of one of the plastic clips, alone, is not enough to cause the tilt in the sleeping surface that ultimately caused the fatality. Indeed, the plastic clips caused the consumer to *assume erroneously that the product was safe,* when key structural elements—the supporting rods—were missing. The proposed requirement would eliminate this hazard, by requiring that the bassinet fail catastrophically if key structural elements are missing.

The commenter is also concerned about the costs of "re-engineering, producing new molds, manufacturing a re-designed product, as well as issues such as the need for larger packaging." We are sympathetic to the costs associated with compliance with the proposed requirement. Thus, we are recommending that the effective date for the play yard mandatory

standard be extended to 12 months, instead of the original recommendation of 6 months. We believe this will give play yard suppliers time to: (1) modify their existing designs in order to attach key structural elements to the bassinet accessory permanently, or (2) design the accessory such that it is obviously unusable when any one key structural element is left out. Additionally, staff created a proof-of-concept prototype of one of the commenter's primary products of concern. All 11 bassinet accessory key structural elements were attached, and they required no special molds or tooling. Staff's prototype can be fit back into the original packaging. Staff disagrees with the commenter and has demonstrated that the commenter's products need not be subjected to the substantial redesign effort described by the commenter.

Finally, the commenter believes that the development of this requirement has been rushed and has not been vetted sufficiently by the ASTM Subcommittee. We disagree. This language is the result of six meetings with important stakeholders who were given ample time to analyze the proposal and submit comments. The proposal was changed significantly over the course of several months. For example, the original draft of the proposal covered all play yard accessories, including changing tables. The original draft also attempted to address accessories that can be assembled with key structural elements oriented incorrectly (for example, upside down, inside out, or backward), as well as accessories that can be assembled with key structural elements attached to the product incorrectly.

Over the course of several months and after six meetings, the task group agreed to limit the proposal to bassinet accessories because they are intended to be used as a sleeping environment and children are meant to be left unattended in them for extended periods of time. Other accessories, such as changing tables, are not covered by a misassembly requirement because they are not intended to be used without adult supervision. The task group also eliminated requirements that address structural elements that can be oriented incorrectly or attached to the product incorrectly. The suggested requirements and test methods to address these issues could not be developed fully to the satisfaction of the task group. Ultimately, the task group developed finely tuned language to address a specific hazard that was found to be the cause of an infant fatality. We are very confident that the proposal will reduce the risk of injuries associated with play yards.

After careful consideration of the commenter's concerns, we decline to take action on them, and we continue to recommend incorporating by reference ASTM F 406-12a, with the addition of the bassinet misassembly provision.

9. Unsafe Sleep Environment

Comment – Five commenters raised concerns about the addition of soft bedding (blankets, pillows, and quilted covers), causing an unsafe sleep environment. Some commenters

suggested methods to educate the public about this issue, including: publishing a safety guide, providing public outreach through traditional and social media, and offering information on saferproducts.gov in addition to cpsc.gov. One commenter also recommended that pictograms depicting the dangers of unsafe sleep environments be added to the existing warnings already in the play yard standard to enhance their effectiveness.

Staff Response – We agree that this is an extremely serious issue, and we are dedicated to public outreach and education campaigns that could prevent infant fatalities caused by unsafe sleep environments and practices. Safety guides, blogs and videos addressing safe sleep are already available on the agency's website, cpsc.gov. Additionally, the CPSC uses traditional media channels, as well as popular social media outlets, such as Twitter, YouTube, and Flickr to disseminate information to the public about unsafe sleep environments and practices.

One commenter felt that products such as play yards should include graphics or pictograms, illustrating the dangers of unsafe sleep practices. Staff believes that graphics on warnings are useful and can potentially enhance the effectiveness of a warning. However, the development of an effective pictogram warning takes considerable testing to ensure that the graphic is not confusing, counter-intuitive, or lessons the effectiveness of current warnings. We continue to evaluate warnings on children's products and will revise such warnings as necessary.

10. Clearance Around Play Yards

Comment – One commenter was concerned about outside objects, such as window blind cords and computer cords, which can fall into the play yard and potentially strangle a child. The commenter felt that requiring a minimum clearance of 24 inches around a play yard would prevent children from reaching out and pulling window blind cords or other hazardous objects into the play yard.

Staff Response – For children who are too young to climb out of the play yard, a minimum clearance of about 3 feet would usually suffice. However, once a child can climb out of the play yard, this minimum clearance has limited utility. For this reason, we feel that the existing required warning on play yards, advising parents to stop using the product once the child can climb out, is the most effective way to prevent these incidents. The ASTM standard also includes warnings that address the hazards of strings, cords, and window blind cords that may fall into the play yard.

11. Play Yard Covers

Comment – One commenter was concerned about fatalities that have occurred when caregivers place improvised covers on the play yard in an attempt to keep children inside the product. In some instances, children were killed when attempting to climb out of the play yard when they became entrapped between the cover and the play yard side rail. The commenter felt that perhaps there is a "market failure in providing adequate, and adequately priced, covers." The commenter also suggested that play yard covers could be subject to mandatory regulations.

Staff Response – Before a child can stand and reach a cover, the cover likely presents little risk. Once the child can reach it, the cover itself becomes a hazard. Staff is aware of two fatal incidents associated with covers and tents that can be affixed on top of play yards and cribs. In one incident, a child was able to tear the tent fabric and strangled in the loose strands. In the other incident, the child was able to deform the tent poles and became trapped beneath the mattress and the inverted poles. Because of these incidents, staff recommends that consumers avoid the use of tents and covers on play yards and cribs. Staff believe that the following existing warning in §9.4.2.6 of ASTM F 406-12a is sufficient to address this hazard: "Child can become entrapped and die when improvised netting or covers are placed on top of product. Never add such items to confine child in product."

12. Risks Associated with Children Climbing Out of Play Yards

Comment – One commenter felt that the CPSC has "unnecessarily disregarded the idea to make the play yard walls higher" as a way to prevent children from climbing out of the product.

Staff Response – Some play yard escapes may be performed without injury; and it is reasonable to expect that falls and injuries may occur. A designer of a play yard 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 could introduce other problems that are potentially of more concern than the climbing out problem. For instance, making the sides higher increases the difficulty caregivers have placing their children, especially the youngest ones, into the play yards. 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 greater 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 current ASTM standard

contains a warning advising parents to stop using the product once a child can climb out of the play yard. We feel that this is the most effective way to prevent injuries associated with children being able to climb out of play yards.

13. Standing/Choking Deaths

Comment – In the NPR, staff reported that 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, then lost consciousness, and suffocated when the pressure from the side rail compressed the airways. One commenter has asked that CPSC staff continue to investigate these deaths and address this hazard.

Staff Response – Staff is very concerned about these deaths. At this time, we are unable to explain how these children died; and thus, we are unable to comment on whether there are changes that could be made to play yard designs that would prevent fatalities like this from occurring. We have reached out to medical professionals and are continuing to collect information that might assist us in understanding the deaths and determining whether there is an engineering solution that could prevent them.

14. Hazards Related to Accessories (Changing Tables; Head and Neck Entrapment in Accessories)

Comment – One commenter noted that the accessories that come with play yards can be dangerous. Specifically, the commenter felt that changing table attachments should come with restraints.

Staff Response – There are strong arguments against changing table attachments having restraints, such as a concern that the presence of restraints will give the consumer a false sense of security about the accessory, and might result in the caregiver walking away while the infant is left on the table. More troubling is the concern that parents will mistakenly use changing tables as a sleep environment, which is not the intended use of the product and can be very dangerous. Thus we cannot recommend that changing tables have restraints.

Comment – One commenter requested that play yard accessories, such as changing tables and bassinets, be banned. Failing this, the commenter asked that they be required to lock in place so that they cannot be manipulated by infants and toddlers. The commenter's 13-month-old daughter died when her head became trapped between a nonlocking changing table attachment and side rail of a play yard.

Staff Response – The current ASTM standard includes a requirement to address this hazard. It can be found at ASTM F 406-12a §5.15, *Entrapment in Accessories*. The requirement was added in 2005. Accessories may not separate from a play yard when an infant-sized head probe is pushed against the attachment from inside the play yard with 25 pounds of force. The pushing direction is varied to evaluate better the security of the attachment to the play yard. Staff feels that this test is adequate to address the hazard mentioned by the commenter, and we are not recommending any further action.

15. Mattress Vertical Displacement Test Repeatability

Comment – One commenter felt that the testing consistency for the mattress vertical displacement test could be improved by adding a provision that accounts for slack in the mattress. The commenter proposed the following language (***bold, italic*** text is the proposed clarification):

> 8.28.2 Attach a 3⁄4-in. (19-mm) diameter clamping surface (see Fig. A1.27) as close to a corner of the mattress or removable segmented floor structure as possible. ***Apply a vertical force of 0.5 lbf (2.2 N) to remove any slack. While maintaining the force,*** record the vertical location of the clamp from a reference point on the clamp near the mattress surface relative to a fixed reference point.

Staff Response – This change, which CPSC staff supports, was approved by ASTM members and published in February 2012 in ASTM F 406-12, and is also contained in F 406-12a, published on May 23, 2012. The change will "improve testing consistency for vertical mattress displacement by ensuring that free movement of fabric is taken up before establishing the initial clamp position reference point."[20]

16. Warning Statements

Comment – One commenter noted that the ASTM standard does not require multilingual warnings. The commenter asked the CPSC to consider requiring the use of multilingual warnings. They argued that the use of multilingual warnings could reasonably be expected to reduce play yard injuries by educating caregivers who do not speak or read English.

Staff Response – Staff is not opposed to the use of multilingual labels. Many manufacturers already use multilingual warnings, although it is not currently required. We feel that play

[20] ASTM F 406-12, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, Note 13, p.16, February 2012.

yard manufacturers are in the best position to determine who is using their product and when to publish labels and instructional material in other languages.

Comment – One commenter felt that the warning label on play yards requiring adult supervision while the child uses the product is unreasonable because you cannot expect a parent to supervise a child who is sleeping in a play yard.

Staff Response – The warning label that this commenter is referring to can be found in §9.4.2.11 of the play yard standard. The warning statement advises caregivers: "(a)lways provide the supervision necessary for the continued safety of your child. When used for playing, never leave child unattended." This warning is intended to address the use of play yards as a play environment, not as a sleep environment. We agree with the commenter that a caregiver will not, and should not be expected to, directly supervise a child who is sleeping in a play yard. This warning is intended for caregivers who are using the product as a play environment.

17. Package and Product Marking to Indicate Compliance with the Mandatory Rule

Comment – One commenter recommended that products be marked clearly to enable a consumer to determine if the product was manufactured after the play yard mandatory standard became effective. This would enable consumers to discern easily which products comply with the mandatory rule, and which were manufactured before the standard became effective.

Staff Response – A date code is already required to be on the product, under section 9.1.1.2 of ASTM F 406-12a. In addition, future changes to the standard may come into effect. Because it is not practicable to delineate every change to the standard through a new mark on the product, we decline to take action on this comment.

TAB E:

Federal Register Notice of Final 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-2011-0064

RIN 3041-AC92

Safety Standard for Play Yards: Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") requires the United States Consumer Product Safety Commission ("Commission," "CPSC," "us," 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. In this rule, we are issuing a safety standard for play yards in response to the CPSIA.

DATES: This rule will become effective on **[INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** and will apply to all play yards manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the *Federal Register* as of **[INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

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

SUPPLEMENTARY INFORMATION

A. Background: Section 104(b) of the Consumer Product Safety Improvement Act

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 the *Federal Register* of September 20, 2011 (76 FR 58167), we published a notice of proposed rulemaking ("NPR") for play yards incorporating by reference ASTM F 406-11, "Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards" with three clarifications. ASTM F 406 is the safety standard for both non-full-size cribs and play yards. In the proposed rule for play yards, we indicated which sections of the ASTM standard apply to play yards, and we excluded those provisions of ASTM 406 that apply to non-full-size cribs.

The ASTM subcommittee on play yards developed a newer edition of this standard, ASTM F 406-12a, which includes the three clarifications we proposed in the NPR. ASTM F 406-12a also contains two clarifications that were suggested in comments we received from the public in response to the NPR. Those two clarifications: (1) added a preload to the mattress

vertical displacement test; and (2) exempted play yards with upward-folding top rails from the top rail configuration requirement.

In this document, we are issuing a safety standard for play yards, which incorporates by reference ASTM F 406-12a with one additional requirement to address the hazards associated with the use of bassinet accessories in play yards that can be assembled with missing key structural elements. In the NPR, we proposed an effective date of 6 months after publication in the *Federal Register*. Because of the new requirement regarding bassinet misassembly, we are now providing a 12-month (from date of publication) effective date for the mandatory play yard standard.

B. The Product

ASTM F 406-12a 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. Some play yards include accessory items that attach to the product, including mobiles, toy bars, canopies, bassinets, and changing tables.

C. Incident Data

The preamble to the NPR (76 FR at 58168) summarized the data for incidents related to play yards reported to us from early November 2007 through early April 2011. The final rule is based on the data provided in the NPR, as well as updated data on incidents related to play yards reported to us from April 2011 through December 31, 2011.

From April 10, 2011 through December 31, 2011, we received information on 41 play yard-related incidents. Fifteen of the 41 incidents were fatal. Of the remaining 26 incidents, eight resulted in injuries to the child.

Eleven of the 15 fatal incidents are attributable to an unsafe sleep environment, such as the presence of soft bedding. For one fatality, very little information was supplied to us and we were unable to determine the cause of the death. Three of the 15 fatalities were play yard related. One child died when the bassinet accessory being used as a sleep environment was assembled without key structural elements, which resulted in a dangerous tilt of the sleep surface. The child slid into the corner of the bassinet and suffocated. In another incident, a child was attempting to climb out of a play yard and, while holding onto a separate bassinet nearby, the canopy of the bassinet fell forward and caught him on the back of the neck, suffocating him. A third child suffocated when he got his head stuck in the torn opening between the floor and the mesh side of the play yard.

The incidents have hazard patterns similar to those reported in the NPR, and include:

- Eleven incidents, all resulting in fatalities, were the result of unsafe sleep environments and unsafe sleep practices.
- Ten incidents were caused by broken or detached component parts, such as loose wheels and loose hardware, which resulted in the instability or collapse of the product. There were three injuries reported in this category.
- Five incidents were related to the mesh or fabric sides of the play yard, such as stitching that unraveled, tears in the fabric, and mesh holes that were too large. There were two injuries and one fatality reported in this category.

- Four incidents were caused by hazardous accessories, such as broken or detached components from the mobile or a tent accessory. There was one injury reported in this category.
- Three incidents were related to the mattress pad or floor of the play yard, including reports that the fasteners designed to keep the floor board in place failed. There were no injuries reported in this category.
- Three incidents were due to the side rail of the play yard collapsing. There were no injuries in this category.
- Two incidents were the result of the child being able to climb out of the play yard. There was one injury and one fatality reported in this category.
- One incident, which resulted in a fatality, can be attributed to assembly issues in the bassinet accessory of a play yard. In this incident, the bassinet was missing key structural elements meant to support the accessory. The sleep surface of the bassinet tilted, and the child slid into the corner and suffocated.
- One incident was the result of a child nearly choking on a sticker that was a component of the play yard.
- For one reported fatality associated with a play yard, there was insufficient information to determine the cause.

D. Response to Comments on the Proposed Rule

The preamble to the NPR invited comments concerning all aspects of the proposed rule. We received comments from 23 individuals or organizations. Many of the comments contained more than one issue. Thus, we organized our responses by issue, rather than responding to each individual commenter. Each comment and response is numbered below to help distinguish

between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance, or the order in which it was received.

All of the comments can be viewed on www.regulations.gov, by searching under the docket number for this rulemaking, CPSC-2011-0064. We also received three communications, all related to the new bassinet misassembly requirement, after the comment period for the NPR closed. These communications can also be viewed on www.regulations.gov, under the docket number for this rulemaking, in the section titled, "Supporting and Related Materials." In this section, we respond to these three communications as well.

1. Generally Unsupportive of Regulations

(Comment 1) – One commenter does not support government regulation of this, or any, consumer product and asserted that the free market will "weed out those manufacturers of unsafe products."

(Response 1) – The CPSIA requires that we promulgate mandatory regulations for durable infant or toddler products, including play yards. This final rule fulfills a statutory obligation given to us by Congress. Accordingly, issuance of a play yard mandatory standard is consistent with the statutory requirements of the CPSIA.

2. The Definition of "Play Yard"

(Comment 2) – One commenter noted a possible loophole in the ASTM F 406 definition of "play yard" because materials other than mesh or fabric could be used to form the walls. According to the commenter, this would allow a manufacturer to circumvent the mandatory play yard rule.

(Response 2) – Play yards with sides made of materials that are not flexible would be considered rigid-sided products. These products would be classified as full-size- or non-full-size cribs,

subject to more severe requirements under 16 CFR part 1219 (full-size cribs) or 16 CFR part 1220 (non-full-size cribs). It would be less burdensome to produce a mesh- or fabric-sided product. Accordingly, we do not believe that a play yard manufacturer would attempt to evade the play yard standard requirements by making a rigid-sided product.

3. ASTM Voluntary Standard as the Basis for the Mandatory Standard

(Comment 3) – Three commenters noted that the ASTM standard might not be the best basis for the mandatory play yard rule. Each commenter asserted that because we do not have data to indicate whether the fatalities and injuries were caused by play yards that are not in compliance with the current ASTM standard, we cannot be sure that incorporating by reference the ASTM standard will result in safer play yards.

(Response 3) – The CPSIA requires that we base our mandatory standard for play yards on a voluntary standard. We chose the ASTM standard because it is the most widely used play yard standard in the United States. The ASTM committees that produce the durable infant and toddler product standards represent a cross section of stakeholders, including manufacturers, retailers, testing laboratories, independent consultants, representatives from consumer advocacy groups, representatives from Health Canada, as well as CPSC staff. The creation of an ASTM standard involves analyzing CPSC incident data in detail, assessing other standards (including international standards), and testing products. The ASTM standard upon which we are basing the mandatory regulation addresses the known hazards of play yards and is the most stringent standard available. Therefore, we believe it is an appropriate standard upon which to base the play yard mandatory rule.

4. Injury Rates

(Comment 4) – One commenter indicated that "the extremely low incidence of injury puts into question the need for regulation at all, outside of the CPSIA mandate, as there probably is no heinous market failure."

(Response 4) – The standard is based on careful analysis of incidents, injuries, and fatalities associated with play yards. Injury rates, when available, are an important part of that analysis. In this case, however, even if we agreed with the commenter that the injury rate is too low, that does not negate the requirement for the issuance of a play yard mandatory standard, which fulfills a statutory obligation given to us by Congress. However, we disagree with the commenter and believe that the incidents, injuries and fatalities justify the issuance of a play yard mandatory standard.

5. American Baby Group Data

(Comment 5) – One commenter said that the "record demonstrates that the Commission relies solely upon information provided by a 2005 survey by American Baby Group for all market data," and that "affected parties may challenge the rule by claiming that the Commission's actions are based on old, inaccurate data."

(Response 5) – The commenter is incorrect in assuming that the 2005 American Baby Group survey (*2006 Baby Products Tracking Study*) was the only source of market information we considered in the rulemaking process. The *Baby Products Tracking Study* was used to provide an estimate of the magnitude of the play yard market. The initial regulatory flexibility analysis recognized the limitations of this data, both for its age and potentially biased sampling methods.

However, we also used independently conducted market research to perform the regulatory flexibility analysis. This research provided information on the number of firms supplying play yards to the U.S. market, their type, their size, and their location. We also

independently researched the number of products supplied by each firm, each firm's compliance with the voluntary standard, as well as details about accessories sold with each play yard. It is this information, along with input from our own staff and play yard manufacturers, that led to the conclusions of the initial regulatory flexibility analysis.

6. Small Business Impact

(Comment 6) – One commenter expressed concerns about how effectively the CPSC complied with the requirements of the Regulatory Flexibility Act ("RFA"). The commenter asserted that the proposed rule will have a significant impact on all small firms.

(Response 6) – The economic impact of the mandatory play yard standard proposed in the NPR would not be significant for play yard suppliers who are already in compliance with the ASTM play yard standard. Many play yard manufacturers and importers have a history of making adjustments to their play yards to remain in compliance with the ASTM standard, and they would likely continue to comply in the absence of a mandatory standard. Firms with a history of voluntary compliance would have few, if any, costs associated with the proposed rule, regardless of their size.

The initial regulatory flexibility analysis recognized that the impact on firms that supply noncompliant play yards to the U.S. market could potentially be significant. However, because the CPSIA requires that we promulgate a mandatory standard that is substantially the same as, or more stringent than, the voluntary standard, the CPSC is limited in how it can minimize the economic impact on small firms that are not in compliance with the standard.

7. International Standards

(Comment 7) – We received two comments regarding international play yard standards. One commenter expressed concern that our play yard mandatory standard could impact trade

agreements and emphasized the importance of standard harmonization as a way to avoid this. Another commenter stated that international harmonization should be a priority.

(Response 7) – When drafting the NPR for play yards, we reviewed, compared, and considered a variety of play yard standards, including the Canadian standard, the European standard, and the Australian/New Zealand standard. There are differences among all of the international standards. Thus, even if we adopt part or all of one of the standards listed here, we still would not have complete international harmonization. We are aware of the utility of having harmonized standards in a global marketplace, and we will continue to strive to achieve this harmonization whenever possible.

8. Adequacy of Testing

(Comment 8) – One commenter stated that the proposed test methods for play yards, which do not include any cyclic tests (tests that involve hundreds or thousands of testing cycles in order to evaluate a product's durability), are insufficient because play yards are set up and taken down more often than cribs.

(Response 8) – Cyclic testing is time-consuming and expensive. For play yards, we have found that using very heavy loads applied for one testing cycle (instead of cyclic testing which would require relatively lighter loads and testing cycles that are repeated hundreds or thousands of times) can simulate a lifetime of use. The tests found in the play yard standard were developed over time and have been found to be reliable indicators of when a play yard could present a hazard.

9. Quality Control

(Comment 9) – One commenter stated that the CPSC should establish a mandatory set of production and manufacturing inspection standards for the industry.

(Response 9) – The CPSC's role is to monitor the results of the manufacturing process, not participate in the process itself. We do this in several ways. First, we are able to act preventatively by issuing mandatory standards and requiring that children's products be third party tested by an accredited laboratory. Second, we have the ability to act if the manufacturing process fails and a product is sold that does not meet a mandatory standard, or is defective and presents a substantial risk of injury to the public.

10. Effective Date

(Comment 10) – Several commenters asserted that a 6-month effective date, as proposed in the NPR, is not long enough for play yard suppliers, particularly small suppliers, to come into compliance with the standard. Conversely, one commenter, representing several consumer advocacy groups, recommended a 90-day effective date because "the changes to the voluntary standard proposed by CPSC are minor." The commenter noted that the standard will only affect play yards manufactured (as opposed to sold) after the effective date, and they expressed concern that "manufacturers and retailers have large inventories of children's products and will be able to sell noncompliant product for years after the effective date."

The trade organization representing many producers of juvenile products, the Juvenile Products Manufacturers Association ("JPMA"), initially recommended 6 months for the effective date. However, on May 7, 2012, the JPMA submitted a second letter addressing the issue of the effective date. The JPMA stated that after the comment period closed, we expressed a desire to address the hazards associated with play yard bassinet accessories that can be assembled while missing key structural elements. The letter indicated that the ASTM committee, which includes many JPMA members, has "responded quickly to analyze the details associated with [the incident] and they have also assisted in the development of a draft

requirement to address this recently discovered concern." Because the bassinet misassembly requirement is new, the JPMA has requested that the effective date be extended to 12 months. The May 7, 2012, letter has been added to the "Supporting and Related Materials" on www.regulations.gov, and it can be viewed by searching under the docket number for this rulemaking, CPSC-2011-0064.

(Response 10) – We agree that the new requirement to address bassinet misassembly will require play yard suppliers to modify their existing products or design new products. Therefore, we are providing a 12-month effective date to ensure that suppliers have a sufficient amount of time to come into compliance with the standard.

We share the concern of the commenter who correctly indicated that extending the effective date farther into the future will result in play yards that do not comply with the mandatory standard being sold for a longer period of time. However, the same commenter expressed concern about the hazards associated with bassinet misassembly, and this comment ultimately resulted in the creation of the new requirement. When addressing the issue of the effective date, the commenter stated that if the "CPSC chooses to incorporate any of our suggested changes that involve more changes to the testing, we could support a longer implementation period of up to 6 months." We acknowledge that the commenter did not express support for a 12-month effective date.

However, after assessing the new requirement and acknowledging the changes manufacturers will have to make to comply, we are providing a 12-month effective date. In this case, we feel that the benefits of the new requirements justify a longer implementation period.

11. Bassinet and Cradle Accessory Misassembly

(Comment 11) – One commenter stated that incidents arise from products that appear to be set up correctly but are actually misassembled. The commenter recommended that we add language to the mandatory play yard standard to address this hazard, by requiring products with consumer-assembled components to be designed to prevent misassembly. If that is not possible, the commenter suggested that clear visual indicators be included to alert consumers that the accessory has not been assembled correctly.

(Response 11) – Many play yards are sold with accessories that attach to the product, such as bassinets, changing tables, and mobiles. Bassinet accessories are unique among play yard accessories because they are intended to be used as a sleeping environment and infants are meant to be left unsupervised in them for extended periods of time. Serious injuries or fatalities can result if a play yard bassinet accessory has been assembled without key structural elements, such as rods, tubes, bars, and hooks, that keep the sleep surface flat and level. A tilt in the sleeping surface of the bassinet can result in an infant getting into a position where he or she is unable to breathe and is at risk of suffocation.

It is possible that the omission of key structural elements may not initially be visually evident to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the accessory and inadvertently place a child in danger. If the bassinet's sleep surface tilts while the child is unsupervised, the condition may not be discovered by the caregiver for hours, placing the child in a potentially fatal situation.

Most bassinet accessories consist of a fabric shell that is attached to the side rails of the play yard. The shell is supported by rods, tubes, bars, or hooks. The segmented mattress pad that is used on the floor of the typical play yard is inserted into the bassinet shell. For many play

yards, it is possible to assemble the bassinet without using the rods, tubes, bars, or hooks that provide the structural support for the shell. When this occurs, the bassinet may appear to be assembled correctly because the sleep surface looks flat. However, a bassinet that is missing key structural elements may tilt unexpectedly, causing an unsupervised infant to move into a position where suffocation is possible.

We worked with the ASTM play yard subcommittee in 2012, to develop a requirement to address this hazard. The requirement offers two avenues for compliance. First, the bassinet accessory meets the requirement if all of the key structural elements are permanently attached to the bassinet accessory. Thus, manufacturers who permanently sew the support rods, tubes, bars, or hooks into the bassinet shell would not need to have their product tested to this requirement.

If a manufacturer chooses not to permanently attach key structural elements, the product must be tested by removing each key structural element and numbering them from 1 through *n*. Key structural element number 1 is then removed from the bassinet. In order to pass the test, when an anthromorphic infant dummy is placed in the center of the sleep surface the product must either: (1) collapse completely, or (2) tilt more than 30°. The angle of 30° represents a safety factor of more than three times the 10° maximum safe sleep surface angle of incline. Our Human Factors staff concluded that an angle of 30° would be sufficiently visually obvious to a consumer such that the consumer would be discouraged from continuing to use the bassinet. The test continues until each key structural element has been tested individually (thus, key structural element number 1 is inserted back into the product, key structural element number 2 is removed, and the test is repeated.)

The requirement is meant to ensure that the omission of a key structural element is so visually obvious that the consumer will not use the product, inadvertently placing the child in

danger. It should be noted that in order to *pass* this test, the item must *catastrophically fail* when a key structural element is omitted.

Most manufacturers will use rods, tubes, bars, or hooks to support the bassinet shell. Thus, the mattress pad is not a key structural element under this provision, unless the manufacturer chooses to stiffen the mattress pad itself in order to provide structural support to the bassinet. If the mattress pad provides the structural support for the bassinet, it becomes a key structural element and must either be permanently attached to the bassinet or designed in such a way that omission of the mattress pad causes the bassinet to become obviously unusable.

The final rule incorporates by reference ASTM F 406-12a, with the addition of a requirement and test method to address bassinet misassembly. We believe that this additional requirement will reduce the risk of injury and death associated with play yards.

(Comment 12) – We received an e-mail on April 12, 2012, from a manufacturer who discovered a patent application that the commenter believes will preclude other play yard manufacturers from complying with the bassinet misassembly requirement. The e-mail has been added to the "Supporting and Related Materials" on www.regulations.gov, and it can be viewed by searching under the docket number for this rulemaking, CPSC-2011-0064.

(Response 12) – We reviewed U.S. Patent Application US 2011/0283457 A1, published on November 24, 2011, and filed on May 21, 2011, by Graco Children's Products, Inc. The application details 10 different methods to stiffen a play yard mattress pad before it is used in a play yard bassinet accessory. The methods in the patent application include attaching rods, tubes, bars, and boards to the pad. Two of the stiffening methods depicted show rods or bars permanently attached to the mattress pad. In addition to the designs that stiffen the mattress pad, one method stiffens the shell of the play yard bassinet by inserting two long removable boards.

We are not aware of any products on the market today that would be impacted by this patent application. We believe play yard manufacturers have numerous avenues for compliance with the rule, regardless of whether the patent application is approved. For example, a majority of play yard bassinet accessories on the market add tubes or rods to the floor of the bassinet shell to provide a stable mattress pad platform. These manufacturers can continue to use their existing design, but can modify the product by permanently attaching key structural elements to the shell. Therefore, the patent application does not affect our recommendation regarding the bassinet misassembly requirement.

(Comment 13) – On May 14, 2012, we received a letter from a play yard manufacturer who has several concerns about the bassinet misassembly requirement. The letter has been added to the "Supporting and Related Materials" on www.regulations.gov, and it can be viewed by searching under the docket number for this rulemaking, CPSC-2011-0064.

First, the commenter questioned the causation of the underlying fatality, which led to the bassinet accessory misassembly requirement. After reviewing the redacted In-Depth Investigation report ("IDI"), which we supplied to the ASTM Subcommittee in October 2011, the commenter opined that the incident was caused by the detachment of a plastic clip that secures the bassinet shell to the side rails of the play yard. Second, the commenter is concerned about the costs associated with the bassinet misassembly requirement. Third, the commenter stated that the development of the requirement and the test method were rushed and that insufficient time was allotted to research the implications of the provision.

(Response 13) – In addition to reviewing the IDI, we tested an exemplar model of the bassinet accessory and play yard involved in the fatality and concluded that the incident was caused by the omission of key structural elements. As the commenter stated, the bassinet did have plastic

clips attached to the shell that secured the shell to the side rails of the play yard. Sometime after the child was placed in the bassinet accessory, one of the plastic clips detached. However, our testing indicates that detachment of one of the plastic clips is not enough to cause the tilt in the sleeping surface, which ultimately caused the fatality. Indeed, the plastic clips caused the consumer to *erroneously assume that the product was safe* when key structural elements, the supporting rods, were missing. The new requirement would eliminate this hazard, by requiring that the bassinet accessory key structural elements be attached permanently or fail catastrophically if the play yard is missing any of its key structural elements.

The commenter also expressed concern about the costs of "re-engineering, producing new molds, manufacturing a re-designed product, as well as issues such as the need for larger packaging." We are sympathetic to the costs associated with compliance with the new requirement. Thus, we are providing a 12-month effective date for the play yard mandatory standard, instead of the original proposal of 6 months as contained in the NPR. We believe this will give play yard suppliers time to: (1) modify their existing designs in order to permanently attach key structural elements to the bassinet accessory, or (2) design the accessory such that it fails catastrophically when any one key structural element is left out. A later effective date will allow manufacturers to spread their costs over a longer period of time.

Finally, the commenter stated that the development of this requirement has been rushed and that it has not been vetted sufficiently by the ASTM Subcommittee. We disagree. This language is the result of six meetings with important stakeholders who were given ample time to analyze the provision and submit comments. The provision was changed significantly over the course of several months. For example, the original draft of the provision covered all play yard accessories, including changing tables. The original draft also attempted to address accessories

that can be assembled with key structural elements oriented incorrectly (for example, upside down, inside out, or backwards), as well as accessories that can be assembled with key structural elements attached to the product incorrectly.

Over the course of several months and after the six meetings mentioned above, the task group agreed to limit the provision to play yard bassinet accessories because they are intended to be used as a sleeping environment and children are meant to be left unattended in them for extended periods of time. It was decided that other accessories, such as changing tables, should not be covered by a misassembly requirement because they are not intended to be used without adult supervision.

The task group also eliminated requirements that address structural elements that can be oriented incorrectly or attached to the product incorrectly. The suggested requirements and test methods to address these issues could not be developed fully to the satisfaction of the task group. The result of the task group's efforts is additional language to address the specific hazard that resulted in the death of an infant. The new requirement will reduce the risk of injuries and deaths associated with play yards.

Accordingly, we will incorporate by reference ASTM F 406-12a, with the addition of the bassinet misassembly provision.

12. Play Yards with Upward Folding Side Rails

(Comment 14) – One commenter, a play yard manufacturer, stated that play yards with side rails that fold upward should be excluded from the top rail configuration requirement. The commenter noted that most play yards form a dangerous V-shape if the side rail latch mechanisms are not locked properly. The commenter stated that his firm's play yards are designed differently than the "typical" play yard, in that the top rail folds upward, which instead

forms a nondangerous upside down V-shape. If a child were to put their weight on the top rail by leaning on it, their weight would actually lock the top side rail further, rather than unlock it. The commenter requested that the play yard standard exempt play yards that fold upward from the top rail configuration requirement because they will not expose a child to a dangerous V-shape.

(Response 14) – We agree with the commenter. The top rail configuration requirements, found in section 7.10 of ASTM F 406-12a, are intended to address entrapment hazards associated with side rails folding and creating a V-shape. If a child's neck is caught in the V-shape, the child could suffocate. The exemption for play yards with upward folding side rails has already been added to ASTM F 406-12a. By incorporating by reference ASTM F 406-12a, we support the inclusion of this clarification in the play yard mandatory standard.

13. Unsafe Sleep Environment

(Comment 15) – Five commenters raised concerns about the addition of soft bedding, such as blankets, pillows, and quilted covers, which can create an unsafe sleep environment for an infant. Some commenters suggested methods to educate the public about this issue, including: publishing a safety guide, providing public outreach through traditional and social media, and offering information on www.saferproducts.gov in addition to www.cpsc.gov.

(Response 15) – We agree that this is an extremely serious issue, and we are dedicated to public outreach and education campaigns that could prevent infant fatalities caused by unsafe sleep environments and practices. Safety guides, blogs, and videos addressing safe sleep are already available on the agency's website at: www.cpsc.gov. Additionally, we use traditional media channels, as well as popular social media outlets, such as Twitter, YouTube and Flickr, to disseminate information to the public about unsafe sleep environments and practices.

(Comment 16) – One commenter recommended that graphics or pictograms depicting the dangers of unsafe sleep environments be added to the existing warnings in the play yard standard in order to enhance their effectiveness.

(Response 16) – We believe that graphics on warnings are useful and can potentially enhance their effectiveness. However, the development of an effective pictogram warning takes considerable testing to ensure that the graphic is not confusing or counterintuitive or does not lessen the effectiveness of current warnings. We continue to evaluate warnings on play yards and other children's products and will revise such warnings as necessary.

14. Clearance Around Play Yards

(Comment 17) – One commenter was concerned about outside objects, such as window blind cords and computer cords, which can fall into the play yard and potentially strangle a child. The commenter felt that requiring a minimum clearance of 24 inches around a play yard would prevent children from reaching out and pulling window blind cords or other hazardous objects into the play yard.

(Response 17) – For children who are too young to climb out of the play yard, a minimum clearance of about 3 feet would usually suffice. However, once a child can climb out of the play yard, this minimum clearance has limited utility. For this reason, we feel that the existing required warning on play yards, advising parents to stop using the product once the child can climb out, is the most effective way to prevent these incidents. The ASTM standard also includes warnings that address the hazards of strings, cords, and window blind cords that may fall into the play yard.

15. Play Yard Covers

(Comment 18) – One commenter was concerned about fatalities that have occurred when caregivers place improvised covers on the play yard in an attempt to keep children in the product. In some instances, children were killed when attempting to climb out of the play yard because they became trapped between the cover and the play yard side rail. The commenter felt that perhaps there is a "market failure in providing adequate, and adequately priced, covers." The commenter also suggested that play yard covers could be subject to mandatory regulations.

(Response 18) – Before a child can stand and reach a cover, the cover likely presents little risk. Once the child can reach it, the cover itself becomes a hazard. We are aware of two fatal incidents associated with covers and tents that can be affixed on top of play yards and cribs. In one incident, a child was able to tear the tent fabric and strangled in the loose strands. In the other incident, the child was able to deform the tent poles and became trapped beneath the mattress and the inverted poles. Because of these incidents, we recommend that consumers avoid the use of tents and covers on play yards and cribs. We believe that the following existing warning in section 9.4.2.6 of ASTM F 406-12a is sufficient to address this hazard: "Child can become entrapped and die when improvised netting or covers are placed on top of product. Never add such items to confine child in product."

16. Risks Associated with Children Climbing Out of a Play Yard

(Comment 19) – One commenter felt that the CPSC has "unnecessarily disregarded the idea to make the play yard walls higher" as a way to prevent children from climbing out of the product.

(Response 19) – A designer of a play yard faces limited options for preventing children from climbing out of the product. The play yard is essentially a lidless box. Play yards that prevent climbing out would require either higher sides or lids to be effective. Both designs could introduce other problems that are potentially of more concern than the climbing out problem.

For instance, making the sides higher increases the difficulty caregivers have placing their children, especially the youngest ones, into the play yards. This could increase the use of alternative sleeping arrangements, such as allowing children to sleep in adult beds, which can have serious hazards associated with them. Introducing a lid or some other kind of cover to a play yard creates more movable parts and the potential for mechanical failures that could lead to entrapment, entanglement, or strangulation.

We have been unable to identify a performance requirement 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 current ASTM standard contains a warning advising parents to stop using the product once a child can climb out of the play yard. We feel that this is the most effective way to prevent injuries associated with children being able to climb out of play yards.

17. Standing/Choking Deaths

(Comment 20) – In the NPR, we reported that 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 (perhaps to reach an object that the child had thrown outside the play yard), lost consciousness, or suffocated when the pressure from the side rail compressed their airway. One commenter asked that we continue to investigate these deaths and address this hazard.

(Response 20) – We are very concerned about these deaths. At this time, we are unable to explain how these children died; and thus, we are unable to comment on whether there are changes that could be made to play yard designs that would prevent fatalities like this from occurring. We have reached out to medical professionals and are continuing to collect

information that might assist us in understanding the deaths and determining whether there is an engineering solution that could prevent them.

18. Hazards Related to Accessories

(Comment 21) – One commenter noted that the accessories that come with play yards can be dangerous. Specifically, the commenter felt that changing table attachments should come with restraints.

(Response 21) – There are strong arguments against changing table attachments having restraints, including the concern that the presence of restraints will give the consumer a false sense of security about the accessory. Restraints might lead to the caregiver walking away while the infant is left on the table. More troubling is the concern that parents will mistakenly use changing tables as a sleep environment, which is not the intended use of the product and can be very dangerous. Thus, we cannot recommend that changing tables have restraints.

(Comment 22) – One commenter requested that play yard accessories, such as changing tables and bassinets, be banned completely. Failing this, the commenter asked that these products be required to lock in place so that they cannot be manipulated by infants and toddlers. The commenter's 13-month-old daughter died when her head became trapped between a nonlocking changing table attachment and side rail of a play yard.

(Response 22) – The current ASTM standard includes a requirement to address this hazard. It can be found in section 5.15 of ASTM F 406-12a, titled, *Entrapment in Accessories*. The requirement was added in 2005. The standard requires that accessories not separate from a play yard when an infant-sized head probe is pushed against the attachment from inside the play yard with 25 pounds of force. The pushing direction is varied to better evaluate the security of the

attachment to the play yard. We feel that this test is adequate to address the hazard mentioned by the commenter, and we are not recommending any further action.

(Comment 23) – One commenter stated that the cyclic testing required for rigid-sided products, contained in section 8.5 of ASTM F 406-12a, should be required for mesh-sided products, such as play yards. The commenter stated that a cyclic test would better assess the integrity of play yard accessory attachment points used to secure bassinets and changing tables to the side rails of play yards. The commenter recommended that the cyclic testing in section 8.5 of the ASTM standard be repeated with and without the attachments installed. The commenter stated that it appears that many incidents reported to the CPSC occur when the accessory became unattached at one or more attachment points and that additional durability testing will ensure that the attachment points will hold through a lifetime of use.

(Response 23) – The purpose of the cyclic testing requirement, found in section 8.5, is to evaluate the attachment security of threaded fasteners, such as screws, used in rigid-sided products, specifically full- and non-full-size cribs. Of the accessories mentioned by the commenter, bassinet play yard accessories are of the greatest concern because they are intended to be used while an infant is sleeping unsupervised. The majority of play yard bassinet accessories are structureless, fabric shells that attach to the top rails of play yards. Because they have no structure of their own they will be substantially unaffected by this kind of cyclic testing. The attachment components in play yards typically consist of plastic clips, hook-and-loop (Velcro) straps, or snaps sewn into soft material around the inner perimeter of the play yard. These attachment means are substantially different than the threaded fasteners this test is intended to evaluate. Thus, we feel that cyclic testing would not adequately test the durability of attachment points in play yard accessories.

We identified five incidents where the attachment points of a play yard bassinet accessory failed. None of the incidents resulted in an injury to the child. Three incidents were caused by weak fabric or poor stitching. These hazards are addressed in the ASTM standard for play yards at sections 7.7 and 7.8, which address the durability of fabric and the strength of seams. The other two incidents were caused by separated hook-and-loop (Velcro) closures. On one, the closure failed to secure during the consumer's first use of the product and permitted the sleep surface to tilt slightly. The consumer immediately noticed the problem. We have evaluated the incident and have determined that it can be attributed, most likely, to poor quality control in the manufacturing process. In the other incident, the hook-and-loop closure, used as a back-up means of attachment, wore out over time. The concern is that if the primary attachment were to fail, the worn hook-and-loop closure might permit the sleep surface to tilt. However, in this case, because the hook-and-loop closure was a secondary means of attachment, the product did not cause an injury or incident.

We share the commenter's concern about the robustness of bassinet and cradle attachments, but we do not agree that requiring cyclic testing for the attachment points will address those concerns. At this point, we cannot recommend a performance requirement and test method that would reduce the risk of injury associated with this hazard. Incoming data will be monitored to ensure that any emerging trends are identified.

19. Mattress Vertical Displacement Test Repeatability

(Comment 24) – One commenter felt that the consistency of the mattress vertical displacement test could be improved by adding a provision that accounts for slack in the mattress.

(Response 24) – The change suggested by the commenter will improve testing consistency for vertical mattress displacement by ensuring that free movement of fabric is taken up before

establishing the initial clamp position reference point. It has already been approved by ASTM members and was published in ASTM F 406-12. It is also contained in F 406-12a. By incorporating by reference ASTM F 406-12a, we support the inclusion of this clarification in the play yard mandatory standard.

20. Impact on Play Yard

(Comment 25) – One commenter stated that small children have "wobbly legs and can fall down" and sustain an injury because the play yard is not firmly secured to the floor, or it might be placed on an unlevel floor. The commenter suggested securing play yards to hard surface floors with suction cups.

(Response 25) – Our incident data suggest that most children who are injured by falling in a play yard simply lose their balance. Thus, we disagree that children fall in play yards because the products are not firmly secured to the floor. However, even if that were the case, we disagree that suction cups will provide an improved attachment to hard surfaces. The length of time for which the suction effect can be maintained depends significantly on the porosity, flatness, and cleanliness of the floor surface. Furthermore, play yards typically are set up and taken down multiple times and are used on a multitude of indoor surfaces, including carpet, hardwood, and tile, as well as outdoor surfaces, such as grass or dirt. A consumer would not only have to inspect the suction cups for cleanliness and physical deformation before each use, but also remember to remove and install suction cups, as needed, depending on the floor surface. Therefore, we feel that requiring suction cups is not an adequate means of preventing injuries to children from falling in play yards.

21. Warnings Statements

(Comment 26) – One commenter noted that the ASTM standard does not require multilingual warnings, and they asked us to consider requiring them. The commenter argued that the use of multilingual warnings could reasonably be expected to reduce play yard injuries by educating caregivers who do not speak or read English.

(Response 26) – We are not opposed to the use of multilingual labels. Many manufacturers already use multilingual warnings, although it currently is not required. We feel that play yard manufacturers are in the best position to determine who is using their product and decide when to publish labels and instructional materials in other languages.

(Comment 27) – One commenter felt that the warning label on play yards requiring adult supervision while the child uses the product is unreasonable because you cannot reasonably expect a parent to supervise a child who is sleeping in a play yard.

(Response 27) – The warning label that this commenter is referring to can be found in section 9.4.2.11 of ASTM F 406-12a and it advises caregivers that they should "(a)lways provide the supervision necessary for the continued safety of your child. When used for playing, never leave child unattended." This warning is intended to address the use of play yards as a play environment, not as a sleep environment. We agree with the commenter that a caregiver would not be continuously supervising a child who is sleeping in a play yard. This warning is intended for caregivers who are using the product as a play environment.

22. Package and Product Marking to Indicate Compliance with the Mandatory Rule

(Comment 28) – One commenter recommended that products be clearly marked to enable a consumer to determine if the product was manufactured after the play yard mandatory standard became effective. This would enable consumers to discern easily which products comply with the mandatory rule, and which were manufactured before the standard became effective.

(Response 28) – A date code is already required to be on the product, under section 9.1.1.2 of ASTM F 406-12a. In addition, future changes to the standard may come into effect. Because it is not practicable to delineate every change to the standard through a new mark on the product, we decline to take action.

E. Summary of ASTM F 406-12a and Description of the Final Rule

For the play yard final rule, we are incorporating by reference ASTM F 406-12a, with one major addition, a requirement to address the hazards associated with play yard bassinet accessories that can be assembled without key structural elements. The final rule also excludes sections of ASTM F 406-12a that apply only to non-full-size cribs. In this section, we (1) summarize the requirements of ASTM F 406-12a; and (2) describe the final rule, including the additional requirement for bassinet accessories, as well as the excluded provisions of ASTM F 406-12a that only apply to non-full-size cribs.

1. Summary of ASTM F 406-12a

In the NPR (76 FR at 58169 through 58170), we described in detail the key provisions of ASTM F 406-11 that apply to play yards. ASTM F 406-12a differs from ASTM F 406-11 in the following ways:

- It includes the three changes to the play yard standard we proposed in the NPR, specifically two clarifications to the testing method used to measure the strength of the play yard floor, and one change to the Top Rail to Corner Post Attachment Test that would allow testers to choose the shape and area of the clamping surface, within a specified range. We reviewed the language that ASTM adopted and, while not exactly the same as the wording we proposed in the NPR, we believe it provides better clarity

than what we proposed. By incorporating by reference ASTM F 406-12a, we support the inclusion of these clarifications in the play yard mandatory standard.

- On its own initiative, the ASTM committee clarified the Top Rail to Corner Post Attachment Test, as well as the accompanying explanatory graphics. By incorporating by reference ASTM F 406-12a, we support the inclusion of these clarifications in the play yard mandatory standard.
- A preload was added to the Mattress Vertical Displacement Test in order to improve testing consistency by ensuring that free movement of fabric is taken up before establishing the initial clamp position reference point. We also received a comment to the NPR suggesting this change. By incorporating by reference ASTM F 406-12a, we support the inclusion of this clarification in the play yard mandatory standard.
- An exemption was included in the Top Rail Configuration requirement to exclude play yards with side rails that fold upward. The side rails of most play yards move downward vertically. If the side rail latch mechanisms are not locked properly, they can form a dangerous V-shape. If the child's neck is caught in the V-shape, the child could suffocate. Play yards with side rails that fold upward, however, do not create this risk. We also received a comment to the NPR suggesting this change. By incorporating by reference of ASTM F 406-12a, we support the inclusion of this clarification in the play yard mandatory standard.

2. Description of the Final Rule

The final play yard rule incorporates by reference ASTM F 406-12a, with one major addition, a bassinet misassembly requirement, and several exclusions for provisions that apply only to non-full-size cribs.

a. The Bassinet Misassembly Requirement

The bassinet misassembly requirement is described in detail in section D.11 of this preamble. In addition to the performance requirement and test method described in that section, we are also modifying one definition, adding one definition, and including several graphics in the mandatory play yard standard in order to ensure that this requirement is clear to both play yard suppliers and testing laboratories. We are modifying the definition of "key structural elements" to include "the components that provide the supporting frame and/or means of attachment for a bassinet/cradle accessory." We are also adding a new term, "bassinet/cradle accessory," defined as "a supported sleep surface that attaches to a non-full-size crib or play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (nonrocking) position."

We are including four new graphics that will assist stakeholders in understanding the new requirement. The first is a figure of the "CAMI Newborn Dummy" that will be used in the bassinet misassembly test method. In other ASTM standards, the reference to a CAMI Dummy is included in a section at the beginning of a standard titled, "Referenced Documents." Following ASTM custom, we are adding the CAMI Newborn Dummy to this section, accompanied by a footnote to indicate that the figure we are using is copied from a drawing provided by the U.S. Department of Transportation.

We are also including three other graphics to illustrate: (1) examples of bassinet/cradle key structural elements; (2) the infant CAMI dummy positioned for the bassinet/cradle accessory sleep surface test; and (3) the bassinet/cradle accessory sleep surface test angle measurement.

b. Excluded provisions of ASTM F 406-12a

The final rule applies 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 final rule excludes provisions of ASTM F 406-12a that apply to non-full-size cribs, including the following:

- section 5.17 of ASTM F 406-12a, containing the requirements for mattresses in rigid-sided products;
- section 5.20 of ASTM F 406-12a, containing record keeping requirements for non-full-size cribs;
- the entirety of section 6 of ASTM F 406-12a, containing the performance requirements for rigid-sided products;
- sections 8.1 through 8.10.5 of ASTM F 406-12a, containing the test methods for rigid-sided products;
- a portion of section 9.4.2.10 of ASTM F 406-12a, containing warning label requirements for nonrectangular cribs; and
- section 10.1.1.1 of ASTM F 406-12a, containing instructional literature requirements for non-full-size cribs.

F. Effective Date

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

In the NPR, we proposed an effective date of 6 months. However, after assessing the new bassinet misassembly requirement and acknowledging the changes that suppliers will have to make to comply, we are providing a 12-month effective date. In this case, we feel that the benefits of the new requirement justify a longer implementation period.

G. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601–605, requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that we prepare a final regulatory flexibility analysis when promulgating final rules. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. a succinct statement of the need for, and objectives of, the rule;

2. a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

3. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

4. a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

5. a description of the steps that the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the

alternative adopted in the final rule, and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

2. The Market

There are 21 domestic firms known to be producing or selling play yards in the United States. Ten are domestic manufacturers, and 11 are domestic 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, nine domestic manufacturers and 10 domestic importers known to supply play yards to the U.S. market are small businesses. The remaining domestic entities are one large manufacturer and one large importer. There are also three foreign firms supplying play yards to the U.S. market. There may be additional unknown small manufacturers and importers operating in the U.S. market.

The Juvenile Products Manufacturers Association ("JPMA") runs a voluntary certification program for juvenile products. Certification under the JPMA program is based on the most recent ASTM voluntary play yard standard, typically with a 6-month delay. Six of the nine small manufacturers produce play yards that are certified as compliant with the ASTM voluntary play yard standard by the JPMA. Of the importers, three import play yards that have been certified as compliant with the ASTM voluntary standard. One additional importer claims compliance with the ASTM standard but is not JPMA certified.

3. Impact of the Standard on Small Businesses

a. Costs of Complying with the Voluntary Standard

The extent to which each firm will be impacted by the play yard mandatory standard depends on whether the firm's play yards currently comply with the ASTM voluntary standard.

Small firms whose play yards already comply with the voluntary standard will only potentially incur costs related to our additions and modifications to the standard. Many of these firms are active in the ASTM standard development process and compliance with the voluntary standard is part of an established business practice. Thus, it is likely that most of the firms that already comply with the ASTM standard would continue to do so, even in the absence of a mandatory regulation.

b. Small Domestic Manufacturers

Six of the small manufacturers produce play yards known to comply with the voluntary standard. For most of these firms, the costs associated with our changes to the voluntary standard are not expected to be significant. However, the impact could be significant for firms that opt to redesign their play yards.

For the three manufacturing firms whose play yards may not be compliant with the voluntary standard, the costs could be more significant. Meeting the existing voluntary standard could require manufacturers to redesign their product. The impact on manufacturers with both compliant and noncompliant play yards may be mitigated if the costs are treated as new product expenses and amortized over time.

This scenario also assumes that the three firms whose play yards are not JPMA certified do not meet the voluntary standard. In fact, we have identified many instances in which a juvenile product not certified by the JPMA does comply with the ASTM voluntary standard. To the extent that these firms may already supply play yards that meet the ASTM voluntary standard, the costs incurred would be lower.

c. Small Domestic Importers

Four of the 10 small importers produce play yards known to comply with the voluntary standard. Three are certified by the JPMA, and one additional firm claims compliance with the ASTM standard. For these firms, the costs, if any, associated with our changes to the voluntary standard are not expected to be significant. However, any increase in production costs experienced by their suppliers may be passed on to them.

The costs to the six importers whose play yards may not be compliant with the voluntary standard could be more significant. Importers of play yards would need to find an alternate source if their existing supplier does not come into compliance with the standard. Purchasing compliant, higher quality play yards could increase the cost of the product.

This will not be an option for two of the noncompliant play yard importers because they specialize in the importation of play yards from a specific foreign company. Thus, finding an alternative supply source is probably not an option for them. These firms could respond to the rule by discontinuing the import of play yards. The impact of this decision could be mitigated by replacing play yards with a different infant or toddler product. Deciding to import an alternative infant or toddler product would be a reasonable and realistic way to offset any lost revenue.

As with manufacturers, to the extent that some of the firms believed to supply noncompliant play yards may actually supply play yards that meet the ASTM voluntary standard, the costs incurred would be lower.

d. Costs of Complying with our Changes to the Voluntary Standard

We are incorporating by reference ASTM F 406-12a, with the addition of a requirement and test method intended to prevent the assembly of a bassinet accessory to a play yard with missing key structural elements. Not every play yard manufacturer makes a bassinet accessory for their product. For firms that do, in order to meet this requirement, play yard manufacturers

will have to: (1) modify their existing designs in order to permanently attach key structural elements to the bassinet accessory, or (2) design the accessory such that it is obviously unusable when any one key structural element is left out.

It is likely that most suppliers will choose to comply with this requirement by permanently attaching key structural elements to the bassinet accessory. We know of one manufacturer that produces a play yard with a bassinet accessory that is already compliant with this requirement. Several of the firms impacted by this new requirement were involved in the ASTM language development and have indicated that they are moving toward permanently attaching key structural elements. The cost to manufacturers who elect to meet the requirement in this way is expected to be minimal, primarily involving additional stitching, rivets, or other methods of attachment.

As noted earlier, one manufacturer submitted a comment indicating that the new requirement will involve "reengineering, producing new molds, manufacturing a redesigned product," in addition to designing new packaging to accommodate the product. The manufacturer anticipates meeting the requirement by designing the accessory such that it is obviously unusable when key structural elements are left out. This approach is likely to be more costly than permanently attaching key structural elements because, currently, no design has been identified by manufacturers that would succeed in visibly failing when each key structural element is removed individually.

4. Alternatives

We identified two alternatives that could minimize the economic impact on small business. These are: (1) incorporating by reference ASTM F 406-12a without the bassinet misassembly requirement; and (2) providing an effective date longer than 12 months.

Incorporating by reference ASTM F 406-12a without the bassinet misassembly provision could reduce the economic impact on some firms. The reduction will be less for firms that choose to permanently attach key structural elements, and greater for firms that choose to design a product that visibly fails when each key structural element is removed. We have not chosen this alternative because we believe that the bassinet misassembly requirement is an important and necessary safety provision that will reduce the risk of infant injuries and fatalities in play yards.

Providing an effective date longer than 12 months is another alternative that could reduce the economic impact on some firms. However, the JPMA, which represents many play yard manufacturers, felt that a 12-month effective date was adequate to allow suppliers to come into compliance with the mandatory standard, including the new bassinet misassembly requirement. We agree. Therefore, we have chosen a 12-month effective date for the play yard mandatory standard.

5. Issues Raised by Public Comment

We received several comments from the public in response to the initial regulatory flexibility analysis, including comments regarding the use of market data, the impact on small businesses, and the appropriate effective date. A summary of those comments and our responses can be found in part D of this preamble, titled, "Response to Comments on the Proposed Rule."

6. Conclusion of the Final Regulatory Flexibility Analysis

We are providing a 12-month effective date, instead of a 6-month effective date as proposed in the NPR, to reduce the economic impact on small entities. This will give suppliers sufficient time to come into compliance with the new bassinet misassembly requirement, as well

as the rest of the mandatory standard. A 12-month effective date will also allow suppliers to spread the costs of coming into compliance over a longer period of time.

H. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. Our rules generally have "little or no potential for affecting the human environment" and are, therefore exempt from any requirement to prepare an environmental assessment or impact statement. 16 CFR 1021.5(c)(1). This rule falls within the categorical exemption.

I. Paperwork Reduction Act

This 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. The preamble to the proposed rule (76 FR at 58173 through 58174) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Briefly, sections 9 and 10 of ASTM F 406-12a 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).

OMB has assigned control number 3041-0152 to this information collection. We did not receive any comments regarding the information collection burden of this proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated suppliers subject to the information collection burden is now estimated to be 13 firms rather than the 9 firms initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1221.2(a)	13	3	39	1	39

There are 24 known firms supplying play yards to the U.S. market. Eleven produce play yards with labels that comply with the standard; therefore, there is no additional burden on these firms. We assume that the 13 other firms use labels on their products and packaging, but they might need to modify their existing label. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies three different models of play yards; therefore, the estimated burden associated with labels is 1 hour per model x 13 entities x 3 models per entity = 39 hours. We estimate the hourly compensation for the time required to create and update labels is $27.33. This is based on data provided by the U.S. Bureau of Labor Statistics. The information is available at: http://www.bls.gov/ncs, in the December 2011 "Employer Costs for Employee Compensation," 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 labeling requirements is $1,065.87 ($27.33 per hour x 39 hours = $1,065.87).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. § 3507(d)), we have submitted the information collection requirements of this final rule to the OMB.

J. Preemption

Section 26(a) of the Consumer Product Safety Act ("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 establish or continue in effect a requirement dealing

with the same risk of injury, unless the state's 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 the rule becomes effective.

K. Certification

Once in effect, the final rule on play yards will make it unlawful for anyone to manufacture, distribute, or import a play yard into the United States that is not in conformity with the standard. 15 U.S.C. § 2068(1). Pursuant to section 14(a)(2) of the CPSA, play yards must be certified by the manufacturer to the final standard based on testing conducted by a CPSC-accepted third party conformity assessment body. The third party testing and certification requirement for play yards will not be in effect until we issue a final notice of requirements ("NOR"). The final NOR establishes requirements for how third party conformity assessment bodies can become accepted by us to test play yards to the final rule. A proposed NOR for play yards was published in the *Federal Register* on May 24, 2012, as part of an NPR titled, "Requirements Pertaining to Third Party Conformity Assessment Bodies." 77 FR 31086. When the final rule is effective and the NOR is final, third party conformity assessment bodies can apply to us for acceptance of their accreditation to test play yards. Play yard manufacturers will be required to certify products to the final play yard rule based on third party testing once we have accepted the accreditation of such laboratories.

List of Subjects in 16 CFR Part 1221

Consumer Protection, Imports, Incorporation by Reference, Infants and Children, Labeling, Law Enforcement, Safety 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 manufactured or imported on or after **[INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

§ 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 406-12a, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards, approved on May 1, 2012. 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; http://www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 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 406-12a standard with the following additions or exclusions:

(1) In addition to complying with section 2.4 of ASTM F 406-12a, comply with the following, along with the accompanying footnote:

(i) 2.5 *Other References:* CAMI Newborn Dummy (Department of Transportation, Federal Aviation Administration, Drawing No.SA-1001). (See Fig. A1.38.)

(ii) [Reserved]

(2) Instead of complying with section 3.1.9 of ASTM F 406-12a, comply with the following:

(i) 3.1.9 *key structural elements*, n – side assemblies, end assemblies, mattress supports or stabilizing bars that create the occupant retention area, or the components that provide the supporting frame and/or means of attachment for a bassinet/cradle accessory. (See Fig. A1.39.)

(ii) [Reserved]

(3) In addition to complying with section 3.1.26 of ASTM F 406-12a, comply with the following:

(i) 3.1.27 *bassinet/cradle accessory*, n – a supported sleep surface that attaches to a non-full-size crib or play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (nonrocking) position.

(ii) [Reserved]

(4) Do not comply with section 5.17 of ASTM F 406-12a.

(5) Instead of complying with section 5.19 of ASTM F 406-12a, comply with the following:

(i) 5.19 *Bassinet/Cradle Accessories Missing Key Structural Elements*:

(ii) 5.19.1 Bassinet/cradle accessories that have all key structural elements permanently attached to the bassinet/cradle accessory, or by any permanent means prohibiting their removal from the bassinet/cradle accessory, are exempt from the following key structural element requirements. For the purpose of this section, a mattress pad without key structural elements permanently attached is not considered a key structural element.

(iii) 5.19.2 Bassinet/cradle accessories that require consumer assembly of key structural element(s), and can be assembled and attached to the product with any key structural element(s) missing, shall meet either 5.19.2.1, or 5.19.2.2 when each key structural element not permanently attached is removed. For the purpose of this section, a mattress pad without key structural elements permanently attached is not considered a key structural element.

(iv) 5.19.2.1 The bassinet/cradle accessory shall collapse such that any part of the mattress pad contacts the bottom floor of the play yard or is not be able to support the newborn CAMI dummy when tested to 8.31.

(v) 5.19.2.2 The bassinet/cradle accessory sleep surface shall tilt by more than 30 degrees when tested to 8.31.

(vi) 5.19.3 *Rationale*: The bassinet/cradle missing key structural elements requirements were included to address IDI 110825CAA2853. Bassinet or cradle accessory misassembly may not be initially visually evident to the consumer. If the accessory with omitted component(s)

supports the 7 lbm. newborn CAMI dummy without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the accessory and inadvertently place a child in danger.

(6) Do not comply with section 5.20 of ASTM F 406-12a.

(7) Do not comply with section 6, Performance Requirements for Rigid-Sided Products, of ASTM F 406-12a, in its entirety.

(8) Do not comply with sections 8.1 through 8.10.5 of ASTM F 406-12a.

(9) In addition to complying with 8.30 of ASTM F 406-12a, comply with the following:

(i) 8.31 Bassinet and Cradle Accessory Sleep Surface Collapse/Tilt

(ii) 8.31.1 Determine the number of removable (*i.e.*, not permanently attached to the accessory) key structural elements used in the assembly of the bassinet/cradle accessory and number them 1 through *n*, until all removable elements are numbered.

(iii) 8.31.2 Assemble the bassinet/cradle accessory to the product according to manufacturer's instructions.

(iv) 8.31.3 Establish a horizontal reference plane by placing an inclinometer on the floor of the testing area, and then zero the inclinometer.

(v) 8.31.4 Remove key structural element #1 used in the assembly of the bassinet/cradle accessory, and attempt to assemble the accessory back onto the product.

(vi) 8.31.4.1 If the accessory can be assembled onto the product without element #1, proceed to 8.31.5.

(vii) 8.31.4.2 If the accessory cannot be assembled onto the product without element #1, the accessory shall be considered to meet 5.19.2. Proceed to 8.31.7.

(viii) 8.31.5 Place a newborn CAMI dummy in the center of the sleep surface, oriented parallel with the longest side of the bassinet/cradle accessory. (See Fig. A1.40.) Visually determine if the bassinet/cradle accessory collapses or it no longer supports the newborn CAMI within 2 sec.

(ix) 8.31.6 If collapse does not occur, measure the sleep surface's angle of incline relative to the horizontal plane established in 8.31.3 at the location(s) most likely to meet the angle requirement in 5.19.2.2. Record this angle. (See Fig. A1.41.)

(x) 8.31.7 Replace the removed key structural element.

(xi) 8.31.8 Repeat 8.31.4 – 8.31.7 removing and replacing each key structural element (identified in 8.31.1) one at a time, starting with #2 through *n* and evaluating the resulting condition.

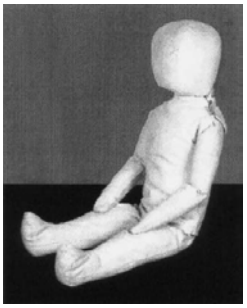
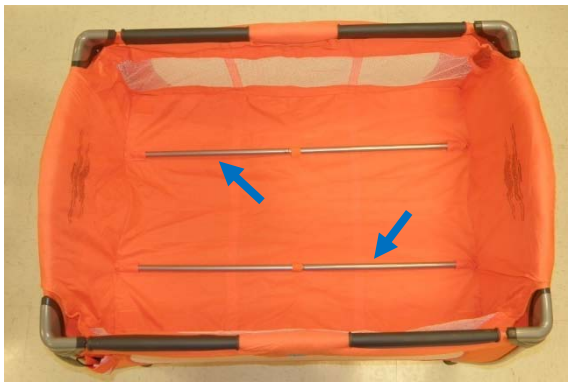


FIG. A1.38 CAMI Newborn Dummy (7.5 lb, 3.4 kg)

(a)



(b)

FIG. A1.39 Examples of bassinet/cradle accessory key structural elements: (b) mattress pad support bars and (b) accessory end panel attachment bar.

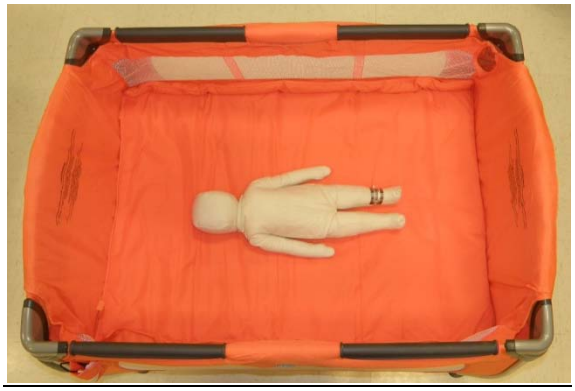


FIG. A1.40 Infant CAMI dummy positioned for bassinet/cradle accessory sleep surface test.

FIG. A1.41 Bassinet/cradle accessory sleep surface test angle measurement.

(10) Instead of complying with section 9.4.2.10 of ASTM F 406-12a, 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 406-12a.

Dated: _____.

_____
Todd A. Stevenson,
Secretary, Consumer Product Safety Commission