



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

The contents of this document will be discussed at the Commission Meeting (Briefing) tentatively scheduled for July 9, 2013.

This document has been electronically approved and signed.

DATE: June 26, 2013

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: To Be Determined

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Leah Wade, Attorney, OGC

SUBJECT: Final Rule: Amendment to Play Yard Standard

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the *Federal Register*. The final rule would amend the safety standard for play yards codified at 16 C.F.R. part 1221, by incorporating by reference, ASTM F406-13, pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options:

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

(Signature)

(Date)

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

(Signature)

(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice of Final Rule to Amend the Safety Standard for Play Yards



Staff Briefing Package

Section 104 of the Consumer Product Safety Improvement Act of 2008: Play Yard Bassinet Accessory Misassembly Final Rule

June 19, 2013

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

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically
approved and signed.

Memorandum

Date: June 19, 2013

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director – Safety Operations

FROM : Andrew G. Stadnik, P.E.
Associate Executive Director
Directorate for Laboratory Sciences

Gregory K. Rea, Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

SUBJECT : Final Rule for Play Yard Bassinet Accessory Misassembly

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (CPSC, Commission) 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 related voluntary consumer product safety standard. The Commission will then promulgate a mandatory consumer product safety standard that is substantially the same as the voluntary standard, or more stringent, if the Commission determines that a more stringent standard would further reduce the risk of injury associated with the product.

The final rule establishing a safety standard for play yards was published in the *Federal Register* on August 29, 2012.¹ The rule became effective on February 28, 2013. Also on August 29, 2012, the Commission published a notice of proposed rulemaking (NPR), seeking comment on

¹ 77 Fed. Reg. 52220.

the addition of a requirement to the play yard mandatory standard addressing the hazards associated with the use of play yard bassinet accessories that can be assembled with missing key structural elements.² Since the Commission published the play yard bassinet accessory misassembly (PYBAM) NPR, CPSC staff worked closely with the ASTM subcommittee on play yards to refine the requirement addressing this issue. The requirement, and accompanying test method, can now be found in ASTM F406-13, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, approved on May 1, 2013, and published in May 2013. Therefore, staff is recommending that the Commission incorporate by reference ASTM F406-13 (excluding the provisions of the standard that apply to non-full-size cribs).

This briefing package provides staff's responses to the comments on the PYBAM NPR, as well as staff's recommendations regarding the final rule. In addition, the briefing package presents an assessment of the possible economic impact of the staff-recommended final rule on small businesses.

II. THE PRODUCT AND HISTORY OF THE PLAY YARD MANDATORY STANDARD

ASTM F406-13 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." Play yards are intended for children who are less than 35 inches tall who cannot climb out of the product. Play yards are convenient because they usually fold for storage or travel. Some play yards include accessory items that attach to the product, including mobiles, toy bars, canopies, bassinets, and changing tables. The accessory item(s) usually attaches to the side rails or corner brackets of the play yard.

A "bassinet/cradle accessory" per ASTM F2194-13 is defined as "a supported sleep surface that attaches to a crib or play yard designed to convert the product into a bassinet/cradle intended to have a sleep surface less than or equal to 10° from horizontal while in a rest (non-rocking or swinging) position." Similarly, a "bassinet/cradle accessory" is defined in ASTM F406-13 as "an elevated sleep surface that attaches to play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (non-rocking) position." Thus, a play yard bassinet accessory is designed to convert a play yard into a bassinet. Bassinet accessories commonly consist of a textile shell with four vertical side walls and a large rectangular floor. The floor has the same dimensions as the play yard floor and has four sides

² 77 Fed. Reg. 52272.

that are about nine inches or taller.³ The floor is usually reinforced with mattress support rods to ensure a flat, stable sleep surface. The top edges of the sides are secured to the play yard top rails with any number of devices, most often plastic clips sewn on the sides of the shell. Metal rods are sometimes used, typically inserted into a sleeve on the top edge of the shell's side wall and clipped into a play yard's corner brackets.

In the *Federal Register* of September 20, 2011,⁴ the Commission published an NPR to establish a safety standard for play yards. The NPR proposed incorporating by reference ASTM F406-11, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*. Because ASTM F406 is the safety standard for non-full-size cribs as well as play yards, the NPR indicated which sections of the ASTM standard apply to play yards and excluded the provisions of ASTM F406 that apply only to non-full-size cribs.

The September 2011 NPR received a comment stating that incidents arise when products that appear to be set up correctly are actually misassembled. The comment was prompted by an incident involving the death of a child in the bassinet accessory of a play yard. In that incident, the child died while sleeping in a bassinet accessory assembled without end support rods, resulting in a dangerous tilt of the sleep surface. The child slid into the corner of the bassinet and suffocated.

In the *Federal Register* of August 29, 2012, the Commission published a final rule to establish a Safety Standard for Play Yards incorporating by reference ASTM F406-12a. On the same date, the Commission published an NPR proposing an addition to the play yard mandatory standard to address hazards associated with the use of play yard bassinet accessories that can be assembled with missing key structural elements.

III. INCIDENT DATA

The staff briefing package accompanying the original play yard NPR provided a comprehensive and detailed review of the incident data associated with play yards. The data were 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

³ ASTM F2194 requires that "the upper surface of the noncompressed mattress of a bassinet/cribble, when the mattress support is in any position, must be at least 7.5 in. (191 mm) lower than the upper surface of the lowest side in all intended bassinet/cribble use positions."

⁴ 76 Fed. Reg. 58167.

related to play yards. Additionally, the final rule briefing package detailed 41 additional incidents reported to the Commission between April 11, 2011 and December 31, 2011.⁵

Included in those 41 incidents is a report received in August 2011, regarding an infant fatality in the bassinet accessory of a play yard. The child died when the sleeping surface of the bassinet tilted, causing the child to slip into the corner, where she suffocated. A review of the In-Depth Investigation Report (IDI), 110825CAA2853, as well as staff's tests on an exemplar model of the bassinet accessory and play yard involved in the fatality, led the staff to conclude that the incident was caused by the omission of key structural elements. That incident led to the creation of the play yard bassinet accessory misassembly requirement.

Incidents related to play yards are reviewed by staff on an ongoing, weekly basis. From January 2012 through May 2013, no incidents have been received pertaining to play yard bassinet accessory misassembly.

IV. DESCRIPTION OF PYBAM, AS CONTAINED IN THE AUGUST 29, 2012 NPR

Many play yards are sold with accessories, such as bassinets, changing tables, and mobiles, that attach to the product. Play yard 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 the rods, tubes, bars, and hooks, which connect the bassinet to the play yard, keeping 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.

As mentioned above in Section III of this memorandum, in August 2011, we received a report of an infant fatality in the bassinet accessory of a play yard. As mentioned in section II of this memorandum, we received a comment to the original play yard NPR that mentioned the incident and requested that we address the hazards associated with misassembly of play yard bassinet accessories.

In the August 2011 incident, the baby was sleeping in a bassinet accessory of a play yard that employed two means of attaching the bassinet accessory to the play yard rails: (1) sewn-on clips

⁵ The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the National Electronic Injury Surveillance System (NEISS). These reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to play yards.

that attach the sides of the fabric bassinet accessory shell to the play yard rails; and (2) metal end rods that ensure that the bassinet's ends are securely attached to the play yard. A review of the IDI, as well as tests on an exemplar model of the bassinet accessory and play yard involved in the fatality, led CPSC staff to conclude that the incident was caused by the omission of metal rods that were used to secure the bassinet accessory's ends to the side of the play yard. The consumer had used the sewn-on plastic clips, but at some point, one of those clips detached. CPSC staff testing indicates that detachment of one of the plastic clips is not enough to cause the tilt in the sleeping surface that led to the fatality when the metal end rods are used. Indeed, the plastic clips caused the consumer to assume erroneously that the product was safe, when the end support rods, *i.e.*, the metal tubes that secured the ends of the bassinet accessory textile shell to the play yard frame, were missing. The baby died when the sleeping surface of the bassinet tilted, causing the child to slip into the corner of the bassinet accessory, where she suffocated.

As seen in the infant fatality report, it is possible that the omission of supporting rods initially may not 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 accessory's sleep surface tilts while the child is unsupervised, the caregiver may not discover the condition for hours, placing the child in a potentially fatal situation.

The PYBAM NPR proposed addressing this hazard by giving manufacturers two compliance options. The first option prevents misassembly by requiring that all rods, tubes, bars, and hooks be attached permanently to the bassinet shell. The second method of compliance is designed to alert consumers that a key structural element is missing, by requiring that removal of even one key structural element results in a catastrophic failure of the bassinet. Under the proposed PYBAM requirement, a catastrophic failure occurs when either the bassinet accessory shell collapses, or the sleep surface tilts by more than 30°. In this briefing package, the test for this method of compliance is referred to as the "catastrophic failure test."

Since publication of the NPR, the ASTM play yard subcommittee carefully assessed the incident that prompted this proposed requirement. The subcommittee carefully scrutinized the proposed requirement and chose for ASTM to address the bassinet accessory misassembly hazard in two different ASTM standards: the play yard standard, ASTM F406 (addresses bassinet accessory attachment components that attach the bassinet accessory to the play yard) and the bassinet standard, ASTM F2194 (addresses the mattress support rods for mattress flatness). That approach is now part of the current standards, ASTM F406-13 and F2194-13. CPSC staff believes that this approach addresses the hazards associated with play yard bassinet misassembly; therefore, staff recommends that the Commission amend CPSC's play yard standard to incorporate by reference ASTM F406-13. CPSC staff is also recommending that the Commission issue a final rule for bassinets and cradles that will incorporate by reference ASTM F2194-13. More information

about that recommendation and standard can be found in the bassinet and cradle final rule briefing package, dated June 26, 2013.

Staff recommends that the Commission publish a final rule that would revise the current CPSC standard for play yards to incorporate by reference the most recent version of ASTM's play yard standard, ASTM F406-13. The staff believes that ASTM F406-13, along with a standard for bassinets and cradles that incorporates by reference ASTM F2194-13, will address the hazards identified in the PYBAM NPR.

V. STAFF'S RECOMMENDATIONS

The work on the PYBAM began after the misassembly comment was submitted to the original play yard NPR. Staff worked with the ASTM play yard subcommittee from January 2012 through April 2012, to develop the language that was eventually contained in the PYBAM NPR. After the August 2012 publication of the PYBAM NPR, staff continued to work with the ASTM subcommittee on play yards through early 2013, to help ASTM develop language to address this hazard in ASTM's standard.

The result of this effort is the language, presented below, published in ASTM F406-13. The language in ASTM's standard is different from the PYBAM NPR in two substantive respects. .

First, in the PYBAM NPR, key structural elements, which had to be attached permanently or were subject to the catastrophic failure test, included all rods, tubes, bars, and hooks that supported or were used in assembling the bassinet accessory. Not only did key structural elements, as defined in the PYBAM NPR include the rods, tubes, bars, and hooks that function to connect the bassinet to the play yard, but it also encompassed the mattress support rods that support the bassinet accessory's mattress and keep the mattress flat.

When the play yard bassinet misassembly provision was added to F406, the play yard subcommittee intentionally excluded play yard bassinet accessory mattress support rods from the misassembly performance requirement because the hazard posed by a non-flat bassinet mattress is best addressed in the bassinet voluntary standard, ASTM F2194. As previously mentioned, this standard is currently the focus of another CPSIA section 104 rulemaking project. The ASTM subcommittees for play yards and bassinets coordinated their respective standards so that this hazard is now addressed in ASTM F2194-13, which was, published in April 2013. Thus, the requirement in the ASTM F406-13 play yard bassinet misassembly provision now covers only "accessory attachment components" of bassinet accessories. The staff recommends that the CPSC standards for play yards and bassinets/cradles reflect the approach that ASTM is taking.

The second substantive difference between the ASTM play yard standard and the PYBAM NPR is the replacement of the 7.5 pound newborn CAMI dummy in the catastrophic failure test with a four-pound test mass. This mass represents the mass of the smallest newborn known to staff that would be released from a hospital. This allows the PYBAM requirement to cover all expected play yard bassinet accessory occupants. Using a smaller test mass makes the PYBAM provision in ASTM F406-13 more severe than the provision the Commission proposed in the PYBAM NPR.

The language published in ASTM F406-13 is:

New definitions:

3.1.2 *accessory attachment components, n*—the components that provide the means of attachment for a bassinet/cradle accessory to a play yard. (See Fig. A1.1.)



Figure A1.1. Example of bassinet/cradle accessory attachment component.

3.1.3 *bassinet/cradle accessory, n*—an elevated sleep surface that attaches to a(?) play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (non-rocking) position.

New general requirement:

5.19 *Bassinet/Cradle Accessories - Missing Accessory Attachment Components:*

5.19.1 Bassinet/cradle accessories that have all accessory attachment components permanently attached to the bassinet/cradle accessory, or by any permanent means prohibiting their removal from the bassinet/cradle accessory, are exempt from the requirements in 5.19.2.

5.19.2 Bassinet/cradle accessories which require consumer assembly of accessory attachment component(s), and that can be assembled and attached to the product with any

accessory attachment component(s) missing, shall meet either 5.19.2.1 or 5.19.2.2 when each accessory attachment component not permanently attached is removed.

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 4.0 lbm test mass when tested to 8.31.

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

Rationale: The Bassinet/cradle missing accessory attachment components requirements were included to address ID1110825CAA2853 involving a bassinet accessory used in a play yard where accessory attachment components were omitted during the assembly, installation and use of the bassinet accessory. The omission of such critical components may result in a hazardous condition. The requirement allows for visual cues for the bassinet accessory during testing including collapse or surface tilt of at least 30.° These requirements were considered obvious cues to the consumer to indicate that the product is not assembled or installed correctly. Children weighing less than 4 lb are typically not released from the hospital consequently the 4-lb mass is based on the minimum expected weight of the youngest occupant.

New test procedure:

8.31 Bassinet and Cradle Accessory - Sleep Surface Collapse/Tilt:

8.31.1 *Equipment* One 4.0-lbm (1.8 kg) test mass made from an aluminum bar with dimensions 1 by 4 by 10.25 in. (25 by 101 by 260 mm).

8.31.2 Determine the number of removable (that is, not permanently attached to the accessory) accessory attachment components used in the assembly of the bassinet/cradle accessory and number them 1 through *n*, until all removable elements are numbered.

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

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

8.31.5 Remove accessory attachment component #1 used in the assembly of the bassinet/cradle accessory and attempt to assemble the accessory back onto the product.

8.31.5.1 If the accessory can be assembled onto the product without element #1, proceed to 8.31.6.

8.31.5.2 If the accessory cannot be assembled onto the product without element #1, the accessory shall be considered to meet 5.19.2. Proceed to 8.31.8.

8.31.6 Place the 4.0-lbm (1.8-kg) test mass in the center of the sleep surface, oriented parallel with the longest side of the bassinet/cradle accessory (see Fig. A1.39). Visually determine if the bassinet/cradle accessory collapses or it no longer supports the test mass within 2 s.



Figure A1.39. Test mass positioned for bassinet/cradle accessory sleep surface test.

8.31.7 If collapse does not occur, measure the sleep surface's angle of incline relative to the horizontal plane established in 8.31.4 at the location(s) most likely to meet the angle requirement in 5.19.2.2. Record this angle (see Fig. A1.40).



Figure A1.40. Bassinet/cradle accessory sleep surface test angle measurement.

8.31.8 Replace the removed accessory attachment component.

8.31.9 Repeat 8.31.5-8.31.8 removing and replacing each accessory attachment component (identified in 8.31.2) one at a time, starting with #2 through n and evaluating the resulting condition.

In conclusion, staff recommends that the Commission incorporate by reference ASTM F406-13 as the play yard mandatory standard.

VI. EFFECTIVE DATE

The PYBAM NPR proposed a six-month effective date for the play yard standard, and requested comments on the impact of such an effective date. We received several comments regarding when the mandatory standard should become effective. The suggested effective dates included one, three and six months. Staff considered each comment that addressed the issue. However, none of the comments provided adequate justification to deviate from the standard six-month effective date that the Commission has used for other durable infant and toddler products.⁶ Therefore, staff recommends a six-month effective date for the play yard standard.

VII. ASSESSMENT OF IMPACT ON SMALL ENTITIES (TAB A)

Play yards are typically produced and/or marketed by juvenile product manufacturers and distributors. CPSC staff estimates that there are currently at least 26 firms supplying play yards to the U.S. market. However, only 15 of those firms currently supply at least one play yard to the U.S. market that includes a bassinet accessory. Based on U.S. Small Business Administration guidelines, eight are small firms—five domestic manufacturers and three domestic importers—likely to be affected by the bassinet accessory misassembly requirement, as described in the Directorate for Economic Analysis memo (Tab A).

Staff expects that any newly manufactured or imported play yards will comply with the current mandatory play yard safety standard, therefore only the effect of the bassinet accessory misassembly requirement needs to be assessed. The play yards of all but one firm currently meet the bassinet misassembly requirements recommended by CPSC staff, and the remaining firm has compliant play yards under development. Therefore, the staff-recommended requirements are not expected to have a significant impact on a substantial number of small entities, and the Commission could certify to that effect.

VIII. STAFF RESPONSES TO PUBLIC COMMENTS (TABS A & B)

The preamble to the August 2012 PYBAM NPR invited comments concerning all aspects of the proposed rule. Thirteen comments were received from various individuals or organizations. Table 1 lists the commenters and comment numbers. For a full copy of all comments visit: www.regulations.gov, and review Public Submissions 0031 through 0043 for Docket No. CPSC-2011-0064.

⁶ See Tab A Section V “ISSUES RAISED BY PUBLIC COMMENTS.”

Table 1: Public Comments to Play Yard Bassinet Accessory Misassembly Proposed Rule
(Docket No. CPSC-2011-0064-0030)

| Docket #: CPSC-2011-0064 | | |
|--------------------------|-----------------|--|
| Comment # | Name | Organization/Affiliation |
| 1 | Robert Coughlin | Kids II, Inc. |
| 2 | Mo Anooshah | Kolkraft Enterprises |
| 3 | Katalina Meyer | (no affiliation given) |
| 4 | Sharon Forshpan | Arm's Reach Concepts, Inc. |
| 5 | Sharon Forshpan | Arm's Reach Concepts, Inc. |
| 6 | Sharon Forshpan | Arm's Reach Concepts, Inc. |
| 7 | Bob Farley | (no affiliation given) |
| 8 | Fletcher Smith | (no affiliation given) |
| 9 | Nancy Cowles | Joint comment from Kids In Danger, Consumers Union, Consumer Federation of America, Consumer Reports, and Public Citizen |
| 10 | Lisa Madigan | Office of the Illinois Attorney General |
| 11 | Mark Fellin | Juvenile Products Manufacturers Association (JPMA) |
| 12 | Julie Wilson | University of Arizona law student |
| 13 | Wang Lizhou | China, AQSIQ, Peoples Republic of China* |

*Supporting and related material document CPSC-2011-0064-0044.

The comments regarding economic impact and the effective date are addressed in Tab A of this briefing package. Technical comments regarding the proposed rule and the ASTM standards are addressed in Tab B, as are comments that involved legal issues and all other general comments.

Many comments supported the proposed rule, including the proposed modifications to the ASTM standard. The comments raised 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 A, Appendix A)

1. Cost of Bassinet Misassembly Requirement (Comment 6)
2. Effective date (Comments 3, 9, 10 & 12)

Technical Comments (Tab B)

1. Coordination between the play yard and the bassinet standard (Comments 1, 2, 4, 5 & 11)
2. Clarity of "Key Structural Element" definition (Comment 2)
3. Redundant product safety features (Comment 11)
4. Other options for compliance (Comment 11)
5. Catastrophic failure test and the test mass size, use, and location (Comments 3 & 12)
6. Catastrophic failure test and the basis for the 30° mattress angle requirement (Comments 11, 12 & 13)

Legal and Other General Comments (Tab B)

7. Generally unresponsive (Comment 5, 6, 7 & 8)

8. Generally supportive (Comments 9, 10 & 12)
9. Catastrophic failure test is confusing or is arbitrary and capricious (Comments 3 & 12)
10. Ability to Launder (Comment 4)
11. Concern that patent-only technology may be required (Comment 11)
12. International Harmonization/Impact on Trade (Comment 13)
13. Deference to ASTM Standard (Comment 11)

IX. STAFF FINAL RULE RECOMMENDATIONS

CPSC staff recommends that the Commission publish a final rule, as drafted by the Office of the General Counsel. This draft final rule incorporates by reference the play yard-specific portions of voluntary standard, ASTM F406-13, *Standard Consumer Safety Specification for Non-Full-Size Cribs/Play Yards*, without modification. ASTM F406-13 now includes the PYBAM language discussed in section V of this memorandum. CPSC staff also recommends an effective date of six months after publication of the final rule.

TAB A:

Review of the Potential Impact on Small Entities from the Staff-Recommended Bassinet Misassembly Amendment to the Play Yard Standard



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: May 8, 2013

TO : Gregory K. Rea
Project Manager, Play Yards
Director, Division of Mechanical Engineering
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 : Review of Potential Impact on Small Entities from the Staff-Recommended
Bassinets Misassembly Amendment to the Play Yard Standard

I. INTRODUCTION

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, the Danny Keysar Child Product Safety Notification Act, 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 the applicable voluntary standard, or more stringent than the voluntary standard if the Commission determines that more stringent standards would further reduce the risk of injury. Play yards are among the durable products specifically named in section 104.

On August 29, 2012, the Commission published a final rule for play yards in the *Federal Register* (FR) (77 FR 52220), as well as a notice of proposed rulemaking (NPR) for play yards (77 FR 52272). The NPR proposed to amend the final play yard rule to address hazards associated with play yard bassinets accessories that can be assembled with missing key structural elements. Since then, ASTM and CPSC staff have continued to refine the bassinet misassembly requirements. Staff recommends amending the play yard standard to incorporate by reference

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the recently published ASTM standard, ASTM F406-13, which includes requirements that address play yard bassinet misassembly.

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 agency promulgates a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. CPSC staff has reviewed the potential impact of the rule and concludes that the rule is not expected to have a significant impact on a substantial number of small entities, which would allow the Commission to certify. This memo provides the factual basis for that conclusion.

II. THE PRODUCT⁷

Play yards, also known as playpens, are made of mesh- or fabric- sided 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 final rule. Those accessories would need to comply with the relevant ASTM standard as well (*i.e.*, bassinet accessories 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.

III. 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 26 firms supplying play yards to the U.S. market. However, not all of these suppliers market play yards with bassinet accessories that would be affected by the staff-recommended play yard bassinet misassembly requirements. Of the 26 firms supplying play yards to the U.S. market, 11 do not currently supply any with bassinet accessories. The remaining 15 firms supply at least one play yard to the U.S. market that includes a bassinet accessory: 13 are domestic manufacturers or importers; one

⁷ ASTM F406-13.

is a foreign manufacturer; and one is a foreign importer that imports from a foreign company and distributes from outside of the United States.⁸

The CPSC safety standard for play yards, which incorporates the relevant sections of ASTM F406-12a by reference, went into effect on February 28, 2013. Staff expects that all play yards manufactured or imported on or after this date will meet the CPSC play yard safety standard, including the sections of ASTM F406-12a applicable to play yards.

Play yards are generally used for the first year or two of a child's life. When children are very young, they are typically placed in the bassinet attachment; they are moved to the play yard once they are able to roll over onto their hands and knees. There is no upper age limit recommended for use of a play yard, but parents are advised to stop using the product once children can climb out; this generally occurs once they reach around 35 inches in height.

National injury estimates are not available for play yard bassinet accessories. Separate injury estimates are also not available for play yards with and without bassinet accessories or for injuries that occur due to the misassembly of those accessories. Therefore, staff cannot provide estimates of the risk of injury that would be addressed by the bassinet accessory misassembly requirements under consideration.

IV. REQUIREMENTS OF THE STAFF-RECOMMENDED FINAL RULE

CPSC staff recommends incorporating by reference ASTM F406-13, which now includes language to address the hazards associated with play yard bassinet accessory misassembly. Under the staff-recommended requirements, bassinet/cradle accessories must either:

1. have all accessory attachment components permanently attached to the accessory; or
2. be obviously unusable when attached to the play yard with any accessory attachment components removed.

The bassinet could be obviously unusable because it: (a) collapses so that some part of the mattress pad contacts the floor of the play yard; or (b) is unable to support a test mass (4 lbm) representing the minimum expected weight of the youngest occupant. There are no reporting or recordkeeping requirements associated with this staff-recommended change to the play yard safety standard.

⁸ Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites. Since the August 2012 NPR, several firms have stopped or started supplying play yards to the U.S. market.

Currently, all but one of the 15 known firms supplying play yards with bassinet attachments have accessory attachment components permanently attached to their bassinet accessories. Therefore, there is only one known firm that may be affected by the staff-recommended requirement. That firm has already started developing a design that permanently attaches all accessory attachment components.

V. ISSUES RAISED BY PUBLIC COMMENTS

There were two issues raised by public comments in response to the initial regulatory flexibility analysis presented in the NPR. The first concerned the appropriate effective date. One commenter supported the six-month effective date, while two others felt that the period until effectiveness should be shorter. Because the majority of play yard bassinets already meet the staff-recommended final rule (and compliance activities are available to remove any unsafe play yards that remain), staff believes that six months is an appropriate effective date. This would facilitate the ability of the remaining non-compliant firms to come into compliance or secure alternate sources of supply versus a shorter effective date.

The second issue raised by public comments was the costs associated with meeting the bassinet misassembly requirements. Specifically, one commenter believed that the misassembly requirements as presented in the NPR would be costly to meet and felt that additional research was needed. Since the August 2012 proposal, CPSC staff and ASTM have worked together on language that would address the hazard. The additional work, published by ASTM as part of F406-13, has reduced the expected costs, and all suppliers are expected to soon be in compliance with the standard. The staff recommends that the final rule incorporate ASTM F406-13 by reference.

VI. IMPACT ON SMALL BUSINESSES

There are approximately 15 firms currently known to be marketing play yards with bassinet accessories 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 importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, about eight are small firms—five domestic manufacturers and three domestic importers. There may be additional unknown small play yard suppliers operating in the U.S. market whose products include bassinet accessories.

Staff expects that any newly manufactured or imported play yards will comply with the current mandatory play yard safety standard that became effective on February 28, 2013. The only new

requirement is for bassinet accessory misassembly and the play yards of all but one firm currently meet the bassinet misassembly requirements recommended by CPSC staff, and the remaining firm has compliant play yards under development. Therefore, the staff-recommended final rule is not expected to have a significant impact on a substantial number of small entities, and the Commission could certify to that effect.

TAB B:

Staff Responses to Technical, Legal, and General Comments on
the Notice of Proposed Rulemaking for Play Yard Bassinet
Accessory Misassembly



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

This document has been electronically
approved and signed.

Memorandum

Date: June 3, 2013

TO: The Commission
Todd A. Stevenson, Secretary

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

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

FROM : Gregory K. Rea, Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

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

SUBJECT : Staff Responses to Comments on the Notice of Proposed Rulemaking for Play
Yard Bassinet Accessory Misassembly

I. INTRODUCTION

This memorandum provides a summary of the comments received on the notice of proposed rulemaking (NPR), which proposed amending the play yard mandatory safety standard to include the play yard bassinet accessory misassembly (PYBAM) requirement.

The preamble to the NPR invited comments concerning all aspects of the proposed rule. We received 13 comments from various individuals or organizations. All of the comments can be viewed on: www.regulations.gov, by searching under the docket number for this rulemaking, CPSC-2011-0064, and then searching under ID: CPSC-2011-0064-0030.

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

II. STAFF’S RESPONSES TO COMMENTS

A. Technical Comments

1. Coordination between the play yard and the bassinet standards (Comments 1, 2, 4, 5 & 11)

Comment – Five comments discussed the overlap between the mattress flatness requirement being developed for inclusion in ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*, and the proposed PYBAM requirements. The commenters stated that the PYBAM, as published in the August 2012 NPR, contained requirements that are more appropriately addressed in the bassinet surface flatness requirement contained in the bassinet voluntary standard.

Staff Response – Staff on the CPSC PYBAM and Bassinet/Cradle rulemaking teams agree with these comments. The commenters’ primary concern was that the proposed PYBAM requirement applied to all play yard bassinet accessory key structural elements, including the mattress support rods. A joint PYBAM and Bassinet ASTM task group teleconference was held on November 11, 2012. Members of both task groups agreed to focus the PYBAM requirement in the ASTM play yard standard on the systems that attach the bassinet accessory to the play yard. Concurrently, the ASTM bassinet task group sought to address any issues related to misassembly of the mattress support rods in the bassinet voluntary standard. In this manner, all misassembly issues associated with play yard bassinet accessory installation would be addressed in the appropriate voluntary standard.

2. Clarity of “Key Structural Element” definition (Comment 2)

Comment – One commenter asked that the definition of “key structural element” be clarified. Specifically, the commenter wished to know if the following are key structural elements: (1) clips sewed to the play yard bassinet accessory shell, and (2) metal bars that provide support for the bassinet mattress.

Staff Response – The ASTM subcommittee developed a different definition of “key structural element” than the one the Commission proposed in the PYBAM NPR to address this issue. Staff supports this change. The language published in ASTM F406-13, which now limits the scope of PYBAM requirement, is:

3.1.2 *accessory attachment components, n*—the components that provide the means of attachment for a bassinet/cradle accessory to a play yard.

Thus, clips sewn to the play yard bassinet accessory shell that attach the bassinet accessory to the play yard are accessory attachment components. Metal bars that provide support to the bassinet accessory mattress, and that do not serve to attach the bassinet accessory to the play yard, are not accessory attachment components, and, thus, are not subject to the PYBAM requirement contained in ASTM F406-13. The draft final rule incorporates ASTM F406-13 by reference.

3. Redundant product safety features (Comment 11)

Comment – One commenter stated that the PYBAM NPR requirement “may compel manufacturers [. . .] to eliminate redundant safety features that are already a component of the product.” The commenter used mattress support rods as an example of a structure that is not necessary to comply with the voluntary standard but does improve product safety by helping to create a “flatter and more stable sleeping position.” The commenter concluded that the added cost of being required to permanently affix redundant structures would lead to the structures being eliminated to avoid this cost, resulting in compliant but less safe products being sold.

Staff Response – ASTM stakeholders involved in both PYBAM and bassinet voluntary standard development, addressed the issue of mattress support rod misassembly in ASTM F406-13 and ASTM F2194-13. The PYBAM requirement in ASTM F406-13 is no longer applicable to mattress support rods. ASTM F2194-13, meanwhile, does not require redundant mattress support rods, *i.e.*, those that are not required to be installed to meet the mattress flatness requirement, to be attached permanently to the play yard bassinet accessory, if the accessory passes the bassinet mattress flatness test when the mattress support rods are removed.

4. Other options for compliance (Comment 11)

Comment – The commenter asked that a third option for compliance be considered in addition to the two already proposed in the PYBAM NPR. (The first two options are permanently attaching all key structural elements and passing the catastrophic failure test.) The third option the commenter proposed is to remove all key structural elements and if the product continues to meet the requirements of ASTM F406, it also meets the PYBAM requirements.

Staff Response – Staff agrees with the approach that ASTM takes in its bassinet standard, ASTM F2194-13 as applied to mattress support rods. ASTM F2194-13 requires non-redundant mattress support rods to be permanently attached. If the mattress support rods are not permanently attached, the bassinet must be tested pursuant to the mattress flatness tests contained in ASTM F2194-13 without the rods in place. If the product passes the mattress flatness test, even without the mattress support rods in place, the product meets the requirements.

Staff does not agree, however, that the approach taken by the ASTM F2194-13 to address mattress support rod misassembly should be an option for accessory attachment components meant to attach the bassinet accessory to the play yard rails. In the fatal incident, one of the accessory attachment components, the end support rods, were omitted, and only the plastic clips were used. The fatality resulted when the caregiver assumed that the product was safe because there were no visually obvious cues that it was unsafe. Therefore, for accessory attachment components, staff feels that the accessory attachment components should be either permanently attached or pass the catastrophic failure test by obviously failing when an accessory attachment component is missing.

5. Catastrophic failure test and the test mass size, use, and location (Comments 3 & 12)

Comment – One commenter questioned the use of the newborn CAMI dummy weighing 7.5 pounds, as proposed in the PYBAM NPR. The commenter ultimately questioned the use of a test mass at all, hypothesizing that the requirement could be more severe if no test mass were used. Another commenter recommended that the CPSC consider a lighter test mass so that a greater proportion of the newborn population will be covered by the PYBAM requirement.

Staff Response – Staff agrees that the mass of the newborn CAMI dummy is too heavy. Staff developed a new 4.0-pound test mass and presented it to the ASTM PYBAM task group for review after the commission published the NPR. As stated in the ASTM F406-13 section 5.19 rationale, this mass represents the weight of the smallest newborn known to staff that would be released from a hospital. Using the smallest reasonable mass makes the published ASTM PYBAM requirement more severe. Eliminating the test mass entirely from the test procedure would be unnecessarily restrictive.

6. Catastrophic failure test and the basis for the 30° mattress angle requirement (Comments 11, 12 & 13)

Comment – Several commenters objected to the 30° tilt requirement in the catastrophic failure test. Many commenters felt that the requirement is not adequately supported by scientific data.

Staff Response – The angle of 30° represents a safety factor of three times the 10° maximum safe sleep surface angle of incline. CPSC 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. Staff then recommended that the ASTM PYBAM task group review and critique the 30° angle. ASTM stakeholders agreed with staff that 30° was reasonable and would be considered by caregivers to be obviously hazardous. This angle requirement has since been published in ASTM F406-13. CPSC staff will revisit the magnitude

of the tilt angle requirement should empirical evidence be presented to staff or ASTM stakeholders that the angle is too small or large.

B. Legal and Other General Comments

7. Generally unresponsive (Comments 5, 6, 7 & 8)

Comment – Two commenters indicated that they generally do not support the requirement. Both commenters felt that the regulation was unnecessary because the hazard was caused by misassembly of the product.

Staff Response – The CPSIA requires that the Commission promulgate mandatory regulations for durable infant and toddler products, including play yards, that are substantially the same as an existing voluntary standard, or more stringent than a voluntary standard if the Commission determines that more stringent standards would reduce the risk of injury. In this case, the CPSC believes that this requirement is appropriate to reduce the risk of injury. Therefore, the issuance of this final rule fulfills a statutory mandate given to the CPSC by Congress.

In addition, the staff disagrees with the assertion that hazards caused by misassembly should not be addressed through mandatory regulations. The CPSC is often faced with hazardous risks that result from the reasonably foreseeable use of consumer products. Preventing the possibility of misassembly is especially critical when the product in question has been designed to provide a safe sleep environment for an infant, and when the result of misassembly could be severe, such as an infant fatality. It is reasonable for the CPSC to assess whether there are solutions that would minimize the possibility of misassembly. One solution could be to improve assembly instructions or warning labels. Another solution, and the one that has been chosen here, is to require products that must be assembled by consumers to be designed in such a way that they are very difficult to misassemble.

Comment – One commenter expressed a number of concerns about the new requirement. Specifically, the commenter felt that the requirement: (1) does not completely address the hazards that caused the infant fatality; (2) was created too quickly and that the process was rushed; (3) is design restrictive; and (4) will fail safe products.

Staff Response – The bassinet misassembly performance requirement and test method were fine-tuned for more than a year, from January 2012 through April 2013. Significant changes were made so that the requirement would address the hazard in the least burdensome manner. Notably, the PYBAM scope in ASTM F406-13 has been reduced by narrowing the safety requirement's focus from all key structural elements to just accessory attachment components. The requirement was created and approved by members of the ASTM subcommittee, which

includes many play yard importers and manufacturers, as well as other stakeholders, such as retailers, testing laboratories, independent consultants, representatives from consumer advocacy groups, representatives from Health Canada, and CPSC staff.

The creation of any ASTM standard involves analyzing CPSC incident data in detail, assessing other standards (including international standards), and performing tests to validate new test procedures. The fatality was reviewed in detail, and the requirement was crafted to address the specific circumstances that resulted in the death.

To provide manufacturers with options, and to avoid creating a design-restrictive standard, two methods of compliance were provided – a manufacturer can attach permanently all accessory attachment components or design a product that passes the catastrophic failure test. Finally, if the standard is found to be too severe and is failing safe products, it can be updated as more data is received by the CPSC and the ASTM committee.

8. Generally supportive (Comments 9, 10 & 12)

Comment – Several commenters supported the new requirement. One commenter noted: “(o)ur organizations strongly support these specific requirements and test methods as well as the general principle that misassembly is a design safety issue and should be adequately addressed in product safety standards.” Another commenter indicated: “(w)hile I strongly support and would prefer to see all key structural elements permanently attached to the bassinet accessory, the catastrophic failure test provides an option for manufacturers to come into compliance and appears to address the hazards associated with play yard bassinet accessories.” Commenter 12 expressed “overall support” for the requirement and noted: “(o)ne infant death is too many, and the CPSC has acted quickly to develop a new safety standard for bassinet accessories.”

Staff Response – Staff agrees with the commenters.

9. Catastrophic failure test is confusing or is arbitrary and capricious (Comments 3 & 12)

Comment – One commenter indicated that it would be easier and cause less confusion if the provision simply required that all key structural elements be attached permanently to the bassinet accessory, instead of giving manufacturers the option of complying with the catastrophic failure test. Another commenter indicated that the permanent affixture test should be the only method of complying with the requirement and noted that the catastrophic failure test (CFT) is not the least burdensome requirement and violates the Administrative Procedure Act because it is arbitrary and capricious.

Staff Response – The catastrophic failure test can appear confusing and counterintuitive because, to pass the test, the product must fail catastrophically when one piece is missing. However, this test was thoroughly vetted during the ASTM process. These stakeholders felt that the test is a sound alternative to permanently attaching all accessory attachment components. In fact, staff’s initial proposal to ASTM stakeholders in spring 2012 was to require all key structural elements to be attached permanently. The catastrophic failure option was added at the request of manufacturers’ representatives on the ASTM PYBAM task group. However, as the requirement goes into effect, should issues arise when a firm attempts to meet the requirement using the CFT, ASTM and the CPSC will monitor those issues and address them as necessary.

Additionally, the CFT is an alternative to the permanent affixture test. While the CPSC staff does not feel that the permanent affixture test is design restrictive, it is important to provide alternatives for compliance so that products with drastically different designs are able to meet the requirement.

10. Ability to launder (Comment 4)

Comment – One commenter indicated that permanently affixing key structural elements to the product may interfere with the ability to launder the product. The commenter is specifically concerned about the metal rods that support a bassinet accessory mattress. If the metal rods were required to be affixed permanently to the liner, it would be difficult to clean.

Staff Response – Although CPSC’s primary concern is that play yards and bassinet accessories are safe, the CPSC does consider practical issues, such as the ability to launder when we consider new requirements. Commenter 4’s specific concern regarding the ability to launder a bassinet accessory shell that is supported by metal support rods is no longer addressed by the PYBAM requirement because it no longer applies to mattress support rods. Instead, PYBAM focuses only on accessory attachment components that attach the bassinet accessory to the play yard.

The bassinet standard also does not require that the metal rods be permanently attached to the liner. If the product passes the mattress flatness test contained in the bassinet standard with the mattress support rods removed, the mattress support rods do not need to be permanently attached. Also, the mattress support rods could be permanently attached to the underside of the mattress board, which is a component that does not go into a washing machine. In addition, manufacturers have the option of stiffening the mattress and the liner so that support rods are not needed.

11. Concern that patent-only technology may be required (Comment 11)

Comment – One commenter indicated that there is a patent application pending, detailing 10 different methods to “stiffen a play yard mattress pad before it is used in a play yard bassinet accessory.” The commenter acknowledged that “there may not be any products on the market today that would be impacted by this patent application” but indicated that the CPSC should “evaluate this issue and avoid design restrictions that limit marketplace competition.”

Staff Response – The concern regarding how a firm stiffens a mattress pad is no longer an issue addressable by the PYBAM requirement because it no longer applies to mattress support rods or any other methods of stiffening a mattress pad. Instead, it only focuses on accessory attachment components that attach the bassinet accessory to the play yard. The bassinet standard does not require that a specific design be used in order to pass the standard. There are different ways outside of the scope of the patent in which the bassinet mattress flatness test can be met.

12. International harmonization/impact on trade (Comment 13)

Comment – One commenter expressed concerns that the requirement could impact trade agreements and emphasized the importance of international standard harmonization.

Staff Response – When drafting the NPR for the play yard mandatory standard, staff 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 the Commission adopts part or all of one of the standards listed here, we still would not have complete international harmonization. Staff is aware of the utility of having harmonized standards in a global marketplace, and continues to strive to achieve this harmonization whenever practicable. Notably, no other standard addresses the risk of play yard bassinet accessory misassembly. However, staff will continue to monitor the effects that our standards have on international standards.

13. Deference to ASTM standard (Comment 11)

Comment – Commenter 11 requests that staff defer to the ASTM standard.

Staff Response – Under section 104 of the CPSIA, the Commission must establish a mandatory standard for play yards and cannot defer to a voluntary standard. However, the CPSC is incorporating the current ASTM standard, ASTM F406-13, by reference.

TAB C:

Federal Register Notice of Final Rulemaking to Amend
the 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: The United States Consumer Product Safety Commission (Commission or CPSC or we) is issuing a final rule, amending the play yard mandatory standard codified at 16 CFR part 1221. Currently, the CPSC play yard standard incorporates by reference ASTM F406-12a, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*. In this final rule, the Commission is amending the play yard standard to incorporate by reference the most recent version of ASTM's play yard standard, ASTM F406-13. Through this amendment, the Commission is addressing hazards associated with misassembly of play yard bassinet accessories.

DATES: This rule will become effective on **[INSERT DATE 6 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 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: Justin Jirgl, Compliance Officer,
Office of Compliance and Field Investigations, U.S. Consumer Product Safety
Commission, 4330 East West Highway, Bethesda, MD 20814; e-mail: jjirgl@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

On August 29, 2012, the Commission published a final rule establishing a CPSC safety standard for play yards. 77 FR 52220. On the same date, the Commission published a notice of proposed rulemaking (NPR), seeking comments on the addition of a requirement to the play yard mandatory standard to address the hazards associated with play yard bassinet accessories that can be assembled without key structural elements. 77 FR 52272. The NPR was prompted by the death of an infant in a play yard bassinet accessory, in which the end support rods, which attached two of the bassinet accessory's four sides to the play yard rails, were omitted during assembly. The other two sides were attached with plastic clips. After the infant was left to sleep, one of the plastic clips that attached the bassinet accessory to the play yard detached. Because the support rods were not in place to secure the bassinet accessory, the bassinet sleep surface tilted, and the infant slid into the corner of the tilted bassinet accessory and suffocated.

In the August 2012 NPR, we proposed a provision that would require that all “key structural elements” be permanently attached to the bassinet accessory or pass the “catastrophic failure test,” which is described in more detail in section D of this preamble. In the August 2012 NPR, the term “key structural elements” included all structures that attach the bassinet accessory to the play yard, as well as all structures that

reinforce the bassinet accessory mattress by keeping it flat and stable, such as the mattress support rods.

Since publication of the August 2012 NPR, the ASTM play yard subcommittee carefully assessed the incident that prompted this requirement. The subcommittee worked closely with the ASTM bassinet/cradle subcommittee and chose to address the hazards associated with bassinet accessory misassembly in two different ASTM standards: (1) the play yard standard, ASTM F406-13, now addresses safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard); and (2) the bassinet standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, addresses safety issues related to mattress support rods (and all other structures that ensure that the bassinet accessory mattress is flat and stable) through the segmented mattress flatness test contained in the bassinet standard. That approach is now part of the current ASTM standard for play yards, ASTM F406-13, and for bassinets, ASTM F2194-13. Likewise, the Commission is following this approach in the CPSC standard for play yards and in the CPSC standard for bassinets and cradles. The Commission believes that this approach addresses the hazards known to CPSC staff associated with play yard bassinet misassembly.

B. The Product

ASTM F406-13 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 and who cannot climb out of the product. Some

play yards include accessory items that attach to the product, such as mobiles, toy bars, canopies, bassinets, and changing tables. The accessory item usually attaches to the side rails or corner brackets of the play yard.

A “bassinet/cradle accessory” is defined in ASTM F406-13 as “an elevated sleep surface that attaches to a play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (non-rocking) position.” Play yard bassinet accessories commonly consist of a textile shell that provides an elevated sleep surface within the play yard. The floor of the bassinet accessory is typically the same dimensions as the play yard floor. Usually, the segmented mattress pad that is used on the floor of the play yard is inserted into the bassinet shell. The floor of the bassinet accessory is typically reinforced with mattress support rods to ensure a flat, stable sleep surface. The top edges of the sides of the bassinet accessory can be secured to the play yard top rails with any number of devices, but most often is done through plastic clips sewn onto the sides of the shell. Metal rods may also be used to secure the bassinet to the play yard. These metal rods are usually inserted into a sleeve on the top edge of the shell’s side wall and clipped into a play yard’s corner brackets.

C. History of the Play Yard Mandatory Standard

In the *Federal Register* of September 20, 2011 (76 FR 58167), the Commission published an NPR to establish a safety standard for play yards. The NPR proposed incorporating by reference ASTM F406-11. It is important to note that ASTM F406 is the safety standard for both non-full-size cribs and play yards. The NPR for play yards indicated which sections of the ASTM standard would apply to play yards and excluded from CPSC’s play yard standard the provisions of ASTM F406 that apply to non-full-size

cribs. After publication of the 2011 NPR, CPSC staff became aware of an incident, mentioned in section A of this preamble and described in more detail in section D of this preamble, where an infant died while sleeping in a play yard bassinet accessory that had been assembled without end supports. The Commission received a comment to the 2011 NPR requesting that we address play yard bassinet accessory misassembly.

On August 29, 2012, the Commission published a final rule to establish a safety standard for play yards that incorporated by reference ASTM F406-12a. 77 FR 52220. The final rule did not address the hazards associated with the use of play yard bassinet accessories that can be assembled missing key structural elements. On the same date, the Commission published an NPR proposing an addition to the play yard mandatory standard to address the hazards associated with the use of play yard bassinet accessories that can be assembled missing key structural elements and asking for comments on the proposal. 77 FR 52272.

D. The Play Yard Bassinet Accessory Misassembly Provision

1. Summary of the Hazard and the Infant Fatality

Many play yards are sold with accessories that attach to the product, such as mobiles, toy bars, canopies, bassinets, and changing tables. Play yard 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 support structures. Those structures are intended to attach the bassinet accessory to the side of the play yard, as well as support the bassinet accessory mattress in order to 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.

In August 2011, the CPSC received a report of an infant fatality that occurred in the bassinet accessory of a play yard. The child died when the sleeping surface of the bassinet tilted, causing the child to slip into the corner of the bassinet accessory, where she suffocated. A review of the In-Depth Investigation Report (IDI), as well as CPSC staff testing on an exemplar model of the bassinet accessory and play yard involved in the fatality, led CPSC staff to conclude that the incident was caused by the omission of metal support rods that were used to secure two of the bassinet accessory's ends to the side of the play yard. The bassinet accessory also had sewn-on plastic clips that attached the product to the side rails of the play yard. Sometime after the child was placed in the bassinet accessory, one of the plastic clips detached. If the metal support rods had been used in the assembly of the play yard, the detachment of the plastic clip would not have been enough to cause the tilt in the sleeping surface that led to the fatality. However, the plastic clips caused the consumer to assume erroneously that the product was safe when key structural elements, the end support rods that secured the bassinet accessory's ends to the play yard end rails, were missing. The omission of the metal support rods caused the fatal tilt of the bassinet accessory sleep surface and resulted in the infant's death.

As in this case, a consumer initially may not see that supporting rods are missing. 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 caregiver may not discover the condition for hours, placing the child in a potentially fatal situation.

2. The Bassinet Misassembly Requirement Contained in the August 2012 NPR

The requirement the Commission proposed in the August 2012 NPR was designed to address the hazards that can occur when play yard bassinet accessories are misassembled by omitting key structural elements during assembly. The NPR proposed two compliance options. First, the bassinet accessory would meet the requirement if all of the key structural elements were attached permanently to the bassinet accessory. This would prevent any support rods, tubes, bars, and hooks from being omitted inadvertently when the consumer assembles the bassinet accessory. Manufacturers who choose to affix all key structural elements to their bassinets permanently would not need to conduct further testing on their product to meet the requirement.

The second method for compliance proposed in the NPR involved a test method that CPSC refers to as the “catastrophic failure test.” If a manufacturer chooses not to attach support rods, tubes, bars, or hooks permanently to the bassinet, the bassinet would have to be tested by removing each key structural element and numbering each from 1 through n. Subsequently, all of the key structural elements would be put back into place. Key structural element number 1 would then be removed from the bassinet. To pass the test when an anthropomorphic infant dummy is placed in the center of the sleep surface, the product must: (1) collapse completely, or (2) tilt more than 30°. The angle of 30° represents a safety factor of three times the 10° maximum safe sleep surface angle of incline. CPSC Human Factors staff concluded that an angle of 30° would be sufficiently obvious to a consumer to discourage the consumer from continuing to use the bassinet.

The test would continue until each key structural element has been tested individually (thus, key structural element number 1 would be inserted back into the product, key structural element number 2 would be removed, and the test would be repeated.)

The proposed requirement was meant to ensure that the omission of a key structural element would be so visually obvious that the consumer would not use the product and place the child in danger inadvertently. To pass this test, the item must fail catastrophically when each key structural element is omitted.

3. The Bassinet Misassembly Requirement Contained in ASTM F406-13 and Incorporated in the Final Rule

The work on the play yard bassinet accessory misassembly requirement began after we received a comment on the issue in response to the September 2011 play yard NPR. CPSC staff worked with the ASTM play yard subcommittee for more than a year to develop the language to address this hazard. The ASTM play yard subcommittee is made up of key stakeholders, including manufacturers, retailers, third party test laboratories, independent consultants, consumer advocates, representatives from Health Canada, and CPSC staff.

The result of this effort is the language now contained in ASTM F406-13, which this rule incorporates by reference. The requirement addressing play yard bassinet accessory misassembly is essentially the same as the requirement proposed in the August 2012 NPR, with two important differences that were suggested in comments that the Commission received in response to the August 2012 NPR.

The first difference involves addressing the bassinet accessory structural supporting elements in two different standards: play yards and bassinets/cradles. In the

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August 2012 NPR, the term “key structural elements,” included all rods, tubes, bars, and hooks that supported the bassinet accessory or that were used in assembling the bassinet accessory. Not only did the term include structures that attach the bassinet to the play yard, but the term also encompassed the mattress support rods and other structures that support the bassinet accessory mattress in order to keep the sleep surface flat and stable. The ASTM play yard subcommittee, working closely with the ASTM bassinet/cradle subcommittee, determined that any issues dealing with misassembly of the mattress support rods should be addressed in the bassinet standard. Thus, both ASTM subcommittees agreed that: (1) the play yard standard, ASTM F406-13, will address safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard); and (2) the bassinet standard, ASTM F2194-13, will address mattress support rods (and all other structures that keep the bassinet accessory mattress flat and stable) through the segmented mattress flatness test contained in the bassinet standard.

The second substantive difference is also the result of a comment received in response to the August 2012 NPR. As proposed in the August 2012 NPR, the catastrophic failure test is conducted with a 7.5-pound newborn CAMI dummy. ASTM F406-13 requires that the test be conducted with a four-pound test mass. This weight represents the mass of the smallest newborn known to staff that would be released from a hospital, and thus, the smallest expected play yard bassinet accessory occupant. Using a smaller test mass makes the play yard bassinet misassembly provision in ASTM F406-13 more stringent than the requirement the Commission proposed in the August 2012 NPR.

The final rule incorporates by reference ASTM F 406-13. By referencing this newer version of the ASTM play yard standard, the CPSC standard addresses the hazards known to CPSC staff posed by misassembly of play yard bassinet accessories in substantially the same manner as the Commission proposed in the 2012 NPR. The final rule continues to exclude from the CPSC's play yard standard the provisions in ASTM F 406 that apply to non-full-size cribs. The Commission has a separate standard for non-full-size cribs. See 16 CFR part 1220.

E. Response to Comments on the Proposed Rule

The preamble to the NPR invited comments concerning all aspects of the proposed rule. We received 13 comments. Many of the comments contained more than one issue. Thus, we organized our responses by issue, rather than respond to each commenter individually. All of the comments can be viewed on www.regulations.gov, by searching under the docket number for this rulemaking, CPSC-2011-0064.

1. Generally Unsupportive

(Comment 1) - Two commenters indicate that they generally do not support the requirement. Both commenters feel that the regulation is unnecessary because the hazard was caused by misassembly of the product.

(Response 1) - The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires that we promulgate mandatory regulations for durable infant and toddler products, including play yards, that are substantially the same as an existing voluntary standard, or more stringent than the voluntary standard if the Commission determines that more stringent standards would reduce the risk of injury associated with the product. In this case, we believe that

the proposed final rule incorporating by reference ASTM F406-13 is appropriate to reduce the risk of injury associated with play yards. Therefore, the issuance of this final rule fulfills a statutory mandate given to the CPSC by Congress.

In addition, we disagree with the assertion that hazards caused by misassembly should not be addressed through mandatory regulations. The CPSC is often faced with hazards that result from the reasonably foreseeable use of consumer products. Preventing the possibility of misassembly is especially critical when the product in question has been designed to provide a safe sleep environment for an infant, and when the result of misassembly could be severe, such as an infant fatality. The CPSC must assess whether there are solutions that would minimize the possibility of misassembly. One solution could be to improve assembly instructions or warning labels. Another solution, and the one that has been chosen here, is to require that products that must be assembled by consumers be designed in such a way that they are very difficult to misassemble.

(Comment 2) – One commenter expresses a number of concerns about the new requirement. Specifically, the commenter feels that the requirement: (1) does not address completely the hazards that caused the infant fatality; (2) was created too quickly and the process rushed; (3) is design restrictive; and (4) will fail safe products.

(Response 2) – The bassinet accessory misassembly performance requirement and test method were fine-tuned for more than a year from January 2012 through April 2013. The circumstances involving the infant fatality were analyzed in detail and significant changes were made to the requirement to ensure that it addressed the hazard in the least burdensome manner. Notably, the scope of the play yard bassinet accessory misassembly requirement was reduced by focusing only on accessory attachment

components and not all key structural elements. This reduction in scope was a direct result of careful analysis of the circumstances that resulted in the infant fatality.

The requirement was created and approved through consultation with members of the ASTM play yard subcommittee, which includes many play yard importers and manufacturers, as well as other stakeholders, such as retailers, testing laboratories, independent consultants, representatives from consumer advocacy groups, and representatives from Health Canada.

To provide manufacturers with options, and to avoid creating a design restrictive standard, two methods of compliance were provided. A manufacturer can permanently attach all accessory attachment components or design a product that passes the catastrophic failure test. Finally, if the standard is found to be too severe and is failing safe products, it can be updated as more data is received by the CPSC.

2. Generally Supportive

(Comment 3) - Several commenters support the new requirement. One commenter notes:

“(o)ur organizations strongly support these specific requirements and test methods as well as the general principle that misassembly is a design safety issue and should be adequately addressed in product safety standards.” Another commenter indicates:

“(w)hile I strongly support and would prefer to see all key structural elements permanently attached to the bassinet accessory, the catastrophic failure test provides an option for manufacturers to come into compliance and appears to address the hazards associated with play yard bassinet accessories.” Another commenter expresses “overall support” for the requirement and notes: “(o)ne infant death is too many, and the CPSC has acted quickly to develop a new safety standard for bassinet accessories.”

(Response 3) – We agree with the commenters.

3. Effective Date

(Comment 4) – We received four comments addressing the appropriate effective date for this regulation. One individual indicates her agreement with the proposed six-month effective date. Other commenters recommend a shorter effective date. Some commenters suggest that a 90-day effective date would be more appropriate because safer products would be available sooner, and manufacturers have had adequate notice that the play yard bassinet accessory misassembly requirement will soon be mandatory. Some commenters note that only products manufactured after the effective date are impacted by the regulation. Thus, products made before the effective date (products that may not be in compliance with the bassinet accessory misassembly requirement contained in ASTM F406-13) can continue to be sold.

(Response 4) – The CPSC has generally recommended a six-month effective date for rules issued under section 104 of the CPSIA and we find no compelling reason to deviate from this practice for this rule. We share concerns about noncompliant products, those manufactured or imported before the effective date, being available for years beyond the effective date. However, ongoing compliance activities would continue to be used to remove unsafe play yards from the market.

4. Coordination Between the Play Yard and Bassinet Standard

(Comment 5) – Four commenters discuss the overlap between the mattress flatness requirement contained in ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, and the proposed play yard bassinet accessory misassembly requirements. The commenters state that the play yard bassinet accessory misassembly

requirements, as published in the August 2012 NPR, contain requirements that are more appropriately addressed in the bassinet segmented mattress flatness requirement contained in the bassinet voluntary standard.

(Response 5) – The CPSC agrees with these comments. As discussed above, the play yard bassinet accessory misassembly requirement contained in ASTM F406-13 now only applies to accessory attachment components (*i.e.*, those structures that attach the bassinet accessory to the play yard). Misassembly issues related to mattress support rods are now addressed in ASTM F2194-13, the standard for bassinets and cradles. ASTM F2194-13 requires that if the mattress support rods are not permanently attached, the bassinet must be tested pursuant to the mattress flatness test contained in ASTM F2194-13, and the product must pass the mattress flatness test both with and without the mattress support rods in place. The CPSC is finalizing a rule for bassinets/cradles that incorporates by reference ASTM F2194-13.

5. Clarity of “Key Structural Element” Definition

(Comment 6) – One commenter asks that the definition of “key structural element” be clarified. Specifically, the commenter asks if the following are key structural elements: (1) clips that are sewn to the play yard bassinet accessory shell; and (2) metal bars that provide support for the bassinet mattress.

(Response 6) – The definition of “key structural element” presented in the August 2012 NPR has been modified. The final rule incorporates by reference ASTM F406-13. The language published in ASTM F406-13 now limits the scope of the play yard bassinet misassembly requirement by defining “accessory attachment components” as “the

components that provide the means of attachment for a bassinet/cradle accessory to a play yard.”

Thus, clips sewn to the play yard bassinet accessory shell that attach the bassinet accessory to the play yard are accessory attachment components. Metal bars that provide support to the bassinet accessory mattress, and that do not attach the bassinet accessory to the play yard, are not accessory attachment components; therefore, they are not subject to the play yard bassinet accessory misassembly requirement contained in ASTM F406-13.

6. Catastrophic Failure Test Is Confusing or Is Arbitrary and Capricious

(Comment 7) – One commenter indicates that it would be easier, and cause less confusion, if the play yard bassinet accessory misassembly provision simply required that all key structural elements be permanently attached to the bassinet accessory instead of giving manufacturers the option of complying with the catastrophic failure test. Another commenter indicates that the permanent affixture test should be the only method of complying with the requirement and asserts that the catastrophic failure test is not the least burdensome requirement and violates the Administrative Procedure Act because it is arbitrary and capricious.

(Response 7) – The catastrophic failure test can appear confusing and counterintuitive because, in order to pass the test, the product must fail catastrophically when one piece is missing. However, this test was thoroughly vetted during the ASTM process. The ASTM subcommittee stakeholders felt that the test is a sound alternative to permanently attaching all accessory attachment components. In fact, initially, CPSC staff suggested that the only method of compliance should be to require that all key structural elements

be permanently attached. The catastrophic failure option was added at the request of manufacturers' representatives. However, once the requirement goes into effect, both ASTM and the CPSC will monitor any issues that arise in using the catastrophic failure test to meet the requirement and will address them as necessary.

Additionally, the catastrophic failure test is an alternative to the permanent affixture test. Although the CPSC does not feel that the permanent affixture test is design restrictive, providing as many alternatives for compliance as possible is important, so that products with drastically different designs are able to meet the requirement.

7. Catastrophic Failure Test and the Test Mass Size, Use, and Location

(Comment 8) – One commenter questions the use of the newborn CAMI dummy (weighing 7.5 pounds), as proposed in the August 2012 NPR. The commenter ultimately questions the use of a test mass at all, hypothesizing that the requirement could be more severe if no test mass were used. Another commenter recommends that the CPSC consider a lighter test mass so that a greater proportion of the newborn population will be covered by the play yard bassinet accessory misassembly requirement.

(Response 8) – We agree that the mass of the newborn CAMI dummy is too large. CPSC staff developed a new four-pound test mass and presented the four-pound test mass proposal to the ASTM play yard subcommittee for review and consideration. The play yard bassinet accessory misassembly requirement, contained in section 5.19 of ASTM F406-13, contains a rationale that states that the four-pound mass represents the weight of the smallest newborn who would be using the bassinet accessory because infants smaller than four pounds are unlikely to be released from a hospital. Using the smallest reasonable mass makes the play yard bassinet accessory misassembly requirement more

stringent than the proposal in the August 2012 NPR. Eliminating the test mass entirely, as one commenter suggests, is unnecessarily restrictive.

8. Catastrophic Failure Test and the Basis for the 30° Mattress Angle Requirement

(Comment 9) – Several commenters object to the 30° tilt requirement in the catastrophic failure test. Many commenters feel that the requirement is not adequately supported by scientific data.

(Response 9) – The angle of 30° represents a safety factor of three times the 10° maximum safe sleep surface angle of incline. CPSC 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. Staff then recommended that the ASTM play yard subcommittee review and critique the 30° angle. ASTM stakeholders agreed with CPSC staff that 30° was reasonable and would be considered by caregivers to be obviously hazardous. CPSC staff, as well as ASTM members, can reconsider the tilt angle requirement should evidence be presented indicating that the angle is too small or large.

9. Redundant Product Safety Features

(Comment 10) – One commenter states that the play yard bassinet accessory misassembly requirement, as contained in the August 2012 NPR, may result in manufacturers eliminating “redundant safety features that are already a component of the product.” The commenter mentions mattress support rods as an example of a structure that is not necessary to comply with the voluntary standard but does improve product safety, by helping to create a “flatter and more stable sleeping position.” The commenter concludes that the added cost of being required to permanently affix redundant structures would

lead to the elimination of the structures to avoid this cost, resulting in compliant but less safe products being sold.

(Response 10) – Like many members of the ASTM play yard subcommittee, this commenter is concerned that regulating mattress support rods in the play yard rule through the bassinet accessory misassembly requirement is inappropriate. Members of the play yard and bassinet subcommittees resolved this issue by agreeing to regulate bassinet accessory attachment components in the play yard standard, and by agreeing to regulate bassinet accessory mattress support rods in the bassinet/cradle standard. As a result, the play yard bassinet accessory misassembly requirement in F406-13 now only applies to accessory attachment components. Misassembly issues related to mattress support rods are now addressed in ASTM F2194-13, the voluntary standard for bassinets and cradles. ASTM F2194-13 requires that bassinets with removable mattress support rods be tested both with and without the mattress support rods. The bassinet must pass the segmented mattress flatness test contained in ASTM F2194-13 with and without the mattress support rods. In this way, all misassembly issues known to CPSC staff related to play yard bassinet accessories are addressed in either the play yard or the bassinet standard.

10. Other Options for Compliance

(Comment 11) – One commenter asks that a third option for compliance be considered in addition to the two already proposed in the August 2012 NPR. The commenter suggests that a product be considered to be in compliance if the product continues to meet the standard's requirements after all of the key structural elements are removed.

(Response 11) – This approach has been adopted in the bassinet standard contained in ASTM F2194-13. ASTM F2194-13 requires that removable mattress support rods be tested pursuant to the segmented mattress flatness tests contained in ASTM F2194-13 without the rods in place. If the product passes the mattress flatness test, even without the mattress support rods in place, the product meets the requirements.

We do not agree, however, that this commenter’s proposal should be an option for accessory attachment components meant to attach the bassinet accessory to the play yard rails. In the fatal incident, one of the accessory attachment components, the end support rods, was omitted and only the plastic clips were used. The fatality resulted when the caregiver assumed that the product was safe because no visually obvious cues suggested that the product was unsafe. Therefore, for accessory attachment components, we believe that the standard should require that the accessory attachment components be either permanently attached or pass the catastrophic failure test by obviously failing when an accessory attachment component is missing.

11. Cost of Play Yard Bassinet Accessory Misassembly Requirement

(Comment 12) – One commenter indicates that cost of “re-engineering” and “retooling” would be significant. The commenter also mentions that the requirement would necessitate a change to the packaging. The commenter believes that the issue merits additional research.

(Response 12) – Although the new requirement might impose additional costs on manufacturers and importers, staff consulted and worked closely with members of the industry to devise an acceptable solution that would address the safety hazard but not impose unnecessary costs.

12. Ability to Launder

(Comment 13) – One commenter indicates that permanently affixing key structural elements to the product may interfere with the ability to launder the product. The commenter is specifically concerned about the metal rods that support a bassinet accessory shell or liner. If the metal rods were required to be affixed permanently to the liner, the bassinet accessory shell would be difficult to clean.

(Response 13) – Although the CPSC’s primary concern is that play yards and bassinet accessories are safe, the CPSC does consider practical issues, such as the ability to launder, in connection with new standards and requirements. The commenter’s specific concern regarding the ability to launder a bassinet accessory shell that is supported by metal support rods is no longer an issue addressable by the play yard bassinet accessory misassembly requirement because ASTM F406 no longer applies to mattress support rods. Instead, ASTM F406-13 focuses only on accessory attachment components that attach the bassinet accessory to the play yard.

The bassinet standard applies to mattress support rods. However, the bassinet standard does not require the metal rods to be attached permanently to the liner. If the product passes the segmented mattress flatness test contained in the bassinet standard with the mattress support rods removed, the mattress support rods do not need to be permanently attached.

13. Concern that Patent-Only Technology May Be Required

(Comment 14) – One commenter indicates that there is a patent application pending detailing 10 different methods to “stiffen a play yard mattress pad before it is used in a play yard bassinet accessory.” The commenter acknowledges that “there may not be any

products on the market today that would be impacted by this patent application” but that the CPSC should “evaluate this issue and avoid design restrictions that limit marketplace competition.”

(Response 14) – The concern regarding the means of stiffening a mattress pad is no longer an issue for the play yard rule because the play yard bassinet accessory misassembly requirement no longer applies to mattress support rods or any other methods that might be used to stiffen a mattress pad. Instead, the play yard rule only focuses on accessory attachment components that attach the bassinet accessory to the play yard.

Likewise, the bassinet rule, which does address mattress flatness, does not require that a specific design be used to pass the standard. As a result, the bassinet mattress flatness test can be met in a variety of ways without necessarily implicating patented technology.

14. International Harmonization/Impact on Trade

(Comment 15) – One commenter expresses concerns that the requirement could impact trade agreements and emphasizes the importance of international standard harmonization.

(Response 15) – When drafting the NPR for the play yard mandatory standard, published in September 2011, CPSC staff reviewed, compared, and considered a variety of play yard standards, including the Canadian standard, the European standard, and the Australian/New Zealand standard. These international standards vary in a variety of respects. Thus, even if we adopt all or part of an international standard, we still would not achieve complete international harmonization. We are aware of the utility of having harmonized standards in a global marketplace, and we continue to strive to achieve this harmonization whenever practicable. Notably, no other standard addresses the risks

associated with play yard bassinet accessory misassembly. However, we will continue to monitor the effects that our standards have on international standards.

15. Deference to ASTM Standard

(Comment 16) – One commenter requests that staff defer to the ASTM standard.

(Response 16) – Under section 104 of the CPSIA, the Commission must establish a mandatory standard for play yards and cannot defer to a voluntary standard. However, the CPSC is incorporating the current ASTM standard, ASTM F406-13, by reference.

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). We are providing a six-month effective date, as proposed in the NPR. The CPSC has generally recommended a six-month effective date for rules issued under section 104 of the CPSIA and we find no reason to deviate from this practice for this rule.

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, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained in this section, we certify that the rule will not have a significant impact on a substantial number of small entities.

2. The Market

There are 26 firms known to be supplying play yards to the U.S. market. However, not all 26 firms supply bassinet accessories with the play yard. Of the 26 firms, 11 do not supply bassinet accessories. The remaining 15 firms supply at least one model of a play yard that is accompanied by a bassinet accessory: 13 are domestic manufacturers or importers; one is a foreign manufacturer; and one is a foreign importer who imports from a foreign country and distributes the products from outside the United States. Under U.S Small Business Administration Guidelines, eight of the 15 firms are small firms (five domestic manufacturers and three domestic importers).

3. Impact of the Standard on Small Businesses

Currently, all but one of the 15 firms supplying play yards to the U.S. market that are accompanied by bassinet accessories have their accessory attachment components permanently attached to the bassinet accessory. The remaining firm has started developing a design that permanently attaches all of the accessory attachment components to the bassinet accessory. Therefore, the CPSC believes that this requirement is not likely to have a significant impact on a substantial number of small entities.

H. Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521

ASTM F406-12a, which is incorporated by reference into the play yard standard codified at 16 CFR part 1221, requires labels and instructions to be supplied with the product. The PRA requirements for the play yard standard codified at 16 CFR part 1221 have been submitted to the Office of Management and Budget (OMB), and OMB has assigned control number 3041-0152 to the information collection. We estimate that there

are no additional burden hours associated with incorporating by reference ASTM F406-13.

I. 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 therefore, our rules are generally exempt from any requirement to prepare an environmental assessment or impact statement. 16 CFR 1021.5(c)(1). This rule falls within the categorical exclusion.

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 and Notice of Requirements (NOR)

1. Background

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Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA (or to a similar rule, ban, standard or regulation under any other act enforced by the Commission) must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children's products subject to a children's product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body (or laboratory). Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for laboratories to assess conformity with a children's product safety rule to which a children's product is subject. The rule for 16 CFR part 1221, "Safety Standard for Play Yards," is a children's product safety rule that requires the Commission to issue an NOR.

The Commission recently published a final rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies," 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as part 1112), and became effective on June 10, 2013. Part 1112 establishes requirements for accreditation for third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. The final rule also codifies a list of all the NORs that the CPSC had published, to date, at the time part 1112 was issued. The Commission published an NOR for the play yard rule in the final rule for part 1112. The play yard standard is listed along with all the other children's product safety rules for which the CPSC has issued NORs.

2. Play Yards

Testing laboratories applying to be a CPSC-accepted third party conformity assessment body to test to the standard for play yards are required to meet the accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1221, “Safety Standard for Play Yards,” included in the laboratory’s scope of accreditation. All of the CPSC safety rules included in a laboratory’s scope of accreditation are listed on the CPSC website at: www.cpsc.gov/labsearch.

Testing to Functionally Equivalent Provisions of ASTM F406-12a and ASTM 406-13

For purposes of testing, the provisions of revised ASTM F406-13 are equivalent or functionally equivalent to ASTM F406-12a, with one significant exception discussed below. (By “functionally equivalent,” we mean that the standards organization made certain changes in the revised standard compared to the earlier standard, but the changes are not substantial and do not affect the associated conformance testing.)

Consequently, the Commission is continuing to recognize acceptance of accreditation of laboratories currently accredited under ASTM F406-12a for the provisions in ASTM F406-13 that are equivalent or functionally equivalent to their corresponding provisions in ASTM F406-12a. The laboratories should test play yards for compliance with ASTM F406-13, and based on such testing, manufacturers should issue certificates under section 14(a)(2) of the CPSA. Laboratories that are accredited to test to provisions of ASTM F406-12a that are equivalent or functionally equivalent for children’s product certification purposes do not need to become accredited to ASTM F406-13 before the next time their accreditation body reassesses that laboratory and

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recognizes that the scope of the laboratory's accreditation includes ASTM F406-13. In the course of applying to the CPSC for acceptance of their accreditation, the laboratory must submit CPSC Form 223 with the applicable accompanying documents to continue to have their accreditation to 16 CFR part 1221 (incorporating by reference ASTM F406-13) accepted. We will revise our listing for the laboratory when the laboratory becomes accredited to 16 CFR part 1221 (incorporating by reference ASTM F406-13) and the CPSC accepts the laboratory's application for accreditation.

Testing to the New Bassinet Misassembly Provisions

ASTM F406-13 added one new testing requirement that is not present in ASTM F406-12a. Section 8.31 of ASTM F406-13 adds a new test to evaluate conformity with a new substantive requirement found in section 5.19 regarding missing accessory attachment components for play yard bassinet/cradle accessories. Neither of these provisions existed in ASTM F406-12a. Third party testing for section 8.31, as required by the new performance requirement contained in section 5.19, is required only for play yards with bassinet/cradle accessories and applies to products manufactured or imported after this final rule becomes effective.

If a laboratory wishes to test play yards for compliance with the play yard bassinet accessory misassembly requirement, the laboratory will need to become accredited under ASTM F406-13 first. This may mean that the laboratory will need to become accredited to ASTM F406-13 before the regularly scheduled reassessment by their accreditation body.

New Applicants

New third party conformity assessment body applicants that apply for CPSC acceptance on or after [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], must be accredited to 16 CFR part 1221 (incorporating by reference ASTM F406-13), when applying for CPSC acceptance of their accreditation to test play yards

3. Retrospective Testing

Some laboratories may want to start testing play yards to assess conformity with the play yard bassinet accessory misassembly requirement before the Commission is able to accept their accreditation to 16 CFR part 1221 (incorporating by reference ASTM F406-13.) Laboratories may begin testing for conformance with the play yard bassinet accessory misassembly requirement before the CPSC accepts their accreditation, and their test results will be valid retrospectively, if the following conditions are met:

- At the time of testing, the product was tested by a laboratory that was ISO/IEC 17025:2005(E) accredited by an ILAC–MRA member at the time of the test. At the time of testing, the scope of the third party conformity body accreditation, as reported by the accreditation body, must include testing in accordance with ASTM F406-13 or 16 CFR part 1221 (incorporating by reference ASTM F406-13). In addition, for firewalled third party conformity assessment bodies, the firewalled third party conformity assessment body must be one that the Commission, by order, has accredited on or before the time that the children’s product was tested, even if the order did not include ASTM F406-13 or 16 CFR part 1221 (incorporating by reference ASTM F406-13) at the time of initial Commission acceptance. For governmental third party conformity assessment

bodies, accreditation of the body must be accepted by the Commission on or before the time that the children's product was tested, even if the scope of accreditation did not include ASTM F406-13 or 16 CFR part 1221 (incorporating by reference ASTM F406-13) at the time of initial CPSC acceptance.

- The test results show compliance with ASTM F406-13 or 16 CFR part 1221 (incorporating by reference ASTM F406-13).
- The play yard was tested on or after May 1, 2013, the date that ASTM approved ASTM F406-13, and before **[INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.
- The laboratory's accreditation remains in effect through **[INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 amends Title 16 of the Code of Federal Regulations as follows:

PART 1221-SAFETY STANDARD FOR PLAY YARDS

1. The authority citation for part 1221 continues to read:

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

2. Revise § 1221.1 to read as follows:

§ 1221.1 Scope.

This part establishes a consumer product safety standard for play yards manufactured or imported on or after **[INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

3. Revise § 1221.2 to read as follows:

§ 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 F406-13, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, approved on May 1, 2013. 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 F406-13 standard with the following exclusions:

(1) Do not comply with section 5.17 of ASTM F406-13.

(2) Do not comply with section 5.20 of ASTM F406-13.

(3) Do not comply with section 6, Performance Requirements for Rigid-Sided Products, of ASTM F406-13, in its entirety.

(4) Do not comply with sections 8.1 through 8.10.5 of ASTM F406-13.

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(5) Instead of complying with section 9.4.2.10 of ASTM F406-13, comply only with 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.

(ii) [Reserved]

(6) Do not comply with section 10.1.1.1 of ASTM F406-13.

Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission