



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  
Barbara E. Little, Attorney, OGC

**SUBJECT:** Final Rule: Bassinets and Cradles

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 establish a safety standard for bassinets and cradles 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.)

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\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

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

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

IV. Take other action. (Please specify.)

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(Signature)

\_\_\_\_\_  
(Date)

Attachment: Draft *Federal Register* Notice of Final Rule to Establish a Safety Standard for Bassinets and Cradles

**Billing Code 6355-01-P**

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Parts 1112 and 1218**

**Docket No. CPSC-2010-0028**

**Safety Standard for Bassinets and Cradles**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final Rule.

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

**DATES:** The rule will become effective on [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], with the exception of the removable bassinet bed attachment requirements. The removable bassinet bed attachment requirements will become effective on [INSERT DATE 18 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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:** William Dewgard, Directorate for Compliance, Consumer Product Safety Commission, telephone: 301-504-7599; e-mail:WDewgard@cpsc.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Background and Statutory Authority**

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be substantially the same as applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” Bassinets and cradles are specifically identified in section 104(f)(2)(L) of the CPSIA as a durable infant or toddler product.

On April 28 2010, the Commission issued a notice of proposed rulemaking (NPR) for bassinets and cradles. 75 FR 22303. The NPR proposed to incorporate by reference the voluntary standard, ASTM F2194-07a<sup>e1</sup>, *Standard Consumer Safety Specification for Bassinets*

*and Cradles*, with certain changes to provisions in the voluntary standard to strengthen the ASTM standard.

The Commission published a supplemental notice of proposed rulemaking (SNPR) on October 18, 2012. 77 FR 64055. The SNPR proposed to incorporate the voluntary standard, ASTM F2194-12, with: (1) modifications to sections pertaining to scope and terminology and the stability test procedure, and (2) the addition of new provisions for a segmented mattress flatness test and a removable bed stability requirement.

In this document, the Commission is issuing a safety standard for bassinets and cradles. Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this standard, largely through the ASTM process. The rule incorporates the voluntary standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles* (ASTM F2194-13), by reference, with the following modifications and additions: a clarification to the scope of the bassinet/cradle standard; a change to the pass/fail criterion for the mattress flatness test; an exemption from the mattress flatness requirement for bassinets that are less than 15 inches across; the addition of a removable bed stability requirement; and a change to the stability test procedure requiring the use of a newborn CAMI dummy rather than an infant CAMI dummy.

## **II. The Product**

ASTM F2194-13 defines “bassinet/cradle” as a “small bed designed primarily to provide sleeping accommodations for infants, supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base.” While in a rest position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from

horizontal. The bassinet/cradle is not intended to be used beyond the age of approximately five months or when a child is able to push up on his hands and knees. Bassinet and cradle attachments for non-full-size cribs or play yards are considered part of the bassinet/cradle category, as are bedside sleepers that can be converted to four-sided bassinets not attached to a bed.

Cribs, Moses baskets, and products used in conjunction with an inclined infant swing or stroller, and products that are intended to provide only an inclined sleep surface of greater than 10 degrees horizontal, are not included under the category of “bassinets/cradles.” (A Moses basket is a portable cradle for a newborn or infant, often made of straw or wicker, that can be used with a variety of rocking and stationary stands. As with other bassinets and cradles, Moses baskets are not intended for use after a child can push up on its hands and knees.) However, Moses baskets and carriage accessories that can be converted to a bassinet or cradle by attachment to a separate base/stand would be considered bassinets/cradles when used with the base/stand. Similarly, products that could be used at an incline of 10 degrees or less from horizontal, as well as more than 10 degrees from horizontal, would be considered bassinets/cradles when in the flatter configuration(s).

### **III. Incident Data**

The preamble to the SNPR summarized incident data involving bassinets and cradles reported to the Commission as of January 18, 2012. 77 FR 64055 (October 18, 2012). CPSC’s Directorate for Epidemiology, Division of Hazard Analysis has updated this information to include bassinet- and cradle-related incident data reported to the Commission from January 18, 2012 through March 31, 2013. A search of the CPSC epidemiological databases showed that there were 71 new incidents related to bassinets and cradles reported during this time frame.

Thirty-eight of the 71 were fatal, and 33 were nonfatal. Sixteen of the nonfatal incidents involved injuries. Almost all of the new incidents reportedly occurred between 2010 and 2012. Reporting is ongoing, however, so the incident totals are subject to change.

#### **A. Fatalities**

The majority of the deaths (32 out of 38) were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and additional bedding. All but four of the 38 decedents were five months or less in age, the ASTM-recommended age range for bassinet use; three of the decedents were six months old and another was an eight-month-old.

Two of the 38 deaths were associated with design aspects of the product. One of these was a suffocation death in a corner of the bassinet whose rocking feature contributed to its non-level resting position; the other fatality occurred when the bassinet was knocked over by an older sibling.

There were three fatalities with insufficient information and one fatality with confounding information preventing CPSC from determining the hazard scenario.

#### **B. Nonfatal Incidents**

A total of 33 bassinet-related nonfatal incidents were reported from January 18, 2012 through March 31, 2013. Of these, 16 reports indicated an injury to an infant using the bassinet or cradle at the time of the incident. The majority of these injuries (11 out of 16, or 69 percent) were due to falls out of the bassinets. All 11 fall injuries were reported through NEISS, with little or no circumstantial information on how the fall occurred. However, the reports do indicate that 55 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of five months. All of the falls resulted in head injuries.

Among the remaining five nonfatal injuries, mostly head injuries, no hospitalizations were reported. All but six of the injured were five months or less in age.

The remaining 17 incident reports indicated that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

### **C. Hazard Pattern Identification**

The hazard patterns identified in the 71 new incident reports were similar to the hazard patterns that were identified in the incidents considered for the SNPR and are grouped in the following categories (in descending order of frequency of incidents):

1. *Non-product-related issues*: Thirty-four of the 71 reports (48 percent) concerned incidents that involved no product defect or failure. This category consisted of 32 fatalities that were associated with the use of soft/extra bedding, prone positioning, and/or the infant getting wedged between the side of the bassinet and additional bedding. In addition, there were two nonfatal injury incidents that did not involve any product-related issues.
2. *Product-related issues*: The hazard scenarios in 25 of the 71 reported incidents (35 percent) were attributed to a failure/defect or a potential design flaw in the product. This category includes one fatality and 13 injuries. Listed below are the reported problems, beginning with the most frequently reported concerns:
  - Reports of infants *falling or climbing out* of bassinets/cribbedles accounted for a total of 13 incidents, all of which were received from emergency departments around the United States. Eleven of the incidents reported a nonfatal injury; the remaining two infants were reported to be uninjured.

- Lack of *structural integrity*, which includes issues such as instability, loose hardware, and product collapse, among others, was reported in nine incidents—one with a fatality and two with nonfatal injuries.
  - Problems with *accessories* (such as the stand or sheets), which were sold with the bassinets, were reported in two incidents. However, no injuries were reported.
  - One *Other* product-related problem, involving the battery compartment of an older product, was reported in one non-injury incident.
3. *Recalled product-related issues*: There were six reports (eight percent) that were associated with three different recalled product-related issues. (Two of the recalls were published since the incident data for the SNPR briefing package was presented; at the time, these issues were classified under the “structural integrity” and “rocking” categories.) Although there were no injuries, there was a fatality included among the six incident reports. In the fatal incident, it is reported that the tilting of the bassinet caused the decedent to roll and press up against the side and suffocate.
4. *Miscellaneous other issues*: The remaining six incident reports (eight percent) were related to other unspecified issues. The reports described the incidents with insufficient specificity or provided confounding information, preventing CPSC staff from identifying the hazard scenario. There were four fatalities, one nonfatal injury, and one non-injury incident reported in this category.

#### **IV. Overview of ASTM F2194**

ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*, establishes safety performance requirements, test methods, and labeling requirements to minimize the identified hazard patterns associated with the use of bassinets/cradles. ASTM first

published a consumer product safety standard for bassinets and cradles in 2002. The standard was revised several times over the next 11 years. The current version of the standard is ASTM F2194-13. The more significant requirements of ASTM F2194 include:

- Scope—describes the types of products intended to be covered under the standard.
- Spacing of rigid side components—is intended to prevent child entrapment between both uniformly and non-uniformly spaced components, such as slats.
- Openings for mesh/fabric—is intended to prevent the entrapment of children’s fingers and toes, as well as button ensnarement.
- Static load test—is intended to ensure structural integrity even when a child three times the recommended (or 95<sup>th</sup> percentile) weight uses the product.
- Stability requirements—is intended to ensure that the product does not tip over when pulled on by a two-year-old male.
- Sleeping pad thickness and dimensions—is intended to minimize gaps and the possibility of suffocation due to excessive padding.
- Tests of locking and latching mechanisms—is intended to prevent unintentional folding while in use.
- Suffocation warning label—is intended to help prevent soft bedding incidents.
- Fabric-sided openings test—is intended to prevent entrapments.
- Rock/swing angle requirement—is intended to address suffocation hazards that can occur when latch/lock problems and excessive rocking or swinging angles press children into the side of the bassinet/cradle.
- Occupant restraints—is intended to prevent incidents where unused restraints have entrapped and strangled children.

- Side height requirement—is intended to prevent falls.
- Segmented mattress flatness—is intended to address suffocation hazards associated with “V” shapes that can be created by the segmented mattress folds.

The voluntary standard also includes: (1) torque and tension tests to prevent components from being removed; (2) requirements for several bassinet/cradle features to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature; and (5) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing that a child may be wearing from catching on a projection.

#### **V. The SNPR and ASTM F2194-13**

The SNPR proposed to incorporate by reference ASTM F2194-12, with four modifications/additions to the voluntary standard:

- 1) **Scope and Terminology:** The SNPR proposed excluding inclined products from the scope of the standard, by revising the scope and including a detailed note with examples of what products were and were not included in the scope of the standard. The SNPR also proposed two existing definitions be revised for clarity.
- 2) **Segmented Mattress Flatness Test:** The SNPR proposed a new test requirement and associated test procedure to address suffocation incidents in segmented mattresses. As discussed in the preamble to the SNPR, the mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission’s

pass/fail criteria proposed in the SNPR, a bassinet attachment with a segmented mattress would fail if any tested seam creates an angle greater than 10 degrees.

3) **Removable Bed Stability Requirement:** The SNPR proposed a new test requirement and associated test procedure to address fatal and nonfatal incidents associated with bassinets that have removable bassinet beds. In the proposed requirement, a removable bassinet bed that was not properly attached or assembled to its base would be required to meet one of the following requirements:

- a. The base/stand shall not support the bassinet (*i.e.*, the bassinet bed falls from the stand so that it is in contact with the floor); or
- b. The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action); or
- c. The stand/base shall not be capable of supporting the bassinet bed within 20 degrees of horizontal; or
- d. The bassinet shall contain a visual indicator mechanism that shall be visible on both sides of the product to indicate whether the bassinet is properly attached to the base; or
- e. The bassinet shall not tip over and shall retain the CAMI newborn dummy when subjected to the stability test outlined in the standard.

4) **Stability Test Procedure:** The SNPR proposed a revised test procedure for stability. The revision specifies the use of a newborn CAMI dummy, rather than the six month CAMI dummy that is referenced in the ASTM standard.

The SNPR's provisions concerning the scope and terminology and the proposed segmented mattress flatness test requirement were balloted by ASTM in 2012, and the provisions

are now included in the latest revision of the voluntary standard, ASTM F2194. Although the mattress flatness test procedure in ASTM F2194-13 is identical to what is proposed in the SNPR, the pass/fail criterion is different. As stated previously, under the Commission's pass/fail criteria, as proposed in the SNPR, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees.

The removable bed stability requirement proposed in the SNPR is not in the current ASTM standard, but a similar version is expected to be balloted by ASTM for inclusion in the next revision. Similarly, the change in the stability test procedure proposed in the SNPR is not in ASTM F2194-13, but it is expected to be balloted by ASTM for inclusion in its next revision.

## **VI. Response to Comments**

There were 27 comments received on the SNPR, including: one from Health Canada; one from a group of consumer's groups (Kids In Danger, Consumers Union, American Academy of Pediatrics, Consumer Federation of America, Public Citizen, and U.S. PIRG); one from the Juvenile Products Manufacturers Association (JPMA); and two from bassinet manufacturers. The remaining 22 comments were from consumers, law students, or unaffiliated sources. The comments raised several issues, which resulted in two changes to the final rule. Several commenters made general statements supporting the overall purpose of the proposed rule. All of the comments can be viewed at: [www.regulations.gov](http://www.regulations.gov), by searching under the docket number of the rulemaking, CPSC-2010-0028. Following is a summary of and responses to the comments.

### **Scope**

Comment: Two commenters provided almost identical comments and suggestions for changes to the scope. The commenters asserted that the scope was unclear about what products are included in the scope and under what conditions. For instance, one comment stated that it was not clear from the SNPR how products with an inclined seat back surface (reclined seat back), such as infant seats, infant bouncer seats, and infant rockers that do not provide an “inclined sleep surface” would be treated under the standard.

Response: The scope that was proposed in the SNPR has subsequently been adopted by ASTM and is the scope in the current version of the ASTM standard, ASTM F2194-13. The comments received reflect continued ambiguity regarding some aspects of the scope. Therefore, the Commission is providing additional clarity in the final rule.

Inclined products fall under a variety of different ASTM standards, depending on the product’s function. For instance, ASTM standards include a handheld carrier standard, an infant bouncer standard, and a new rocker standard that is currently under development. None of those products is intended for sleep. An inclined product intended for sleeping would fall under the inclined sleep product standard currently under development by ASTM. The Commission’s intent is that the scope of the bassinet standard exclude all inclined products when the incline is more than 10 degrees from horizontal.

However, the Commission intends that any product that has both a flat (10 degrees or less) sleep surface and an inclined surface greater than 10 degrees from horizontal shall fall under the scope of the bassinet standard when configured in the flat mode, and will fall under the scope of the appropriate inclined product standard(s) while in the inclined mode. In this manner, all uses of the product are addressed by safety standards. This type of product is considered a

multimode product, or a combination product, *i.e.*, the product can convert from one use mode to another.

During the recent ASTM F15 juvenile products subcommittee meetings held in April 2013, scope clarity was raised in various product subcommittees where multimode products are commonly considered. Most of those product subcommittees proposed to modify the scope section of the appropriate standard to clarify that these combination products shall fall under the scope of all relevant standards when in the corresponding use mode.

This intent to include multimode products under multiple standards is well established in ASTM standards, including the bassinet standard. One example of a multimode product is a carriage basket that is removable from a stroller base. The scope section of ASTM F2194-13 clearly states that products used in conjunction with a stroller are not covered by the standard. Yet, the current scope section also states: “Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1.” Clearly, the intent of the ASTM standard is to see that this multimode product falls within the scope of the stroller standard when attached to the stroller frame and falls within the scope of the bassinet standard when attached to a separate frame/stand.

Thus, to remove any ambiguity regarding multimode products, the Commission’s standard modifies the note that accompanies the scope provision of ASTM F2194-13 to clarify that a multimode product with a bassinet-use mode must meet the bassinet standard when in the bassinet-use mode.

Comment: One commenter suggested that the scope of the standard needs more specific age restrictions.

Response: The scope of a standard is intended to define broadly an entire product category.

Within that category, manufacturers have the freedom to tailor their product to a specific market niche, which might be more specialized than other products in the same category. Providing too many specific restrictions within the scope of a standard makes the standard weaker by excluding many products that ought to be included. In general, ASTM standards are defined by their respective industries, using terms that produce a standard that is as useful as possible to that industry. The Commission agrees with the bassinet industry on the existing age recommendations in the ASTM standard.

### **Removable Bassinet Bed Requirements**

Comment: One group of commenters suggested that the Commission eliminate the two “passive” pass conditions (20 degrees and passing stability) of the removable bassinet bed stability requirement in favor of the other pass criteria, which the group of commenters said they believe makes the user actively aware that the bassinet is not attached properly.

Response: The SNPR proposed several options to meet the removable bassinet bed requirements. This approach is less restrictive than prescribing one pass criterion, and the approach allows for more innovation in product designs. By permitting five different options to meet this requirement, manufacturers have a variety of design choices available.

Comment: Some commenters said they believe that allowing the bassinet to “fail” (by falling to the ground or to a 20 or more degree angle) encourages manufacturers to make products that are less stable to ensure that their bassinets pass this requirement. Another commenter stated that it was foreseeable that some caregivers may attempt to attach the bassinet bed to its stand while the child is in the product and that this might expose children to unnecessary hazards.

Response: Two of the five options to pass the removable bed requirement are closely related to one another. These two options are: (1) the sleep surface shall be at least 20 degrees off from a horizontal plane; and (2) the bassinet bed falls from the stand and contacts the floor. These two requirements were added after consultations with stakeholders (ASTM task group members). Several stakeholders stated that if a bassinet stand was designed to support the bassinet bed only if it were locked properly, then the bassinet stand should be able to pass the requirement. For instance, in the case of a stand that looks like a saw horse, or “A” frame that has a lock/latch connection at the top of the “A” on the frame and on the underside of the bassinet bed, the caregiver would have to line up both halves of the lock/latch to attach the bed to the stand. It would be unreasonable to believe that caregivers would place the bassinet bed on an “A” frame stand without engaging the lock/latch because the design of the stand would cause the bassinet bed to fall to the ground if the lock was not engaged.

Rather than specifying a design requirement, the task group converted the requirement to a performance requirement, by simulating what would happen if the unreasonable act occurred. In other words, this option requires the bassinet bed to fall to the ground if the lock is not properly engaged.

Once that requirement was vetted by the task group, another stakeholder raised the possibility that the bassinet bed, in the act of falling, might get caught on the stand before hitting the ground. The stakeholder asserted that simply because the bassinet bed did not hit the ground should not constitute a failure. Thus, the 20-degree tilt option was added to address the possibility that the bassinet bed, in the process of falling, might get caught on the stand and to complement the fall-to-the-ground option.

A bassinet that relies on either of these two options to pass the requirement would be considered to provide immediate positive feedback. Caregivers who attempt to place the bassinet bed on this type of stand without locking it in place will realize instantly that they did not engage the lock because the bassinet bed will not assume a stable position that allows the caregivers to release their grasp. The immediate feedback of instability will minimize the possible hazards, making falling unlikely. The Commission believes that the steep angle needed to pass is unlikely to allow consumers to let children fall. The instability of such a unit is immediately obvious to the user, precluding a delayed response. Consumers are likely to check the stability of the product before removing their hands from it. Even in the case of a caregiver who attempts to place an occupied bassinet bed on a stand using this option, the caregiver will be present and potentially will be able to prevent or arrest the fall of the bassinet bed. The Commission considers the possibility of a fall hazard in this scenario to be highly unlikely; and on the rare chance that a fall occurs, the fall in these circumstances would be considered less significant than an unattended fall to the floor.

Comment: One commenter stated that the option—“The lock/latch shall automatically engage under the weight of the bed (without any other force/action)”—should be a requirement for all bassinets.

Response: The Commission is providing manufacturers with options to meet the removable bassinet bed requirements. This approach is less restrictive than prescribing one requirement and allows for more innovation in product designs.

Comment: One commenter stated that adding the removable bassinet bed stability requirement is premature. The commenter expressed the belief that the requirement should be removed from the regulation and that ASTM should be allowed to continue working on the issue.

Response: The Commission is aware of two deaths associated with this hazard scenario. (One of these deaths occurred in Canada; thus, it was not included in incident data counts reported in the SNPR briefing package.) Therefore, the Commission does not believe that this requirement is premature. The Commission believes that stakeholders have had plenty of time to test, review, discuss, and refine the proposed requirements before and after the SNPR was published. In fact, the language recommended for the final rule is essentially the same as what ASTM expects to ballot soon as a new requirement to address the same hazard.

Comment: A commenter stated that color-only visual indicators should not be allowed as an option to pass the removable bassinet bed requirement because people who are color-blind would not be able to distinguish between locked and unlocked.

Response: The requirement for visual indicators allows manufacturers to design a visual indicator that can be recognized by a person with a color vision deficiency. In addition, there are many other options to pass the requirement, and individuals who are color-blind can choose to purchase a product that does not use color indicators.

Comment: Some commenters expressed a belief that allowing removable bassinet beds to pass the stability test by tilting to a 20-degree angle was hazardous because consumers might think that a 20-degree angle is still usable, perhaps as an inclined sleeper.

Response: The Commission believes that an angle of 20° or more is acceptable to demonstrate that the bassinet is not useable. A steeper angle would also be acceptable, but the Commission is not convinced this is needed. Twenty degrees is twice the maximum allowable tilt for bassinets, which are intended to have a flat sleeping surface. In deciding on the 20° angle, the ASTM task group noted an incident (101101HCC3107) where a consumer clearly saw that something was

wrong with his bassinet when he saw it tilted and deemed it to be unusable. From the photos, the tilt was estimated to be approximately 17.°

### **Mattress Flatness**

Comment: Some commenters suggested that the mattress flatness requirements should be limited to 8° from the horizontal rather than 10.°

Response: Although the Commission would be amenable to using this more conservative margin of safety, *i.e.*, a tolerance of 16° of motion rather than 20,° the industry has maintained that a larger tolerance is necessary, due to the inherent variability of manufacturing products with fabric and foam. The industry claims that tighter tolerances on a segmented mattress made with the materials that are commonly used in these products would make it impossible to manufacture such mattresses. The Commission believes that the 10° limit is adequate to protect the expected user population.

Comment: A commenter suggested that the threshold limit for flatness should be 14° to preserve test-retest reliability.

Response: ASTM F2194-13 now includes the mattress flatness test requirement and procedure, as written in the SNPR, with the exception of the angle requirement. ASTM's requirement allows the use of an average for measurements over 10° and under 14,° while the SNPR proposed a maximum allowable measurement of 10.° Based on testing performed by an ASTM task group that was established to assess the reliability and repeatability of the mattress flatness test, the reliability of the test is adequate when the test is performed on products designed to pass the test. The commenter did not provide any new or different information to the Commission to support the suggestion for using the averaging method; thus, the Commission continues to support the 10° flatness criterion as proposed in the SNPR.

Comment: Some commenters questioned the use of a cylinder as a surrogate for a human occupant, and another commenter suggested that an automated human model would be more appropriate.

Response: An automated human model is not readily available. It is customary in the juvenile product industry to use easily manufactured shapes made from common materials. This testing strategy enhances the repeatability of the test. An ASTM task group conducted a repeatability and reproducibility study to compare various surrogates for use in the mattress flatness test. The cylinder was the best choice, based on the study results.

Comment: Some commenters suggested using the dummy in the test for mattress flatness so that infant position would be a factor.

Response: The test cylinder is a repeatable method that identifies hazardous products to the satisfaction of industry and the Commission. Unfortunately, the CAMI dummy is too stiff to be useful for simulating suffocation positions and would not be suitable to serve that purpose.

Comment: Some commenters wanted more explanation of how the cylinder sufficiently simulates an infant rolling into a mattress crease, as demonstrated in the mattress flatness test.

Response: The Commission has examined bassinets that pass the test and bassinets that fail. When visual comparisons and measurements of angles are made to compare the movements of the mattresses during a test using an anthropomorphic dummy versus tests using a cylinder, few discernible differences are evident. The shape of the test weight does not seem to be as important as the mass of the test weight in identifying hazardous products.

Comment: Two commenters offered opinions about the mattress flatness testing and designs of bassinet accessories that use support rods underneath the mattress. One of the two comments suggested that the mattress flatness test be performed with and without the bars in place.

Moreover, the commenter suggested that if the bars are required to be in place to pass the flatness test, then they should be attached permanently. Similarly, the other comment suggested that the frame supporting the floor (mattress) should come preassembled to eliminate the possibility that the consumer can misassemble the product.

Response: The Commission agrees with these comments. In January 2013, ASTM balloted a revised mattress flatness test, requiring that any segmented mattress that has consumer-assembled mattress support rods, be tested with and without the mattress support rods. This requirement resulted from the Commission's play yard misassembly NPR that was published in August 2012. The ballot item passed and is now part of ASTM F2194-13. The final rule incorporates by reference ASTM F2194-13; thus, the test will include the suggestion from the commenters.

Comment: A commenter stated that that the mattress flatness test could not be performed on bassinets that were less than 15 inches wide because of the width of the cylinder and the block used in that test method. Furthermore, the commenter noted that such a small, narrow occupant-retention space would not present the same hazards involved in incidents with wider play yard bassinet accessories.

Response: The Commission agrees that bassinets with occupant-retention spaces that are narrower than the test apparatus are unlikely to be used with an infant placed orthogonally between walls that are so narrow. In the case where an infant is placed in a narrow bassinet correctly and then moves or shifts 90,<sup>o</sup> the narrowness of the bassinet would likely not permit the infant to lie in a fully prone position, face down in an orthogonal seam. Thus, an exemption from the flatness test for mattress pad seams that run orthogonally between the sides of a bassinet

with a width of 15 inches or less seems reasonable. Therefore, the Commission is modifying the standard to exempt from the mattress flatness test bassinets that are narrower than 15 inches.

### **Effective Date**

**Comment:** We received several comments on the effective date proposed in the SNPR. One commenter, representing several advocacy groups, supported the six-month effective date proposed in the SNPR. A second commenter agreed, expressing concerns that if the date were extended and a death occurred, “consumers might view the death as the result of the CPSC putting the interests of for-profit entities . . . ahead of the safety of infants who use their products.”

In contrast, several other commenters, including one manufacturer, recommended longer effective dates to reduce the impact of the rule, particularly for small businesses that have “fewer resources and connections within the industry” and that “may have to significantly alter their means of production.” Suggested effective dates ranged from 9 to 15.5 months, with commenters recommending that the CPSC focus on relief for firms that would be disproportionately impacted by the rule. Commenters suggested longer effective dates for firms newly covered by the expanded scope, and firms whose products would be subject to the removable bassinet bed requirement.

A manufacturer commenting on the effective date stated that a longer effective date is needed for firms that will need to redesign their products to meet the removable bassinet bed requirement. This firm stated that an effective date of at least 15.5 months is needed to reflect accurately the challenges of redesigning the product.

**Response:** The Commission recognizes that some manufacturers will be required to redesign, test new prototype products, and then retool their production process to meet the new removable

bassinet bed provision. Based on a comment from one manufacturer who stated it would need a minimum of 15.5 months to redesign its product, the Commission considers 18 months to be a reasonable time period to accommodate other manufacturers that might also need to redesign their products. Therefore, the Commission is implementing a six-month effective date for the final rule, with the specific exception of extending the effective date for the removable bassinet bed test requirement to 18 months.

### **Stability Testing – CAMI Dummy**

Comment: Some commenters suggested using an infant and a newborn dummy in the stability test methods, while others said they believe the incident data do not support the need to change from an infant dummy to a newborn dummy because this change neglects the evidence that larger infants also use bassinets and cradles.

Response: The use of both dummies is unnecessary because the worst case scenario for stability is the smaller size dummy. The larger size dummy makes the product more stable. Therefore, if a product passes with a newborn, the product will also pass with an infant. Performing the test with two different dummies would be redundant and would only add to the cost of testing.

The Commission is requiring use of the newborn CAMI to make the test more stringent. Even if a majority of the incidents were not directly attributable to product stability, the instability of the product, in many incidents, was to blame, including two fatal incidents (one of which was reported from Canada).

### **Incident Data Analysis**

Comment: Some commenters asserted that a causal relationship could not be established for fatalities that the Commission attributed to design defects. They also stated that the information used by the Commission to analyze fall incidents was circumstantial. Other commenters

suggested that additional information should be collected to determine the extent to which product design was at fault, to evaluate the cause of falls, and to “improve and expand on the regulations and guidelines set forth in the proposed rule.”

Response: The Commission gathered as much information as possible on every cited product-related fatality through an in-depth, on-site field investigation. Although the Commission agrees with the commenters that additional information-gathering on all nonfatal injuries could be useful, given resource limitations, the Commission cannot follow up on every injury report with an in-depth investigation. Many of the nonfatal injuries were based on emergency department-treated cases from NEISS hospitals, and confidentiality requirements often prevent any additional contact with patients. In addition, even with cases that are followed, completion of the investigation is not guaranteed because of a lack of consumer cooperation or the inability to establish contact with the consumer.

Short of a controlled experimental setting, causal links are difficult to establish from observational data based on un-witnessed incidents. However, the combined judgment of subject matter experts at CPSC, corroborated by investigating state/county/local officials, supports the conclusions.

Comment: One set of commenters expressed the belief that the data presented in the SNPR is skewed and purposely misleading. There were specifics outlined in the comment, which are addressed in the response.

Response: The Commission disagrees strongly with the commenters’ assertion regarding the way the data are presented. For fatalities, the commenters contend that almost all of the incidents were due to caregiver negligence, even the ones that the Commission considered to be product related.

The commenters first argued that the Commission needed to gather more information on the fatalities deemed by the Commission to be product related. CPSC staff gathered as much information as possible on every cited product-related fatality through an in-depth, on-site field investigation. Because these incidents were not witnessed, the judgments of subject matter experts at CPSC and state/county/local investigating officials were combined to arrive at the conclusions about the manner of the deaths.

Second, the commenters asserted that of the three deaths that were due to infants sliding out of the fabric-sided opening, two were of the infants were older than the recommended-user age. Hence, the commenters further asserted, these two deaths cannot be counted as product-related because they were the result of caregiver negligence. The Commission disagrees with this assertion because the third decedent, who died in the same manner, was well within the recommended age limit. Therefore, the age of the other two decedents, barely a month above the recommended age limit, was deemed not to be a factor in the entrapments.

Third, the commenters stated that the non-product-related deaths appear to be due to caregiver negligence and do not justify CPSC's increasing the economic burden on manufacturers through added regulations. This argument has no basis because CPSC's regulation does not make any changes to the current voluntary standard based on these non-product-related fatalities.

For the nonfatal injuries, the commenters said they believe there is no justification for placing a burden on manufacturers by including one injury, due to a moldy mattress, in the report. CPSC staff includes all in-scope incidents in its hazard sketch, even if the Commission is not proposing any provisions to address the issue. Therefore, the manner in which staff reports the incident data does not impose any burden on manufacturers.

In addition, the commenters argued that six percent of the injuries from bassinets that were damaged during delivery were instances of blatant negligence on the part of the owners. First, to clarify, the Commission reported that six percent of the incidents, not injuries, involved bassinets damaged during delivery. Second, there were no injuries associated with these incidents, and the Commission did not propose any provisions to address the issue.

Comment: Some commenters said that the Commission needs to provide justification for its statement that the descriptions in the noninjury incident reports indicated the potential for serious injury. The commenters stated that without any further explanation, the statement seems “arbitrary.”

Response: CPSC staff has reviewed a number of incidents in which the caregiver was reported to be nearby and was able to rescue the infant from danger. Similar scenarios, with the infant unattended, have led to less favorable outcomes. Thus, the potential for serious consequences is not conjecture, and the statement is justified.

#### **Size and Weight Limits**

Comment: Some commenters suggested that the weight of an infant occupant should be considered in the standard’s scope to safeguard infants who exceed the recommended weight and size.

Response: The maximum weight of an occupant is already considered in the static load requirements in ASTM F2194-13, which the rule incorporates by reference. The industry requires a bassinet to be loaded to three times the manufacturer’s recommended weight. The side heights are also intended to account for the largest infants who might still use the bassinet.

#### **Bassinet Misuse**

Comment: One commenter expressed concern that the possibility of consumer misuse of bassinets would negate any effects of the new requirements.

Response: The Commission believes that strengthening the standard is the best way to improve product safety and that if significant product misuse becomes evident in injury reports, more developments are possible.

Comment: Another commenter suggested that educational campaigns about the proper and improper uses of bassinets would be sufficient.

Response: The Commission believes that educational campaigns play an important role in injury prevention but are best preceded by mechanical and physical safety requirements designed to make accidents as unlikely as possible to occur.

### **Restraints**

Comment: One commenter expressed the belief that the lack of incidents with harnesses could be due to other factors, as much as to the lack of harnesses in bassinets.

Response: Deaths and injuries in other infant products have been attributed to restraints/harness that were not used or were used improperly. Therefore the Commission is not making any changes regarding the current prohibition of restraints in bassinets.

### **Warnings**

Comment: Some commenters recommended the use of pictures or visual aids to clarify the warning messages.

Response: The Commission acknowledges that well-designed graphics can be useful in certain circumstances. However, the design of effective graphics can be difficult. Some seemingly obvious graphics are poorly understood and can give rise to interpretations that are opposite the intended meaning (so called “critical confusions”); therefore, a warning pictogram should be

developed with empirical study and well tested on the target audience. Although the Commission may take action in the future if it believes graphic symbols are needed to reduce the risk of injury associated with these products, the rule permits, but does not mandate, such supporting graphics.

With respect to the idea of creating a pictogram to communicate the dangers of soft bedding, the Commission agrees that a well-developed and tested pictogram could increase comprehension and acknowledges that such elements could be developed with some empirical study; the Commission, however, does not have the resources for such a project at this time and could not validate a warning graphic without research. However, there are a number of products for which such a soft bedding pictogram could be useful, such as bedside sleepers, bassinets, cribs, play yards, inclined sleep products, and others. Because of this, an ASTM cross-product ad hoc working group may be the best place to develop such a pictogram. This could foster cross-product harmonization of such a pictogram and would allow testing and validation of the pictogram. CPSC staff will gladly participate in any such group, and should the need arise, staff will consider future action once such a graphic is developed.

Comment: A commenter suggested adding statistics to the suffocation warning.

Response: Crafting a warning requires balancing the brevity of the message with its attention-grabbing features and informational content. Too much information makes a long label that is likely to be ignored by consumers. On the other hand, too little information leaves consumers unsure of the message. CPSC staff's opinion is that the addition of statistical information on the suffocation warning label will not increase the effectiveness of the warning.

Comment: A commenter suggested that the warnings contain the maximum recommended age of the bassinet occupant, *i.e.*, five months.

Response: The current warning contains a developmental milestone, rather than an age maximum. Developmental milestones have the advantage of allowing for individual variability in use patterns. Some children will gain strength and coordination faster than others and will need to be removed from the bassinet sooner. Since children's abilities are more important than their age when evaluating the applicability of the warning, the age is not included in the warning.

Comment: A commenter suggested that the warnings should be displayed in a prominent position.

Response: The ASTM standard, which the rule incorporates by reference, already contains a common definition for "conspicuous" warnings in Section 3.3.3, with corresponding requirements in Sections 8.3, 8.4, and 8.5.

Comment: A commenter suggested strengthening the warning labels by requiring mattress pads to have the following statement: "This padding has been tested to reduce the risk of suffocation to a minimal level," adding that "additional padding increases this risk substantially and has caused fatalities."

Response: Although the standard does contain a requirement for the mattress pad to remain level, the standard does not contain a test for reducing the risk of suffocation created by the softness of the padding, which seems to be the assumption made by the commenter. The standard already contains a warning in Section 8.4.2, instructing against the use of additional bedding materials. This required warning must be visible to the consumer when the product is in the manufacturer's recommended-use position. Thus, the warning will not be covered by sheets, which are allowed, and will be more effective than on the mattress pad where any messages will be covered.

Comment: Another commenter suggested that consumers need to be warned of the hazards associated with segmented mattresses.

Response: Warnings are the last stage at which attempts are made to remove a hazard from a product. Changing the product is more effective. The standard contains performance requirements designed to eliminate the hazards associated with segmented mattresses, so it is not necessary to include a warning.

Comment: Several commenters suggested that warnings should have larger fonts, duplication on opposing walls of the bassinet, duplication on the packaging and on the product, more detailed hazard descriptions, and more information in supporting educational materials and product advertisements.

Response: Although CPSC staff agrees that any warning could be strengthened with a size, color, or other graphical features, the product's final appearance also needs to be considered because exceptionally large or graphic warnings may cause consumers to remove or deface the warnings, thereby rendering them ineffective for later users. The current warning requirements match industry standards for many juvenile products.

### **The Necessity for a Standard**

Comment: Several commenters stated that the proposed standard for bassinets and cradles should not be adopted because the number of injuries and fatalities due to design defects was very low.

Response: The Consumer Product Safety Improvement Act (CPSIA) requires the Commission to issue a mandatory standard for bassinets and cradles, regardless of the number of incidents involving those products. Given the the CPSIA directive, the options are either to adopt the existing voluntary standard, as is, or revise the standard to make improvements. Even if a majority of the incidents were not directly attributable to defects in the product design, many incidents were. Congress mandated that CPSC adopt a more stringent standard if the

Commission determined that a more stringent standard “would further reduce the risk of injury.” The Commission feels strongly that the final rule would do so.

**Mattress Thickness (Rigid Products and Falls)**

Comment: Some commenters expressed concern that the standard allows for rigid-sided bassinets with thicker mattresses than soft-sided bassinets. These commenters said they feel that thicker mattresses may pose more of a risk of babies falling out when a baby rolls to one side and the product tilts.

Response: There are two requirements in the existing ASTM standard, which the rule incorporates by reference, which would prevent the scenario described by the commenters. The first is the side height requirement, which states that the side height of the bassinet be 7.5" above the uncompressed surface of the mattress. Thus, if a bassinet maker supplies a thick mattress with the rigid-sided bassinet, the side heights must account for the thicker mattress and still yield 7.5" of side height above the mattress surface. In addition, the standard has a rock/swing angle requirement that limits the maximum angle a rocking bassinet can have, as well as a maximum rest angle it can have. The rest angle is measured using a CAMI doll placed up against the side of the bassinet. Thus, the standard uses a worst-case placement scenario for the occupant during the testing.

**Health Canada Standard**

Comment: A representative of Health Canada corrected a statement in the SNPR and the corresponding staff briefing package, which states: “The Canadian standard (SOR 86-962:2010) includes requirements for cribs and non-full-size cribs. This standard does not distinguish between a bassinet and non-full-size cribs.” The commenter noted that this overview statement

was incorrect because on November 18, 2010, the amended Cribs, Cradles, and Bassinets Regulations (SOR/2010-261) came into effect, and now bassinets are included in the scope.

Response: The Commission thanks Health Canada staff for the correction and the subsequent information regarding how SOR 2010/261 distinguishes bassinets, cradles, and cribs. As the Commission now understands, Health Canada defines these three products according to the sleep surface area contained in the product.

#### **Play Yard Misassembly Requirement in Docket CPSC-2011-0064**

Comment: The commenter repeated comments submitted for Docket CPSC-2011-0064, regarding the play yard misassembly requirement that was proposed in August 2012.

Response: The Commission has addressed these comments in the final rule briefing package for Play Yard Misassembly Requirement, dated June 26, 2013.

#### **International Standards**

Comment: Commenters remarked that more information regarding the international standards that were mentioned in the SNPR would be helpful.

Response: The Commission provided the names and designations of the standards, plus a description of where they differed substantially from the ASTM standard. Due to copyright laws, the Commission was not able to provide full copies of the standards. All of the standards are available for purchase online by anyone who seeks more information.

#### **ASTM Copyright and Accessibility**

Comment: Some commenters stated that the ASTM standard for bassinets and cradles should not be the basis of a mandatory rule because, as a copyrighted standard, the ASTM standard is not easily accessible to the public and creates an undue financial burden on small manufacturers and the general public.

Response: Section 104(b) of the CPSIA requires the Commission to issue standards for durable infant or toddler products that are substantially the same as applicable voluntary standards or are more stringent if more stringent standards would further reduce the risk of injury. Incorporating a voluntary standard, such as incorporating the ASTM standard by reference, is a well-recognized procedure for agencies. The incorporation satisfies the requirement of publication in the *Federal Register*. See 5 U.S.C. § 552(a)(1)(E) (“matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register”).

**Falls from Bassinets/Side Height**

Comment: Some commenters suggested that the side height requirements need to be higher because consumers seem to be using bassinets with children older than the recommended ages. One commenter expressed the belief that the standard should match the Canadian side height requirement.

Response: The ASTM subcommittee discussed the side heights of bassinets for years. There was no side height requirement until recently. Consumers use the products longer than manufacturers recommend. High side heights could cause consumers to use their bassinets even longer than they have been using them because the older, larger children who can push up on their hands and sit unassisted will look safer in a bassinet with tall sides. The unintended consequence of taller sides might be an increase in falls from bassinets because older children are stronger and more agile than newborns. After much discussion, the ASTM subcommittee agreed to a 7.5-inch side height, based on the precedent set by the Canadians, who measure from the bottom of the bassinet rather than the mattress top. This difference in measurement landmarks makes it appear that the ASTM standard permits shorter sides; but in reality, the effective side height of a

bassinet in Canada is the same as in the ASTM standard. This side height requirement did not necessitate drastic changes in the bassinet designs on the market; so it would be unlikely that instituting the requirement would have any effect on consumer behavior.

Comment: Several commenters suggested that side height requirements might not be effective against misuse. One commenter expressed the belief that the burden should be placed on caregivers and that the standard needs no modification to address falls. Another suggested that warning labels should be strengthened instead.

Response: The side height requirement (7.5-inch minimum) is already part of ASTM F2194-13, which this rule incorporates by reference. The rule does not add anything further because the Commission believes that the requirements should be effective against misuse. The Commission believes that, at a minimum, this requirement will help protect infants who have not exceeded the maximum age requirement for bassinet use. Additionally, the Commission supports the current warnings in the ASTM standard.

### **Existing Inventory**

Comment: One commenter expressed concern that the Commission did not address the existing cradle and bassinet inventory that would need “to be discarded or recalled” when the regulation becomes effective.

Response: The bassinet and cradle standard is prospective. It will apply to products manufactured or imported on or after the effective date. Therefore, existing inventory would not be affected.

### **Cost Benefit Analysis**

Comment: Several commenters expressed the belief that a cost-benefit analysis should be performed, and they stated that the proposed rule should not be adopted because costs are likely to exceed benefits.

Response: Section 104(b) of the Consumer Product Safety Improvement Act (CPSIA), part of the Danny Keysar Child Product Safety Notification Act, requires the CPSC to issue a standard at least as stringent 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 such products. Thus, the Commission must issue a mandatory standard for bassinets and cradles, regardless of the costs and benefits of the rule.

#### **Third Party Testing Cost**

Comment: Two commenters expressed concern about the “substantial additional costs” that will result from a new requirement for third party testing that will be added by the bassinet/cradle standard.

Response: The testing costs referred to by the commenters result from the third party testing and certification requirements imposed under sections 14(a)(2) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. The costs associated with testing will be substantially the same, regardless of the form the final bassinet/cradle standard takes.

#### **Definition of a Small Business**

Comment: One commenter questioned defining “small manufacturers” as those with fewer than 500 employees. The commenter noted that business size can vary widely within such a broadly defined group. The commenter expressed concern that the economic impact could be disproportionately significant for the very smallest firms.

Response: The U.S. Small Business Administration (SBA) is the source of the definition of “small manufacturers” of bassinets and cradles. Regardless of the desirability of a finer gradation in defining small businesses, the SBA definition governs the small business determination in the context of a regulatory flexibility analysis.

### **Impact of Expanding the Scope**

Comment: One commenter expressed concern about the “adverse monetary impact” that expanding the scope of the standard to include Moses baskets would have upon some suppliers. The commenter felt that the alternative of ceasing to supply stands for these newly covered products requires further inquiry before “suggesting that this is a viable alternative.” Other commenters questioned methods firms might use to mitigate their “upfront costs,” including amortizing, “increased product sales,” and passing “the additional costs on to consumers.”

Response: When used with a stand, Moses baskets meet the definition of a “bassinet” (or “cradle,” in the case of a rocking stand), and therefore, they must be tested as a bassinet. Given that most suppliers of Moses baskets do not include stands, supplying Moses baskets without stands is one viable option that firms are already practicing.

Similarly, the statement that “direct impact may be mitigated if costs are treated as new product expenses that can be amortized” recognizes one of the methods firms use routinely in the development of new products to reduce the immediate financial impact; rather than incurring all of the development costs up front, amortizing allows the firm to spread the impact over time. Finally, for most products, firms are usually able to pass on some, but not all, increases in production costs to consumer. The portion of costs that are passed on (i.e. not absorbed by the firm) partially offset or mitigate the impact of the rule.

### **Aiding Small Businesses**

Comment: One commenter suggested that the Commission “create a framework with which to aid some of the smaller manufacturers and distributors with finding the resources, information and connections they need to comply with the new standards.”

Response: CPSC’s Small Business Ombudsman provides small businesses with guidance to assist them in complying with CPSC requirements. Assistance is available to firms in understanding and complying with CPSC regulations (<http://www.cpsc.gov/en/Business--Manufacturing/Small-Business-Resources/>).

### **Small Bedding Suppliers**

Comment: One commenter asked that the Commission put “less weight” on small bedding suppliers in the regulatory flexibility analysis. The commenter expressed concern that:

“[N]oncompliant bedding could potentially negate the efficiency of . . .” safety measures such as strangulation warnings “. . . or require manufacturers to take additional steps to correct noncompliant bedding.”

Response: The standard does not include any bedding requirements. However, in investigating the bassinet/cradle market, staff could not determine the underlying source of bassinets for several suppliers of bassinets. The firms for whom the bassinet source could not be identified shared one major characteristic: they were primarily bedding suppliers who sold bassinets or cradles with the appropriate bedding covering the bassinet/cradle frame. Because these firms supply bassinets/cradles, they are affected by the rule and impacts must be fully considered under the Regulatory Flexibility Act.

### **Labeling Costs**

Comment: One commenter objected to the costs that will be associated with changing the warning labels.

Response: The commenter misunderstood the information presented in the Paperwork Reduction Act section of the SNPR. The commenter interpreted the cost per burden hour associated with labeling (\$27.55) to be the increased cost per unit, which is an incorrect conclusion.

## **VII. Assessment of Voluntary Standard ASTM F2194-13 and Description of Final Rule**

Consistent with section 104(b) of the CPSIA, this rule establishes new 16 CFR part 1218, “Safety Standard for Bassinets and Cradles.” The new part incorporates by reference the requirements for bassinets and cradles in ASTM F2194-13, with certain additions and changes to strengthen the ASTM standard, to further reduce the risk of injury. The following discussion describes the final rule, the changes, and the additions to the ASTM requirements. (The description of the amendment to 16 CFR part 1112 may be found in Section XIII of this preamble.)

### **A. Scope (§ 1218.1)**

The final rule states that part 1218 establishes a consumer product safety standard for bassinets and cradles manufactured or imported on or after the date that is six months after the date of publication of a final rule in the FEDERAL REGISTER, except that the effective date for the removable bassinet bed requirements would be 18 months after the date of publication of a final rule in the FEDERAL REGISTER.

### **B. Incorporation by Reference (§ 1218.2)**

Section 1218.2(a) explains that, except as provided in § 1218.2(b), each bassinet and cradle must comply with all applicable provisions of ASTM F2194-13, “Standard Consumer Safety Specification for Bassinets and Cradles,” which is incorporated by reference. Section 1218.2(a) also provides information on how to obtain a copy of the ASTM standard or to inspect a copy of the standard at the CPSC. The Commission received no comments on this provision in

the SNPR, but the Commission is changing the language in the incorporation in the final rule to refer to ASTM F2194-13, the current version of the ASTM standard.

### **C. Changes to Requirements of ASTM F2194-13**

1. Clarification of Scope. (§ 1218.2(b)(1)(i)). The final rule modifies the scope of ASTM F2194-13 to clarify that multimode combination products must meet the bassinet/cradle standard in any configuration where the seat incline is 10 degrees or less from horizontal. This modification resulted from comments on the SNPR seeking clarification on what products are included in the scope, as more fully discussed in Section VI.

2. Change to Stability Test Procedure. (§ 1218.2(b)(2) and § 1218.2(b)(6)). In the SNPR, the Commission proposed that bassinet/cradle stability testing be conducted with a CAMI newborn dummy, rather than the CAMI infant dummy. Because ASTM has yet to adopt this modification (although it is expected to be balloted in the near future), the Commission is including it in the final rule.

It is appropriate that the smaller newborn CAMI dummy be used for stability testing, because bassinets and cradles are intended to be used by very young children. The heavier (17.5-pound) infant CAMI currently specified for stability testing in ASTM F2194-13 could make these products more stable when tested than they would actually be in a real-world situation.

3. Removable Bassinet Bed. (§ 1218.(b)(3), (5), and (7)). In the SNPR, the Commission proposed adding a requirement for removable bassinet beds (along with test procedures and new definitions). As stated in the preamble of the SNPR (77 FR 64061), there have been several incidents involving bassinet beds that were designed to be removed from their stand, four of which have In-Depth Investigations. During the incidents, the bed portion of the unit was not locked completely or attached properly to its stand. The bed portion of the unit appeared to be

stable, giving the caregivers a false sense of security. For various reasons, the bed portion fell or tilted off of its stand. There have also been nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand, or the latch failed to engage as intended. In May 2012, 46,000 bassinets that could appear to latch to the stand when they actually had not latched were recalled.

(<http://www.cpsc.gov/cpscpub/prerel/prhtml12/12173.html>).

The SNPR proposed multiple options for a bassinet with a removable bed attachment to pass the proposed requirement. These options include: 1) ensuring that the bed portion of the bassinet is inherently stable when the bassinet bed is placed on the stand unlatched; 2) use of a false lock/latch visual indicator mechanism; 3) use of a stand that collapses if the bassinet bed is not properly attached; and 4) the presence of an obvious unsafe angle (more than 20 degrees) or a bassinet bed falls to the floor when it is not properly attached to the stand.

Since the issuance of the SNPR, ASTM has made several clarifying changes to the removable bassinet bed requirement, definitions, and test procedures, and ASTM is expected to send these changes out for ballot in the near future. Most of the differences are editorial changes to provide clarity to the test requirement and the test procedure. The significant, noneditorial differences between the requirement proposed in the SNPR and what ASTM is expected to ballot are as follows:

- The next ASTM ballot is expected to exclude play yard bassinets, as defined in the standard, from the removable bassinet bed definition. Thus, play yard bassinets would not be subject to the removable bassinet bed stability requirement.

- The next ASTM ballot is expected to expand on one of the pass criteria for the removable bed stability requirement, to allow bassinet stands that cannot remain in their proper use position unless the bassinet bed is properly attached.

The Commission agrees with these revisions and is adding the revised removable bassinet bed requirement as part of the final bassinet/criadle rule.

4. Mattress Flatness. (§ 1218.2(b)(4)(i)). A segmented mattress flatness requirement and associated test procedures were proposed by the Commission as part of the SNPR. ASTM adopted the requirement with modified, less stringent pass/fail criteria. The final rule modifies the pass/fail criteria in ASTM F2194-13 to mirror the SNPR proposal.

As stated in Section V, the mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees. As discussed in the preamble to the SNPR, the 14-degree angle was based on an extrapolation of angles formed by dimensions of *average* infant faces. 77 FR 64060-64061. The Commission is uncomfortable using the *average* infant facial dimension as the basis for this requirement. Therefore, instead of using the average infant anthropometrics as a basis for the pass/fail criteria, the Commission continues to support using the smallest users' anthropometrics to set the test requirement of 10 degrees maximum for each measurement taken.

5. Exemption from Mattress Flatness Requirement. (§ 1218.2(b)(4)(i)). The final rule exempts from the mattress flatness requirement bassinets that are less than 15 inches across. These products do not pose the hazard the requirement is intended to address, and they are also not wide enough to test using the required procedures and equipment.

### **VIII. 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). The Commission is setting an effective date for the standard six months after publication for products manufactured or imported on or after that date, with the exception of the removable bassinet bed test requirement and procedure.

The Commission recognizes that some manufacturers will be required to redesign, test new prototype products, and then retool their production process in order to meet the new removable bassinet bed provision. Based on a comment from a manufacturer who asked for a minimum of 15.5 months to redesign its product, the Commission considers 18 months to be a reasonable time period to take into account other manufacturers who might also need to redesign their product. Therefore, the Commission is setting an 18-month effective date for the removable bassinet bed test requirement.

### **IX. Regulatory Flexibility Act**

#### **A. Introduction**

The Regulatory Flexibility Act (RFA) requires that agencies review rules for their potential economic impact on small entities, including small businesses. 5 U.S.C. 604. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis when they promulgate 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. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

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

#### **B. The Market for Bassinets/Cradles**

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which

have separate divisions for juvenile products. CPSC staff believes that there are currently at least 62 suppliers of bassinets and/or cradles to the U.S. market; 26 are domestic manufacturers; 19 are domestic importers; three are domestic retailers; and two are domestic firms with unknown supply sources. Twelve foreign firms currently supply the U.S. market: 10 manufacturers, one firm with an unknown supply source, and one importer that imports from foreign companies and distributes from outside of the United States. Eight additional firms specialize in children's bedding, some of which is sold with bassinets or cradles; the supply sources for these eight firms could not be identified.

Bassinets and cradles from 11 of the 62 firms have been certified as compliant by the Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers. Firms supplying bassinets or cradles would be certified to the ASTM voluntary standard F2194-12a, while firms supplying play yards with bassinet/cradle attachments would also have to meet F406-12a. (JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. ASTM F2194-12a was published in September 2012, and therefore, the standard would have become effective in March 2013. The more recent standard, ASTM F2194-12b, was published in December 2012, and therefore, that standard was not yet effective when research for this rule was conducted.) Twenty-four additional firms claim compliance with the relevant ASTM standard for at least some of their bassinets and cradles. Whether the bassinets or cradles supplied by the eight bedding suppliers comply with ASTM F2194 is not known.

According to a 2005 survey conducted by the American Baby Group (2006 Baby Products Tracking Study), 64 percent of new mothers own bassinets; 18 percent own cradles; and 39 percent own play yards with bassinet attachments. Approximately 50 percent of

bassinets, 56 percent of cradles, and 18 percent of play yards were handed down or purchased secondhand. Thus, approximately 50 percent of bassinets, 44 percent of cradles, and 82 percent of play yards were acquired new. These statistics suggest annual sales of a total of approximately three million units sold per year, consisting of about 1.3 million bassinets (.5 x .64 x 4 million births per year), 317,000 cradles (.44 x .18 x 4 million), and 1.3 million play yards with bassinet attachments (.82 x .39 x 4 million). (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2010," *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.)

National injury estimates were not reported by the Directorate for Epidemiology in the supplemental NPR or in the current FR briefing package because the data failed to meet NEISS publication criteria. However, emergency department injury estimates over the approximately five years covered by the supplemental NPR and the current FR briefing package, from 2008 through 2012, averaged less than 250 annually. Based on data from the 2006 Baby Products Tracking Study, approximately 4.8 million bassinets and cradles were owned by new mothers. Therefore, the injury rate may be on the order of about 0.5 emergency department-treated injuries per 10,000 bassinets/cradles available for use in the households of new mothers ((250 injuries ÷ 4.84 million products in households of new mothers) x 10,000).

### **C. Reason for Agency Action and Legal Basis for the Rule**

The Danny Keysar Child Product Safety Notification Act requires the CPSC to promulgate a mandatory standard for bassinets/cradles that is substantially the same as, or more stringent than, the voluntary standard. The Commission is adopting ASTM F2194-13 with five

modifications or additions that reflect: (1) changes proposed in the SNPR that are not part of F2194-13; (2) responses to public comments; and/or (3) additional work undertaken by ASTM, but not yet adopted. The changes will address a variety of known hazard patterns, including suffocation and positional asphyxia.

#### **D. Requirements of the Final Rule**

As stated in Section VII, the Commission is incorporating the voluntary standard for bassinets/cribbs, ASTM F2194-13, by reference, with five changes.

The Commission is implementing two modifications to ASTM F2194-13 in response to SNPR comments; neither is expected to have a negative impact on firms. The first is a modification to the scope that would clarify that multimode or combination products must meet the bassinet/cribble standard in any configuration where the seat incline is 10 degrees or less from horizontal. Because the clarifying modifications do not change the scope of the standard, the modifications have no additional impact. The second is an exemption from the mattress flatness requirement for bassinets that are less than 15 inches across. Because of the characteristics of the narrower bassinets, these products are not subject to the hazard that the requirement is intended to address. Additionally, these narrower bassinets are not wide enough to test using the required procedures and equipment.

The Commission is implementing three additional changes to ASTM F2194-13, each of which is considered in separate sections below.

##### **1. Stability testing**

As stated in Section V of this preamble, in the SNPR, the Commission proposed that bassinet/cribble stability testing be conducted with a CAMI newborn dummy, rather than the CAMI infant dummy. Because ASTM has yet to adopt this modification (although the

modification is expected to be balloted in the near future), the Commission is including the modification in the final rule. Based on limited testing, many bassinets/cradles appear to be able to pass this modified test procedure without modification. However, a few products may potentially require modifications to meet the revised stability test procedure. Staff believes that the modified test procedure is likely to affect only a few manufacturers, and likely will not require product redesign. Affected firms would most likely increase the stability of their product by widening the structure, making the bassinet bed deeper, or making the base heavier. The cost of meeting the modified requirement could be more significant if a change to the hard tools used to manufacture the bassinet is necessary. During the production process, a hard tool, which is a mold of the desired bassinet component shape, is injected with plastic or another material using a molding machine.

## 2. Mattress Flatness

A segmented mattress flatness requirement and associated test procedures were proposed by the Commission as part of the SNPR. ASTM adopted the requirement with modified (and less stringent) pass/fail criteria. The Commission is modifying the pass/fail criteria in ASTM F2194-13 to mirror the SNPR proposal.

The mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees.

Based on staff's testing, the play yard bassinet attachments of many suppliers (both compliant and non-compliant) appear to pass the requirement without any modifications. Bassinet attachments that would require some modification would need to increase the mattress support in their bassinets. Additional mattress support could be accomplished, for example, by retrofitting play yard bassinets to use longer rods or a better-fitting mattress shell. The cost of such a retrofit is unknown and would likely vary from product to product; however, a retrofit generally is less expensive than a product redesign.

### 3. Removable Bassinet Bed

As stated in Section V of this preamble, in the SNPR, the Commission proposed adding a requirement for removable bassinet beds (along with test procedures and new definitions). Since then, an ASTM task group has made several clarifying changes to the requirement, definitions, and test procedures and is expected to recommend them for ballot. The Commission is adopting the revised removable bassinet bed requirement as part of the final bassinet/cradle rule.

There are several firms supplying bassinets with removable bassinet beds to the U.S. market. The majority will require no modifications to meet the requirement. However, at least three firms are expected to need changes to one or more of their bassinets. Firms could meet the removable bassinet requirement in a number of ways, including redesigning the product entirely. However, many firms are likely to opt for less expensive alternatives, such as more sensitive locks that activate with little pressure (*i.e.*, with just the weight of the bassinet), where possible.

The costs and time involved in a redesign could be significant; one manufacturer stated in SNPR comments that the manufacturer would require 15.5 months to redesign its product to meet the removable bassinet bed requirement. Therefore, the Commission is setting an 18-

month effective date for this requirement, while maintaining a six-month effective date for the remainder of the final rule.

#### **F. Other Federal or State Rules**

A final rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule). Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards: (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product; (ii) for the testing of representative samples to ensure continued compliance; (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules; and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because bassinets and cradles will be subject to a mandatory children's product safety rule, these products also will be subject to the third party testing requirements of section 14(a)(2) of the CPSA and the 1107 rule when the bassinet/cradle mandatory standard and the notice of requirements become effective.

#### **G. Impact on Small Businesses**

At least 62 firms are currently known to be marketing bassinets and/or cradles in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bassinets/cradles is small if the business has 500 or fewer employees; importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, about 39

of the 62 total firms are small firms—21 domestic manufacturers, 16 domestic importers, and two firms with unknown supply sources. An additional eight small firms supplying bassinets/cribbs along with their bedding; these may or may not originate from one of the 62 firms already accounted for. Other unknown small bassinet/cribble suppliers also may operate in the U.S. market.

### ***Small Manufacturers***

The expected impact of the final standard on small manufacturers will differ based on whether their bassinets/cribbs are already compliant with F2194-12a. (Play yards with bassinet attachments must comply with the effective play yard standard (F406), which includes a requirement that the attachment meet the bassinet/cribble standard.) In general, firms whose bassinets and cribbes meet the requirements of F2194-12a are likely to continue to comply with the voluntary standard as new versions are published. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. Firms supplying bassinets and cribbes that comply with ASTM F2194-12a are likely also to comply with F2194-13 before the final bassinet/cribble rule becomes effective.

The majority of the changes to the voluntary standard (ASTM F2194-13) are the same as at the SNPR level; only the expanded scope proposed in the SNPR has been completely incorporated into the voluntary standard. Therefore, the expected impact of the final rule remains substantially the same as the impact presented in the initial regulatory flexibility analysis for the SNPR.

For manufacturers whose products are likely to meet the requirements of ASTM F2194-13 (14 of 21 firms), the direct impact could be significant for one or more firms if they must

redesign their bassinets to meet the final rule. Although the products of all firms would be subject to the stability testing requirements, in most cases, modifications are unlikely to be required and the costs are not expected to be significant. The products of five firms could be affected by the mattress flatness requirement (*i.e.*, they produce play yards with bassinet attachments), and at least three (and possibly five) of the known firms may be affected by the removable bassinet bed requirement. For the most part, the bassinets/cradles and bassinet cradle attachments supplied by these firms will be able to meet the changes to ASTM F2194-13 without modification. In cases where modifications are necessary, firms would most likely opt to retrofit their products, rather than undertake an expensive redesign. However, some products may require redesign, particularly to meet the new removable bassinet bed requirement, and therefore, costs could be significant in some cases. The Commission is adopting an 18-month effective date for the removable bassinet bed portion of the final rule to reduce the impact on affected firms.

Meeting ASTM F2194-13's requirements could necessitate product redesign for at least some bassinets/cradles not believed to be compliant with F2194-12a (7 of 21 firms). These firms could require redesign regardless of the modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but could be more significant if changes to the frame are required, including changes to side height. One manufacturer estimated that a complete play yard redesign, including engineering time, prototype development, tooling, and other incidental costs, would cost approximately \$500,000. The Commission believes that a bassinet redesign would tend to be comparable. Consequently, the final rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2194-12a. Any direct financial impact may be mitigated if a firm

chooses to treat costs as new product expenses that can be amortized over time rather than a large, one time expense.

Some firms whose bassinets/cradles are neither certified as compliant, nor claim compliance with F2194-12a, in fact, may be compliant with the standard. The Commission has identified many such cases with other products. To the extent that some of these firms may supply compliant bassinets/cradles and have developed a pattern of compliance with the voluntary standard, the direct impact of the final rule will be less significant than described above. If two small firms with unknown supply sources, none of whose products appear to comply with F2194-12a, are manufacturers, these firms also may need to redesign their products to meet the final rule.

In addition to the direct impact of the final rule described above, the rule will have some indirect impacts. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107). Third party testing will pertain to any physical and mechanical test requirements specified in the bassinet/cradle final rule; lead and phthalates testing is already required. Impacts of third party testing are not due directly to the bassinet/cradle rule's requirements, but are due to the testing rule's requirements. Consequently, impacts from the testing rule are indirect impacts from the bassinet/cradle final rule, and such indirect impacts could be significant.

One manufacturer estimated that testing to the ASTM voluntary standard runs around \$1,000 per model sample, although the manufacturer noted that the costs could be lower for some models where the primary difference is fabric rather than structure.

On average, each small domestic play yard manufacturer supplies seven different models of bassinets/cribbeds and play yards with bassinet/cribble accessories to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$7,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2194-13 is unlikely to be significant if only one bassinet/cribble sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third party testing costs could have a significant impact on a few of the small manufacturers.

### ***Small Importers***

As with manufacturers of compliant bassinets/cribbeds, the seven small importers of bassinets/cribbeds currently in compliance with F2194-12a could experience significant direct impacts as a result of the final rule if product redesign is necessary. In the absence of regulation, these importing firms would likely continue to comply with the voluntary standard as it evolves, as well as the final mandatory standard. Any increase in production costs experienced by their suppliers may be passed on to the importers.

Importers of bassinets/cribbeds would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the final rule, which may be the case with the nine importers of bassinets/cribbeds not believed to be in compliance with F2194-12a. Some could respond to the rule by discontinuing the import of their noncomplying bassinets/cribbeds, possibly discontinuing the product line altogether. The impact of such a decision could be mitigated by replacing the noncompliant bassinet/cribble with a compliant bassinets/cribble, or by deciding to import an alternative product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers that must perform the testing themselves if more than one sample per model were required.

### ***Other Possible Suppliers***

Eight known small firms specialize in the supply of bedding, including bedding for bassinets and cradles, and the eight firms sell bassinet and cradle bedding *with* a bassinet or cradle. Although these firms do not manufacture the bassinets or cradles themselves, whether they purchase the bassinets or cradles domestically or from overseas is not known. These firms may source the bassinets and cradles sold with bedding in full or in part from one of the 62 firms discussed above. If the eight firms do not source from one of the 62 firms, then the eight firms represent additional suppliers to the U.S. market.

The eight firms with unknown supply sources would be affected in a manner similar to importers; they would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the final rule. Unlike most importers, however, the firms would not have the option of replacing a noncompliant bassinet/cradle with another product. Although the firms could opt to sell the bedding without the associated bassinet/cradle, such an approach would represent a change from their historical method of sale and might adversely impact their business strategy.

As with manufacturers and importers, these eight firms will also be subject to third party testing and certification requirements, and will experience costs similar to those for manufacturers if their supplying firm(s) does not perform third party testing. The resulting costs

could have a significant impact on some of these small bassinet or cradle suppliers that must perform the testing themselves.

#### **H. Alternatives**

Under the Danny Keysar Child Product Safety Notification Act of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Doing so would reduce the potential impact on firms whose bassinets/cradles comply with the voluntary standard. However, because of the severity of the incidents associated with removable bassinet beds, instability, and mattress tilt, the Commission is not pursuing this alternative.

The Commission is imposing a six-month effective date for the final rule with an 18-month effective date, supported by SNPR comments submitted by one manufacturer, for the removable bassinet bed requirement. Setting a later effective date for either part will allow suppliers additional time to modify and/or develop compliant bassinets/cradles and spread the associated costs over a longer period of time.

#### **X. Environmental Considerations**

The Commission's regulations address whether the Commission is required to prepare an environmental assessment or an environmental impact statement. These regulations recognize that certain CPSC actions normally have "little or no potential for affecting the human environment." One such action is establishing rules or safety standards for products. 16 CFR 1021.5(c)(1). This rule falls within the categorical exclusion.

#### **XI. Paperwork Reduction Act**

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction

Act of 1995 (44 U.S.C. 3501–3521). The preamble to the proposed rule (77 FR at 64055 through 64076) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Briefly, sections 8 and 9 of ASTM F2194-13 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

OMB has assigned control number 3041-0157 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated suppliers subject to the information collection burden is now estimated to be 62 firms, rather than the 55 firms initially estimated in the proposed rule.

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

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1218	62	5	310	1	310

There are 62 known entities supplying bassinets to the U.S. market. All 62 firms are assumed to use labels already on both their products and their packaging, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about one hour per model. Each entity supplies an average of five different models of bassinets; therefore, the estimated burden associated with labels is 1 hour per model x 55 entities x 5 models per entity = 310 hours. We estimate that the hourly compensation for the

time required to create and update labels is \$27.55 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirement is \$8,540.50 (\$27.55 per hour x 310 hours = \$8,540.50).

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

## **XII. Preemption**

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

## **XIII. Certification and Notice of Requirements (NOR)**

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable 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. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The safety standard for bassinets and cradles 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). This rule became effective June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the bassinet and cradle standard, require an amendment to part 1112. Accordingly, this rule amends part 1112 to include the bassinet and cradle standard in the list with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for bassinets and cradles are required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it can apply to the CPSC to have 16 CFR part 1218, "Safety Standard for Bassinets and Cradles,"

included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

In connection with the part 1112 rulemaking, CPSC staff conducted an analysis of the potential impacts on small entities of the rule establishing accreditation requirements, 78 FR 15836, 15855-58 (March 12, 2013), as required by the Regulatory Flexibility Act and prepared a Final Regulatory Flexibility Analysis (FRFA). Briefly, the FRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would not likely pursue accreditation for this purpose. Similarly, amending the part 1112 rule to include the NOR for the bassinet and cradle standard would not have a significant adverse impact on small laboratories. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards and the only costs to them would be the cost of adding the bassinet and cradle standard to their scope of accreditation. As a consequence, the Commission certifies that the notice requirements for the bassinet and cradle standard will not have a significant impact on a substantial number of small entities.

To ease the transition to new third party testing requirements for bassinets and cradles subject to the standard and to avoid a “bottlenecking” of products at laboratories at or near the effective date of required third party testing for bassinets and cradles, the Commission, will,

under certain circumstances, accept certifications based on testing that occurred before the effective date for third party testing.

The Commission will accept retrospective testing for 16 CFR part 1218, safety standard for bassinets and cradles, if the following conditions are met:

- The children's product was tested by a third party conformity assessment body accredited to ISO/IEC 17025:2005(E) by a signatory to the ILAC–MRA at the time of the test. The scope of the third party conformity body accreditation must include testing in accordance with 16 CFR part 1218. 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 the tests contained in the safety standard for bassinets and cradles at the time of initial Commission acceptance. For governmental third party conformity assessment bodies, accreditation of the body must be accepted by the Commission, even if the scope of accreditation did not include the tests contained in the safety standard for bassinets and cradles at the time of initial CPSC acceptance.
- The test results show compliance with 16 CFR part 1218.
- The bassinet or cradle was tested on or after the date of publication in the *Federal Register* of the final rule for 16 CFR part 1218 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**

**16 CFR Part 1112**

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

**16 CFR Part 1218**

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations as follows:

**PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES**

- 1. The authority citation for part 1112 continues to read as follows:

**Authority:** 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

- 2. Amend Part 1112.15 by adding paragraph (b)(37) to read as follows:

**§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?**

\* \* \* \* \*

(b) The CPSC has published the requirements for accreditation for third party conformity assessment bodies to assess conformity for the following CPSC rules or test methods:

\* \* \* \* \*

(33) 16 CFR part 1218, Safety Standard for Bassinets and Cradles.

**PART 1218-SAFETY STANDARD FOR BASSINETS AND CRADLES**

- 3. Add a new part 1218 to read as follows:

Sec.

1218.1 Scope.

1218.2 Requirements for Bassinets and Cradles.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

**§ 1218.1 Scope.**

This part establishes a consumer product safety standard for bassinets and cradles manufactured or imported on or after **[INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, except for the removable bassinet bed attachment requirements at §§ 1218(b)(3)(i)-(iv), 1218(b)(5), and 1218(b)(7), which are effective **[INSERT DATE 18 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**§ 1218.2 Bassinets and Cradles.**

(a) Except as provided in paragraph (b) of this section, each bassinet and cradle must comply with all applicable provisions of ASTM F2194-13, Standard Consumer Safety Specification for Bassinets and Cradles, approved on April 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/cpsc.htm>. 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) Comply with ASTM F2194-13 standard with the following additions or exclusions:

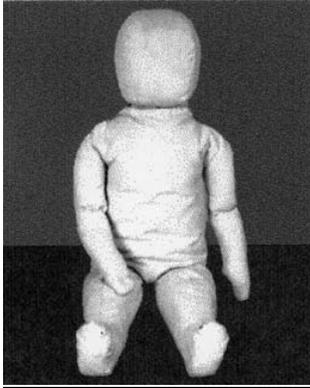
(1) Instead of complying with Note 1 of section 1.3.1 of ASTM F2194-13, comply with the following:

(i) **Note 1**--Cradle swings with an incline less than or equal to 10° from horizontal while in the rest (non-rocking) position are covered under the scope of this standard. A sleep product that only has inclined sleeping surfaces (intended to be greater than 10° from horizontal while in the rest (non-rocking) position) does not fall under the scope of this standard. If a product can be converted to a bassinet/cradle use mode and meets the definition of a bassinet/cradle found in 3.1.1 while in that mode, the product shall be included in the scope of this standard, when it is in the bassinet/cradle use mode. For example, strollers that have a carriage/bassinet feature are covered by the stroller/carriage standard when in the stroller use mode. Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1. In addition, bassinet/cradle attachments to cribs or play yards, as defined in 3.1.2 or 3.1.12, are included in the scope of the standard when in the bassinet/cradle use mode.

(ii) [Reserved]

(2) Add “CAMI Newborn Dummy (see Figure 1A). Drawing numbers 126-0000 through 126-0015 (sheets 1 through 3), 126-0017 through 126-0027, a parts list entitled “Parts List for CAMI Newborn Dummy,” and a construction manual entitled “Construction of the Newborn Infant Dummy” (July 1992). Copies of the materials may be inspected at NHTSA’s Docket Section, 400 Seventh Street S.W., Room 5109, Washington, DC, or at the Office of the Federal

Register, 800 North Capital Street N.W., Suite 700, Washington, DC.” to “2.3 Other References” and use the following figure:



**FIG. 1a CAMI Newborn Dummy**

(3) In addition to complying with section 3.1.17 of ASTM F2194-13, comply with the following:

(i) 3.1.18 *bassinet bed, n* – the sleeping area of the bassinet/cradle, containing the sleep surface and side walls.

(ii) 3.1.19 *removable bassinet bed, n* – A bassinet bed that is designed to separate from the base/stand without the use of tools. Play yard bassinets, as defined in 3.1.13, are excluded from this definition.

(iii) 3.1.20 *false lock/latch visual indicator, n* – a warning system, using contrasting colors, lights, or other similar means designed to visually alert caregivers when a removable bassinet bed is not properly locked onto its base/stand.

(iv) 3.1.21 *intended use orientation, n* – The bassinet bed orientation (*i.e.*, the position where the head and foot ends of the bassinet bed are located), with respect to the base/stand, as recommended by the manufacturer for intended use.

(4) Instead of complying with section 6.7 of ASTM F2194-13, comply with the following:

(i) *6.7 Bassinets with Segmented Mattresses: Flatness Test*—If the bassinet or bassinet accessory has a folding or segmented mattress, or both, any angle when measured in 7.8 less than or equal to 10° is an immediate pass. Any angle when measured in 7.8 greater than 10° is an immediate failure. Segmented bassinet mattresses that have seams (located between segments or where the mattress folds) that are less than 15 inches in length are excluded from this requirement.

(ii) [Reserved]

(5) In addition to complying with section 6.9.2 of ASTM F2194-13, comply with the following:

(i) *6.10 Removable Bassinet Bed Attachment* - Any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the base/stand, shall comply with at least one of the following 6.10.1, 6.10.2, 6.10.3, 6.10.4 or 6.10.5 when tested in accordance with 7.12.

(ii) 6.10.1. The base/stand shall not support the bassinet bed (i.e., the bassinet bed falls from the stand and contacts the floor or the base/stand collapses when the bassinet bed is not locked on the base/stand).

(iii) 6.10.2. The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action) in all lateral positions (Figure 24).

(iv) 6.10.3. The sleep surface of the bassinet bed shall be at an angle of at least 20° from a horizontal plane when the bassinet bed is in an unlocked position.

(v) 6.10.4 The bassinet/cradle shall provide a false latch/lock visual indicator(s). At a minimum, an indicator shall be visible to a person standing near both of the two longest sides of the product.

(vi) 6.10.5. The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when tested in accordance with 7.12.5.3.

(6) Instead of complying with section 7.4.4 of ASTM F2194-13, comply with the following:

(i) 7.4.4 Place the CAMI Newborn Dummy, Mark II, on the sleeping pad in the center of the product face up with the arms and legs straightened.

(A) *Rationale. The newborn CAMI dummy represents a 50<sup>th</sup> percentile newborn infant, which is a more appropriate user of a bassinet than the CAMI infant dummy, which represents a 50<sup>th</sup> percentile 6-month-old infant.*

(B) [Reserved]

(ii) [Reserved]

(7) In addition to complying with section 7.11.4 of ASTM F2194-13, comply with the following:

(i) 7.12 *Removable Bassinet Bed Attachment Tests*

(ii) 7.12.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions in one of the manufacturer's recommended use positions. If the base/stand does not remain in the use position when the bassinet bed is not locked onto it, the product meets the requirements of 6.10.1.

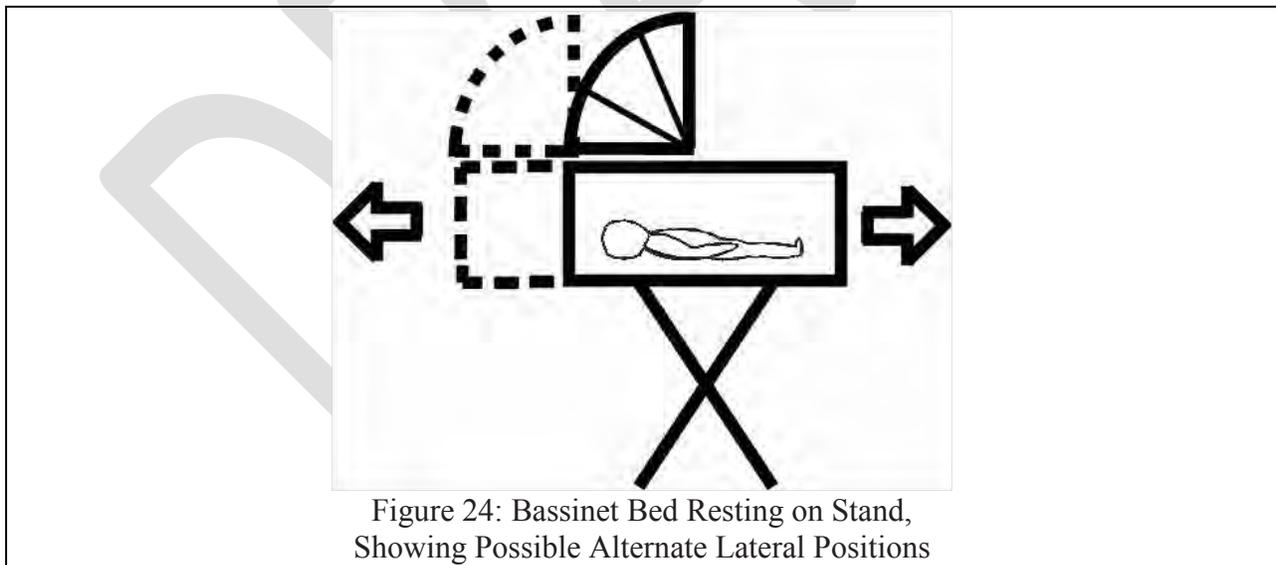
(iii) 7.12.2 Place the base/stand and the inclinometer on a flat level horizontal surface (0 +/- 0.5°) to establish a test plane. Zero the inclinometer.

(iv) 7.12.3 Remove the mattress pad from the bassinet bed.

**Note:** For mattresses that are integral with the mattress support, do not remove the mattress and perform all angle measurements for 7.12 on a 6 by 6 by 3/8-in. nominal aluminum block placed on the center of the mattress.

(iv) 7.12.4 Place the bassinet bed on the base/stand in the intended use orientation without engaging any latch or lock mechanism between the base/stand and the bassinet bed. If the bed automatically engages to the base/stand do not disengage the lock/latch. If the bassinet bed can rest on the base/stand in its intended use orientation in one or more lateral unlocked position (Figure 24), the unit shall be evaluated in the lateral position most likely to fail the requirements specified in 6.10.

(v) Figure 24: Bassinet Bed Resting on Stand, Showing Possible Alternate Lateral Positions.



(vi) 7.12.4.1 If the base/stand supports the bassinet bed in any unlocked position, place the inclinometer on the mattress support at the approximate center of the mattress support. Care

should be taken to avoid seams, snap fasteners, or other items that may affect the measurement reading. Record the angle measurement.

(vii) 7.12.4.2 If the base/stand supports the bassinet bed and the angle of the mattress support surface measured in 7.12.4.1 is less than 20 degrees from a horizontal plane, evaluate whether the bassinet has a false latch/lock visual indicator per 6.10.4.

(viii) 7.12.4.3 If the base/stand supports the bassinet bed, and the angle of the mattress support surface measured in 7.12.4.1 is less than 20 degrees from a horizontal plane, and the bassinet does not contain a false latch/lock visual indicator, test the unit in accordance with sections 7.4.2 through 7.4.7.

(ix) 7.12.5 Repeat 7.12.2 through 7.12.4 for all of the manufacturer's base/stand recommended positions and use modes.

(x) 7.12.6 Repeat 7.12.4 through 7.12.5 with the bassinet bed rotated 180 degrees from the manufacturers recommended use orientation, if the base/stand supports the bassinet bed in this orientation.

(A) *Rationale. This test requirement addresses fatal and nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand or the latch failed to engage as intended. Products that appear to be in an intended use position when the lock or latch is not properly engaged can create a false sense of security by appearing to be stable. Unsecured or misaligned lock/latch systems are a hidden hazard because they are not easily seen by consumers due to being located beneath the bassinet or covered by decorative skirts. In addition, consumers will avoid activating lock/latch mechanisms for numerous reasons if a bassinet bed appears stable when placed on a stand/base. Because of these foreseeable use conditions, this requirement has been*

*added to ensure that bassinets with a removable bassinet bed feature will be inherently stable or it is obvious that they are not properly secured.*

*6.10 allows bassinet bed designs that:*

- 1) cannot be supported by the base/stand in an unlocked configuration,*
- 2) automatically lock and cannot be placed in an unlocked position on the base/stand,*
- 3) are clearly and obviously unstable when the lock/latch is misaligned or unused,*
- 4) provide a visual warning to consumers when the product is not properly locked onto the base/stand, or*
- 5) have lock/latch mechanisms that are not necessary to provide needed stability.*

(B) [Reserved]

Dated: \_\_\_\_\_

\_\_\_\_\_  
Todd A. Stevenson,  
Secretary, Consumer Product Safety Commission



# **Staff Briefing Package**

Draft Final Rule for Bassinets and Cradles under the Danny  
Keysar Child Product Safety Notification Act

June 26, 2013

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# Briefing Memo



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

This document has been electronically  
approved and signed.

## Memorandum

June 26, 2013

TO: The Commission  
Todd A. Stevenson, Secretary

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

FROM: George A. Borlase, Assistant Executive Director  
Directorate for Engineering Sciences

Patricia L. Edwards, Project Manager  
Division of Mechanical Engineering, Directorate for Engineering  
Sciences

SUBJECT: Staff's Draft Final Rule for Bassinets and Cradles under the Danny  
Keysar Child Product Safety Notification Act

### I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act of the Consumer Product Safety Improvement Act (CPSIA) of 2008 requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to study and develop safety standards for certain infant and toddler products. Bassinets/cradles are one of the product categories specifically identified as a durable infant or toddler product in section 104(f)(2) of the CPSIA. The Commission is charged with promulgating a consumer product safety standard that is substantially the same as the voluntary standard for bassinets/cradles or more stringent than the voluntary standard if the Commission determines that a more stringent standard would further reduce the risk of injury associated with bassinets and cradles.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. This consultation process commenced in 2009, during the ASTM International (formerly known as the American Society for Testing and Materials) subcommittee meeting regarding the

ASTM bassinets and cradles voluntary standard, in which CPSC staff participated. Consultations with members of the ASTM subcommittee, who represent producers, users, consumer advocates, government, and academia, are ongoing.

This briefing package includes staff's responses to comments received in response to the supplemental notice of proposed rulemaking (SNPR), which was published in the *Federal Register* (77 Federal Register 64055) on October 18, 2012. The briefing package also assesses changes made to the bassinets and cradles voluntary standard, reviews stakeholder activity, and presents staff's draft final rule to address potential hazards in bassinets and cradles.

## **II. BACKGROUND**

### ***A. Rulemaking History***

In April 2010, the Commission issued a notice of proposed rulemaking (NPR) for bassinets and cradles (75 Federal Register 22303, April 28, 2010). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2194-07a<sup>e1</sup>, *Standard Consumer Safety Specification for Bassinets and Cradles*, with certain changes to specific provisions in the voluntary standard to strengthen the ASTM standard.

After the 2010 NPR, considerable testing and analysis were performed by staff and the ASTM bassinets/cradles subcommittee, and the ASTM standard was revised significantly. Therefore, rather than proceed directly to a final rule, staff recommended that the Commission issue a supplemental notice of proposed rulemaking (SNPR), which the Commission approved and published on October 18, 2012. The SNPR proposed to incorporate by reference the voluntary standard, ASTM F2194-12, with four modifications:

- 1) **Scope and Terminology:** The SNPR proposed to exclude inclined products. To do this, the SNPR proposed to modify the scope section of the ASTM standard to include a detailed note providing examples of what products were, and were not, included in the scope of the standard. In addition, the SNPR proposed to add two new definitions for clarity. In 2012, ASTM balloted language identical to the SNPR's proposed scope and terminology provisions. These are now included in the latest revision of the ASTM standard, F2194-13.
- 2) **Segmented Mattress Flatness Test:** The SNPR proposed to add a new test requirement and associated test procedure to address suffocation incidents in segmented mattresses. A segmented mattress flatness test requirement and procedure were balloted by ASTM in 2012, and are now part of the current standard. The current voluntary standard

contains a test procedure that is identical to the procedure the Commission proposed in the SNPR, but the test requirement (the pass/fail criterion) is different.

- 3) **Removable Bed Stability Requirement:** The SNPR proposed a new test requirement and associated test procedure to address fatal and nonfatal incidents associated with bassinets that have removable bassinet beds. This requirement is not in the current ASTM standard, but a similar version is expected to be balloted by ASTM for inclusion in the next revision of the ASTM standard.
- 4) **Stability Test Procedure:** A revised test procedure was proposed in the SNPR. The revision proposed in the SNPR specifies the use of a newborn CAMI dummy, rather than the six-month CAMI dummy that is referenced in the ASTM standard. This revised procedure is not in the current ASTM standard, but is expected to be balloted by ASTM for inclusion in the next revision of the ASTM standard.

### ***B. ASTM Voluntary Standard Overview***

ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*, is the voluntary standard that addressed the identified hazard patterns associated with the use of bassinets/cradles. The standard was first approved in 2002, and then revised several times over the next 11 years. ASTM F2194-12 is the version that the Commission proposed to incorporate by reference in the SNPR. Following publication of the SNPR, ASTM published three revisions of the standard.

#### **ASTM F2194-12a**

The first revision, F2194-12a, contained a revised scope section and associated definitions that exactly matched what the Commission proposed in the SNPR.

The definition of “bassinet/cradle” was revised at that time. Since F2194-12a, a “bassinet/cradle” has been defined as *a small bed designed primarily to provide sleeping accommodations for infants, supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base. While in a rest (non-rocking or swinging) position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal.*

The definition of “bassinet/cradle accessory” was also updated in F2194-12a 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.* The same definition appears in the current voluntary standard (F2194-13).

The scope of the standard has not changed since it was modified in version F2194-12a. The scope section excludes products used with strollers or swings or products that are intended to provide an inclined sleep surface (head-to-toe direction) of greater than 10° from horizontal. The standard includes a note to help clarify the scope and to explain how multimode products (also referred to as “combination products”) should be handled. A stroller carriage that has a removable basket/bassinet that can be placed on an external stand is the example of a multimode product described in the note. When the basket/bassinet is attached to the stroller/carriage frame, then the product falls under the scope of the stroller standard. When the basket/bassinet is removed from the stroller/carriage base and secured to a stand/frame (that is not intended to be a wheeled conveyance), then it falls under the scope of the bassinet standard.

### **ASTM F2194-12b**

The ASTM standard (F2194-12b) was revised in late 2012, to include a segmented mattress flatness test requirement and procedure. The test procedure in this revision is identical to the one proposed in the SNPR, but the test requirement (pass/fail criterion) is different. The SNPR called for a 10° maximum allowable angle, where the ASTM standard allows for measurements as high as 14°. Therefore, the SNPR requirement is stricter in this regard. As discussed in the SNPR briefing package, staff continues to support the 10° pass/fail criterion for the segmented mattress flatness test to cover the widest range of infants, rather than rely on the ASTM requirement, which only covers about half of the intended user population.

### **ASTM F2194-13**

Finally, in April 2013, the standard was revised to the current version, ASTM F2194-13. In this version, play yard bassinet accessories are required to be tested for mattress flatness with and without mattress support bars, if the support bars are not permanently attached. Staff agrees with this revision to the standard. This requirement was developed based on the Commission’s play yard misassembly NPR published on August 29, 2012 (77 Federal Register 52272). In response to the play yard NPR, the ASTM subcommittee for non-full-size cribs/play yards decided to revise the play yard standard and the bassinet standard, incorporating portions of the play yard NPR requirement into each standard. Additional discussion on this matter appears in the play yard misassembly final rule staff briefing package dated June 19, 2013. The only other change to F2194-13 clarifies the font style for the suffocation warning label. Staff also agrees with this change.

### **Expected Ballot Items**

The SNPR comment period ended January 2, 2013; since then, there have been two ASTM bassinet subcommittee meetings and three stability task group meetings. The minutes for these meetings have been included as supporting materials in Docket CPSC-2010-0028. As a result of these meetings, the ASTM task group is recommending a ballot to change the stability test procedure to use the newborn CAMI dummy instead of the infant (six-month) CAMI dummy. This expected ballot item is identical to one of the modifications proposed in the SNPR.

In addition, the ASTM task group intends to submit a ballot item for a removable bassinet bed test requirement and associated test procedure, along with associated definitions. This item differs in some minor respects from what was proposed in the SNPR; however, it is essentially the same as the staff-recommended requirement for the final bassinet/crib standard outlined in this briefing package.

Most of the differences are editorial changes to provide clarity to the test requirement and the test procedure. The significant (noneditorial) differences between the requirement proposed in the SNPR and what ASTM is expected to ballot are summarized below:

- a) The next ASTM ballot is expected to exclude play yard bassinets, as defined in the standard, from the removable bassinet bed definition. Thus, play yard bassinets would not be subject to the removable bassinet bed stability requirement.
- b) The next ASTM ballot is expected to expand on one of the pass criteria for the removable bed stability requirement, to allow bassinets stands that cannot remain in their proper use position unless the bassinet bed is properly attached.

### **III. DISCUSSION**

#### ***A. Overview of New Incident Data***

A search of the CPSC epidemiological databases showed that there were 71 new incidents related to bassinets and cradles reported between January 18, 2012 and March 31, 2013. Thirty-eight of the 71 were fatal; and 33 were nonfatal. Sixteen of the nonfatal incidents involved injuries. Almost all of the new incidents were reported to have occurred between 2010 and 2012. Reporting is ongoing, however, so the incident totals are subject to change.

The number of emergency department-treated injuries associated with bassinets and cradles, for the timeframe covered, was insufficient to derive any reportable national estimates.<sup>1</sup> Hence, injury estimates are not presented separately; instead, the emergency department-treated cases are included in the total count of reported incidents presented.

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

The hazard patterns identified among the 71 new incident reports were similar to the hazard patterns that were identified among the incidents considered for the SNPR and are detailed in Tab A.

### **Fatalities**

The majority of the deaths (32 out of 38) were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and additional bedding.

Two of the 38 deaths were associated with design aspects of the product. One of these was a suffocation death in a corner of the bassinet, whose rocking feature contributed to its non-level position. The second fatality occurred when the bassinet was knocked over by an older sibling.

In addition, CPSC staff was not able to determine the hazard scenario in four fatalities, three with insufficient information and one with confounding information.

### **Nonfatal Incidents**

A total of 33 bassinet-related, nonfatal incidents were reported from January 18, 2012 through March 31, 2013. Of these, 16 incidents reported an injury to an infant using the bassinet or cradle at the time of the incident.

The majority of these injuries (11 out of 16, or 69 percent) were due to falls out of the bassinets. All 11 fall injuries were reported through the emergency department-treated injury surveillance system (NEISS), with little or no circumstantial information on how the fall occurred. However, the reports indicate that 55 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of five months for use of a bassinet. All of the falls resulted in head injuries. Among the remaining five nonfatal injuries, mostly head injuries, no hospitalizations were reported.

### ***B. Staff Response to NPR Comments***

There were 27 comments received on the SNPR, including: one from Health Canada; one from a conglomerate of consumer's groups (Kids In Danger, Consumers Union, American Academy of Pediatrics, Consumer Federation of America, Public Citizen, and U.S. PIRG); one from the Juvenile Products Manufacturers Association (JPMA); and two from bassinet manufacturers. The remaining 22 comments were from consumers, law students, or unaffiliated sources. Staff's responses to the comments can be found in Tabs A–D. A summary of each comment topic is presented, followed by staff's response. See Table 1 below for the comment topic and the location of staff's response.

**Table 1: Comment Topics and Location of Staff's Response**

<b>Topic</b>	<b>Tab</b>
Aiding Small Businesses	D
ASTM Copyright and Accessibility	B
Bassinet Misuse	C
Cost Benefit Analysis	D
Definition of a Small Business	D
Effective Date	D
Existing Inventory	D
Expanding the Scope Impact	D
Falls from Bassinets/Side Height	C
Health Canada Standard	B
Incident Data Presentation	A
Insufficient Incident Information	A
International Standards	B
Labeling Costs	D
Mattress Flatness Pass/Fail Requirement	C
Mattress Flatness Test/CAMI Dummy or Cylinder Usage	C
Mattress Flatness/Narrow Bassinets	C
Mattress Thickness (Rigid Products and Falls)	B
Play Yard Misassembly	B
Potential for Serious Injury	A
Preemption of State Laws	D
Removable Bassinet Bed Requirements	B
Restraints	C
Scope – Age Restrictions	C
Scope Clarity	B
Segmented Mattress Cost vs. Benefits	B
Segmented Mattress Support Rods	B
Size and Weight Limits	C
Small Bedding Suppliers	D
Stability Testing – CAMI Dummy	C
The Necessity for Additional Standards	A
Third Party Testing Cost	D
Warnings	C

The comments raised several issues, which resulted in two new staff recommendations for the final rule. Several commenters made general statements supporting the overall purpose of the proposed rule. All of the comments can be viewed at: [www.regulations.gov](http://www.regulations.gov), by searching under the docket number of the rulemaking, CPSC-2010-0028.

Staff's responses that impact the recommendations for the final rule are also included in this briefing memorandum below.

### Scope Clarity

#### Comment

*Two commenters provided almost identical comments and suggestions for changes to the scope. The commenters asserted that the scope section is unclear about what products are included in the scope and under what conditions. For instance, one comment stated that from the SNPR it is not clear how products with an inclined seat back surface (reclined seat back), such as infant seats, infant bouncer seats, and infant rockers that do not provide an "inclined sleep surface" would be treated under the standard.*

#### Response

The scope that was proposed in the SNPR has subsequently been adopted by ASTM and is the scope in the current version of the ASTM standard. Comments received reflect continued ambiguity regarding some aspects of the scope. Therefore, staff agrees that further clarity is warranted, and staff recommends a modification for the draft final rule.

Inclined products fall under a variety of different ASTM standards, depending on the product's function. For instance, ASTM standards include a handheld carrier standard, an infant bouncer standard, and a new rocker standard that is currently under development. None of those products is intended for sleep. An inclined product intended for sleeping would fall under the inclined sleep product standard currently under development by ASTM. Staff's intent is that the scope of the bassinet standard exclude all inclined products when the incline is more than 10 degrees from horizontal.

But, staff also intends that any product that has a flat (10 degrees or less) sleep surface AND an inclined surface when the incline is more than 10 degrees from horizontal shall fall under the scope of the bassinet standard, when configured in the flat mode, and under the scope of the appropriate inclined product standard(s) while in the inclined mode. This way, all uses of the product are addressed by safety standards. This type of product is considered a multimode product, or a combination product, *i.e.*, the product can convert from one use mode to another.

During the recent ASTM F15 juvenile products subcommittee meetings held in April 2013, scope clarity was raised in various product subcommittees where multi-mode products are common. Most of those product subcommittees proposed to modify the scope section of the appropriate standard to clarify that these combination products shall fall under the scope of all relevant standards when in the corresponding use mode.

This intent, to include multimode products under multiple standards, is well established in ASTM standards, including the bassinet standard. One example is a carriage basket that is removable from a stroller base. The scope section of ASTM F2194-13 clearly states that products used in conjunction with a stroller are not covered by the standard. Yet, the current scope section also states: “Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1.” Clearly, the intent is that this multimode product falls within the scope of the stroller standard when attached to the stroller frame and falls within the scope of the bassinet standard when attached to a separate frame/stand.

Thus, to remove any ambiguity regarding multimode products, staff is recommending another modification to the note that accompanies the scope of ASTM F2194-13 to clarify that a multimode product with a bassinet use mode must meet the bassinet standard when in the bassinet use mode. The recommended wording for this modification can be found in the Engineering Sciences memo in Tab B.

### **Mattress Flatness/Narrow Bassinets**

#### **Comment**

*A commenter stated that the mattress flatness test could not be performed on bassinets that were less than 15 inches wide because of the width of the cylinder and the block used in that test method. Furthermore, such a small, narrow occupant-retention space would not present the same hazards as those in the incidents which involved wider play yard bassinet accessories, the commenter suggested.*

#### **Response**

Staff agrees that bassinets with occupant-retention spaces that are narrower than the test apparatus are unlikely to be used with an infant placed perpendicular between walls that are narrow. And in the case where an infant is placed in a narrow bassinet correctly and then moves or shifts 90°, the narrowness of the bassinet would likely not permit that infant to lie in a fully prone position, face down in an orthogonal seam. Thus, an exemption from the flatness test for mattress pad seams that run perpendicular between the sides of a bassinet with a width of 15 inches or less seems reasonable.

Therefore, staff is recommending a modification to the standard to exempt from the mattress flatness test bassinets that are narrower than 15 inches.

## **Effective Date**

### **Comment**

*Several commenters weighed in on the appropriate effective date for the proposed rule. One commenter, representing several advocacy groups, supported the proposed six-month effective date. A second commenter agreed, expressing concerns that if the date were extended and a death occurred, “consumers might view the death as the result of the CPSC putting the interests of for-profit entities . . . ahead of the safety of infants who use their products.”*

*In contrast, several other commenters, including one manufacturer, recommended longer effective dates to reduce the impact of the rule, particularly for small businesses that have “fewer resources and connections within the industry” and that “may have to significantly alter their means of production.” Suggested effective dates range from 9 to 15.5 months, with commenters recommending that the CPSC focus on relief for firms that would be disproportionately impacted by the rule. Commenters suggested longer effective dates for firms newly covered by the expanded scope and firms whose products would be subject to the removable bassinet bed requirement.*

*The one manufacturer who provided comments on the effective date stated that a longer effective date is needed for firms that will need to redesign their products to meet the removable bassinet bed requirement. This firm stated that an effective date of at least 15.5 months is needed to reflect accurately the challenges of redesigning the product.*

### **Response**

CPSC staff recognizes that some manufacturers will be required to redesign, test new prototype products, and then retool their production process to meet the new removable bassinet bed provision. Based on a comment from one manufacturer, who stated they would need a minimum of 15.5 months to redesign their product, CPSC staff considers 18 months to be a reasonable time period to take into account other manufacturers who might also need to redesign their product. Therefore, staff recommends that the Commission approve a six-month effective date for the final rule, with the specific exception of extending the effective date for the removable bassinet bed test requirement to 18 months.

## **Removable Bassinet Bed Requirements**

### **Comment**

*One group of commenters suggested that the Commission eliminate the two “passive” pass conditions (20 degrees and passing stability) of the removable bassinet bed stability requirement in favor of the other pass criteria that they feel make the user aware that the bassinet is not properly attached.*

### Response

The SNPR proposed several options to meet the removable bassinet bed requirements. This approach is less restrictive than prescribing one pass criterion and allows for more innovation in product designs. By permitting five different options to meet this requirement, manufacturers have a variety of design choices available.

### Comment

*Some commenters felt that allowing the bassinet to “fail” (by falling to the ground or to a 20 or more degree angle) was encouraging manufacturers to make products that are less stable to ensure that the bassinet passed this requirement. Another commenter stated that it was foreseeable that some caregivers may attempt to attach the bassinet bed to its stand while the child is in the product and that this might expose children to unnecessary hazards.*

### Response

Two of the five options to pass the removable bed requirement are very much related to each other. These two options are: (1) the sleep surface shall be at least 20 degrees off from a horizontal plane, and (2) the bassinet bed falls from the stand and contacts the floor. These two requirements were added after consultations with stakeholders (ASTM task group members). Several stakeholders felt that if a bassinet stand was designed to support the bassinet bed only if it were properly locked, then it should be able to pass the requirement. For instance, envision a stand that looks like a saw horse, or “A” frame and has a lock/latch connection at the top of the “A” on the frame and on the underside of the bassinet bed. The caregiver would have to line up both halves of the lock/latch to attach the bed to the stand. It would be unreasonable to believe that caregivers would place the bassinet bed on an “A” frame stand without engaging the lock/latch because the design of the stand would cause the bassinet bed to fall to the ground if the lock was not engaged.

Rather than specifying a design requirement, the task group converted the requirement to a performance requirement, by simulating what would happen if the unreasonable act occurred. In other words, this option requires the bassinet bed to fall to the ground if the lock is not properly engaged.

Once that requirement was vetted by the task group, another stakeholder raised the possibility that the bassinet bed, in the act of falling, might get caught on the stand before hitting the ground. If the bassinet bed did not hit the ground, should the bassinet bed fail the requirement? Thus, the 20-degree tilt option was added to allow for that possibility and to complement the fall-to-the-ground option.

A bassinet that relies on either of these two options to pass the requirement would be considered to have immediate feedback. If a caregiver attempts to place the bassinet bed on this type of

stand without locking it in place, the caregiver will realize instantly that he or she did not engage the lock because the bassinet bed will not assume a stable position that allows the caregiver to release their grasp. The immediate feedback of instability will minimize the possible hazards, making falling unlikely. Staff believes that the steep angle needed to pass is unlikely to allow consumers to let children fall. The instability of such a unit is immediately obvious to the user, precluding a delayed response. Consumers are likely to check the stability of the product before removing their hands from it. Even in the case of a caregiver who attempts to place an occupied bassinet bed on a stand using this option, the caregiver will be present and potentially able to prevent or arrest the fall of the bassinet bed. Staff considers the possibility of a fall hazard in this scenario to be highly unlikely, and on the rare chance that a fall occurs, the fall in these circumstances would be considered less significant than an unattended fall to the floor.

#### Comment

*One commenter stated that the option —“The lock/latch shall automatically engage under the weight of the bed (without any other force/action)”—should be a requirement for all bassinets.*

#### Response

CPSC recommends providing manufacturers with options to meet the removable bassinet bed requirements. This is less restrictive than prescribing one requirement and allows for more innovation in product designs.

#### Comment

*One commenter stated that adding the removable bassinet bed stability requirement is premature. The commenter believes that the requirement should be removed from the regulation and that ASTM should be allowed to continue work on this.*

#### Response

CPSC staff is aware of two deaths<sup>2</sup> associated with this hazard scenario. Therefore, we do not believe that this requirement is premature. CPSC staff believes that stakeholders have had plenty of time to test, review, discuss, and refine the proposed requirements before and after the SNPR was published. In fact, the language recommended for the final rule is essentially the same as the language that staff expects ASTM to ballot as a new requirement to address the same hazard. A time line regarding identification of this hazard and ASTM’s work to revise the ASTM standard follows:

CPSC staff first discovered the hazard scenario pertaining to the removable bassinet bed requirement in mid-May 2012, following a recall of bassinets for a similar hazard. Immediately after the hazard was identified and associated with a previous death, CPSC staff raised the issue with the ASTM bassinet subcommittee chair and then again at an ASTM bassinet task group

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<sup>2</sup> One occurred in Canada; thus, it was not included in incident data counts reported in the SNPR briefing package.

meeting a few days later. In early June 2012, the hazard was demonstrated and discussed at a full ASTM subcommittee meeting.

At the ASTM subcommittee meeting, a task group was established to address the hazard, and various conference calls and e-mail exchanges took place from July through early August 2012. By that time, the ASTM task group had drafted a performance requirement and test procedure to address the hazard. During the subcommittee meeting in October 2012, subcommittee members reviewed and commented upon the draft requirement and test procedure that the task group developed. The task group did not meet again until seven months later.

In January 2013, the ASTM subcommittee met and discussed the removable bassinet bed stability requirement again. The discussion was limited and the task group chairman stated a revised draft would be submitted at the next subcommittee meeting scheduled for April 2013. No task group meetings were held between the two subcommittee meetings. At the April 2013 subcommittee meeting, no discussion about the requirement occurred, but a task group conference call was scheduled to take place the following week.

On April 18, 2013, the task group held a conference call, and made several revisions to the draft for clarity and also, to allow other bassinet designs that did not present the same hazard. The task group had a follow-up conference call on April 25, 2013. At that time, the task group reviewed the revised draft and reached a consensus regarding what to submit to the subcommittee for ballot. On May 22, 2013, the task group held another conference call to review the proposed ballot item one more time. The task group made additional changes, all editorial in nature, to provide clarity. The goal was to submit the latest revision to ASTM for balloting. As of the writing of this briefing memo, the ballot item has not been submitted to ASTM.

CPSC staff participated in all of the subcommittee and task group meetings and agrees with the task group's latest revision that is expected to be balloted soon by ASTM. Staff believes the revised provision is adequate to prevent the hazard for which it is intended.

Based on the recent work done by the ASTM task group, staff is recommending some changes to the requirement and associated definitions and procedures that the Commission proposed in the SNPR. The changes are essentially the same as what the ASTM task group developed. The staff recommends the changes for clarity and also to allow for different manufacturing designs that do not present the hazard being addressed. The changes are not expected to impact safety.

### Comment

*A commenter stated that color-only visual indicators should not be allowed as an option to pass this requirement because people who are color-blind would not be able to distinguish between locked and unlocked.*

### Response

CPSC's proposed language in the SNPR for visual indicators allows manufacturers to design a visual indicator that can be recognized by a person with a color vision deficiency. In addition, there are many other options to pass the requirement, and individuals who are color-blind can choose to purchase a product that does not use color indicators.

### **Removable Bed Stability Requirement Pass/Fail Criteria**

### Comment

*Some commenters felt that allowing removable bassinet beds to pass the stability test by tilting to a 20-degree angle was hazardous because consumers might think that a 20-degree angle was still usable, perhaps as an inclined sleeper.*

### Response

Staff believes that an angle of 20° or more is acceptable to demonstrate that the bassinet is not useable. A steeper angle would also be acceptable, but staff is not convinced it is needed. Twenty degrees is twice the maximum allowable tilt for bassinets, which are intended to have a flat sleeping surface. In deciding on the 20° angle, the ASTM task group noted an incident (101101HCC3107) where a consumer clearly saw that something was wrong with his bassinet when he saw it tilted and deemed it to be unusable. From the photos, the tilt was estimated to be approximately 17°.

### **Segmented Mattress Support Rods**

### Comment

*Two commenters offered remarks regarding the mattress flatness testing and designs of bassinet accessories that use support rods underneath the mattress. One of the two comments suggested that the mattress flatness test be performed with and without the bars in place. Moreover, the commenter suggested that if the bars are required to be in place to pass the flatness test, then they should be attached permanently. Similarly, the other comment suggested that the frame supporting the floor (mattress) should come preassembled to eliminate the possibility that the consumer can misassemble the product.*

### Response

Staff agrees with these comments, and ASTM does as well. In January 2013, ASTM balloted a revised mattress flatness test requiring that any segmented mattress that has consumer-assembled mattress support rods, be tested with and without the mattress support rods. This requirement resulted from the Commission's play yard misassembly NPR that was published in August 2012. The ballot item passed and is now part of ASTM F2194-13. Staff is recommending that the final rule refer to ASTM F2194-13; thus, the test will incorporate the suggestion from the commenters.

### **Mattress Flatness Pass/Fail Requirement**

#### Comment

*Some commenters suggested that the mattress flatness requirements should be limited to 8° from the horizontal rather than 10°.*

#### Response

While staff would be amenable to using this more conservative margin of safety, *i.e.*, a tolerance of 16° of motion rather than 20°, the industry has maintained that a larger tolerance is necessary due to the inherent variability of manufacturing products with fabric and foam. They claim that tighter tolerances on a segmented mattress made with the materials that are commonly used in these products would make it impossible to manufacture such mattresses. Staff believes that the 10° limit proposed in the SNPR is adequate to protect the expected user population.

#### Comment

*A commenter suggested that the threshold limit for flatness should be 14° to preserve test-retest reliability.*

#### Response

ASTM F2194-13 now includes the mattress flatness test requirement and procedure, as written in the SNPR, except for the angle requirement. ASTM's requirement allows the use of an average for measurements over 10° and under 14°, while the SNPR proposed a maximum allowable measurement of 10°. Based on testing performed by an ASTM task group that was established to assess the reliability and repeatability of the mattress flatness test, the reliability of the test is adequate when the test is performed on products designed to pass the test. The commenter did not provide any new or different information to staff to support the suggestion for using the averaging method, and thus, staff continues to support the 10° flatness criterion as proposed in the SNPR.

## Stability Testing – CAMI Dummy

### Comment

*Some commenters suggested using an infant and a newborn dummy in the stability test methods, while others believe the incident data did not support the need to change from an infant dummy to a newborn dummy because the data neglects the evidence that larger infants also use bassinets and cradles.*

### Response

The use of both dummies is unnecessary because the worst case scenario for stability is the smaller size dummy. The larger size dummy makes the product more stable. Therefore, if a product passes with a newborn, the product will also pass with an infant. Performing the test with two different dummies would be redundant and only add to the cost of testing.

Staff recommends the newborn CAMI to make the test more stringent. Even if a majority of the incidents were not directly attributable to product stability, many incidents were to blame, including two fatal incidents (one of which was reported from Canada).

### ***C. Comparison of SNPR and ASTM F2194-13***

The SNPR proposed to incorporate by reference ASTM F2194-12 *Standard Consumer Safety Specification for Bassinets and Cradles*, with certain modifications. The current voluntary standard for bassinets, ASTM F2194-13, differs from the SNPR in the following ways.

ASTM F2194-13 and the SNPR contain different versions of the following:

- The pass/fail criterion for the mattress flatness test. The SNPR specifies 10°, and ASTM F2194-13 has a two-part criterion that allows a measurement up to 14°.

ASTM F2194-13 contains the following requirements that are not in the SNPR:

- A new and additional mattress flatness test requirement for play yard bassinets that have nonpermanent mattress support bars. The SNPR does not contain this requirement, but the August 29, 2012 play yard NPR contains a provision that is similar. It is staff's opinion that this additional requirement will increase safety.
- A change in how the suffocation warning's font is described. The SNPR does not contain this new language. This difference helps clarify what font style should be used for the warning and should not affect safety.

ASTM F2194-13 does not contain the following requirements that are in the SNPR:

- A removable bed stability requirement (nor the associated definitions and test procedures). A requirement similar to what was included in the SNPR is expected to be balloted by ASTM soon.
- A change to use the newborn CAMI dummy for the stability test procedure. This revision is also expected to be balloted by ASTM soon.

#### ***D. Staff-Recommended Changes from the SNPR to the Final Rule***

Staff recommends that the Commission issue a final rule incorporating by reference the current version of ASTM F2194. Thus, staff recommends referencing ASTM F2194-13 for the final rule, with the following modifications:

##### Segmented Mattress Flatness Minimum Angle

As outlined in the previous section, the current ASTM standard, F2194-13, contains a segmented mattress flatness test including a test procedure that is identical to the procedure proposed in the SNPR; but the pass/fail criterion is different. The SNPR proposed a 10° maximum allowable angle, where ASTM F2194-13 allows for measurements as high as 14°. Therefore, the SNPR requirement is stricter in this regard. As discussed in the SNPR briefing package, staff continues to support the 10° pass/fail criterion. A description of staff's position can be found in Tab C and also in the SNPR briefing package.

Therefore, staff recommends a modification to ASTM F2194-13 to change the pass/fail criterion for this test to match what was proposed in the SNPR. The suggested wording can be found in the Engineering Sciences memo, Tab B.

##### Stability Requirement Procedure Change – CAMI Dummy

Staff recommends that the modification included in the SNPR, to change the CAMI dummy used during stability testing from the infant version to the newborn version, should also be included in the final rule. The staff-recommended modification in the draft final rule is identical to what the ASTM task group is expected to submit for ballot. The suggested wording for the draft final rule is identical to what was in the SNPR and can be found in the appendix to Tab B.

##### Removable Bassinet Bed Stability Provision

For the final rule, staff recommends the removable bassinet bed stability requirement and its associated procedures and definitions that were included in the SNPR, with a few

changes. As outlined previously, this requirement is expected to be balloted by ASTM soon. Thus, the requirement is not part of ASTM F2194-13. Staff's recommendation differs editorially from the modification proposed in the SNPR, in addition to a couple of other differences that should not diminish safety:

(1) Staff's draft final rule excludes "play yard bassinets," as defined in the standard, from the "removable bassinet bed" definition. Thus, play yard bassinets are not subject to the removable bassinet bed stability requirement.

(2) Staff's draft final rule also expands one of the pass criteria for the removable bed stability requirement to allow bassinets that have stands that cannot remain in their proper use position unless the bassinet bed is properly attached.

Thus, staff recommends that the final rule include a modification to add a removable bassinet bed stability provision, including definitions, requirements, and procedures. The staff-recommended modification is essentially the same requirement that the ASTM task group recently developed. This requirement is also expected to be submitted to ballot for consideration in the next version of the ASTM voluntary standard. The suggested wording for the draft final rule can be found in the appendix to Tab B.

Based on the SNPR comments received, staff has two additional recommendations for Commission consideration for the final rule:

#### Segmented Mattress Flatness Minimum Width

Staff recommends a new modification to allow an exemption to the segmented mattress flatness test for narrow bassinets. Narrow bassinets, those that are less than 15 inches wide, cannot be tested because the test procedure cannot be followed due to the narrow width. In addition, such products do not allow consumers to place infants within the occupant retention space in a manner that would permit the infants to get into the seam of the mattress, so the exemption should not create any hazards. A further description of staff's position can be found in Tab C. The suggested wording to modify F2194-13 can be found in Tab B.

#### Scope Clarity

The modified scope, as proposed in the SNPR, was subsequently adopted by ASTM and is the scope in the current version of the standard. It is clear from the comments received that there is still some ambiguity regarding whether multimode products are included in the scope. Therefore, staff agrees that additional clarity is warranted.

Including multimode products under multiple standards is well established in many ASTM standards, including the bassinet standard. Thus, to remove any ambiguity regarding

multimode products, staff is recommending another modification to the note that accompanies the scope provision of ASTM F2194-13 to make it clear that a multimode product that has a bassinet mode must meet the bassinet standard when in the bassinet-use mode. The suggested wording to modify F2194-13 can be found in Tab B.

#### ***E. Potential Small Business Impact***

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which have separate divisions for juvenile products. CPSC staff estimates that there are currently at least 62 suppliers of bassinets and/or cradles to the U.S. market. Based on U.S. Small Business Administration guidelines, 39 are small firms (21 domestic manufacturers, 16 domestic importers, and two firms with unknown supply sources) likely to be affected by the staff-recommended final standard, as described in the Directorate for Economic Analysis memo (Tab D).

In most cases, the 14 small manufacturers and the seven small importers whose products are likely to meet the requirements of ASTM F2194-13 should be able to modify their existing bassinet/cradle designs to meet the staff-recommended final rule. However, it is possible that the direct impact could be significant for one or more firms if they must redesign their bassinets. The direct impact on the seven small manufacturers whose bassinets and/or cradles are not compliant with the voluntary standard is likely to be more significant, as their products are more likely to require a substantial product redesign.

Importers of noncompliant bassinet/cradles may need to discontinue their import if their existing supplier does not come into compliance, possibly replacing the noncompliant bassinet/cradle with a compliant bassinet/cradle or another juvenile product.

#### ***F. Effective Date of Final Rule***

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C. 553(d)). In the SNPR the Commission proposed a six month effective date. CPSC staff believes that the Commission should set an effective date for the standard six months after publication for products manufactured or imported on or after that date, with the exception of the recommended removable bassinet bed test requirement and procedure.

CPSC staff recognizes that some manufacturers will be required to redesign, test new prototype products, and then retool their production process to meet the new removable bassinet bed provision. Based on a comment from one manufacturer who suggested a minimum of 15.5 months to redesign its product, CPSC staff considers 18 months to be a reasonable time period to

take into account other manufacturers who might also need to redesign their product. Therefore, staff recommends an 18-month effective date for the removable bassinet bed test requirement.

#### **IV. STAFF-RECOMMENDED MODIFICATIONS**

CPSC staff recommends incorporating by reference the voluntary standard ASTM F2194-13 as the federal regulation for bassinets and cradles, with the staff-recommended modifications outlined below. Tab B, Appendix A of this briefing memo contains the exact recommended language for the modifications.

- 1) Add new definitions, a test requirement, and test procedure for a new performance requirement pertaining to the stability of bassinets with removable bassinet beds. This recommended modification is similar to what was published in the SNPR but has been revised for clarity and completeness.
- 2) Revise the current stability test procedure by specifying the use of a newborn CAMI dummy, rather than the six-month infant CAMI dummy. This recommendation is identical to what was published in the SNPR.
- 3) Revise the pass/fail criterion for the segmented mattresses flatness test to make it stricter than what is in the ASTM standard. This recommended modification is the same as what was published in the SNPR.
- 4) Exclude from requiring compliance to the segmented mattress flatness test bassinets that are less than 15 inches wide along the width of the mattress. This is a new recommendation/modification not found in the SNPR.
- 5) Revise the scope to clarify the intent that multimode or combination products shall meet the requirements of all standards associated with its use modes. This is a new recommendation to clarify what was proposed in the SNPR and subsequently adopted by ASTM.

**TAB A: Bassinet and Cradle-Related Deaths, Injuries, and Potential Injuries Reported Between January 18, 2012 and March 31, 2013 and Responses to Supplemental NPR-Related Comments**

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

## Memorandum

Date: May 24, 2013

TO : Patricia L. Edwards  
Bassinets Project Manager  
Division of Mechanical Engineering  
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka  
Associate Executive Director  
Directorate for Epidemiology

Stephen Hanway  
Division Director, Division of Hazard Analysis  
Directorate for Epidemiology

FROM : Risana Chowdhury  
Division of Hazard Analysis  
Directorate for Epidemiology

SUBJECT : Bassinet and Cradle-Related Deaths, Injuries, and Potential Injuries Reported  
Between January 18, 2012 and March 31, 2013 and Responses to Supplemental  
NPR-Related Comments<sup>3</sup>

This memorandum updates the data in the bassinets and cradles supplemental notice of proposed rulemaking (SNPR) briefing package presented to the Commission in September 2012. The date of extraction for the earlier data was January 18, 2012. This memorandum includes bassinet- and cradle-related incident data reported to CPSC staff from January 18, 2012 through March 31, 2013. This time frame includes January 18, 2012, because the previous extraction may not have included *all* incidents that were reported to CPSC on the day of extraction. In addition, responses to public comments received in response to the SNPR, which pertain to the incident data, are presented in the second half of this memorandum.

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<sup>3</sup> This analysis was prepared by CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

## Incident Data<sup>4</sup>

A search of the CPSC epidemiological databases showed that there were 71 new incidents related to bassinets and cradles reported between January 18, 2012 and March 31, 2013. Thirty-eight of the 71 were fatal and 33 were nonfatal, of which 16 involved injuries. While reporting is ongoing, almost all of the new incidents reportedly occurred between 2010 and 2012. The number of emergency department-treated injuries associated with bassinets and cradles for the time frame covered were insufficient to derive any reportable national estimates.<sup>5</sup> Hence, injury estimates are not presented separately in this memo; instead, the emergency department-treated cases are included in the total count of reported incidents presented here.

As in the SNPR package, incidents related to multimode products that can function as bassinets, as well as bedside sleepers, have been included in this analysis and also in the analysis for the regulatory work for bedside sleepers. Similarly, incidents related to cradle swings, which are subject to both the infant swing standard and the bassinet standard, have been included in the regulatory work for both products.

### *Fatalities*

Among the 38 fatalities, two were associated with design aspects of the product. One of these was a suffocation death in a corner of the bassinet whose rocking feature contributed to its non-level resting position; the other fatality occurred when the bassinet was knocked over by an older sibling.

The majority of the deaths (32 out of 38, or 84 percent) were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and additional bedding. There were three fatalities with insufficient information and one fatality with confounding information to allow CPSC staff to determine the hazard scenario. All but four of the 38 decedents were five months or less in age, the ASTM-recommended age range; three of the decedents were six months old, and another was an eight-month-old.

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<sup>4</sup> 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). The 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 bassinets and cradles.

Date of extraction for reported incident data on bassinets and cradles was 04/08/13. All data coded under product code 1537 was extracted. Upon careful joint review with ES staff, some cases were considered out of scope for the purposes of this memo. Products such as Moses baskets and other sleeping aids were excluded. With the exception of incidents occurring at U.S. military bases in foreign countries, all incidents occurring outside of the United States have been excluded. Any case where the official report cited a natural cause of death, such as SIDS or pulmonary failure, was excluded. Incidents where the involvement of the bassinet was incidental (such as an incident where an infant was dropped while being placed in or retrieved from a bassinet, or an infant, outside the bassinet, fell on to the bassinet, for example) were considered out of scope as well. However, all incidents where hazardous environments in and/or around the bassinet (through addition of soft/extra bedding, for example) resulted in fatalities, injuries, or near-injuries were retained.

<sup>5</sup> According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

## *Nonfatal Incidents*

A total of 33 bassinet-related nonfatal incidents were reported from January 18, 2012 through March 31, 2013. Of these, 16 incidents reported an injury to an infant using the bassinet or cradle at the time of the incident. The majority of these injuries (11 out of 16, or 69 percent) were due to falls out of the bassinets. All 11 fall injuries were reported through the emergency department-treated injury surveillance system, with little or no circumstantial information on how the fall occurred. However, the reports indicate that 55 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of five months. All of the falls resulted in head injuries. Among the remaining five nonfatal injuries, mostly head injuries, no hospitalizations were reported. All but six of the injured were five months or less in age.

The remaining 17 incidents reported that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

## *Hazard Pattern Identification*

The hazard patterns identified among the 71 new incident reports were similar to the hazard patterns that were identified among the incidents considered for the SNPR and are grouped as follows (in descending order of frequency of incidents):

- A. *Non-product-related issues*: Thirty-four of the 71 reports (48 percent) were about incidents that involved no product defect or failure. This category consisted of 32 fatalities that were associated with the use of soft/extra bedding, prone positioning, and/or the infant getting wedged between the side of the bassinet and additional bedding. In addition, there were two nonfatal injury incidents that did not involve any product-related issues.
- B. *Product-related issues*: The hazard scenarios in 25 of the 71 reported incidents (35 percent) were attributed to some sort of failure/defect or a potential design flaw in the product itself. This category includes one fatality and 13 injuries. Listed below are the reported problems, beginning with the most frequently reported concerns:
  - Reports of infants *falling or climbing out* of bassinets/cradles accounted for a total of 13 incidents, all of which were received from emergency departments around the United States. Eleven of the incidents reported a nonfatal injury; the remaining two infants were reported to be uninjured.
  - Lack of *structural integrity*, which includes issues such as instability, loose hardware, and product collapse, among others, was reported in nine incidents—one with a fatality and two with nonfatal injuries.
  - Problems with *accessories* (such as the stand or sheets), which were sold with the bassinets, were reported in two incidents. However, no injuries were reported.
  - One *Other* product-related problem, involving the battery compartment of an older product, was reported in one noninjury incident.

- C. *Recalled product-related issues*: There were six reports (8 percent) that were associated with three different recalled product-related issues. Two of the recalls were published since the incident data for the SNPR briefing package was presented; at the time, these issues were classified under the *structural integrity* and *rocking* categories. While there were no injuries, there was a fatality included among the six incident reports; in the fatal incident, it is reported that the tilting of the bassinet caused the decedent to roll and press up against the side and suffocate.
- D. *Miscellaneous other issues*: The remaining six incident reports (8 percent) were related to other unspecified issues. The reports described the incidents with insufficient specificity or provided confounding information for CPSC staff to identify the hazard scenario. There were four fatalities, one nonfatal injury, and one noninjury incident reported in this category.

## Responses to Supplemental Notice of Proposed Rulemaking Public Comments

Among the many comments received in response to the SNPR published in September 2012, some of the comments pertained to the incident data presented in the package. The comments are organized by topic and shown in italics below. CPSC staff's response follows in non-italic font.

### *The Necessity for Additional Standards*

Comment:

*Several commenters stated that the proposed standard for bassinets and cradles should not be adopted because the number of injuries and fatalities due to design defects was very low.*

Response:

The Consumer Product Safety Improvement Act (CPSIA) requires the Commission to issue a mandatory standard for bassinets and cradles, regardless of the number of incidents involving those products. Given that, the options are either to adopt the existing voluntary standard, as is, or to revise the standard to make improvements. Even if a majority of the incidents were not directly attributable to defects in the product design, many incidents were. Congress mandated that CPSC adopt a more stringent standard if the Commission determined that a more stringent standard "would further reduce the risk of injury." Staff feels strongly that the standard staff recommends would do so.

### *Insufficient Incident Information*

Comment:

*Some commenters asserted that a causal relationship could not be established for fatalities that staff attributed to design defects. They also stated that the information used by staff to analyze fall incidents was circumstantial. Other commenters suggested that additional information should be collected to determine the extent to which product design was at fault, to evaluate the*

*cause of falls, and to “improve and expand on the regulations and guidelines set forth in the proposed rule.”*

Response:

CPSC staff gathered as much information as possible on every cited product-related fatality through an in-depth, on-site field investigation. While we agree with the commenters that additional information gathering on all nonfatal injuries could be useful, given resource limitations, CPSC staff cannot follow up on every injury report with an in-depth investigation. Many of the nonfatal injuries were based on emergency department-treated cases from NEISS hospitals, and confidentiality requirements often prevent any further contact with patients. In addition, even with cases that are followed up, completion of the investigation is not guaranteed because of an inability to establish contact with the consumer or noncooperation by the consumer.

Short of a controlled experimental setting, establishing causal links in observational data based on un-witnessed incidents is difficult. However, the combined judgment of subject matter experts at CPSC corroborated by that of investigating state/county/local officials, support the conclusions.

#### *Incident Data Presentation*

Comment:

*One set of commenters expressed the belief that the data presented in the SNPR is skewed and purposely misleading. There were specifics outlined in the comment, which will be addressed below.*

Response:

CPSC staff strongly disagrees with the commenters and their assertion regarding the way the data are presented. For fatalities, the commenters contend that almost all of the incidents were due to caregiver negligence, even the ones that CPSC staff considered to be product related. The first argument made was that CPSC staff needed to gather more information on the fatalities that they deemed to be product related. CPSC staff gathered as much information as possible on every cited product-related fatality through an in-depth, on-site field investigation. Because these were unwitnessed incidents, the judgment of subject matter experts at CPSC and state/county/local investigating officials was combined to arrive at the conclusions regarding the manner of the deaths. Second, the commenters specifically argued that of the three deaths that occurred due to infants sliding out of the fabric-sided opening, two were older than the recommended age of use. Hence, their argument continued, these two deaths cannot be counted as product related because they were due to caregiver negligence. CPSC staff disagrees because the third decedent, who died in the same manner, was well within the recommended age limit. So, the age of the other two decedents, barely a month above the recommended age limit, was deemed not to be a factor in the entrapments. Third, the commenters cited that the non-product-related deaths appear to be due to caregiver negligence and do not justify CPSC’s increasing the economic burden on manufacturers through added regulations. This argument has no basis because there are no changes being proposed to the current voluntary standard that use these non-product-related fatalities as justification.

For the nonfatal injuries, the commenters said they believe there is no justification for placing a burden on manufacturers by including one injury, due to a moldy mattress, in the report. This is a nonargument. CPSC staff includes all in-scope incidents in its hazard sketch, even ones like the one referenced above, where there is nothing being proposed in the SNPR to address the issue. Therefore, there is no burden put on manufacturers associated with how staff reports the incident data. In addition, the commenters argued that six percent of the injuries from bassinets that were damaged during delivery were instances of blatant negligence on the part of the owners. First, to clarify, CPSC staff reported six percent of the incidents, not injuries, involved bassinets damaged during delivery. Second, there were no injuries associated with these incidents, and nothing is being proposed to address the issue.

*Potential for Serious Injury*

Comment:

*Some commenters said that staff needs to provide justification for their statement regarding the potential for serious injury. They stated: “without any further explanation, this statistic seems arbitrary...”*

Response:

CPSC staff has reviewed a number of incidents where the caregiver was reported to be nearby and was able to rescue the infant from danger; similar scenarios, with the infant unattended, have led to less favorable outcomes. Thus, the potential for serious outcomes is not conjecture on CPSC staff’s part, and the statement is justified.

**TAB B: Division of Mechanical Engineering  
Recommendations for the Final Bassinet and Cradles  
Standard**

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B  
B**



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

## Memorandum

Date: May 24, 2013

TO : Patricia L. Edwards  
Bassinets Project Manager  
Division of Mechanical Engineering  
Directorate for Engineering Sciences

THROUGH: George A. Borlase, Ph.D., P.E.  
Associate Executive Director  
Directorate for Engineering Sciences

FROM : Mark E. Kumagai, P.E.  
Division Director,  
Division of Mechanical Engineering  
Directorate for Engineering Sciences

SUBJECT : Division of Mechanical Engineering Recommendations for the Final Bassinet and Cradles Standard

### **I Background/Overview**

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act (CPSIA), requires CPSC staff to: (1) examine and assess voluntary safety standards for certain infant and toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. The list of products in section 104 includes bassinets and cradles.

In the 2012 supplemental notice of proposed rulemaking (SNPR), staff recommended several changes to the ASTM voluntary standard F2194-12, *Standard Consumer Safety Specification for Bassinets and Cradles* and requested comments from the public. The following modifications to ASTM F2194-12 were included in the SNPR:

- 1) Scope and Terminology: The SNPR contained a modification to exclude inclined products. To do this, the scope was revised and included a detailed note providing

examples of what products were, and were not, included in the scope of the standard. In addition, two new definitions were added to the standard for scope clarity.

- 2) Segmented Mattress Flatness Test: A new test requirement and associated test procedure were added in the SNPR to address suffocation incidents in segmented mattresses.
- 3) Removable Bed Stability Requirement: A new test requirement and associated test procedure were included in the SNPR to address fatal and nonfatal incidents associated with bassinets that have removable beds.
- 4) Stability Test Procedure: A revised test procedure was proposed in the SNPR. The revision specifies the use of a newborn CAMI dummy rather than the six-month CAMI dummy that is referenced in the ASTM standard.

This memorandum explains the major issues related to the proposed modifications in the SNPR and the suggested changes to the current standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*. Also included is a response to related comments submitted in response to the SNPR.

## **II. Public Comments and Staff Responses**

### **Removable Bassinet Bed Requirements**

*Comment: One group of commenters suggested that we eliminate the two “passive” pass conditions (20 degrees and pass stability) of the removable bassinet bed stability requirements in favor of the other pass criterion, which they said they feel makes the user aware that the bassinet is not attached properly.*

*Response: The SNPR outlined several options to meet the removable bassinet bed requirements. This is less restrictive than prescribing one pass criterion and allows for more innovation in product designs. By permitting five different options on how to meet this requirement, manufacturers have a variety of design choices at their disposal.*

*Comment: Some commenters said they feel that allowing the bassinet to “fail” (by falling to the ground or to a 20° or more angle) encourages manufacturers to make products that are less stable to ensure that the bassinet passed this requirement. Another commenter stated that it was foreseeable that some caregivers may attempt to attach the bassinet bed to its stand while the child is in the product and that might expose children to unnecessary hazards.*

*Response: Two of the five options to pass the removable bed requirement are very much related to each other. These two options are: (1) the sleep surface shall be at least 20 degrees off from a horizontal plane, and (2) the bassinet bed falls from the stand and contacts the floor. These two requirements were added after consultations with stakeholders (ASTM task group members). Several stakeholders felt that if a bassinet stand was designed so that it would only support the bassinet bed if it were properly locked, then it should be able to pass the requirement. For instance, envision a stand that looks like a saw horse, or “A” frame, and has a lock/latch connection at the top of the “A” and on the underside of the bassinet bed. The caregiver would have to line up both halves of the lock/latch to attach the bed to the stand. It would be unreasonable to believe that caregivers would place the bassinet bed on an “A” frame stand*

without engaging the lock/latch because the design of the stand would cause the bassinet bed to fall to the ground if the lock was not engaged.

And rather than specify a design requirement, the task group turned it into a performance requirement by simulating what would happen if the unreasonable act occurred. In other words, this option requires the bassinet bed to fall to the ground if the lock is not properly engaged. Once the task group vetted that requirement, another stakeholder brought up the possibility that the bassinet bed, in the act of falling, might get caught on the stand before hitting the ground. And, if it did not hit the ground, should it fail the requirement? Thus, the 20-degree tilt option was added to allow for that possibility and to complement the fall to the ground option.

A bassinet that relies on either of these two options to pass the requirement would be considered to have immediate positive feedback. Caregivers who attempt to place the bassinet bed on this type of stand without locking it in place will realize instantly that they did not engage the lock because the bassinet bed will not assume a stable position that allows them to release their grasp. The immediate feedback of instability will reduce the possible hazards, making falling unlikely. Staff believes that the steep angle needed to pass is unlikely to allow consumers to let children fall. The instability of such a unit is immediately obvious to the user, not a delayed response. Consumers are likely to check the stability of the product before letting go of it. Even in the case where a caregiver attempts to place an occupied bassinet bed on a stand that uses this option, the caregiver will be present and potentially able to prevent or arrest the fall of the bassinet bed. Staff considers the possibility of a fall hazard in this scenario to be highly unlikely and on the rare chance a fall occurs, it is considered to be less significant than an unattended fall to the floor.

*Comment: One commenter stated that the option: “The lock/latch shall automatically engage under the weight of the bed (without any other force/action),” should be a requirement.*

*Response: CPSC staff proposes providing manufacturers with options to meet the removable bassinet bed requirements. This is less restrictive than prescribing one requirement and allows for more innovation in product designs.*

*Comment: One commenter stated that adding the removable bed stability requirement is premature; the commenter expressed the belief that the requirement should be removed from the regulation and that ASTM should be allowed to continue work on this.*

*Response: CPSC staff is aware of two deaths<sup>6</sup> associated with this hazard scenario. Therefore, we do not believe that this requirement is premature. Moreover, the language recommended for the final rule is identical to what the ASTM task group recently developed as a new requirement to address the same hazard. The time line regarding identification of this hazard and ASTM’s involvement demonstrates that there has been ample time to review, discuss, and refine the proposed requirements following their publication in the SNPR:*

The hazard scenario pertaining to the removable bassinet bed requirement was first discovered in mid-May 2012, by CPSC staff following a recall of bassinets for a similar hazard. Immediately

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<sup>6</sup> One occurred in Canada, thus it was not included in incident data counts reported in the SNPR briefing package.

after the hazard was identified and associated with a previous death, CPSC staff raised the issue with the bassinet subcommittee chair, and then again at an ASTM bassinet task group meeting. In June 2012, the hazard was demonstrated and discussed at a full subcommittee meeting.

At the subcommittee meeting, a task group was established to address the hazard, and various conference calls and e-mail exchanges took place during July up through early August 2012. By that time, the task group had a draft performance requirement and test procedure to address the hazard. During the October 2012 subcommittee meeting, the draft requirement and test procedure, as developed by the task group, were reviewed, and comments and suggestions were made. No other task group meetings were held. In January 2013, another subcommittee meeting was held, and the removable bassinet bed stability requirement was raised again. The discussion was limited, and the subcommittee was told that the task group would submit a revised draft at the next subcommittee meeting scheduled for April 2013. No other task group meetings were held. At the April 2013 subcommittee meeting, no discussion occurred, but a task group conference call was scheduled to take place during the following week.

On April 18, 2013, a task group conference call was held where several revisions were made to the draft to clarify the requirement and modify the requirement to allow other bassinet designs that did not present the same hazard. The task group had a follow-up conference call on April 25, 2013. At that time, the revised draft was reviewed, and a consensus was reached regarding what to submit to the subcommittee for ballot. On May 22, 2013, another task group conference call was held to review the proposed ballot item. As of the writing of this briefing memorandum, the removable bed requirement has not been submitted to ASTM for balloting.

CPSC staff participated in all of the subcommittee and task group meetings and agrees with the latest revision created by the task group that is expected to be balloted by ASTM. Staff believes the requirement is adequate to prevent the hazard for which it is intended.

Based on the recent work done by the ASTM task group, staff is recommending some changes to the requirement and associated definitions and procedures that were presented in the SNPR. The changes are the same as what the ASTM task group developed, and the changes are recommended for clarity and to accommodate different manufacturing designs that do not present the hazard being addressed. The changes are not expected to affect safety.

*Comment: A commenter stated that color-only visual indicators should not be allowed as an option to pass this requirement, as individuals who are color blind would not be able to distinguish between locked and unlocked.*

*Response:* CPSC's proposed language in the SNPR for visual indicators allows manufacturers to design a visual indicator that can be recognized by a person with a color vision deficiency. In addition, there are many other options to pass the requirement, and individuals who are color blind can choose to purchase a product that does not use color indicators.

### **Segmented Mattress Cost vs. Benefits**

*Comment: One commenter suggested that a cost-benefit analysis and risk assessment should be conducted to determine whether segmented mattress designs should be maintained.*

Response: CPSC staff avoids design-specific solutions to product hazards whenever possible. In this case, the mattress flatness test included in the staff-recommended final rule will address the known hazard without limiting the design option available to suppliers.

### **Mattress Thickness (Rigid Products and Falls)**

*Comment: Some commenters raised an issue regarding rigid-sided bassinets and how they are allowed thicker mattresses than soft-sided bassinets. These commenters said they feel that thicker mattresses may pose more of a risk of babies falling out when a baby rolls to one side and the product tilts.*

Response: There are two requirements in the existing ASTM standard that would prevent the scenario described by the commenters. The first is the side height requirement, which states that the side height of the bassinet be 7.5" above the uncompressed surface of the mattress. Thus, if a bassinet maker supplies a thick mattress with the rigid-sided bassinet, the side heights must still account for the thicker mattress and still yield 7.5" of side height above the mattress surface. In addition, the standard has a rock/swing angle requirement that limits the maximum angle a rocking bassinet can have, as well as a maximum rest angle it can have. The rest angle is measured using a CAMI doll placed up against the side of the bassinet. Thus, the standard uses a worst-case placement scenario for the occupant during the testing.

### **Health Canada Standard**

*Comment: A representative of Health Canada corrected a statement in the staff briefing package and in the SNPR, which states: "The Canadian standard (SOR 86-962:2010) includes requirements for cribs and non-full-size cribs. This standard does not distinguish between a bassinet and non-full-size cribs." The commenter added that this overview statement was incorrect because on November 18, 2010, the amended Cribs, Cradles, and Bassinets Regulations (SOR/2010-261) came into effect, and now bassinets are included in the scope.*

Response: Staff thanks Health Canada staff for the correction and the subsequent information regarding how SOR 2010/261 distinguishes bassinets, cradles, and cribs. As staff now understands, Health Canada defines these three products according to the sleep surface area contained in the product.

### **Segmented Mattress Support Rods**

*Comment: Two commenters offered remarks regarding the mattress flatness testing and designs of bassinet accessories that use support rods underneath the mattress. One of the two comments suggested that the mattress flatness test should be performed with and without the bars in place. If the bars are required to pass the flatness test, then the bars should be attached permanently, the commenter remarked. Similarly, the other comment suggested that the frame supporting the floor (mattress) should come preassembled to eliminate the possibility that the consumer can misassemble the product.*

Response: Staff agrees with these comments, and ASTM does as well. In January 2013, ASTM balloted a revised mattress flatness test requiring that any segmented mattress with consumer-assembled mattress support rods be tested with and without the mattress support rods. This ballot passed and is now part of ASTM F2194-13. Staff is recommending that the final rule refer to ASTM F2194-13; and thus, staff will incorporate the suggestion.

#### **Play Yard Misassembly Requirement in Docket CPSC-2011-0064**

*Comment: The commenter repeated comments submitted for Docket CPSC-2011-0064, regarding the play yard misassembly requirement that was proposed in August 2012.*

Response: Staff has addressed these comments in the final rule briefing package for Play Yard Misassembly Requirement, dated June 19, 2013.

#### **International Standards**

*Comment: Commenters mentioned that it would be helpful to have more information regarding the international standards that were mentioned in the SNPR.*

Response: Staff provided the names and designations of the standards, plus a description of where they differed substantially from the ASTM standard. Due to copyright laws, staff was not able to provide full copies of the standards. All of the standards are available for purchase online, for anyone who wants more information.

#### **Scope Clarity**

*Comment: Two commenters provided almost identical comments and suggestions for changes to the scope. The commenters asserted that the scope section is unclear about what products were included in the scope and under what conditions. For instance, one comment stated: "The CPSC proposed changes identify the specific product categories of "products used in conjunction with an inclined infant swing or stroller"; then the commenter focused only on products that provide an inclined sleep surface and that are intended to provide sleeping accommodations, such as inclined sleep products. The revised wording with the proposed CPSC change leaves it unclear and open for interpretation about how products with an inclined seat back surface (reclined seat back), such as infant seats, infant bouncer seats, and infant rockers that do not provide an "inclined sleep surface" would be treated under the standard.*

Response: The proposed scope, as outlined in the SNPR, has subsequently been adopted by ASTM and is the scope in the current version of the standard. It is clear from the comments received that there is still some ambiguity regarding some aspects of the scope. Therefore, staff agrees that additional clarity is warranted.

Inclined products fall under a variety of ASTM standards, depending on their function. For instance, there is a handheld carrier standard, an infant bouncer standard, and a new rocker standard that is currently under development. None of those products are intended for sleep. An inclined product meant for sleeping would fall under the inclined sleep product standard currently under development by ASTM. It is staff's intent that the scope of the bassinet standard exclude inclined sleep products when the incline is more than 10 degrees from horizontal.

But, it is also staff's intent that any product that has a flat (10 degrees or less) sleep surface AND an inclined surface shall fall under the scope of the bassinet standard when configured in the flat mode, and that the product shall fall under the scope the appropriate inclined standard(s) while in the inclined mode. In this manner, all uses of the product are addressed by safety standards. This type of product is considered a multiuse or combination; *i.e.*, the product can convert from one use mode to another.

At the ASTM F15 April 2013, juvenile products subcommittee meetings, the issue of scope clarity was raised in various product subcommittees where dual-use modes exist. The proposed solution in those subcommittees was to modify the scope section of the appropriate standard to clarify that conversion products shall fall under the scope of all relevant standards when the product is in the corresponding use mode.

This intent to include multimode products under multiple standards is well established in ASTM standards, including the bassinet standard; for example, carriage baskets that are removable from stroller bases. The scope of ASTM F2194-13 clearly states that products used in conjunction with a stroller are not covered by the standard. Yet, the current scope in the bassinet standard states: "Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1."

Thus, to remove any ambiguity regarding multimode products, staff is recommending another modification to the note that accompanies the scope of ASTM F2194-13 to make it clear that a multimode product that has a bassinet mode must meet the bassinet standard when in the bassinet-use mode.

### **ASTM Copyright and Accessibility**

*Comment: Some commenters stated that the ASTM standard for bassinets and cradles should not be the basis of a mandatory rule because, as a copyrighted standard, it is not easily accessible to the public and creates an undue financial burden on small manufacturers and the general public.*

*Response: The Commission is required to use the applicable voluntary standard, in this case the ASTM standard for bassinets and cradles, as the basis for its mandatory rule. Section 104(b) of the CPSIA requires the Commission to issue standards for durable infant or toddler products that are substantially the same as applicable voluntary standards or are more stringent if more stringent standards would further reduce the risk of injury. Incorporating a voluntary standard, such as incorporating the ASTM standard by reference, is a well-recognized procedure for agencies. The incorporation satisfies the requirement of publication in the *Federal Register*. See 5 U.S.C. § 552(a)(1)(E) ("matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register").*

### **III. Stakeholder Response to SNPR**

The stakeholders with whom staff consulted are members of, or participants at, ASTM bassinet/cradle meetings. This section outlines the actions taken by ASTM since the SNPR.

Following publication of the SNPR, ASTM published a new version of the standard, F2194-12a. This version contained a revised scope and associated definitions match exactly what was proposed in the SNPR. A month later, the standard was revised (F2194-12b) to include a segmented mattress flatness test requirement and procedure. The test procedure in this revision is identical to the modification in the SNPR, but the test requirement is different. The test requirement included in the SNPR is stricter than what is included in the ASTM standard.

In 2013, the ASTM standard was revised to include two new changes. One requires play yard bassinet accessories to be tested for mattress flatness with and without mattress support bars, if the support bars are not permanently attached. This requirement is from the play yard misassembly NPR published in September 2012. The ASTM subcommittee for non-full size cribs/play yards decided that the best way to respond to the play yard misassembly NPR was to revise the play yard standard and the bassinet standard, incorporating portions of the requirement from the NPR into each standard. For more discussion on this matter, please refer to the play yard misassembly requirement final rule briefing package dated June 19, 2013. Staff agrees with this revision to the standard. The second change in F2194-13 deals with a clarification to the font style for the suffocation warning label. Staff agrees with this change as well.

ASTM is expected to issue a ballot, which contains several items associated with stability testing. The expected ballot is essentially the same as two of staff's recommended modifications to F2194.13: the removable bed stability requirement (and associated definitions and procedures) and the stability test revision.

#### **IV. Staff-Recommended Changes to F1294-13**

Based on the comments to the 2012 SNPR and subsequent work done by the ASTM task group, staff is recommending changes to ASTM F1294-13 to:

- 1) Keep the language in the 2012 SNPR, with some clarifications regarding the definitions, requirements, and test methods for removable bassinet bed stability.
- 2) Keep the language in the 2012 SNPR regarding the Stability Test Procedure, which specifies using a newborn CAMI dummy rather than the six-month CAMI dummy.
- 3) Keep the language in the 2012 SNPR regarding the pass fail criterion for segmented mattresses flatness.
- 4) Based on a comment addressed in the HF memo (Tab C), staff recommends excluding from the segmented mattress flatness test bassinets that are less than 15 inches wide along the width of the mattress. It is unlikely that an infant is placed or moves orthogonally between 15-inch walls.
- 5) Based on a comment, staff recommends revising the scope of the ASTM standard to clarify the intent that dual-mode or combination products shall meet the requirements of both (or all) standards associated with the use modes.

CPSC staff recommends that the Commission publish a final rule that incorporates by reference the voluntary standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, with revisions as written in the appendix to this memo.

**Appendix A**  
**CPSC Staff-Recommended Revisions to ASTM F2194-13 Standard**  
(~~strikeouts~~ reflect deleted language; underline reflects added language; **Yellow highlighted language reflects differences from the SNPR**)

**A) *Segmented Mattress Flatness Test – Modify the pass/fail criterion in F2194-13 to be identical to what is in the SNPR, and add and exclusion for bassinets that are less than 15 inches wide:***

6.7 Bassinets with Segmented Mattresses: Flatness Test—If the bassinet or bassinet accessory has a folding or segmented mattress, or both, any angle when measured in 7.8 less than or equal to 10° is an immediate pass. Any angle when measured in 7.8 greater than ~~14~~ 10° is an immediate failure. ~~If any angle measurement is greater than 10° and less than or equal to 14°, repeat the same angle measurement test two more times and take the arithmetic mean of the three readings. If the resultant arithmetic mean angle is greater than 10° that is also a failure.~~ Segmented bassinet mattresses that have seams (located between segments or where the mattress folds) that are less than 15 inches in length are excluded from this requirement.

**B) *Scope –Further clarify the intent that dual mode or combination products shall meet the requirements of both (or all) standards associated with the use modes***

Note 1 – Cradle swings with an incline less than or equal to 10° from horizontal while in the rest (non-rocking) position are covered under the scope of this standard. A sleep product that only has an inclined sleeping surfaces (intended to be greater than 10° from horizontal while in the rest (non-rocking) position) does not fall under the scope of this standard. If a product can be converted to a bassinet/cradle use mode and meets the definition of a bassinet/cradle found in 3.1.1 while in that mode, the product shall be included in the scope of this standard, when it is in the bassinet/cradle use mode. For example, strollers that have a carriage/bassinet feature are covered by the stroller/carriage standard when in the stroller use mode. Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1. In addition, bassinet/cradle attachments to cribs or play yards, as defined in 3.1.2 or 3.1.12, are included in the scope of the standard when in the bassinet/cradle use mode.

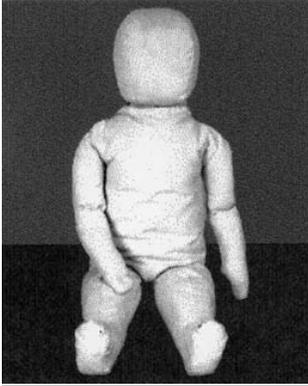
**C) *Stability Procedure – Two modifications (exactly matching the language in the SNPR).***

**Add reference for the CAMI Newborn dummy:**

**2.3 CAMI Newborn Dummy (See Fig 1a)<sup>7</sup>**

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<sup>7</sup> Drawing numbers 126-0000 through 126-0015 (sheets 1 through 3), 126-0017 through 126-0027, a parts list entitled “Parts List for CAMI Newborn Dummy,” and a construction manual titled, “Construction of the Newborn Infant Dummy” (July 1992). Copies of the materials may be inspected at NHTSA’s Docket Section, 400 Seventh Street, S.W., Room 5109, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.



**FIG. 1a CAMI Newborn Dummy**

**Change testing procedures to use CAMI Newborn dummy:**

7.4.4 Place the CAMI ~~Infant~~ Newborn Dummy, ~~Mark II~~, on the sleeping pad in the center of the product face up with the arms and legs straightened.

Rationale

The newborn CAMI dummy represents a 50<sup>th</sup> percentile newborn infant, which is a more appropriate user of a bassinet than the CAMI infant dummy, which represents a 50<sup>th</sup> percentile 6-month-old infant.

**D) *New Associated Definitions and Performance Requirement/Test Procedure to Address Hazards Associated with the Stability of Removable Bassinet Beds:* **Yellow** highlighted language reflects noneditorial differences to the SNPR)**

**New Associated definitions:**

3.1.18 *bassinet bed, n* – the sleeping area of the bassinet/cradle, containing the sleep surface and side walls.

3.1.19 *removable bassinet bed, n* – A bassinet bed that is designed to separate from the base/stand without the use of tools. **Play yard bassinets, as defined in 3.1.13, are excluded from this definition.**

3.1.20 *false lock/latch visual indicator, n* – a warning system, using contrasting colors, lights, or other similar means designed to visually alert caregivers when a removable bassinet bed is not properly locked onto its base/stand.

3.1.21 *intended use orientation, n* – The bassinet bed orientation (*i.e.*, the position where the head and foot ends of the bassinet bed are located), with respect to the base/stand, as recommended by the manufacturer for intended use.

**Test Requirement:**

6.10 *Removable Bassinet Bed Attachment* - Any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the base/stand, shall comply with at least one of the following 6.10.1, 6.10.2, 6.10.3, 6.10.4 or 6.10.5 when tested in accordance with 7.12.

6.10.1. The base/stand shall not support the bassinet bed (*i.e.*, the bassinet bed falls from the stand and contacts the floor **or the base/stand collapses when the bassinet bed is not locked on the base/stand**).

6.10.2. The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action) in all lateral positions (Figure 24).

6.10.3. The sleep surface of the bassinet bed shall be at an angle of at least 20° from a horizontal plane when the bassinet bed is in an unlocked position.

6.10.4 The bassinet/cradle shall provide a false latch/lock visual indicator(s). At a minimum, an indicator shall be visible to a person standing near both of the two longest sides of the product.

6.10.5. The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when tested in accordance with 7.12.5.3.

**Test Procedure:**

7.12 Removable Bassinet Bed Attachment Tests

7.12.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions in one of the manufacturer's recommended use positions. If the base/stand does not remain in the use position when the bassinet bed is not locked onto it, the product meets the requirements of 6.10.1.

7.12.2 Place the base/stand and the inclinometer on a flat level horizontal surface (0 +/- 0.5°) to establish a test plane. Zero the inclinometer.

7.12.3 Remove the mattress pad from the bassinet bed.

NOTE —For mattresses that are integral with the mattress support, do not remove the mattress and perform all angle measurements for 7.12 on a 6 by 6 by 3/8-in. nominal aluminum block placed on the center of the mattress.

7.12.4 Place the bassinet bed on the base/stand in the intended use orientation without engaging any latch or lock mechanism between the base/stand and the bassinet bed. If the bed automatically engages to the base/stand do not disengage the lock/latch. If the bassinet bed can rest on the base/stand in its intended use orientation in one or more lateral unlocked position (Figure 24), the unit shall be evaluated in the lateral position most likely to fail the requirements specified in 6.10.

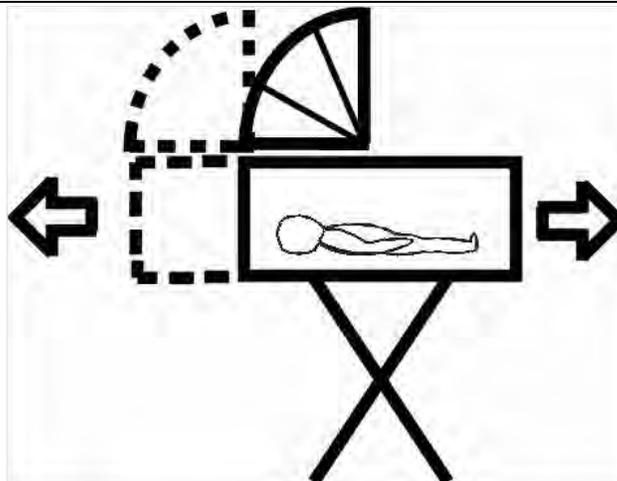


Figure 24: Bassinet Bed Resting on Stand, Showing Possible Alternate Lateral Positions

7.12.4.1 If the base/stand supports the bassinet bed in any unlocked position, place the inclinometer on the mattress support at the approximate center of the mattress support. Care should be taken to avoid seams, snap fasteners, or other items that may affect the measurement reading. Record the angle measurement.

7.12.4.2 If the base/stand supports the bassinet bed and the angle of the mattress support surface measured in 7.12.4.1 is less than 20 degrees from a horizontal plane, evaluate whether the bassinet has a false latch/lock visual indicator per 6.10.4.

7.12.4.3 If the base/stand supports the bassinet bed, and the angle of the mattress support surface measured in 7.12.4.1 is less than 20 degrees from a horizontal plane, and the bassinet does not contain a false latch/lock visual indicator, test the unit in accordance with sections 7.4.2 through 7.4.7.

7.12.5 Repeat 7.12.2 through 7.12.4 for all of the manufacturer's base/stand recommended positions and use modes.

7.12.6 Repeat 7.12.4 through 7.12.5 with the bassinet bed rotated 180 degrees from the manufacturers recommended use orientation, if the base/stand supports the bassinet bed in this orientation.

**Rationale:**

*This test requirement addresses fatal and nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand or the latch failed to engage as intended. Products that appear to be in an intended use position when the lock or latch is not properly engaged can create a false sense of security by appearing to be stable. Unsecured or misaligned lock/latch systems are a hidden hazard because they are not easily seen by consumers due to being located beneath the bassinet or covered by decorative skirts. In addition, consumers will avoid activating lock/latch mechanisms for numerous reasons if a bassinet bed appears stable when placed on a stand/base. Because of these foreseeable use conditions, this requirement has been added to ensure that bassinets with a removable bassinet bed feature will be inherently stable or it is obvious that they are not properly secured.*

*6.10 allows bassinet bed designs that:*

- 1) cannot be supported by the base/stand in an unlocked configuration,*
- 2) automatically lock and cannot be placed in an unlocked position on the base/stand,*
- 3) are clearly and obviously unstable when the lock/latch is misaligned or unused,*
- 4) provide a visual warning to consumers when the product is not properly locked onto the base/stand, or*
- 5) have lock/latch mechanisms that are not necessary to provide needed stability.*

**TAB C: Bassinets and Cradles Standard: Human Factors Issues**

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C**



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

## Memorandum

Date: May 23, 2013

TO: Patricia L. Edwards, Project Manager for Bassinets  
Division of Mechanical Engineering, Directorate for Engineering Sciences

THROUGH: George A. Borlase, Ph.D., P.E.  
Associate Executive Director, Directorate for Engineering Sciences

Bonnie B. Novak  
Director, Division of Human Factors

FROM: Jonathan D. Midgett, Ph.D., Office of Hazard Identification and Reduction

SUBJECT: Bassinets and Cradles Standard: Human Factors Issues

### I. Introduction

The Consumer Product Safety Improvement Act of 2008, Public Law 110–314 (CPSIA) was enacted on August 14, 2008. Section 104 of the CPSIA, also known as the Danny Keysar Child Product Safety Notification Act, requires the Commission to promulgate mandatory consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The Commission proposed a safety standard for bassinets and cradles in the Federal Register (75 Fed. Reg. 22303, April 28, 2010), based on the voluntary standard, ASTM F2194 – 07a<sup>e1</sup>, “Standard Consumer Safety Specification for Bassinets and Cradles.” This notice of proposed rulemaking (2010 NPR) requested comments from the public. A second round of notice and comment, or supplemental notice of proposed rulemaking, for bassinets and cradles was issued on October 18, 2012 (SNPR), and was based on ASTM F2194 - 12.

Since fall 2012, ASTM has updated the bassinet and cradle standard three times, and the latest version is F2194 - 13. Staff recommends that the Commission incorporate by reference F2194 - 13 in the final rule as the safety standard for bassinets and cradles, with a few modifications. This memorandum responds to the major human factors issues raised in the comments submitted after the SNPR and that pertain to the final rule on bassinets and cradles.

## **II. Human Factors-Recommended Modifications to F2194-13**

### Segmented Mattress Flatness Minimum Angle

The current ASTM standard, F2194 – 13, contains a segmented mattress flatness test. The test procedure in the ASTM standard is identical to what was proposed in the SNPR, but the pass/fail criterion is different. The SNPR called for a 10° maximum allowable angle, where ASTM F2194 - 13 allows for measurements as high as 14°. Therefore, the SNPR requirement is stricter. As discussed in the SNPR, staff supports the 10° pass/fail criterion for the segmented mattress flatness test to cover the widest range of infants possible, rather than rely on the ASTM requirement. Staff believes the 10° criterion to be more protective. Additional information on staff's position can be found in section III below, as well as in the SNPR briefing package.

Therefore, staff recommends a modification to ASTM F2194 - 13 to change the pass/fail criterion for this test to match what was proposed in the SNPR. The suggested wording can be found in the Engineering Sciences (ES) memorandum in Tab B.

### Segmented Mattress Flatness Minimum Width

Staff supports a new recommendation from an ASTM member to allow an exception to the segmented mattress flatness test for narrow bassinets. Narrow bassinets, those that are less than 15 inches wide, cannot be tested because the test cylinder and the platform for the inclinometer will not fit within such a narrow space. Such units do not allow consumers to place infants within the occupant retention space in a manner that would permit infants to get into the seam of the mattress, so the exemption should not create any hazards. Additional information on staff's position can be found in section III below. The suggested wording to modify F2194 - 13 can be found in the ES memorandum in Tab B.

## **III. Public Comments**

### Falls from Bassinets/Side Height

Comment:

*Some commenters suggested that the side height requirements need to be higher because consumers seem to be using bassinets with children older than the recommended ages. One commenter expressed the belief that the standard should match the Canadian side height requirement.*

Response:

The ASTM subcommittee discussed the side heights of bassinets for years. There was no side height requirement until recently. The main objection to setting any side height requirement was that consumers use the products longer than intended. High side heights could cause consumers to use their bassinets even longer than they have been using them because the older, larger children who can push up on their hands and sit unassisted will look safer in a bassinet with tall sides. The unintended consequence of taller sides might be an increase in falls from bassinets because older children are stronger and more agile than newborns. After much discussion, the

subcommittee agreed to a 7.5-inch side height based on the precedent set by the Canadians who measure from the bottom of the bassinet rather than the mattress top. This difference in measurement landmarks makes the ASTM standard appear shorter; but in reality, the effective side height of a bassinet in Canada is the same as in the ASTM standard. This side height did not require drastic changes in the bassinet designs on the market, so it would be unlikely that instituting the requirement would have any effect on consumer behavior.

Comment:

*Several commenters suggested that side height requirements might not be effective against misuse. One commenter said they believe that the burden should be placed upon caregivers and that the standard needs no modification to address falls. Another suggested that warning labels be strengthened instead.*

Response:

The side height requirement (7.5-inch minimum) is already part of the latest version of the current voluntary standard that will become a regulation upon Commission adoption. The draft final rule does not add or recommend anything further because staff believes that the requirements should be effective against misuse. Staff feels that, at a minimum, this requirement will help protect infants who have not exceeded the maximum age requirement for bassinet usage. Additionally, staff supports the current warnings in the standard.

#### Removable Bed Stability Requirement Pass/Fail Criteria

Comment:

*Some commenters said they feel that allowing removable bassinet beds to pass the stability test by tilting to a 20-degree angle was hazardous because consumers might think that a 20-degree angle was still usable, perhaps as an inclined sleeper.*

Response:

Staff believes that an angle of 20° or more is acceptable to demonstrate a nonuse mode. A steeper requirement would also be acceptable, but staff is not convinced it is needed. Twenty degrees is twice the maximum allowable tilt for bassinets, which are intended to have a flat sleeping surface. In deciding on the 20° angle, the ASTM task group noted an incident (101101HCC3107), where a consumer clearly saw that something was wrong with his bassinet when he saw it tilted and deemed it to be unusable. From the photos, the tilt was estimated to be approximately 17°.

#### Mattress Flatness/Narrow Bassinets

Comment:

*A commenter suggested that the mattress flatness test could not be performed on bassinets that were less than 15 inches wide because of the width of the cylinder and the block used in that test method. Furthermore, such a small, narrow occupant retention space would not present the same hazards as those in the incidents which involved wider play yard bassinet accessories, the commenter suggested.*

Response:

Staff agrees that bassinets with occupant retention spaces that are narrower than the test apparatus are unlikely to be used with an infant placed orthogonally between walls that are so narrow. In the case where an infant is placed correctly in a narrow bassinet and then moves and shifts 90° the narrowness of the bassinet would likely not permit the infant to lie in a fully prone position, face down in an orthogonal seam. Thus, an exemption from the flatness test for mattress pad seams that run orthogonally between the sides of a bassinet with a width of 15 inches or less seems reasonable.

Therefore, staff is recommending a modification to the standard for the exemption of bassinets that are narrower than 15 inches.

#### Mattress Flatness Test/CAMI Dummy or Cylinder

Comment:

*Some commenters questioned the use of a cylinder as a surrogate for a human occupant, and another commenter suggested that an automated human model would be more appropriate.*

Response:

An automated human model is not readily available. The industry standards in the juvenile product industry typically use easily manufactured shapes made from common materials.

This testing strategy enhances the repeatability of the test. An ASTM task group conducted a repeatability and reproducibility study to compare various surrogates for use in the mattress flatness test. The cylinder was the best choice, based on the study results.

Comment:

*Some commenters suggested using the dummy in the test for mattress flatness so that infant position would be a factor.*

Response:

The test cylinder is a repeatable method that identifies hazardous products to the satisfaction of industry and CPSC staff. Unfortunately, the CAMI dummy is too stiff to be useful for simulating suffocation positions and would not be able to serve that purpose.

Comment:

*Some commenters wanted more explanation of how the cylinder sufficiently simulates an infant rolling into a mattress crease, as demonstrated in the mattress flatness test.*

Response:

Staff has examined bassinets that pass the test and bassinets that fail. When visual comparisons and measurements of angles are made to compare the movements of the mattresses during a test using an anthropomorphic dummy with tests using a cylinder, few discernible differences are

evident. The shape of the test weight does not seem to be as important to identifying hazardous products as the mass of the test weight.

#### Mattress Flatness Pass/Fail Requirement

Comment:

*Some commenters suggested that the mattress flatness requirements should be limited to 8° from the horizontal rather than 10°.*

Response:

While staff would be amenable to using this more conservative margin of safety (*i.e.*, a tolerance of 16° of motion rather than 20°), the industry has maintained that a larger tolerance is necessary, due to the inherent variability of manufacturing products with fabric and foam. They claim that tighter tolerances on a segmented mattress made with the materials that are commonly used in these products would make them impossible to manufacture. Staff believes that the 10°-limit set in the SNPR is adequate to protect the expected user population.

Comment:

*A commenter suggested that the threshold limit for flatness should be 14° to preserve test-retest reliability.*

Response:

ASTM F2194-13 now includes the mattress flatness test requirement and procedure, as written in the SNPR, except for the angle requirement. ASTM's requirement allows the use of an average for measurements over 10° and under 14°, while the SNPR has a maximum allowable measurement of 10°. Based on testing performed by an ASTM task group that was established to assess the reliability and repeatability of the mattress flatness test, the reliability of the test is adequate when the test is performed on products designed to pass the test. The commenter did not provide any new or different information to staff to support their suggestion for using the averaging method, and thus staff continues to support the 10° flatness criterion as presented in the SNPR.

#### Stability Testing – CAMI Dummy

Comment:

*Some commenters suggested using an infant and a newborn dummy in the stability test methods. On the other hand, others said they believe the incident data did not support changing from an infant dummy to a newborn dummy because the rationale neglects the evidence that larger infants also use bassinets and cradles.*

Response:

The use of both dummies is unnecessary because the worst-case scenario for stability is the smaller size dummy. The larger size dummy makes the product more stable; so if a product passes with a newborn, it will also pass with an infant. Performing the test with two different dummies would be redundant and only add to the cost of testing.

The newborn CAMI is being proposed for the stability test to make the test more stringent. Even though a majority of the incidents were not directly attributable to product stability, many incidents were, including one fatal incident.

### Size and Weight Limits

Comment:

*Some commenters suggested that the weight of an infant occupant should be considered in the standard's scope to safeguard infants who exceed the recommended weight and size.*

Response:

The maximum weight of an occupant is already considered in the Static Load requirements (Section 7.3). The industry requires a bassinet to be loaded to three times the manufacturer's recommended weight. The side heights are also intended to account for the largest infants who might still use the bassinet.

### Bassinet Misuse

Comment:

*One commenter worried that the possibility of consumer misuse of bassinets would negate any effects of the new requirements.*

Response:

Staff believes that strengthening the standard is the best way to improve product safety and that if significant product misuse becomes evident in injury reports, more developments are possible.

Comment:

*Another commenter suggested that educational campaigns about the proper and improper uses of bassinets would be sufficient.*

Response:

Staff believes that educational campaigns play an important role in injury prevention but are best preceded by mechanical and physical safety requirements designed to make accidents as unlikely to occur as possible.

### Restraints

Comment:

*One commenter said they believe that the lack of incidents with harnesses could be due to other factors as much as to the lack of harnesses in bassinets.*

Response:

Deaths and injuries in other infant products have been attributed to restraints/harness that were not used or were used improperly. Therefore staff is not making any recommendations with regard to changing the current prohibition of restraints in bassinets.

## Scope – Age Restrictions

Comment:

*One commenter suggested that the scope of the standard needs more specific age restrictions.*

Response:

The scope of a standard is intended to define broadly an entire product category. Within that category, manufacturers have the freedom to tailor their product to a specific market niche, which might be more specialized than other products in the same category. Providing too many specific restrictions within the scope of a standard makes the standard weaker by excluding many products that ought to be included. In general, ASTM standards are defined by their respective industries, using terms that produce a standard that is as useful as possible to that industry. Staff agrees with the bassinet industry on the existing age recommendations in the standard.

## Warnings

Comment:

*Some commenters recommended the use of pictures or visual aids to clarify the warning messages.*

Response:

We acknowledge that well-designed graphics can be useful in certain circumstances. However, the design of effective graphics can be difficult. Some seemingly obvious graphics are poorly understood and can give rise to interpretations that are opposite the intended meaning (so called “critical confusions”); therefore, a warning pictogram should be developed with empirical study and well tested on the target audience. Although the staff may recommend that the Commission may take action in the future if the staff believes graphic symbols are needed to reduce the risk of injury associated with these products, the rule permits, but does not mandate, such supporting graphics.

With respect to the idea of creating a pictogram to communicate the dangers of soft bedding, staff agrees that a well-developed and tested pictogram could increase comprehension and acknowledges that such elements could be developed with some empirical study; however, staff does not have the resources for such a project at this time and could not validate a warning graphic without research. However, there are a number of products for which such a soft bedding pictogram could be useful, such as bedside sleepers, bassinets, cribs, play yards, inclined sleep products, and others. Because of this, an ASTM cross-product ad hoc working group may be the best place to develop such a pictogram. This could foster cross-product harmonization of such a pictogram and would allow testing and validation of the pictogram. Staff will gladly participate in any such group, and, should the need arise, staff will consider future action once such a graphic is developed.

Comment:

*A commenter suggested adding statistics to the suffocation warning.*

Response:

Crafting a warning requires balancing the brevity of the message with its attention-grabbing features and informational content. Too much information makes a long label that is likely to be ignored by consumers; and not enough information leaves consumers unsure of the message. Staff's opinion is that the addition of statistical information to the suffocation warning label will not increase the effectiveness of the warning.

Comment:

*A commenter suggested that the warnings contain the maximum recommended age of the bassinet occupant, i.e., five months.*

Response:

The current warning contains a developmental milestone, rather than an age. Developmental milestones have the advantage of allowing for individual variability in use patterns. Some children will gain strength and coordination faster than others and will need to be removed from the bassinet sooner. Since children's abilities are more important than their age when evaluating the applicability of the warning, the age is not included in the warning.

Comment:

*A commenter suggested that the warnings should be displayed in a prominent position.*

Response:

The ASTM standard already contains a common definition for "conspicuous" warnings in Section 3.3.3, with corresponding requirements in Sections 8.3, 8.4, and 8.5.

Comment:

*A commenter suggested strengthening the warning labels by requiring mattress pads to have the following statement: "This padding has been tested to reduce the risk of suffocation to a minimal level, adding additional padding increases this risk substantially and has caused fatalities."*

Response:

While the standard does contain a requirement for the mattress pad to remain level, the standard does not contain a test for reducing the risk of suffocation created by the softness of the padding, which seems to be the assumption made by the commenter. It may be possible to adopt requirements that address the softness of the padding in the future. The standard already contains a warning in Section 8.4.2 prohibiting additional bedding materials. This required warning must be visible to the consumer when the product is in the manufacturer's recommended use position. As such, the warning will not be covered by sheets, which are allowed, and will be more effective than on the mattress pad where any messages will be covered.

Comment:

*Another commenter suggested that consumers need to be warned of the hazards associated with segmented mattresses.*

Response:

Warnings are the last stage when attempting to remove a hazard from a product. Changing the product is more effective. The standard contains performance requirements designed to eliminate the hazards associated with segmented mattresses, so it is not necessary to include a warning.

Comment:

*Several commenters suggested that warnings should have larger fonts, duplication on opposing walls of the bassinet, duplication on the packaging and on the product, more detailed hazard descriptions, and more information in supporting educational materials and in product advertisements.*

Response:

While staff agrees that any warning could be strengthened with a size, color, or other graphical features, the product's final appearance also needs to be considered because exceptionally large or graphic warnings may cause consumers to remove or deface them, thereby rendering them ineffective for later users. The current warning requirements match industry standards for many juvenile products.

**TAB D: Final Regulatory Flexibility Analysis of Staff-Recommended Final Rule for Bassinets and Cradles**

**T  
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Date: May 21, 2013

TO : Patricia L. Edwards  
Project Manager, Bassinets  
Division of Mechanical Engineering  
Directorate for Engineering Sciences

THROUGH: Gregory B. Rodgers, Ph.D.  
Associate Executive Director  
Directorate for Economic Analysis

Deborah V. Aiken, Ph.D.  
Senior Staff Coordinator  
Directorate for Economic Analysis

FROM : Jill L. Jenkins, Ph.D.  
Economist  
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis of Staff-Recommended Final Rule for  
Bassinets and Cradles

## 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. Bassinets and cradles are among the durable products specifically named in section 104.

On April 28, 2010, the CPSC published a notice of proposed rulemaking (NPR) in the Federal Register (FR) (75 FR 22303). The proposed rule incorporated by reference the voluntary ASTM International (formerly known as the American Society for Testing and Materials) standard for bassinets and cradles (F2194-07a<sup>e1</sup>), with several modifications, including mattress flatness and rock/swing angle requirements. As a result of new issues raised during the 2010 NPR comment period, and due to some changes in staff recommendations, the CPSC published a supplemental notice of proposed rulemaking (SNPR) for bassinets and cradles on October 18, 2012 (77 FR 64055).

The SNPR proposed four changes to the voluntary standard. Since the SNPR was published, ASTM has adopted one proposal without modification (scope) and another with different pass/fail criteria (segmented mattress flatness). In addition, remaining two SNPR items are expected to be balloted soon: stability testing with newborn CAMI (identical to the SNPR proposal); and removable bassinet bed requirement and test methods with modifications that

mirror those recommended by staff for adoption as part of the final bassinet/cradle rule. As a result, staff recommends that the Commission adopt ASTM F2194-13 with five changes: add the removable bassinet bed requirement; modify the stability testing; modify the pass/fail criterion for the segmented mattress flatness test; clarify the scope; and exempt certain bassinets from segmented mattress flatness testing. The last two changes are recommended as a result of the public comments received in response to the SNPR.

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis when the Commission promulgates a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

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

## **The Product**

A bassinet/cradle is a small bed for infants “supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base.” Bassinets/cradles are not intended to be used beyond the age of approximately five months or when a child is able to push up on their hands and knees. Bassinet and cradle attachments for non-full-size cribs or play yards are considered a part of this product category, as are bedside sleepers that can be converted to a four-sided bassinet not attached to a bed.

Cribs, Moses baskets,<sup>8</sup> and products used in conjunction with an inclined infant swing or stroller, and products that are intended to provide only an inclined sleep surface of greater than

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<sup>8</sup> A Moses basket is a portable cradle, typically made from wicker or cloth, with no legs or a stand.

10 degrees from horizontal, are *not* included under this product definition. However, Moses baskets and carriage accessories that can be converted to a bassinet or cradle by attaching it to a separate base unit would need to comply with the staff-recommended final standard when used with the base.<sup>9</sup> Similarly, products that could be used at an incline of 10 degrees or less from horizontal, as well as more than 10 degrees from horizontal, would be subject to the bassinet/cradle standard when in the flatter configuration(s).

Therefore, for the purposes of the standard, there are three relevant categories of products:

1. Bassinets—this includes bedside sleepers *if* they can be used as a four-sided bassinet and other products that can be attached to a base unit and used as a bassinet;
2. Cradles—this is a rocking bassinet and includes other products that can be attached to a base unit and used as a cradle; and
3. Play yards—only those with bassinet/cradle attachments.

### **The Market for Bassinets/Cradles**

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which have separate divisions for juvenile products. CPSC staff believes that there are currently at least 62 suppliers of bassinets and/or cradles to the U.S. market: 26 are domestic manufacturers; 19 are domestic importers; three are domestic retailers; and two are domestic firms with unknown supply sources. There are also 12 foreign firms supplying the U.S. market: 10 manufacturers, one firm with an unknown supply source, and one importer that imports from foreign companies and distributes from outside of the United States.<sup>10</sup> There are eight additional firms that specialize in bedding, some of which is sold with bassinets or cradles. It is unclear whether their bassinets/cradles are supplied by one of the 62 firms already accounted for.

Bassinets and cradles from 11 of the 62 firms have been certified as compliant by the Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers. Firms supplying bassinets or cradles would be certified to the ASTM voluntary standard, F2194-12a, while firms supplying play yards with bassinet/cradle attachments would also have to meet F406-12a.<sup>11</sup> Twenty-four additional firms claim compliance with the relevant ASTM standard for at least some of their bassinets and cradles. It is not known whether the bassinets or cradles supplied by the eight bedding suppliers comply with ASTM F2194.

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<sup>9</sup> For example, several companies sell separate stationary (or, in some cases, rocking) bases for Moses baskets and stroller carriage accessories.

<sup>10</sup> Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

<sup>11</sup> JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. ASTM F2194-12a was published in September 2012, and therefore, the standard would have become effective in March 2013. The more recent standard ASTM F2194-12b was published in December 2012, and therefore, was not yet effective when research for this memo was conducted.

According to a 2005 survey conducted by the American Baby Group (2006 Baby Products Tracking Study),<sup>12</sup> 64 percent of new mothers own bassinets, 18 percent own cradles, and 39 percent own play yards with bassinet attachments. Approximately 50 percent of bassinets, 56 percent of cradles, and 18 percent of play yards were handed down or purchased secondhand.<sup>13</sup> Thus, about 50 percent of bassinets, 44 percent of cradles, and 82 percent of play yards were acquired new. This suggests annual sales of about 1.3 million bassinets (.5 x .64 x 4 million births per year), 317,000 cradles (.44 x .18 x 4 million), and 1.3 million play yards with bassinet attachments (.82 x .39 x 4 million).<sup>14</sup> This yields a total of approximately 3 million units sold per year that could be affected by the bassinet/cradle standard.

National injury estimates were not reported by the Directorate for Epidemiology in the SNPR or in the current FR briefing package because the data failed to meet NEISS publication criteria. However, emergency department injury estimates over the approximately five years covered by the SNPR and the current FR briefing package, from 2008 through 2012, averaged less than 250 annually. Based on data from the 2006 Baby Products Tracking Study, approximately 4.8 million bassinets and cradles were owned by new mothers. Therefore, the injury rate may be on the order of about 0.5 emergency department-treated injuries per 10,000 bassinets/cradles available for use in the households of new mothers ((250 injuries ÷ 4.84 million products in households of new mothers) x 10,000).

### **Reason for Agency Action and Legal Basis for the Staff-Recommended Final Rule**

The Danny Keysar Child Product Safety Notification Act requires the CPSC to promulgate a mandatory standard for bassinets/cradles that is substantially the same as, or more stringent than, the voluntary standard. CPSC staff recommends that the Commission adopt ASTM F2194-13 with five modifications or additions that reflect: (1) changes proposed in the SNPR that are not part of F2194-13; (2) responses to public comments; and/or (3) additional work undertaken by ASTM, but not yet adopted. The recommended changes will address a variety of known hazard patterns, including suffocation and positional asphyxia.

### **Requirements of the Staff-Recommended Final Rule**

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<sup>12</sup> The data collected for the Baby Products Tracking Study does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, because the most recent survey information is from 2005, it may not reflect the current market. In particular, it is possible that the mandatory crib standard that went into effect for manufacturers, importers, and retailers on June 28, 2011, could have changed the demand for bassinets/cradles and play yards with bassinet/cradle attachments.

<sup>13</sup> The data on secondhand products for new mothers was not available. Instead, data for new mothers and expectant mothers was combined and broken into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage that were handed down or purchased secondhand.

<sup>14</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2010," *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.

CPSC staff recommends adopting the voluntary ASTM standard for bassinets and cradles (F2194-13), with five changes.

### ***ASTM F2194-13***

Some of the more significant requirements of ASTM F2194-13 are listed below. The requirements that were added or modified since the SNPR are in italics.

- Scope—describes the types of products intended to be covered under the standard. *ASTM adopted the revised scope included in the SNPR, which was intended to clarify when products would be considered bassinets. The definitions of a “bassinet/cradle” and a “bassinet/cradle accessory” were also updated to be consistent with the modified scope.*
- Spacing of rigid-side components—intended to prevent child entrapment between both uniformly and nonuniformly spaced components, such as slats.
- Openings for mesh/fabric—intended to prevent the entrapment of children’s fingers and toes, as well as button ensnarement.
- Static load test—intended to ensure structural integrity even when a child three times the recommended (or 95<sup>th</sup> percentile) weight uses it.
- Stability requirements—intended to prevent the product from tipping over when pulled on by a two year old male.
- Sleeping pad thickness and dimensions—intended to reduce gaps and the possibility of suffocation due to excessive padding.
- Tests of locking and latching mechanisms—intended to prevent unintentional folding while in use.
- Suffocation warning label—intended to help prevent soft bedding incidents.
- Fabric-sided openings test—intended to prevent entrapments.
- Rock/swing angle requirement—intended to address suffocation hazards that can occur when latch/lock problems and excessive rocking or swinging angles press children into the side of the bassinet/cradle.
- Occupant restraints—intended to prevent incidents where unused restraints have entrapped and strangled children.
- Side height requirement—intended to prevent falls.
- *Segmented mattress flatness—intended to address suffocation hazards associated with “V” shapes that can be created by the segmented mattress folds. A similar requirement and test procedure was included in the SNPR, but the pass/fail criteria are less stringent than the one the Commission proposed.*

The voluntary standard also includes: (1) torque and tension tests to prevent components from being removed by children; (2) requirements for several bassinet/cradle features to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature; and (5) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing that a child may be wearing from catching on a projection. ASTM F2194-13 includes no reporting or record-keeping requirements.

### ***Staff-Recommended Changes***

CPSC staff is recommending two modifications to ASTM F2194-13 in response to SNPR comments; neither is expected to have a negative impact on firms. The first is a modification to the scope that would clarify that multimode or combination products must meet the bassinet/cradle standard in any configuration where the seat incline is 10 degrees or less from horizontal. Because this does not change the scope of the standard, there is no additional impact due to this clarification. The second is an exemption from the mattress flatness requirement for bassinets that are less than 15 inches across. These products are not subject to the hazard that the requirement is intended to address, and they are also not wide enough to test using the required procedures and equipment.

CPSC staff recommends three additional changes to ASTM F2194-13, each of which is considered in separate sections below:

- A. Stability testing—specify the use of the more appropriate infant CAMI dummy, as proposed in the SNPR;
- B. Mattress flatness—modify the pass/fail criteria to match the SNPR proposal; and
- C. Removable bassinet beds—add definitions, a test requirement, and a test method to address the stability of bassinets with removable beds, as proposed in the SNPR.

#### ***A. Stability Testing***

In the SNPR, the Commission proposed that bassinet/cradle stability testing be conducted with a CAMI newborn dummy, rather than the CAMI infant dummy. Because ASTM has yet to adopt this modification, staff recommends that it be included in the final rule.

As discussed in the initial regulatory flexibility analysis, it is appropriate that the smaller newborn CAMI dummy be used for stability testing because bassinets and cradles are intended to be used by very young children. The heavier (17.5 pound) infant CAMI currently used for stability testing in F2194-13 could make these products more stable when tested than they would actually be in a real-world situation. Based on limited staff testing, it appears that many bassinets/cradles will be able to pass this modified test procedure without changes. However, it is possible that a few products may require modifications to meet the revised stability test procedure. It is likely to affect only a few manufacturers and probably will not require product redesign. Affected firms would most likely increase the stability of their product by widening the structure, making the bassinet bed deeper, or making the base heavier. The cost of meeting the modified requirement could be more significant if a change to the hard tools used to manufacture the bassinet is necessary.<sup>15</sup>

#### ***B. Mattress Flatness***

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<sup>15</sup> During the production process, a hard tool, which is a mold of the desired bassinet component shape, is injected with plastic or another material using a molding machine.

A segmented mattress flatness requirement and associated test procedures were proposed by the Commission as part of the SNPR. ASTM adopted the requirement with modified (and less severe) pass/fail criteria. Therefore, staff recommends that the pass/fail criteria in ASTM F2194-13 be modified to mirror the SNPR proposal.

The mattress flatness requirement is aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard.<sup>16</sup> Under staff's recommended pass/fail criteria, a bassinet attachment with a segmented mattress would fail if any tested seam created an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees.

Based on staff testing, it appears that the play yard bassinet attachments of many suppliers (both compliant and noncompliant) would pass the staff-recommended requirement without any modifications. Those requiring modifications would need to increase the mattress support in their bassinets. This could be accomplished, for example, by retrofitting their play yard bassinets to use longer rods or a better-fitting mattress shell. The cost of such a retrofit is unknown and would likely vary from product to product; however, it should be less expensive than a product redesign.

### ***C. Removable Bassinet Bed***

In the SNPR, the Commission proposed adding a requirement for removable bassinet beds (along with test procedures and new definitions). Since then, the ASTM task group has made several clarifying changes to the requirement, definitions, and test procedures and intends to submit it to ASTM for ballot. Staff recommends that the Commission adopt the revised removable bassinet bed requirement as part of the final bassinet/cradle rule.

There are several bassinet designs that allow for the bassinet bed to be removed from the stand easily (*i.e.*, without the use of tools) and used separately. In many cases, the bassinet bed sits securely on the stand without any attachment mechanism. In other cases, clips or locks may be used to retain the bassinet bed during use. Incidents have arisen where the attachments have failed or have not been used, rendering the bassinet bed unstable. Under the staff-recommended requirement, the products will need to be modified to be inherently stable (automatically lock or stable even without the locks) or obviously unstable (unsupportable or obviously tilted without locks or an indicator that locks are not in use).

There are several firms supplying bassinets with removable bassinet beds to the U.S. market. The majority will require no modifications to meet the staff-recommended requirement.

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<sup>16</sup> Memorandum from Jonathan D. Midgett, Office of Hazard Identification and Reduction, dated July 30, 2012, Subject: Bassinets and Cradles Standard: Human Factors Issues; memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated April 10, 2012, Subject: Bassinet and Cradle-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007– December 2011; and memorandum from Mark E. Kumagai, Division Director, Division of Mechanical Engineering, dated July 30 2012, Subject: ESME Recommendations for the Bassinet & Cradles Standard.

However, at least three firms are expected to need changes to one or more of their bassinets. There are a number of ways that firms could meet the staff-recommended requirement, including redesigning the product entirely. However, it seems likely that, where possible, many firms would opt for less expensive alternatives, such as more sensitive locks that activate with little pressure (*i.e.*, with just the weight of the bassinet). The costs and time involved in a redesign could be significant; one manufacturer said in their SNPR comments that they would require 15.5 months to redesign their product to meet the removable bassinet bed requirement. Therefore, staff recommends an 18-month effective date for this requirement, while maintaining a six-month effective date for the remainder of the staff-recommended final rule.

### **Issues Raised by Public Comments**

There were several issues raised by public comments in response to the initial regulatory flexibility analysis. These include concerns about existing inventory, the lack of a cost benefit analysis, third party testing costs, and the effective date, among others. These comments and their responses are presented in Appendix A.

Additionally, there were two comments that resulted in changes to the staff-recommended final rule. One resulted in the exclusion of bassinets less than 15 inches across from the segmented mattress flatness requirement because they are not subject to the hazard of concern and cannot be tested using the recommended procedure. The second resulted in some additional clarification regarding the intended scope of the bassinet/cradle standard.

### **Other Federal or State Rules**

A final rule implementing sections 14(a)(2) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule). Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(d)(2) of the CPSA requires the Commission to establish protocols and standards (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because bassinets and cradles will be subject to a mandatory children's product safety rule, they will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA and the 1107 rule when the bassinet/cradle mandatory standard and the notice of requirements become effective.

### **Impact on Small Businesses**

There are at least 62 firms currently known to be marketing bassinets and/or cradles in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bassinets/cradles 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 39 are small firms—21 domestic manufacturers, 16 domestic importers, and two firms with unknown supply sources. There are an additional eight small firms supplying bassinets/cradles along with their bedding; these may or may not originate from one of the 62 firms already accounted for. There may also be other unknown small bassinet/cradle suppliers operating in the U.S. market.

### ***Small Manufacturers***

The expected impact of the staff-recommended final standard on small manufacturers will differ based on whether their bassinets/cradles are already compliant with F2194-12a.<sup>17</sup> In general, firms whose bassinets and cradles meet the requirements of F2194-12a are likely to continue to comply with the voluntary standard as new versions are published. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. It is likely that firms supplying bassinets and cradles that comply with ASTM F2194-12a would also comply with F2194-13 before the final bassinet/cradle rule becomes effective.

The majority of the staff-recommended changes to the voluntary standard (ASTM F2194-13) are the same as at the SNPR level; only the scope proposed in the SNPR has been completely incorporated into the voluntary standard. Therefore, the expected impact of the staff-recommended final rule remains substantially the same as the impact presented in the initial regulatory flexibility analysis for the SNPR.

For manufacturers whose products are likely to meet the requirements of ASTM F2194-13 (14 of 21 firms), the direct impact could be significant for one or more firms if they must redesign their bassinets to meet the staff-recommended final rule. While the products of all firms would be subject to the stability testing requirements (see section A above), it is unlikely that many will require modifications, and the costs are not expected to be significant in most cases. The products of five firms could be affected by the mattress flatness requirement (*i.e.*, they produce play yards with bassinet attachments) (see section B), and at least three (and possibly five) of the known firms may be affected by the removable bassinet bed requirement (see section C). For the most part, the bassinets/cradles and bassinet cradle attachments supplied by these firms will be able to meet the staff-recommended changes to ASTM F2194-13 without modification. In cases where modifications are necessary, they would most likely opt to retrofit their products, rather than undertake an expensive redesign. However, it is possible that some products may require redesign, particularly to meet the new removable bassinet bed requirement (see section C), and therefore, costs could be significant in some cases. Staff recommends that the Commission adopt an 18-month effective date for the removable bassinet bed portion of the staff-recommended final rule to reduce the impact on affected firms.

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<sup>17</sup> Play yards with bassinet attachments must comply with the effective play yard standard (F 406), which includes a requirement that the attachment meet the bassinet/cradle standard.

Meeting ASTM F2194-13's requirements could necessitate product redesign for at least some bassinets/cribels not believed to be compliant with F2194-12a (7 of 21 firms). These firms could require redesign regardless of the staff-recommended modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but redesign could be more significant if changes to the frame are required, including changes to side height. One manufacturer estimated that a complete play yard redesign, including engineering time, prototype development, tooling, and other incidental costs, would cost approximately \$500,000. Staff believes that a bassinet redesign would tend to be comparable. Consequently, the staff-recommended final rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2194-12a. Any direct financial impact may be mitigated if a firm chooses to treat costs as new product expenses that can be amortized over time rather than a large, one time expense.

It is possible that some firms whose bassinets/cribels are neither certified as compliant, nor claim compliance with F2194-12a, are, in fact, compliant with the standard. CPSC staff has identified many such cases with other products. To the extent that some of these firms may supply compliant bassinets/cribels and have developed a pattern of compliance with the voluntary standard, the direct impact of the staff-recommended final rule will be less significant than described above. There are also two small firms with unknown supply sources, none of whose products appear to comply with F2194-12a. If these firms are manufacturers, they may also require redesign to meet the staff-recommended final rule.

In addition to the direct impact of the final rule described above, the rule will have some indirect impacts. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107). Third party testing will pertain to any physical and mechanical test requirements specified in the bassinet/cribble final rule; lead and phthalates testing is already required. Impacts of third party testing are not due directly to the bassinet/cribble rule's requirements, but are due to the testing rule's requirements. Consequently, impacts from the testing rule are indirect impacts from the bassinet/cribble final rule, and such indirect impacts could be significant.

One manufacturer estimated that testing to the ASTM voluntary standard runs around \$1,000 per model sample, although they noted that the costs could be lower for some models where the primary difference is fabric rather than structure.

On average, each small domestic play yard manufacturer supplies seven different models of bassinets/cribels and play yards with bassinet/cribble accessories to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$7,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2194-13 is unlikely to be significant if only one bassinet/cribble sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third party testing costs could have a significant impact on a few of the small manufacturers.

### ***Small Importers***

As with manufacturers of compliant bassinets/cradles, the seven small importers of bassinets/cradles currently in compliance with F2194-12a could experience significant direct impacts as a result of the staff-recommended final rule if product redesign is necessary. In the absence of regulation, these importing firms would likely continue to comply with the voluntary standard as it evolves, as well as the final mandatory standard. Any increase in production costs experienced by their suppliers may be passed on to the importers.

Importers of bassinets/cradles would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the staff-recommended final rule, which may be the case with the nine importers of bassinets/cradles not believed to be in compliance with F2194-12a. Some could respond to the rule by discontinuing the import of their non-complying bassinets/cradles, possibly discontinuing the product line altogether. The impact of such a decision could be mitigated by replacing the noncompliant bassinet/cradle with a compliant bassinets/cradle, or by deciding to import an alternative product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements; consequently, they will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers that must perform the testing themselves if more than one sample per model were required.

### ***Other Possible Suppliers***

Eight known small firms specialize in the supply of bedding, including bedding for bassinets and cradles, and the eight firms sell bassinet and cradle bedding with a bassinet or cradle. Although these firms do not manufacture the bassinets or cradles themselves, whether they purchase the bassinets or cradles domestically or from overseas is not known. These firms may source the bassinets and cradles sold with bedding in full or in part from one of the 62 firms discussed above. If the eight firms do not source from one of the 62 firms, then the eight firms represent additional suppliers to the U.S. market.

The eight firms with unknown supply sources would be affected in a manner similar to importers; they would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the final rule. Unlike most importers, however, the firms would not have the option of replacing a noncompliant bassinet/cradle with another product. Although the firms could opt to sell the bedding without the associated bassinet/cradle, such an approach would represent a change from their historical method of sale and might adversely impact their business strategy.

As with manufacturers and importers, these eight firms will also be subject to third party testing and certification requirements, and will experience costs similar to those for manufacturers if their supplying firm(s) does not perform third party testing. The resulting costs could have a significant impact on some of these small bassinet or cradle suppliers that must perform the testing themselves.

## Alternatives

Under the Danny Keysar Child Product Safety Notification Act of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Doing so would reduce the potential impact on firms whose bassinets/cribds comply with the voluntary standard. However, because of the severity of the incidents associated with removable bassinet beds, instability, and mattress tilt,<sup>18</sup> staff does not recommend this alternative.

Staff is recommending a six-month effective date for the final rule with an 18-month effective date for the removable bassinet standard, supported by SNPR comments submitted by one manufacturer for the removable bassinet bed requirement. Setting a later effective date for either part would allow suppliers additional time to modify and/or develop compliant bassinets/cribds and spread the associated costs over a longer period of time.

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<sup>18</sup> Chowdhury, 2012.

## **Appendix A: Response to Public Comments**

Presented below are the responses to comments directed toward the initial regulatory flexibility analysis prepared for the bassinets and cradles SNPR. A comment regarding the preemption of state laws has been included as well.

### **Existing Inventory**

Comment:

*One commenter expressed concern that the Commission did not address the existing cradle and bassinet inventory that would need “to be discarded or recalled” when the regulation becomes effective.*

Response:

The draft bassinet and cradle standard is prospective. It would apply to products manufactured or imported on or after the effective date. Therefore, existing inventory would not be affected.

### **Cost Benefit Analysis**

Comment:

*Several commenters said they believe that a cost-benefit analysis should be performed and feel that the proposed rule should not be adopted because costs are likely to exceed benefits.*

Response:

Section 104(b) of the Consumer Product Safety Improvement Act (CPSIA), part of the Danny Keysar Child Product Safety Notification Act, requires the CPSC to issue a standard at least as stringent 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 such products. Thus, the Commission must issue a mandatory standard for bassinets and cradles regardless of the costs and benefits of the rule.

### **Third Party Testing Cost**

Comment:

*Two commenters expressed concern about the “substantial additional costs” that will result from a new requirement for third party testing that will be added by the bassinet/cradle standard.*

Response:

Testing costs referred to by the commenters are actually a result of the third party testing and certification requirements that result from the implementation of sections 14(a)(2) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. The costs associated with testing will be substantially the same, regardless of the form the final bassinet/cradle standard takes.

## **Definition of a Small Business**

Comment:

*One commenter questioned defining small manufacturers as those with less than 500 employees. They noted that business size can vary widely within such a broadly defined group. The commenter expressed concern that the economic impact could be disproportionately significant for the very smallest firms.*

Response:

The U.S. Small Business Administration (SBA) is the source of the definition for small manufacturers of bassinets and cradles. Regardless of the desirability of a finer gradation in defining small businesses, it is this definition that must be used in the preparation of a regulatory flexibility analysis.

## **Effective Date**

Comment:

*Several commenters weighed in on the appropriate effective date for the proposed rule. One commenter, representing several advocacy groups, supported the proposed six-month effective date. A second commenter agreed, expressing concerns that if the date were extended and a death occurred, “consumers might view the death as the result of the CPSC putting the interests of for-profit entities . . . ahead of the safety of infants who use their products.”*

*Several commenters recommended longer effective dates to reduce the impact of the proposed rule, particularly for small businesses that have “fewer resources and connections within the industry” and “may have to significantly alter their means of production.” Suggested effective dates range from 9 to 15.5 months, with commenters recommending that the CPSC focus on relief for firms that would be disproportionately impacted by the proposed rule. Groups singled out for longer effective dates include firms newly covered by the expanded scope and firms whose products would be subject to the removable bassinet bed requirement.*

Response:

Staff believes that a six-month effective date is sufficient for the majority of the staff-recommended final rule. However, CPSC recommends that the Commission extend the effective date for the removable bassinet bed attachment performance requirement to 18 months. CPSC staff recognizes that some manufacturers will need to redesign, test new prototype products, and then retool their production process to meet the new removable bassinet bed provision. Based on a comment from one manufacturer who suggested that a minimum of 15.5 months would be necessary to redesign their product, CPSC staff considers 18 months a reasonable time period to take into account other manufacturers who might also need to redesign their products.

## **Expanding the Scope Impact**

Comment:

*One commenter expressed concern about the “adverse monetary impact” that expanding the scope of the standard to include Moses baskets would have upon some suppliers. The*

*commenter said they feel that the alternative of ceasing to supply stands for these newly covered products requires further inquiry before “suggesting that this is a viable alternative.” Other commenters questioned methods firms might use to mitigate their “upfront costs,” including amortizing, “increased product sales,” and passing “the additional costs on to consumers.”*

Response:

When used with a stand, Moses baskets meet the definition of a “bassinet” (or “cradle”, in the case of a rocking stand), and therefore, they must be tested as a bassinet. Given that most suppliers of Moses basket do not also supply stands, it is clear that supplying Moses baskets without stands is a viable option for firms, although staff does not assume that this will be the option selected.

Similarly, the statement that “direct impact may be mitigated if costs are treated as new product expenses that can be amortized” recognizes one of the methods firms use routinely in the development of new products; costs are incurred up front and then recouped over time through sales. Finally, the analyses by CPSC staff did not suggest that all cost increases associated with the proposed rule would be passed on to consumers, but rather, some portion of those costs could be passed on, thereby mitigating the impact of the proposed rule on small businesses.

### **Aiding Small Businesses**

Comment:

*One commenter suggested that the Commission “create a framework with which to aid some of the smaller manufacturers and distributors with finding the resources, information and connections they need to comply with the new standards.”*

Response:

CPSC’s Small Business Ombudsman provides small businesses with guidance to get their products into compliance. Assistance is available to firms in navigating, understanding, and complying with CPSC regulations.

### **Small Bedding Suppliers**

Comment:

*One commenter asked that CPSC staff put “less weight” on small bedding suppliers in the regulatory flexibility analysis. They expressed concern that: “[N]oncompliant bedding could potentially negate the efficiency of . . .” safety measures such as strangulation warnings “. . . or require manufacturers to take additional steps to correct noncompliant bedding.”*

Response:

The staff-recommended final standard does not include any bedding requirements, nor is this the reason small bedding suppliers are discussed in a separate section of the analysis for the SNPR. While investigating the bassinet/cradle market, staff found that there were several suppliers of bassinets whose underlying source could not be determined. These firms shared one major characteristic: they were primarily bedding suppliers who sold bassinets or cradles with the appropriate bedding covering the bassinet/cradle frame. Because the source of these

bassinets/cradles was unknown, and, more particularly, because each of these firms could represent additional importers if their supply sources differed, it was important to consider the potential impact on each. However, only modifications to bassinets/cradles might be necessary, *not* modifications to bassinet/cradle bedding.

### **Labeling Costs**

Comment:

*One commenter objected to the costs that will be associated with changing the warning labels.*

Response:

The commenter misunderstands the information presented in the Paperwork Reduction Act section of the notice of proposed rulemaking. The commenter interprets the cost per burden hour associated with labeling (\$27.55) to be the increased cost per unit, which is an inaccurate conclusion.

**TAB E: Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Bassinets and Cradles Standard**

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E**



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
BETHESDA, MD 20814

**Memorandum**

Date: May 20, 2013

TO : Patricia L. Edwards  
Project Manager, Bassinets  
Division of Mechanical Engineering  
Directorate for Engineering Sciences

THROUGH: Gregory 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 : Regulatory Flexibility Analysis of the Accreditation Requirements for  
Conformity Assessment Bodies for Testing Conformance to the Bassinets and  
Cradles Standard

In accordance with section 14 of the Consumer Product Safety Act (CPSA), children's products that are subject to a children's product safety rule must be tested by an accredited conformity assessment body for compliance with the product safety rule. Staff is proposing an amendment to 16 CFR part 1112 that would establish the requirements for the laboratory acceptance of the accreditation of a conformity assessment body to test for compliance with the bassinet/cradle final rule. This memorandum assesses the impact of the amendment on the small laboratories.

Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or testing laboratories) to test for conformance with each children's product safety rule. Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity*

*Assessment Bodies*, 78 Fed. Reg. 15836 (March 12, 2013), which codifies part 1112. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) 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 all of the NORs that the CPSC has published to date. All new NORs, such as the bassinet/cradle standard, require an amendment to this rule.

On March 12, 2013, staff conducted an analysis of the potential impacts on small entities of the proposed rule establishing accreditation requirements, 78 Fed. Reg. 15836, 15855-58, as required by the Regulatory Flexibility Act and prepared a Final Regulatory Flexibility Analysis (FRFA). Briefly, the FRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would not likely pursue accreditation for this purpose. Similarly, amending the rule to include the NOR for the bassinet/cradle standard would not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the bassinet/cradle standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards and the only costs to them would be the cost of adding the bassinet/cradle standard to their scope of accreditation. As a consequence, the Commission could certify that the notice of requirements for the bassinet/cradle standard will not have a significant impact on a substantial number of small entities.