

SGS C&P – Connectivity & Products

Babies' Sleep Products and Mattresses: US, Canada




Juvenile Products Safety Forum | Piyush Shah, Dennis Lancion, Catherine Follin-Arbelet | October 24, 2022




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Summary

- Products : advice vs reality
- Brief history
- Safety issues
- Regulation
- What about mattresses for children ?


Markets : US and Canada

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Advice vs Reality




Recommendations for a safe sleep environment include

- supine positioning,
- the use of a firm sleep surface,
- room-sharing without bed-sharing,
- the avoidance of soft bedding and overheating


- Parents looking for a cosier environment
- Some babies 'sleep better', when placed at a certain angle ?
- Bed-sharing ?
- Protect from hard – rigid surfaces



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Brief history, regulation


- 2010**
 - SOR/2010-261, Cribs, Cradles and Bassinets Regulations published
 - 16 CFR 1219, Safety Standards for Full-Size Baby Cribs final rule issued
 - 16 CFR 1220, Safety Standards for Non-Full-Size Baby Cribs final rule issued
- 2012**
 - 16 CFR 1219, Revisions to Safety Standards for Full-Size Baby Cribs direct final rule issued
 - 16 CFR 1221, Safety Standard for Play Yards final rule issued
- 2013**
 - 16 CFR 1221, Revision to Safety Standard for Play Yards final rule issued
 - 16 CFR 1218, Safety Standard for Bassinets and Cradles final rule issued
 - 16 CFR 1219, Revisions to Safety Standards for Full-Size Baby Cribs direct final rule issued
- 2014**
 - 16 CFR 1222, Safety Standard for Bedside Sleepers final rule issued
- 2016**
 - SOR/2016-152 Cribs, Cradles and Bassinets Regulations published repealing SOR/2010-261



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Brief history, regulation

- 2018**
 - 16 CFR 1220, Safety Standards for Non-Full-Size Baby Cribs direct final rule issued
- 2019**
 - 16 CFR 1219, Revisions to Safety Standards for Full-Size Baby Cribs direct final rule issued
 - 16 CFR 1220, Revisions to Safety Standards for Non-Full-Size Baby Cribs direct final rule issued
 - 16 CFR 1221, Revisions to Safety Standards for Play Yards direct final rule issued
- 2021**
 - 16 CFR 1236, Safety Standard for Infant Sleep Products final rule issued
- 2022**
 - 16 CFR 1241, Safety Standard for Crib Mattresses final rule issued
 - Safe Sleep for Babies Act of 2021 (SSBA) signed by US President, requiring that crib bumpers and inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product
 - 16 CFR 1309 (Ban of Crib Bumpers) and 16 CFR 1310 (Ban of Inclined Sleepers for Infants) notice of proposed rulemaking issued



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Safety issues




- Reclined products : Positioning**
 - Chin to chest position : impairs flow of air
 - Baby able to turn on its belly, but not back

A maximum angle of 10°
- Padded/soft products : Asphyxia**
 - Baby « sinking » into soft filled materials
 - Carbodioxide pooling

Measure breathability (?)
- Restraint : Asphyxia**
 - Impairs breathing movement


No restraint, or keep loose
- Forseeable misuse**
 - Bed sharing
 - Placed on soft surfaces (sofa ...)



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2021 Estimated Number of Injuries Based on US CPSC National Electronic Injury Surveillance System (NEISS)


Product Title: Cribs, nonportable or not specified Product Code: 1552		Product Title: Bassinets or cradles Product Code: 1537	
Diagnosis	No. of Diagnosis	Diagnosis	No. of Diagnosis
62 - Internal Organ Injury	157	62 - Internal Organ Injury	25
57 - Fracture	70	71 - Other/Not Stated	8
71 - Other/Not Stated	64	57 - Fracture	5
53 - Contusions, Abrasions	60	53 - Contusions, Abrasions	4
59 - Laceration	43	65 - Anoxia	2
Others	77	Others	6
Total	471	Total	50



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2021 Estimated Number of Injuries Based on US CPSC National Electronic Injury Surveillance System (NEISS)

Product Title: Playpens and play yards Product Code: 1513		Product Title: Baby mattresses or pads Product Code: 1542	
Diagnosis	No. of Diagnosis	Diagnosis	No. of Diagnosis
59 - Laceration	16	62 - Internal Organ Injury	2
62 - Internal Organ Injury	15	71 - Other/Not Stated	2
71 - Other/Not Stated	12	52 - Concussions	1
53 - Contusions, Abrasions	12	57 - Fracture	1
57 - Fracture	11	59 - Laceration	1
Others	18	Others	-
Total	84	Total	7




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Recalls




Date: March 24, 2021
Reporting Agency: Health Canada
Product: BABYZEN YOYO bassinet in various colours
Hazard Identified:

- Strangulation hazard (handles of the product may be pulled into the sleeping area)




Date: May 5, 2021
Reporting Agency: Health Canada
Product: Lull Bedside Bassinet
Hazard Identified:

- Injury hazard (unstable when used as a stand-alone bassinet)



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Recalls



Date: May 6, 2021
Reporting Agency: Health Canada
Product: Natural Hooded Moses Basket
Hazard Identified:


- Injury hazard (product is unstable and can tip over)
- Strangulation hazard (the ribbon from the hood is too long and can be pulled into the sleeping area)

Note: Moses baskets are bassinets in Canada and must meet the Cribs, Cradles and Bassinets Regulations




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Recalls




Date: December 27, 2012
Reporting Agency: CPSC US
Product: Infant recliner
Hazard Identified:

- CPSC is warning parents and caregivers that these baby recliners contain defects in the design, warnings and instructions, which pose a substantial risk of injury and death to infants.



Date: April 12, 2019
Reporting Agency: CPSC US
Product: Infant sleepers
Hazard Identified:

- Infant fatalities have occurred in Rock 'n Play Sleepers, after the infants rolled from their back to their stomach or side while unrestrained, or under other circumstances



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Recalls



Date: May 5, 2021
Reporting Agency: CPSC US
Product: Inclined sleeper accessory

Hazard Identified:
 • Infant fatalities have been reported with other manufacturers' inclined sleep products, after the infants rolled from their back to their stomach or side, or under other circumstances

All brands distributing inclined sleepers have recalled their products



Date: January 29, 2020
Reporting Agency: CPSC US
Product: Inclined sleeper
Hazard Identified: Infant fatalities have been reported with other manufacturers' inclined sleep products, after the infants rolled from their back to their stomach or side, or under other circumstances



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Recalls



Date: September 23, 2021
Reporting Agency: CPSC US
Product: 'Loungers'

Hazard Identified:
 • Infants can suffocate if they roll, move, or are placed on the lounger in a position that obstructs breathing, or roll off the lounger onto an external surface, such as an adult pillow or soft bedding that obstructs breathing



Date: June 3, 2021
Reporting Agency: CPSC US
Product: Infant rockers - gliders
Hazard Identified:
 • Infants who are placed unrestrained in the product and later found on their stomach are at risk of suffocation



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Regulation

- On June 23, 2021, US CPSC has published the final rule, **16 CFR 1236** establishing a safety standard for **Infant Sleep Products** intended for sleep and age graded for babies under five months of age. The rule incorporates by reference the voluntary standard ASTM F3118-17a, Standard Consumer Safety Specification for Infant Inclined Sleep Products with modifications and become effective on June 23, 2022.

The consumer product safety standard covers infant sleep products, including inclined and flat sleep surfaces, that applies to all products marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that are not already subject to any of the following standards:

- 16 CFR part 1218 Safety Standard for Bassinets and Cradles;
- 16 CFR part 1219 Safety Standard for Full-Size Baby Cribs;
- 16 CFR part 1220 Safety Standard for Non-Full-Size Baby Cribs;
- 16 CFR part 1221 Safety Standard for Play Yards;
- 16 CFR part 1222 Safety Standard for Bedside Sleepers



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Regulation

- On May 16, 2022, US President Joe Biden signed into law H.R. 3182, the "**Safe Sleep for Babies Act of 2021**" which makes it unlawful to manufacture, sell, or distribute **crib bumpers** or **inclined sleepers** for infants.

Inclined sleepers for infants are defined in the Act as a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodation for an infant up to 1 year old.

Crib bumpers are defined as:

- Any material that is intended to cover the sides of a crib to prevent injury to any crib occupant from impacts against the side of a crib or to prevent partial or complete access to any openings in the sides of a crib or to prevent a crib occupant from getting any part of the body entrapped in any opening
- Includes a padded crib bumper, a supported and unsupported vinyl bumper guard, and vertical crib slat covers; and
- Does not include a non-padded mesh crib liner



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Mattresses for children

- On February 15, 2022, CPSC has published the final rule, **16 CFR 1241**, establishing a safety standard for **Crib Mattresses**. The rule incorporates the latest version ASTM F2933-21, Standard Consumer Safety Specification for Crib Mattresses with modification and will become effective on August 15, 2022.

The standard applies to full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs.

The following are the summary of the modifications to ASTM F2933-21:

- Added cyclic loading test for all crib mattresses that use coils and springs
- Added new test for full-size crib mattresses to reduce the risk of injury associated with corner gap entrapment from compression by fitted sheets
- Added dimensional performance requirement for all non-full size crib mattresses
- Removed references to after-market, non-full-size crib mattresses from section 5.9 of ASTM F2933-21
- Added a mattress firmness test for all crib mattresses within the scope of the standard
- Modified the safety information requirements



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Bassinets and Cradles

- As per CPSC Business Guidance & Small Entity Compliance Guide, "a bassinet/cradle is a small bed designed primarily to provide sleeping accommodations for infants that is supported by freestanding legs, a stationary frame/stand, a wheeled base or a rocking base, or that can swing relative to a stationary base. While in a rest (non-rocking) position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10 degrees from horizontal."

- 16 CFR 1218 (Safety Standard for Bassinets and Cradles) incorporates by reference ASTM F2194-13, with modifications

The standard includes performance and labeling requirements, which include but not limited to:

- Spacing of Rigid Components/Fabric-Sided Enclosed Openings
- Static Load
- Stability
- Sleeping Pad Thickness and Dimensions
- Flatness Test (Bassinets with Segmented Mattresses)
- Rock/Swing Angle
- Marking and Labeling



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