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

DATE: August 17, 2016

BALLOT VOTE SHEET:

This document has been electronically approved and signed.

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Meridith L. Kelsch, Attorney, OGC

SUBJECT: Proposed Rule: Safety Standard for Baby Changing Products

Ballot Vote Due: Tuesday, August 23, 2016

The Office of the General Counsel is providing for Commission consideration the attached draft notice of proposed rulemaking for publication in the *Federal Register*. The proposed rule would establish a safety standard for baby changing products under 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)

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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 Proposed Rulemaking to Establish a Safety Standard for Baby Changing Products

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

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Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1236

[Docket No. CPSC-2016-XXXX]

Safety Standard for Baby Changing Products

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104(b) 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 must be substantially the same as applicable voluntary standards or more stringent than the voluntary standard if the Commission determines that more stringent requirements would further reduce the risk of injury associated with a product. Pursuant to the direction under section 104(b) of the CPSIA, the Commission is proposing a safety standard for baby changing products. The proposed rule would incorporate by reference ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use* ("ASTM F2388-16") into 16 CFR part 1236 and impose more stringent requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature. In addition, the Commission proposes to amend 16 CFR part 1112 to include proposed 16 CFR part 1236 in the list of notice of requirements ("NORs") issued by the Commission.

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

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the labeling and instructional literature requirements of the proposed mandatory standard for baby changing products should be directed to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2016-XXXX, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

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

Docket: For access to the docket to read background documents or comments received, go to: http://www.regulations.gov, insert docket number CPSC-2016-XXXX into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Mark Kumagai, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2234; e-mail: MKumagai@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

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 or toddler products. Any standard the Commission adopts under this directive must be substantially the same as the applicable voluntary standard or more stringent, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product.

A "durable infant or toddler product," as defined in section 104(f)(1) of the CPSIA, is "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." Section 104(f)(2) lists examples of "durable infant or toddler products," such as cribs, high chairs, and strollers. Although this list of example products does not include baby changing products, baby changing products satisfy the statutory definition, as they are intended for use by children under the age of 5 years and are durable products made of

sturdy material that last for several years; they are similar to the example products listed in the CPSIA; and the Commission has identified changing tables as "durable infant or toddler products" in the product registration rule that the Commission issued under section 104(d) of the CPSIA. 16 CFR 1130.2(a)(14).

Pursuant to section 104(b)(1)(A) of the CPSIA, the Commission consulted with representatives of manufacturers, consumer groups, consultants, retailers, and industry trade groups in reviewing and assessing the effectiveness of the existing voluntary standard for baby changing products, ASTM F2388-16, largely through ASTM International's ("ASTM"; formerly the American Society for Testing and Materials) standard-development process. The standard the Commission proposes in this notice of proposed rulemaking (NPR) is based on ASTM F2388-16 with more stringent requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature.

The testing and certification requirements of section 14(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089) apply to the standards promulgated under section 104 of the CPSIA. Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (*i.e.*, test laboratories) to assess whether a children's product conforms to applicable children's product safety rules. If adopted, the proposed rule for baby changing products would be a children's product safety rule that requires the issuance of an NOR. For this reason, this NPR also proposes to amend 16 CFR part 1112 to include proposed 16 CFR part 1236, the section in which the standard for baby changing products would be codified.

II. The Product

A. Definition

ASTM F2388-16 applies to baby changing tables and other changing products. The standard defines "changing tables" as "elevated, freestanding structures" designed "to support and retain a child" with a body weight up to 30 pounds (13.6 kilograms) for the purpose of a diaper change. Changing tables may convert to other furniture pieces, such as dressers or play yards, and they may have storage or other pull-out or drop-down features. ASTM F2388-16 also applies to other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables. Contoured changing pads have barriers designed to keep children up to 30 pounds on the pad for diaper changes on elevated surfaces. Add-on changing units are used with pieces of furniture to provide changing surfaces and/or barriers to keep children on the products during diaper changes.

The majority of changing tables and add-on changing units are made of wood; contoured changing pads are generally made of a combination of synthetic-covered foam. Changing tables come in various designs, some of which include drawers, cabinets, or retractable stairs.

Throughout this NPR, the Commission uses the term "baby changing products" to refer to changing tables and other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables.

B. Market Description

Commission staff identified 85 firms, including manufacturers, importers, and wholesalers, that supply baby changing products to the U.S. market. Seventy-one of these firms are domestic, consisting of 57 manufacturers, 12 importers, one wholesaler, and one retailer; 14 are foreign, consisting of 12 manufacturers, one importer, and one retailer. Of the domestic

firms, 59 are small businesses, as discussed is Section XI. Regulatory Flexibility Act, below, and 12 are large. Eighty-one of the firms market their products to consumers, while seven also market them for commercial daycare use. Fifty-six of the firms offer multiple baby changing products.

Stand-alone changing tables intended for home use range widely in price, from approximately $35 to $1,400. Other baby changing products also vary greatly in price. Contoured changing pads range from about $7 to $100; add-on changing units, such as changing trays, range from approximately $12 to $1,050; and other baby products, such as cribs, play yards, dressers, and bath tubs, with attachable or built-in baby changing products, range from approximately $100 to $4,500.

III. Incident Data

The Commission receives data regarding product-related injuries from several sources. One such source is the National Electronic Injury Surveillance System (NEISS), from which CPSC can estimate the number of injuries associated with specific consumer products that are treated in U.S. hospital emergency departments (EDs) nationwide, based on a probability sample. Other sources include reports from consumers and others through the Consumer Product Safety Risk Management System (which also includes some NEISS data) and reports from retailers and manufacturers through CPSC's Retailer Reporting System (collectively referred to as Consumer Product Safety Risk Management System data (CPSRMS)).

Commission staff reviewed the NEISS and CPSRMS databases for incidents involving baby changing products involving children younger than 3 years old because that age corresponds with the 30-pound weight limit in the definition of "changing tables." *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, National Center for Health Statistics, *Data Table of*

Infant Weight-for-Age Charts, http://www.cdc.gov/growthcharts/html_charts/wtageinf.htm (last visited Aug. 5, 2016) (indicating 30 pounds is the 50th percentile weight of boys at 31 months old and girls at 34 months old). Staff considered CPSRMS data from January 1, 2005 through December 31, 2015, and NEISS data from January 1, 2005 through December 31, 2014 (NEISS data was not yet updated for 2015 at the time of analysis).

Through CPSRMS sources, the Commission has received 182 reports of incidents related to baby changing products that occurred between 2005 and 2015. These reports include five fatalities, 30 injuries or adverse health problems, 113 incidents that did not result in injuries, and 34 incidents for which the Commission did not receive sufficient information to determine whether an injury occurred.

EDs participating in NEISS reported 1,305 injuries and no deaths related to baby changing products between 2005 and 2014. Extrapolating from this probability sample, there were approximately 31,780 injuries and no fatalities related to baby changing products treated in EDs between 2005 and 2014. In analyzing the number of injuries that occurred each year between 2005 and 2014, Commission staff found that there was a statistically significant increasing trend in injuries over this period. The NEISS data also indicates that the incidence of injuries was the same for males and females and that 75 percent of the injured children were under 1 year old.

A. Fatalities

The Commission received reports of five fatalities associated with baby changing products between 2005 and 2015. The five reported deaths all involved caregivers using baby changing products as sleep products, which is not their intended use. All of the victims in these incidents were younger than 1 year old.

Four of the incidents involved play yards with changing table attachments. In one of these cases, a strap hanging from a changing table accessory in a play yard strangled a child sleeping in the play yard beneath. In the remaining four deaths, children asphyxiated while sleeping on a baby changing product; three of the products were the changing table attachments on play yards, and one was a portable changing pad placed in a crib as a sleep positioner.

In three of the reports regarding these fatalities, the caregivers and investigators appeared mistaken about the intended use of the product, referring to the changing table product as a "crib" and "bassinet."

B. Nonfatal Injuries

Of the 182 CPSRMS incidents related to baby changing products that occurred between 2005 and 2015, 30 reportedly resulted in injuries or adverse health problems. The most frequently cited injuries were cuts, lacerations, scratches, and bruises; however, there were several more serious injuries reported as well. Three reports indicated that the victim visited the hospital; in one incident involving a leg injury, the victim was treated and released, and in two incidents involving a skull fracture and leg fracture, respectively, the victims were admitted to hospitals.

For injuries estimated through NEISS, 94 percent were treated and released, while 5 percent were admitted to the hospital. The most commonly injured body parts were the head (71 percent) and face (13 percent). The most common types of injuries were injuries to internal organs (50 percent), contusions or abrasions (27 percent), and fractures (9 percent). Of those injuries affecting internal organs, 99 percent were head injuries; of those injuries resulting in contusions or abrasions, 83 percent affected the victim's head or face.

C. Hazard Pattern Identification

CPSC staff reviewed NEISS and CPSRMS data to identify hazard patterns associated with baby changing products. Both sets of data revealed several common hazard patterns, but because CPSRMS data sources generally provide greater detail about incidents, staff was able to identify more distinct hazard patterns using that data. Five hazard patterns emerged from staff's review: (1) issues with structural integrity, (2) design hazards, (3) problems with restraint systems, (4) miscellaneous problems, and (5) undetermined hazards. Table 1 provides the frequency of each hazard pattern and category.

TABLE 1.—*Hazard Patterns for CPSRMS Incidents Involving Baby Changing Products between January 1, 2005 and December 31, 2015*

Hazard Pattern	Total Incidents
Structural Integrity	119
Design	38
Restraint System	14
Miscellaneous	8
Undetermined	3

Structural integrity issues include collapsing or unstable products, hardware issues, and assembly problems. This hazard pattern accounted for approximately 65 percent of CPSRMS incident reports (119 of 182 incidents). Fifty-five percent of the reported incidents in this hazard pattern involved collapsing baby changing products or parts (with 50 percent of those reports attributable to three particular models). The next most common type of structural integrity issue was unstable baby changing products.

Product design issues included limb entrapments, in parts such as slats, rails, and doors, chipping finishes, unstable steps, pinching, children hitting their heads on metal parts, and a strangulation hazard from a restraint strap in a play yard changing table accessory.

Approximately 21 percent of incidents reported through CPSRMS (38 of 182) fell into this hazard pattern. The majority of these incidents involved accessory components that are common to other furniture, as well as changing tables, and are not generally accessible to children when occupying a changing table as intended.

About 8 percent of incidents (14 of 182) related to restraint systems, which include loose, broken, or detached straps, cracked or faulty buckles, pinching, choking on small parts, and the absence of a restraint system.

Approximately 4 percent of CPSRMS incidents (8 of 182) involved miscellaneous issues, including chemical odors and the use of changing tables for unintended purposes, such as sleeping. All of the deaths associated with baby changing products involved children sleeping on the products.

Two percent of the incident reports (3 of 182) did not provide sufficient information for Commission staff to identify a hazard pattern.

The most frequently reported event associated with an injury in both NEISS and CPSRMS data involved children falling off, or through, baby changing products. Within NEISS data, 94 percent of injuries involved falls, while 64 percent of non-fatal CPSRMS incidents involved children falling from baby changing products. These incidents were prevalent in the structural integrity and restraint system hazard patterns. Eight of the CPSRMS fall incidents were the result of the baby changing product or supporting structure collapsing. Ten of the 14 restraint system incidents resulted in actual or potential falls, and one resulted in injury.

Some of the fall incidents resulted in injuries of varying severity. Within the NEISS incidents, several of the fall injuries resulted in a serious head injury, such as a concussion or fractured skull. Ten CPSRMS incidents involving falls also resulted in injuries. One of these 10

incidents resulted in a fractured skull, one a fractured leg, seven involved minor injuries, such as bruises, scratches, and lacerations that did not require medical attention and one did not indicate the severity of injury. Additionally, in several cases, caregivers reported catching a falling child, potentially preventing injuries.

D. Product Recalls

Since January 1, 2005, two firms have recalled baby changing products. In 2006, one firm recalled approximately 130 baby changing products, due to a fall hazard. The products included cloth sections secured by zippers to support occupants. The firm found that if the zipper was misaligned, the cloth section supporting an occupant could detach. In 2007, a second firm recalled approximately 425,000 baby changing products. The product was an infant play yard with a raised changing table accessory that had a restraint strap that formed a loop beneath the changing table, posing a strangulation hazard to a child in the play yard. This recalled product was associated with one child's death.

IV. International Standards for Changing Tables

CPSC is aware of two international standards that apply to baby changing products:

- ASTM F2388-16, and
- British/European Standard BS EN 12221: 2008, *Child use and care articles—Changing units for domestic use, Part 1: Safety requirements, Part 2: Test methods* (European standard).

CPSC staff reviewed the provisions in these standards and believes that ASTM F2388-16 best addresses the hazard patterns indicated in the incident data, and in most areas, ASTM F2388-16 includes more stringent requirements than the European standard. For example, although both standards require barrier durability testing, ASTM F2388-16 requires pre-

conditioning or aging of contoured changing pads before testing. In contrast, the European standard does not require precondition or aging, which makes ASTM F2388-16 the more stringent standard.

There are some areas in which the European standard includes more stringent requirements than ASTM F2388-16. For example, the European standard limits the dimensions of cords and loops, while ASTM F2388-16 does not. However, the incident data does not indicate that cords or loops present a safety hazard, apart from the one strangulation death involving a loop in a play yard, but the play yard standard has since been updated to address that hazard. In reviewing this and other provisions in which the European standard is more stringent than ASTM F2388-16, Commission staff found that the incident data does not indicate that the more stringent requirement is necessary to reduce the risk of injury, and further determined that the requirements in ASTM F2388-16 are sufficient.

Some requirements in the two standards differ in ways that make it difficult to compare their relative stringency. Nevertheless, for these requirements, Commission staff believes that ASTM F2388-16 arguably is more stringent, the incident data does not demonstrate that the European standard is necessary, or the additional requirements proposed in this NPR are the most effective method of addressing the risk. For example, the stability tests in ASTM F2388-16 and the European standard differ in ways that make them difficult to compare, but the incident data indicates that tip-over incidents are not an issue, which suggests that ASTM F2388-16, to which many manufacturers conform, is adequate. Likewise, the load tests in ASTM F2388-16 and the European standard differ, but staff believes that the ASTM test reflects actual load conditions better. Moreover, this NPR proposes additional, more stringent requirements for this test that are not in either standard.

Based on these comparisons, CPSC believes that ASTM F2388-16, in general, is more stringent than the European standard and is better tailored to address the hazard patterns evident in the incident data.

V. ASTM F2388-16

A. History of ASTM F2388-16

ASTM first approved and published a standard for baby changing products in July 2004, as ASTM F2388-04, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*. ASTM has revised the voluntary standard several times since then, adding and modifying requirements. Some of the more substantial revisions, to date, include:

- expanding the scope of the standard to include changing table products, such as contoured changing pads and add-on changing units;
- requiring preconditioning before conducting barrier testing on contoured changing pads;
- marking packaging with the maximum occupant weight; and
- requiring toy accessories to comply with applicable safety requirements.

ASTM approved the current version of the standard, ASTM F2388-16, on July 1, 2016.

B. Description of ASTM F2388-16

CPSC staff, together with stakeholders on the ASTM subcommittee task group for baby changing products, developed modified and new requirements for ASTM F2388-16 to address the hazards associated with these products. ASTM F2388-16 includes the following key provisions: scope, terminology, calibration and standardization, general requirements, performance requirements, test methods, marking and labeling, and instructional literature. The

following provides an overview of these provisions. To view the complete standard, see the instructions in Section IX, Incorporation by Reference.

1. Scope

This section states the scope and intent of the standard.

2. Terminology

This section provides definitions of terms specific to the standard.

3. Calibration and Standardization

This section provides general instructions for conducting tests.

4. General Requirements

This section includes general requirements addressing various safety issues, such as sharp edges and points, small parts, lead in paint, wood parts, openings, changing table attachments to play yards and non-full-size cribs, and toy accessories.

5. Performance Requirements and Test Methods

These sections contain performance requirements and associated test methods for baby changing products. The following summarizes key requirements in these sections.

a. Protective Components: These requirements provide for testing protective components, such as caps and plugs.

b. Structural Integrity: A changing table must not break or fail any other requirements after applying a specified weight for a set time period. The purpose of this requirement is to test whether changing tables can withstand the loads they will bear. Contoured changing pads and add-on changing units that are sold separately are not subject to this requirement.

c. Stability: A changing table must not tip over when pushed downward by a specified force on the edge most likely to cause the product to tip over. The purpose of this requirement is to test the changing table's resistance to tipping over if there is weight on the edge of the product. Contoured changing pads and add-on changing units that are sold separately are not subject to this requirement.

d. Barriers: Baby changing products must include barriers that are integral to the product. These barriers must be on all sides of flat changing surfaces and two sides of contoured surfaces. Barriers must not break or fail any other requirements or allow a test object to fall when holding a rolling test weight at an incline. Contoured changing pads must withstand this test after preconditioning or aging. The purpose of this requirement is to prevent children from rolling off of baby changing products or being injured by damaged barriers.

e. Retention of Contoured Changing Pads and Add-on Changing Units: Contoured changing pads and add-on changing units must not move more than a specified distance during the barrier testing described above. The purpose of this requirement is to prevent children from falling when they move on baby changing products. Changing table accessories for non-full-size cribs and play yards are not subject to this requirement because they are subject to a similar requirement in another standard.

f. Entrapment in Enclosed Openings: Any completely-bounded openings that are accessible to children in or near the base of a changing table must meet specified dimension limits for gaps and openings. The purpose of this requirement is to prevent children's heads from becoming entrapped in openings.

g. Entrapment by Shelves: Any shelf that is not enclosed in doors and that is within a specified distance from the floor must not permit a probe, designed to simulate a child's head, to pass through. The purpose of this requirement is to prevent children from becoming entrapped in shelves on baby changing products.

6. Permanency of Labels and Warnings

This section specifies testing and criteria for determining the permanency of labels.

7. Marking and Labeling

This section contains various requirements related to warnings, package markings, and labels including content, format, and placement requirements.

8. Instructional Literature

This section requires instructions to accompany baby changing products, be easy to read and understand, and include specific content.

C. Ongoing Revisions of ASTM F2388-16

ASTM, with the participation of CPSC staff, has continued to review the effectiveness of ASTM F2388-16 in light of incidents and hazard patterns. As a result, ASTM has developed additional requirements that are currently under review. ASTM participants have voted on these changes and submitted comments, and the committee reviewing ASTM F2388-16 is working to resolve these comments. The requirements that the Commission proposes in this NPR that are more stringent than the requirements in ASTM F2388-16 are the same as, or similar to, the requirements ASTM is currently reviewing. ASTM has authorized the Commission to print requirements that are the same as, or similar to, those ASTM drafted and is currently reviewing.

Additionally, an ASTM group, referred to as the ASTM Ad Hoc Wording Task Group, with CPSC staff's input, has reviewed warning requirements, in general, to develop one set of

requirements that would be useful for various standards. The ASTM Ad Hoc Wording Task Group developed recommendations for product warnings, particularly focusing on form, to provide effective and uniform warning requirements that can be adapted for various products. The goal of this effort was to have one consistent set of requirements from which ASTM committees could draw and adjust, as necessary, when developing or revising individual product standards. The result of the group's work is a set of recommendations, rather than a formalized standard. The ASTM Ad Hoc Wording Task Group requested ASTM participants' input on these recommendations in early 2016, received feedback, and has since finalized its warning recommendations. However, as the group continues to review issues, it may revise and update these recommendations. The labeling and instructional literature requirements that the Commission proposes in this NPR that differ from those in ASTM F2388-16 are drawn from the ASTM Ad Hoc Wording Task Group's recommendations. ASTM authorized the Commission to publish content from these recommendations in this NPR.

Because of the ongoing review and revision of ASTM F2388-16 and the ASTM Ad Hoc Wording Task Group's recommendations, the Commission may, after reviewing comments, finalize the rule as proposed in this NPR or incorporate by reference a revised ASTM standard if that standard adopts changes consistent with the requirements that the Commission proposes in this NPR.

VI. Assessment of ASTM F2388-16

CPSC staff evaluated ASTM F2388-16 in light of the fatalities, injuries, and non-injury incidents associated with baby changing products that occurred between January 1, 2005 and December 31, 2015 to determine whether the voluntary standard addresses the risk of injury associated with baby changing products or whether a more stringent standard would further

reduce the hazards. CPSC believes that ASTM F2388-16 effectively addresses the hazards indicated in the incident data, with the exception of three areas—structural integrity, restraint system integrity, and warnings on labels and in instructional literature. CPSC proposes more stringent requirements for these areas to further reduce the risk of injury associated with changing products.

This section provides CPSC's assessments of how ASTM F2388-16 addresses the hazard patterns shown in the incident data.

A. Structural Integrity

There were 119 CPSRMS incidents involving the structural integrity of baby changing products. The most common incidents in this category involved unstable changing tables and collapses, with the majority of incidents (55 of 119) involving changing table surfaces cracking or collapsing. More than half of these reports involved three particular changing table models. Falls resulting from these instability issues or collapses made up the majority of injuries reported through NEISS and 80 percent of the injuries reported through CPSRMS.

Although most of the reported collapses resulted in minor injuries, such as scrapes and bruises, falls have the potential for serious injuries, such as severe head injuries, which can have long-term effects. As mentioned, some fall injuries have resulted in serious head injuries, such as concussions and fractured skulls, or other fractured bones. Serious head injuries, such as concussions and skull fractures, can cause extensive brain damage and affect development.

The next most common problem in this category was unstable baby changing products, half of which involved cantilevered changing accessories for play yards tilting under the weight of an occupant. No injuries were reported for these incidents.

ASTM F2388-16 has two provisions intended to address the structural integrity of changing tables—a stability test and a structural integrity test. The stability test requires a product to remain upright when testers apply a load that is greater than the maximum recommended weight limit for product occupants to the edge most likely to tip over. The structural integrity test requires baby changing products to withstand a specified load for a set amount of time, without damage.

In addition, ASTM F2388-16 requires baby changing products to have warning labels with specific content about fall hazards, and requires instructions on secure use of contoured changing pads and add-on changing units. ASTM F2388-16 also includes form and placement requirements for warnings and similar content requirements for instructional literature to make the warnings and instructions visible and understandable.

The stability and structural integrity tests have been in ASTM F2388, in a similar form, since ASTM first published the standard in 2004. However, despite these requirements, the incident data still reveals a high occurrence of structural integrity issues. Likewise, fall incidents continue, despite the warnings required in ASTM F2388-16. Therefore, CPSC believes that more stringent requirements would further reduce the risk of injury from collapses and falls. Section VII. Description of Proposed Changes to ASTM Standard, discusses CPSC's proposed requirements regarding threaded fasteners, secondary support straps, and warnings that address this hazard.

B. Design

There were 38 CPSRMS incidents involving design hazards. These issues included children becoming entrapped in gaps between vertical slats and beneath horizontal rails; children pinching their fingers in drawers or doors; and problems with finishes, such as chipped surface

coatings. There was also one fatality associated with this hazard pattern, in which a changing accessory restraint strap in a play yard strangled a child.

Several general requirements in ASTM F2388-16 address this hazard pattern, including provisions on sharp points and edges, small parts, surface coatings, wood parts, and openings. ASTM F2388-16 also includes specific performance requirements for protective components and to prevent entrapments in enclosed openings and shelves. Additionally, ASTM has since revised its play yard standard to address the changing accessory restraint strap hazard.

Most of the incidents in this category involved accessory components that are common in many other types of furniture and are not accessible to children when they are in the changing table as intended. All of the pinching incidents involved children who were not on the baby changing product and involved the same hazard that is present on numerous other furniture items. Commission staff also found that the gaps in changing tables that have entrapped children's limbs are similar in size and shape to spaces between crib slats. When the Commission reviewed the same entrapment hazard for cribs, it found that reducing opening sizes may not prevent entrapments, but instead, may result in younger children being entrapped or pinched, making it difficult to develop a requirement that would prevent all entrapments.

Consequently, the Commission believes that ASTM F2388-16 adequately addresses this hazard pattern and more stringent requirements would not further reduce the risk of injury.

C. Restraint Systems

There were 14 CPSRMS incidents involving restraint systems, including broken straps, detached straps, loose or broken buckles, and concerns that products did not have restraint systems. Ten of these 14 incidents resulted in actual or potential falls, and one resulted in an injury. One of these reports, and several other fall incident reports, indicated that the caregiver

was near the child at the time of the fall, indicating that incidents can occur even when a caregiver is nearby.

ASTM F2388-16 does not include any requirements regarding restraint systems. It does not require restraint systems in baby changing products, but also does not prohibit them; nor does the standard include any performance requirements for restraint systems that are included with products. There are several factors that support not requiring restraint systems. First, barrier requirements in ASTM F2388-16 address the hazard of children rolling off of baby changing products, serving the same safety purpose as a restraint system. Second, it is difficult to design a restraint system that adequately restrains a child and also allows enough mobility for a caregiver to change the child's diaper. The most effective restraint systems are 3-point and 5-point restraints, which would limit a caregiver's ability to change a child's diaper. And third, restraints may give caregivers a sense of safety that diminishes their attentiveness.

CPSC believes that ASTM F2388-16 requirements, particularly regarding barriers, adequately address the risks that restraint systems are designed to mitigate. Accordingly, it is not necessary to require restraint systems on baby changing products. Therefore, the Commission is not proposing a more stringent requirement to mandate the presence of restraint systems on baby changing products. However, the incident data suggests that when a restraint system is present, caregivers expect it to be effective. If caregivers expect restraints to be effective, they are likely to rely on them, necessitating that the restraints function effectively when included on a product.

Because there are numerous incidents involving restraint systems breaking during normal use, the Commission considers the existing absence of restraint system requirements to be inadequate. As such, when restraints are provided, the Commission believes that more stringent requirements regarding restraint system integrity would further reduce the risk of injury. Section

VII. Description of Proposed Changes to ASTM Standard, discusses CPSC's proposed requirements regarding restraint systems.

D. Miscellaneous

There were eight CPSRMS incidents involving miscellaneous issues with baby changing products. These reports included complaints of chemical odors and caregivers using baby changing products as sleep products. Each of the five reported deaths related to baby changing products involved children sleeping on the products. In three of these deaths, caregivers placed the child in the changing accessory of a play yard to sleep. In all three cases, the investigatory reports suggest that consumers may view baby changing products as suitable for sleep because parents and law enforcement personnel, in reporting these incidents, mistakenly referred to the play yard changing accessories as "cribs" or "bassinets."

ASTM F2388-16 addresses chemical content of baby changing products, requiring compliance with 16 CFR part 1303, which bans paint containing lead. Given this requirement, the low incidence of issues, and no injuries involving odors or chemicals, the Commission believes that ASTM F2388-16 adequately addresses this issue.

With respect to caregivers using baby changing products as sleep products, ASTM F2388-16 does not include any requirements to address this safety issue. However, five deaths resulted from children sleeping on baby changing products, which is not their intended use. The Commission believes that more stringent requirements are necessary to reduce the risk of injury associated with this hazard. Section VII. Description of Proposed Changes to ASTM Standard, discusses CPSC's proposed requirements regarding warnings and instructional literature that would address this hazard.

E. Undetermined

Three CPSRMS reports involving baby changing products did not provide sufficient information for CPSC to determine how the incidents occurred. Thus, the Commission cannot assess the effectiveness of ASTM F2388-16 in addressing these issues.

VII. Description of Proposed CPSC Standard for Baby Changing Products

The proposed rule would create part 1236, titled, *Safety Standard for Baby Changing Products*. As explained, the Commission believes that ASTM F2388-16 effectively addresses the safety hazards associated with baby changing products, with the exception of structural integrity, restraint system integrity, and warnings on labels and in instructional literature. For this reason, the Commission proposes to incorporate by reference ASTM F2388-16, with modified requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature. This section discusses the proposed modifications.

A. Structural Integrity

Based on the incident data, CPSC believes that a more stringent standard for structural integrity than what is in ASTM F2388-16 would further reduce the risk of injury from collapses and falls from baby changing products. To identify requirements that would address these hazards, Commission staff reviewed incident data, evaluated design features common in baby changing products involved in incidents, and tested various baby changing products. Based on this information, Commission staff, together with ASTM, developed two provisions regarding threaded fasteners and secondary support straps to improve the structural integrity of baby changing products. Additionally, CPSC staff developed requirements for warnings in labels and instructional literature to address these issues.

1. Threaded Fasteners

Commission staff noted that many of the baby changing products involved in collapse incidents required consumers to assemble the products using self-tapping threaded fasteners, such as wood or sheet metal screws. Threaded fasteners can be difficult to install properly, and installing them incorrectly or attempting to install them multiple times can make the assembled product unstable. Multiple attempts to install threaded hasteners can strip the fastener; an over-tightened threaded fastener may crack the part it is attached to; and an under-tightened threaded fastener can create an insecure connection between parts. These issues are particularly likely with durable products, such as baby changing products, which a consumer may disassemble and reassemble for use with multiple children. Several ASTM standards for durable children's products have recognized the potential for consumers to install threaded fasteners improperly, resulting in unstable products, and certain standards prohibit them in key structural elements that consumers assemble.

For these reasons, the Commission proposes additional requirements that would provide for secure connections between fasteners and key structural elements of changing tables and products. Specifically, the Commission proposes to:

- prohibit the use of threaded fasteners on key structural elements assembled by consumers;
- require a means of preventing manufacturer-installed metal threaded fasteners used in key structural elements from loosening (such as with lock washers); and
- require a means of preventing manufacturer-installed metal inserts in key structural elements from loosening (such as by gluing).

The Commission proposes these limits for key structural elements, such as primary changing surface supports and side, end, base, and leg assemblies to address the stability of components that support the weight of occupants. CPSC believes that these more stringent standards would further reduce the risk of injury associated with baby changing products collapsing.

2. Secondary Support Straps

Commission staff examined many of the baby changing products involved in reported incidents through photographs, by collecting some of the products, and by purchasing changing tables from consumers to examine their post-use condition. Through these examinations, staff observed that several consumers had not installed secondary support straps at all, or had installed them improperly. A secondary support strap is a metal band that runs under the center of the changing surface to provide additional support. Secondary support straps are generally one of the last components that consumers install when assembling baby changing products. If a consumer does not install the strap, or installs the strap incorrectly, the product does not have the added support this feature provides to enhance the product's structural integrity.

To accurately test the structural integrity of baby changing products, the Commission believes that structural integrity testing should reflect the least structurally sound condition the product may be in when consumers use it. Given that consumers often do not install secondary support straps or install them incorrectly, products should be tested without consumer-installed secondary support straps attached. Therefore, the Commission proposes to adopt the structural integrity testing required in ASTM F2388-16, but modify the test to specify that consumer-installed secondary support straps not be installed for the test. CPSC believes that this more stringent standard would further reduce the risk of injury associated with baby changing product collapses.

B. Restraint Systems

ASTM F2388-16 does not require or prohibit restraint systems on baby changing products and does not contain any performance requirements for restraint systems that are included with these products. As discussed, although the Commission does not believe it is necessary to require restraint systems for baby changing products, the Commission does believe that a performance standard that requires restraint systems to be effective and durable when they are included with a baby changing product would further reduce the risk of injury from falls.

To develop requirements for restraint systems that would address the hazard pattern evident in the incident data, CPSC staff conducted lab testing of products and worked with an ASTM task group to review the incident data and ASTM standards addressing restraint systems in other durable children's products. As a result of this effort, the group developed a performance test for restraint systems that identifies baby changing products that were involved in restraint system failures. This test requires any restraint provided with a baby changing product to be secured on a CAMI dummy and pulled in four directions anticipated during normal use with a 30 pound force. To pass this performance standard, straps and buckles must not break or separate from baby changing products more than 1 inch from their initial adjustment positions. CPSC believes that this more stringent standard would further reduce the risk of injury associated with restraint systems, by ensuring that those included with baby changing products function effectively.

C. Warnings in Labels and Instructional Literature

As discussed, the most commonly-reported incidents involving baby changing products were falls, and the most common cause of fatalities was children sleeping on baby changing products. ASTM F2388-16 requires warnings about falls on labels and in instructional literature,

but the standard does not require any warnings about the suffocation hazard when children sleep on baby changing products. Considering the frequency and severity of reported incidents and deaths, CPSC believes that more stringent requirements would further reduce these risks of injury.

To develop appropriate warning requirements, Commission staff examined incident data and research on effective warnings, and worked with the ASTM Ad Hoc Wording Task Group. To further reduce the risk of injury associated with falls and children sleeping on baby changing products, the Commission proposes additional content and form provisions for on-product warning labels and parallel requirements for instructional literature. Tab E of CPSC staff's briefing package for this proposed rule includes additional details about these proposed requirements and the rationale for adding them. The briefing package is available at: http://www.cpsc.gov/Newsroom/FOIA/Commission-Briefing-Packages/.

1. Content

Section 9 of ASTM F2388-16 requires baby changing products to be labeled with a warning that states: "FALL HAZARD—To prevent death or serious injury, always keep child within arm's reach." Additionally, removable pads that are intended to be attached to a support surface must warn users: "Always secure this pad to the support surface by [insert instructions on securing the changing pad]. See instructions." And for contoured changing pads and add-on changing units sold separately, warnings must specify products they attach to or specify that the support surface should be "level, stable, and structurally sound," along with the minimum support surface dimensions. Section 10 of ASTM F2388-16 requires the same warnings to appear in instructional literature for baby changing products.

ASTM F2388-16 does not include warning requirements regarding children sleeping on baby changing products.

To develop proposed warning language, Commission staff reviewed information developed through research on the content of warnings, assessed other standards, and reviewed the ASTM Ad Hoc Wording Task Group recommendations. Literature and guidelines about warnings consistently recommend that warnings include:

- a description of the hazard;
- information about the consequences of exposure to the hazard; and
- instructions about appropriate hazard-avoidance behaviors.

Studies indicate that when a person receives information about a hazard, its consequences, and mitigating actions, that information motivates appropriate behavior.

The Commission believes that the warning statements in ASTM F2388-16 lack important details regarding fall and suffocation hazards, their consequences, and appropriate avoidance behaviors. Moreover, the Commission believes that the warning statements in the standard provide only a vague description of the types of injuries that may occur from falls and the statements do not refer to suffocation at all. The Commission believes that strengthening the requirements in ASTM F2388-16would further reduce the risk of injury associated with falls and suffocation. Additionally, the Commission believes that these proposed changes would improve readability and consistency across standards. CPSC developed the following proposed language to describe the specific hazards, consequent injuries and dangers, and precise actions that can help reduce the likelihood of falls and suffocation. CPSC proposes to require the following warning label to appear on baby changing products:

Fall hazard. Children have suffered serious injuries after falling from changing [tables/pads/areas]. Falls can happen quickly.

- **STAY** in arm's reach.

Manufacturers will select one of the terms in brackets, or a similar term, that most-appropriately describes the particular product. Similarly, CPSC proposes to require the following warning label to appear on contoured changing pads that attach to a support surface and changing products that attach to play yards:

Fall hazard. Children have suffered serious injuries after falling from changing [tables/pads/areas]. Falls can happen quickly.

- **STAY** in arm's reach.
- **ALWAYS** secure this pad to the support surface by [manufacturer's instructions for securing the changing product].

Suffocation hazard. Babies have suffocated while sleeping on changing pads. Changing pad is not designed for safe sleeping.

- **NEVER** allow child to sleep on changing pad.

Manufacturers will select one of the terms in brackets, or a similar term, that most-appropriately describes the particular product. The Commission proposes to require the same modifications to the content of the warnings in instructional literature.

Additionally, the Commission proposes minor changes to the language in section 9 of ASTM F2388-16, as detailed in the proposed regulatory text, to make the warnings clearer, and thereby, more effective and consistent with similar standards.

2. Form

Research indicates that the form of a warning can affect the extent to which consumers notice and read the warning and can communicate the seriousness of a hazard, which can affect compliance with the warning. ASTM F2388-16 does not include any form requirements for on-product warnings, apart from text size, and does not include any form requirements for warnings in instructional literature.

As discussed, Commission staff worked closely with the ASTM Ad Hoc Wording Task Group to develop recommendations for product warnings, particularly focused on form, to provide effective and uniform warning requirements. The requirements for warnings on labeling and in instructional literature that the Commission is proposing in this NPR are drawn from the ASTM Ad Hoc Wording Task Group's recommendations.

The ASTM Ad Hoc Wording Task Group's recommendations are largely consistent with ANSI Z535.4, *Product Safety Signs and Labels* ("ANSI Z535.4"; available at: http://www.ansi.org/), which provides guidance on warning label designs, specifically addressing the design, application, use, and placement of on-product warning labels. ANSI Z535.4 is the primary U.S. voluntary consensus standard for product safety signs and labels and CPSC's Division of Human Factors staff uses the standard regularly. ANSI Z535.4 includes requirements about signal words; sign and label format, arrangement, and placement; word messages; colors; borders; letter styles and sizes; and the durability of labels.

CPSC considered research on effective forms for warnings, including the requirements in ANSI Z535.4, in developing the proposed form requirements. Commission staff and the ASTM Ad Hoc Wording Task Group modified these requirements to account for the unique nature of durable nursery products, the wide range of such products, industry concerns, and insights from

CPSC's past rulemakings on durable nursery products. The resulting recommendations and the requirements the Commission proposes in this NPR are designed to increase consumer attention to warnings, improve comprehension, and increase behaviors that would minimize hazards. These proposed requirements include:

- warnings must conform to the 2011 edition of ANSI Z535.4, which is incorporated by reference into the regulations with certain exceptions;
- warnings must be easy to read and understand, and be in English;
- warnings must be permanent;
- additional markings or labels must not contradict the required warning information or be confusing or misleading; and
- the specific typefaces, size, alignment, layout, and text formats to use to facilitate readability.

The Commission believes that these requirements would further reduce the risk of injury associated with falls and suffocation, by making the warnings regarding these risks more effective. The Commission proposes the same design requirements for on-product warnings and warnings in instructional literature, except that instructional literature need not meet the color requirements in ANSI Z535.4.

Additionally, CPSC proposes to include a note in the regulatory text, referencing ANSI Z535.6, *Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials* ("ANSI Z535.6"; available at: http://www.ansi.org/), for optional additional guidance about the design of product safety messages in instructional literature. CPSC does not propose to require compliance with ANSI Z535.6, but the standard may offer regulated entities additional useful information for developing effective warnings in instructional literature. Although the

Commission believes compliance with this standard is advisable, product instructions vary greatly, depending on the product, purpose, content, length, and other factors. Thus, the Commission believes it is appropriate to reference ANSI Z535.6, but not mandate compliance with it.

3. Placement

ASTM F2388-16 requires warning labels to be "conspicuous," that is, visible to a caretaker standing in a place normally associated with changing a diaper. The Commission believes that this requirement is adequate because it provides caregivers the opportunity to see a warning during routine use of the product and just before they would leave a child unattended, sleeping, or out of their reach on the baby changing product. This requirement is also consistent with ANSI Z535.4.

D. Miscellaneous Additional Requirements

The Commission also proposes several additional minor changes that would further reduce the risk of injury associated with baby changing products and provide greater clarity or detail regarding requirements in ASTM F2388-16. These include:

- adding definitions for "key structural elements" and "non-rigid add-on changing unit accessory";
- adding a provision to prohibit components attached by screws from separating more than 0.04 in. (1 mm) after structural integrity testing; and
- requiring a marking including both the address and telephone number of the manufacturer, distributor, or seller, rather than either.

The proposed definitions would add clarity to the standard and are relevant to the additional requirements. "Key structural elements" are central to the proposed requirements

regarding threaded fasteners, and specific requirements for "non-rigid add-on changing unit accessories" are in the proposed labeling provisions. The separation limit would further reduce the risk of injury associated with structural integrity issues demonstrated in the incident data. Providing the address, as well as the telephone number for firms that supply baby changing products would provide the Commission and consumers with more complete contact information, in case it is necessary to contact a supplier. This would expedite any safety measures necessary and thereby, reduce the risk of safety hazards.

VIII. Amend 16 CFR Part 1112 to Include NOR for Baby Changing Products Standard

Section 14 of the CPSA establishes requirements for product testing and certification. Manufacturers of products that are subject to a consumer product safety rule under the CPSA or another rule the Commission enforces must certify, based on product testing, that their product complies with all such rules. 15 U.S.C. 2063(a)(1). Additionally, manufacturers of children's products that are subject to a children's product safety rule must have these products tested by a third party conformity assessment body that CPSC has accredited, and manufacturers must certify that their products comply with all applicable children's product safety rules. *Id.* at 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule. *Id.* at 2063(a)(3). Because the proposed rule is a children's product safety rule, if the Commission issues 16 CFR part 1236, *Safety Standard for Baby Changing Products*, as a final rule, the CPSC must also issue an NOR.

The Commission published a final rule, codified at 16 CFR part 1112, titled, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, which established requirements for accreditation of third party conformity assessment bodies to test for conformity

with children's product safety rules in accordance with the CPSA. 78 FR 15836 (Mar. 12, 2013). Part 1112 also codifies all of the NORs that the Commission previously issued.

NORs for new children's product safety rules, such as the baby changing products standard, require the Commission to amend part 1112. To accomplish this, as part of this NPR, the Commission proposes to amend part 1112 to add baby changing products to the list of children's product safety rules for which CPSC has issued an NOR.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test for compliance with the proposed standard for baby changing products would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements of a CPSC-accepted third party conformity assessment body, the laboratory can apply to CPSC to have 16 CFR part 1236, *Safety Standard for Baby Changing Products*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

IX. Incorporation by Reference

Section 1236.2(a) of the proposed rule incorporates by reference ASTM F2388-16 and ANSI Z535.4. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. Under these regulations, in the preamble of the NPR, an agency must summarize the incorporated material and discuss the ways in which the material is reasonably available to interested parties or how the agency worked to make the materials reasonably available. 1 CFR 51.5(a). In accordance with the OFR's requirements, Section V. ASTM F2388-16, of this preamble summarizes the provisions of ASTM F2388-16 and Section VII. Description of Proposed Changes to ASTM Standard, summarizes the provisions of ANSI Z535.4 that the Commission proposes to incorporate by reference.

ASTM F2388-16 is copyrighted material. By permission of ASTM, interested parties may view the standard as a read-only document during the comment period of this NPR at: http://www.astm.org/cpsc.htm. Interested parties may also purchase a copy of ASTM F2388-16 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm.

ANSI Z535.4 is also copyrighted material. Interested parties may purchase a copy of ANSI Z535.4 from the American National Standards Institute (ANSI), 1899 L Street, NW, 11th Floor, Washington, DC 20036, or through the ANSI website at: https://www.ansi.org.

Interested parties may also inspect copies of both standards at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923.

X. Effective Date

The Administrative Procedure Act (5 U.S.C. 551-559) 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). To allow time for baby changing products to come into compliance with the standard, the Commission proposes that the standard become effective 6 months after publication of the final rule in the *Federal Register*. Without evidence to the contrary, CPSC generally considers 6 months to be sufficient time for suppliers to come into compliance with a new standard, and 6 months is typical for other CPSIA section 104 rules. Six months is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows for products in its certification program to transition to a new standard after publication.

The Commission also proposes that the amendment to part 1112 become effective 6 months after publication of the final rule.

The Commission requests comments on the proposed effective date.

XI. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) requires agencies to consider the impact of proposed rules on small entities, including small businesses. Section 603 of the RFA requires the Commission to prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the NPR is published. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Specifically, the IRFA must discuss:

- the reasons the agency is considering the action;
- the objectives of and legal basis for the proposed rule;
- the small entities that would be subject to the proposed rule and an estimate of the number of small entities that would be impacted;
- the reporting, recordkeeping, and other requirements of the proposed rule, including the classes of small entities subject to it and the skills necessary to prepare the reports or records; and
- the relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

5 U.S.C. 603.

This section summarizes the IRFA for this proposed rule. The complete IRFA is available in Tab F of staff's briefing package for this proposed rule, available at: http://www.cpsc.gov/Newsroom/FOIA/Commission-Briefing-Packages/. To summarize, the

Commission cannot rule out a significant economic impact for 40 of the 59 (68 percent) small entities that supply baby changing products in the U.S. market.

B. Market Description

CPSC identified 85 firms that supply baby changing products to the U.S. market. Seventy-one of these firms are domestic (57 manufacturers, 12 importers, one wholesaler, and one retailer), and14 are foreign (12 manufacturers, one importer, and one retailer). Eighty-one of these firms market their products to consumers, while seven also market their products for commercial daycare. Fifty-six offer multiple types of baby changing products.

C. Reason for Agency Action, Objectives, and Legal Basis for Proposed Rule

Section 104 of the CPSIA requires the CPSC to promulgate mandatory standards for durable infant or toddler products that are substantially the same as a voluntary standard or more stringent than the voluntary standard if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. As discussed in Section I. Background and Statutory Authority, baby changing products are durable infant or toddler products.

D. Description of the Proposed Rule

CPSC proposes to adopt ASTM F2388-16 with modifications to the structural integrity requirements, restraint system requirements, and provisions on warnings on labels and instructional literature. Section V. ASTM F2388-16, of this preamble discusses key provisions of ASTM F2388-16 and Section VII. Description of Proposed Changes to ASTM Standard, discusses the proposed requirements that are more stringent than ASTM F2388-16. To help evaluate the economic impact of the proposed rule, Commission staff contacted nine industry members who would be impacted by the rule, and three responded.

E. Other Relevant Federal Rules

CPSC has not identified any federal or state rules that would duplicate, overlap or conflict with the proposed rule.

F. Impact of the Proposed Rule on Small Businesses

Under U.S. Small Business Administration (SBA) guidelines, a baby changing product manufacturer is a small business if it has 500 or fewer employees; importers and wholesalers are small businesses if they have 100 or fewer employees. CPSC analyzed domestic firms because SBA guidelines and definitions apply to U.S. entities. CPSC identified 85 firms that currently market baby changing products in the United States; 71 are domestic firms. Fifty-nine of these firms (49 manufacturers, 9 importers, and 1 wholesaler) are small businesses, based on the SBA guidelines and available information about the firms.

To determine the extent to which the proposed rule would impact small businesses, the Commission identified firms that comply with ASTM F2388-16 by considering the following factors: JPMA certification, the firm's claims of compliance, active participation in ASTM standards development, and CPSC compliance testing. Table 2 lists the number of firms by location, size, type, and compliance:

TABLE 2.—*Firms that Market Baby Changing Products in the U.S.*

Category	Number of Firms
Domestic	71
Small	59
Manufacturers	49
Compliant with ASTM F2388	22
Not Compliant with ASTM F2388	27
Importers and Wholesalers	10
Compliant with ASTM F42388	4
Not Compliant with ASTM F2388	6
Large	12
Foreign	14
Total	85

Looking first at the proposed requirements that would prohibit the use of consumer-installed threaded fasteners in key structural elements, the Commission believes that the overall economic impact of this requirement would be small. CPSC testing indicates that most baby changing products on the market already follow this restriction and noncompliant firms could make inexpensive changes to meet this requirement.

With respect to structural integrity testing without consumer-installed secondary support straps, it is possible that some firms would incur costs to comply with this requirement. CPSC testing indicates that some products do not pass structural integrity testing without their consumer-installed secondary support straps; however, none of these products is currently on the market. The cost of complying would vary, depending on the modifications that a firm adopts.

Next, the Commission proposes to adopt a structural integrity test for restraints when they are included with a product. The Commission found that approximately 21 percent of baby changing products on the U.S. market include restraints. Through limited testing, staff found that some of these products do not meet the proposed requirement. To comply with the proposed requirement, firms have several low-cost options to reinforce restraints.

Finally, the Commission is proposing additional requirements for warnings on labels and in instructional literature. All firms would have to modify the wording and format of their warnings to meet these requirements; however, the costs of such changes are generally small, particularly compared to overall firm revenues.

1. Small Manufacturers with Compliant Baby Changing Products

Of the 49 small manufacturers, 22 produce baby changing products that comply with ASTM F2388-16, making the economic impact of adopting ASTM F2388-16 small. Additionally, the proposed requirements for threaded fasteners, restraints, and warnings likely

would also create only small costs for these manufacturers. Compliant manufacturers are unlikely to use consumer-installed threaded fasteners in key structural components because other children's product standards prohibit them. About 10 of these firms produce at least one baby changing product with restraints, but if their products are not compliant, then the firm can remove the restraints or make other low-cost adjustments. Similarly, the cost to comply with the proposed requirements for warnings is also likely to be low because the additional requirements would merely modify the text and format of the ASTM F2388-16 warnings.

In contrast, the proposed additional requirement regarding user-installed secondary support straps may result in significant costs. Five of the compliant manufacturers may use consumer-installed secondary support straps. If these products do not pass the structural integrity test without these supports, the cost of modifying the products could range from minimal to great, depending on the product type and the changes employed. Therefore, staff cannot rule out a significant economic impact for the five manufacturers of compliant products that may employ user-installed secondary support straps.

2. Small Manufacturers with Non-Compliant Baby Changing Products

Twenty-seven of the 49 small manufacturers produce baby changing products that do not comply with ASTM F2388-16. These firms may incur costs to conform to ASTM F2388-16 and the additional proposed requirements. The Commission does not have sufficient information to determine the extent and cost of these changes. Therefore, the Commission cannot rule out a significant economic impact on these firms.

3. Third Party Testing Costs for Small Manufacturers

Under section 14 of the CPSA, if CPSC adopts the proposed requirements, all manufacturers would be subject to the third party testing and certification requirements under 16

CFR part 1107. Third party testing would include any physical and mechanical test requirements, and the cost of obtaining testing would be in addition to the costs of meeting the baby changing products standard.

Almost half of small baby changing product manufacturers (22 out of 49) already test their products for compliance with ASTM F2388, although not necessarily through a third party laboratory. For these manufacturers, the cost of the proposed rule, with respect to third party testing, would be limited to the difference between the cost of their current testing regimes and the cost of third party tests, which is likely to be low.

Of the remaining 27 firms that do not currently test their products for compliance with ASTM F2388-16, third party testing could result in a significant economic impact for five firms. Testing costs may exceed 1 percent of gross revenue for these firms if five or fewer samples are tested (assuming high-end, U.S.-based testing costs of $1,200 per model sample). CPSC could not obtain revenue information for all of the small, non-compliant manufacturers. Therefore, CPSC could not evaluate the economic impact for six firms.

4. Small Importers and Wholesalers with Compliant Baby Changing Products

CPSC considered the economic impact to importers and wholesalers together because both rely on outside firms to supply the products they distribute to the U.S. market. The four small importers that comply with ASTM F2388-16 would require modifications to meet the proposed additional requirements. However, as discussed, the costs of complying with the additional threaded fastener, restraints, and warning requirements are likely to be low.

The proposed requirement regarding user-installed secondary support straps, however, could be more costly and possibly require firms to retrofit or redesign their products. Two of the four importers may require modifications to pass structural integrity testing under this

requirement. Both firms could eliminate changing products from their product lines without a significant adverse impact, but likely could not use an alternate supplier.

5. Small Importers and Wholesalers with Non-Compliant Baby Changing Products

There is insufficient information to rule out a significant impact for any of the five importers and one wholesaler of non-compliant baby changing products. Whether there would be a significant economic impact would depend on the extent of the changes required for these firms to come into compliance and the response of their suppliers, who may pass on the increased costs to the importers and wholesalers.

Four of the six importers and wholesalers with noncompliant products do not appear to have direct ties to their suppliers and may select alternative suppliers. Alternatively, three of these firms supply numerous products. Thus, they could stop supplying baby changing products. However, one firm only supplies baby changing products, so there would be a significant economic impact if that firm left the market.

The remaining two firms are tied to their foreign suppliers, so they are not likely to choose alternative suppliers. However, these foreign suppliers may comply with the proposed requirements to continue to market their products in the United States. Alternatively, these firms may stop selling baby changing products altogether because they represent only a small portion of their product lines. Without sales revenues, CPSC could not determine whether exiting the baby changing products market would generate significant economic impacts.

6. Third Party Testing Costs for Small Importers and Wholesalers

Importers and wholesalers would be subject to costs similar to manufacturers' costs if their foreign suppliers do not obtain third party testing. Four importers already test their products

to verify compliance with the ASTM standard. As such, their costs would be limited to the incremental costs of third party testing over their current testing regimes.

There may be significant costs for two or three firms that do not comply with the ASTM standard. For two firms, the cost of testing as few as two units per model could exceed 1 percent of their gross revenues. For a third firm, testing costs may exceed 1 percent of its gross revenue, depending on how many units per model the firm tests. CPSC was unable to obtain revenue data for one small, non-compliant wholesaler, so could not examine the size of the impact on that firm.

7. Summary of Impacts

The Commission identified 59 small firms that market baby changing products in the United States, of which 49 are domestic manufacturers and 10 are domestic importers or wholesalers. Of the 49 small manufacturers, 17 are unlikely to experience significant economic impacts if the Commission adopts the proposed rule. However, CPSC cannot rule out a significant economic impact for the remaining 32 manufacturers. For two of the small importers and wholesalers, it is likely that the proposed rule would not have a significant economic impact. However, it is possible that the proposed rule would have a significant economic impact on the remaining eight small importers and wholesalers. Therefore, to summarize, CPSC cannot rule out a significant economic impact for 40 of the 59 small firms (68 percent) operating in the U.S. baby changing products market.

8. Impacts of Test Laboratory Accreditation Requirements on Small Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a third party conformity assessment body that has been accredited by CPSC. These third party conformity assessment bodies test products for

compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the NOR for third party conformity testing. CPSC has codified NORs in 16 CFR part 1112. CPSC proposes to amend 16 CFR part 1112 to establish an NOR for testing laboratories to test for compliance with the proposed baby changing products standard. This section assesses the impact of this proposed amendment on small laboratories.

CPSC conducted a Final Regulatory Flexibility Analysis (FRFA) when it adopted part 1112. 78 FR 15836 (Mar. 12, 2013). The FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were laboratories that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

For the same reasons, including the NOR for baby changing products in part 1112 would not have a significant adverse impact on small laboratories. Moreover, CPSC expects that only a small number of laboratories would request accreditation to test baby changing products, based on the number of laboratories that have applied for CPSC accreditation to test other juvenile products. Most laboratories would already have accreditation to test for conformance to other juvenile product standards; accordingly, the only cost would be to add the baby changing products standard to their accreditation. Test laboratories have indicated that this cost is extremely low when they are already accredited for other CPSIA section 104 rules. Therefore, the Commission certifies that the NOR for the baby changing products standard will not have a significant impact on a substantial number of small entities.

G. Alternatives

At least three alternatives are available to minimize the economic impact on small entities supplying baby changing products, while also complying with the direction of section 104 of the CPSIA.

First, the Commission could adopt ASTM F2388-16, with no modifications. Section 104 of the CPSIA directs the Commission to promulgate a standard that is either substantially the same as the voluntary standard or more stringent if the Commission determines that would further reduce the risk of injury associated with the product. Therefore, adopting ASTM F2388-16 with no modifications is the least stringent rule CPSC could adopt. This alternative would reduce the economic impact on all of the small businesses supplying baby changing products to the U.S. market. Although choosing this alternative would not reduce the testing costs associated with the rule, this alternative would eliminate the economic impact of the additional proposed requirements. This option would eliminate the cost of complying with the additional requirements for the 22 small domestic manufacturers and four small importers and wholesalers with baby changing products that conform to ASTM F2388-16. However, adopting ASTM F2388-16 with no modifications would not further reduce the risks associated with falls and suffocations.

Second, the Commission could adopt ASTM F2388-16 with the proposed modifications, except for the requirement regarding secondary support straps. This additional requirement is likely to have the largest economic impact, and removing it would reduce the impact on 11 small suppliers (9 small manufactures and 2 small importers). However, without this requirement, the standard may not reduce the risk of injuries associated with falls as effectively.

Third, the Commission could set a later effective date for the final rule. A later effective date would reduce the economic impact on firms in two ways. First, firms would be less likely to experience a lapse in production or imports if they are unable to modify their products and secure third party testing within the required timeframe. Second, firms could spread costs over a longer period, thereby reducing annual costs and the present value of total costs. CPSC requests comments on the 6-month effective date.

H. Requested Information

The Commission would find comments on the following issues particularly helpful:

- the changes, costs, and time needed to conform to ASTM F2388-16;
- how affected firms would modify their products, the associated costs, and the time needed to meet each of the proposed requirements regarding:
    - threaded fasteners;
    - consumer-installed secondary support straps;
    - restraint system integrity; and
    - labels and instructional literature;
- whether a particular effective date, or time of year would reduce the costs associated with the proposed requirements;
- whether the costs of complying with the proposed ban of consumer-installed threaded fasteners on key structural elements would be "economically significant" (*i.e.*, amount to an impact greater than 1 percent of revenue or similar economic benchmarks);
- the types of baby changing products that include user-installed secondary support straps and their prevalence in the U.S. market;

- the extent to which firms would remove restraints entirely, rather than conform to the proposed requirement, and the associated costs;
- testing costs and incremental costs of third party testing (*i.e.*, how much moving from a voluntary to a mandatory third party testing regime would add to testing costs in total and on a per-test basis); and
- the number of products that must be tested to provide a "high degree of assurance" with respect to third party testing.

XII. Environmental Considerations

The Commission's regulations outline the types of agency actions that require an environmental assessment (EA) or environmental impact statement (EIS). Rules that have "little or no potential for affecting the human environment" fall within a "categorical exclusion" under the National Environmental Policy Act (NEPA; 42 U.S.C. 4231-4370h) and the regulations implementing NEPA (40 CFR parts 1500-1508) and do not normally require an EA or EIS. As stated in 16 CFR 1021.5(c)(1), rules or safety standards that provide design or performance requirements for products fall within that categorical exclusion. Because this proposed rule would create design and performance requirements for baby changing products, the proposed rule falls within the categorical exclusion. Thus, no EA or EIS is required.

XIII. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). Under 44 U.S.C. 3507(a)(1)(D), an agency must publish the following information:

- a title for the collection of information;

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

In accordance with this requirement, the Commission provides the following information:

Title: Safety Standard for Baby Changing Products

Description: The proposed rule would require each baby changing product to comply with ASTM F2388-16, with additional requirements regarding structural integrity, restraint system integrity, and warnings in labels and instructional literature. Sections 9 and 10 of ASTM F2388-16 contain requirements for labels and instructional literature. These requirements fall within the definition of a "collection of information" provided in the PRA at 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import baby changing products.

Estimated Burden: CPSC estimates the burden of this collection of information as follows:

TABLE 3.—*Estimated Annual Reporting Burden*

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1231.2	85	6	510	1	510

CPSC's estimate is based on the following:

Section 9.1.1 of ASTM F2388-16 requires that the name and place of business (mailing address) or the telephone number of the manufacturer, distributor, or seller appear on each baby changing product and its retail package. The additional requirements proposed in this NPR would require both the specified address information and the telephone number, instead of a choice between the two. Section 9.1.2 of ASTM F2388-16 requires a code mark or other product identification on each product and retail package that indicates the date (month and year) of manufacture.

Eighty-five known entities supply baby changing products to the U.S. market and may need to modify their existing labels to comply with ASTM F2388-16. CPSC estimates that the time required to make these modifications is about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of six models of baby changing products. Therefore, the estimated burden associated with labels is 1 hour per model × 85 entities × 6 models per entity = 510 hours. CPSC estimates the hourly compensation for the time required to create and update labels is $33.02 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," Mar. 2016, 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 associated with the proposed labeling requirements is $16,840 ($33.02 per hour × 510 hours = $16,840). No operating, maintenance, or capital costs are associated with the collection.

Section 10.1 of ASTM F2388-16 requires instructions to be supplied with baby changing products. Baby changing products generally require use and assembly instructions. As such, products sold without use and assembly instructions would not compete successfully with those that supply this information. Under OMB's regulations, the time, effort, and financial resources

necessary to comply with a collection of information incurred by parties in the "normal course of their activities" are excluded from a burden estimate when an agency demonstrates that the disclosure activities required are "usual and customary." 5 CFR 1320.3(b)(2). CPSC is unaware of baby changing products that generally require use or assembly instructions but lack such instructions. Therefore, CPSC estimates that no burden hours are associated with section 10.1 of ASTM F2388-16 because any burden associated with supplying instructions with baby changing products would be "usual and customary," and thus, excluded from "burden" estimates under OMB's regulations.

Based on this analysis, the proposed standard for baby changing products would impose a burden to industry of 510 hours at a cost of $16,840 annually.

CPSC has submitted the information collection requirements of this rule to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d). CPSC requests that interested parties submit comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice). Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission invites comments on:

- whether the proposed collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;
- the accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information the Commission proposes to collect;

- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with modifying labels and instructional literature, including any alternative estimates.

XIV. Preemption

Under section 26(a) of the CPSA, no state or political subdivision of a state may establish or continue in effect a requirement dealing with the same risk of injury as a federal consumer product safety standard under the CPSA unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). States or political subdivisions of states may, however, apply to the Commission for an exemption, allowing them to establish or continue such a requirement if the state requirement provides a significantly high degree of protection from the risk of injury and does not unduly burden interstate commerce. *Id.* at 2075(c).

One of the functions of the CPSIA was to amend the CPSA, adding several provisions to CPSA, including CPSIA section 104 in 15 U.S.C. 2056a. As such, consumer product safety standards that the Commission creates under CPSIA section 104 are covered by the preemption provision in the CPSA. Consequently, the rule proposed in this NPR would be a federal consumer product safety standard, and the preemption provision in section 26 of the CPSA would apply.

XV. Request for Comments

This NPR begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for baby changing products and to amend part 1112 to add baby changing products to the list of children's product safety rules for which CPSC has issued

an NOR. We invite all interested persons to submit comments on any aspect of the proposed mandatory safety standard for baby changing products and on the proposed amendment to part 1112. Specifically, the Commission requests comments on the following:

- the requirements in ASTM F2388-16, including their effectiveness in addressing the risks of injury associated with baby changing products and the costs of complying with these requirements;
- the additional requirements proposed for structural integrity, specifically regarding threaded fasteners and secondary support straps, including their effectiveness in addressing the risk of injury associated with collapses and falls and the costs of complying with these requirements;
- the additional requirement proposed for restraint systems, including its effectiveness in addressing the risk of injury associated with restraints and falls and the costs of complying with this requirement;
- the additional requirements proposed for labels and instructional literature, including their effectiveness at addressing the hazards associated with falls and suffocation and the costs of complying with these requirements;
- the costs to small businesses associated with the requirements proposed in this NPR, including the costs to comply with the proposed additional requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature;
- alternatives to the proposed requirements that would reduce impacts on small businesses;
- the proposed effective date and whether an extended effective date would further mitigate the impact on small businesses and to what extent; and

- any additional information relevant to the issues discussed in this NPR and the proposed requirements.

During the comment period, ASTM F2388-16 and ANSI Z535.4 are available for review. Please see Section IX. Incorporation by Reference, for instructions on viewing them.

Please submit comments in accordance with the instructions in the **ADDRESSES** section at the beginning of this NPR.

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 1236

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

For the reasons discussed in the preamble, the Commission proposes to amend 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. No. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend § 1112.15 by adding paragraph (b)(46) to read as follows:

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

*** * * * ***

(b) * * *

(46) 16 CFR part 1236, Safety Standard for Baby Changing Products.

* * * * *

3. Add part 1236 to read as follows:

PART 1236-SAFETY STANDARD FOR BABY CHANGING PRODUCTS

Sec.

Authority: Sec. 104, Public L. No. 110-314, 122 Stat. 3016.

§ 1236.1 Scope.

This part establishes a consumer product safety standard for baby changing products, including changing tables and other changing products, such as contoured changing pads and add-on changing units sold separately for use on furniture products other than changing tables.

§ 1236.2 Requirements for baby changing products.

(a) Except as provided in paragraphs (b) through (m) of this section, each baby changing product must comply with all applicable provisions of ASTM F2388-16, Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use, approved on July 1, 2016, which is incorporated by reference herein. 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.

(b) Comply with ASTM F2388-16 with the additions or exclusions listed in paragraphs (c) through (m) of this section:

(c) In addition to the definitions in section 3.1 of ASTM F2388-16, the following definitions apply to this section:

(1) 3.1.14 *key structural elements, n*—side assemblies, end assemblies, base assemblies, leg assemblies, primary changing surface supports, or other components designed to support the weight of the occupant, or a combination thereof.

(2) 3.1.15 *non-rigid add-on changing unit accessory, n*—a supported changing unit that attaches to a crib or play yard designed to convert the product into a changing table typically having a rigid frame with soft fabric or mesh sides and/or bottom surface.

(d) In addition to complying with sections 5.1 through 5.7 of ASTM F2388-16, comply with the following:

(1) 5.8 *Threaded Fasteners (Wood Screws and Sheet Metal Screws)*—

(i) 5.8.1 No changing table shall require consumer assembly of key structural elements using wood screws or sheet metal fasteners directly into wood components. This shall not apply to non-key structural elements such as drawers, secondary support straps, other storage components, or accessory items.

(ii) 5.8.2 Metal inserts, with external wood screw threads for screwing into a wood component and providing internal machine threads to accommodate a machine screw, that are

used to secure key structural elements shall be glued or include other means to impede loosening or detaching.

(iii) 5.8.3 Metal threaded fasteners, such as sheet metal screws and machine screws, secured into metal components and used to attach key structural elements shall have lock washers, self-locking nuts, or other means to impede loosening or detachment during the testing required by this specification, as described in section 6.2 of ASTM F2388-16.

(2) [Reserved]

(e) Instead of complying with section 6.2 of ASTM F2388-16, comply with the following:

(1) 6.2 *Structural Integrity*—When tested in accordance with 7.2, there shall be no breakage of the unit, nor shall it fail to conform to any other requirements in this specification before and after all testing. Components attached by screws shall not have separated by more than 0.04 in. (1 mm) upon completion of testing.

NOTE 1—Contoured changing pads and add-on changing units that are sold separately are exempt from this requirement.

(2) [Reserved]

(f) In addition to complying with section 6.8 of ASTM F2388-16, comply with the following:

(1) 6.9 *Restraint System*—

NOTE 2—A restraint system may be provided to restrict upward or lateral movement of the occupant's torso. Inclusion of a restraint system is not mandatory.

(i) 6.9.1 If a restraint system is installed on the product or available as an option, it shall meet the following:

(A) 6.9.1.1 A restraint system and its closing means (for example, buckle) shall not break or separate when tested in accordance with 7.8.

(B) 6.9.1.2 The anchorages shall not separate from the unit when tested in accordance with 7.8.

(C) 6.9.1.3 Restraints shall be capable of adjustment with a positive, self-locking mechanism that is capable, when locked, of withstanding the forces of tests in 7.8 without allowing restraint movement or slippage of more than 1 in. (25.4 mm).

(ii) [Reserved]

(2) [Reserved]

(g) Instead of complying with section 7.2 of ASTM F2388-16, comply with the following:

(1) 7.2 *Structural Integrity*—Assemble the unit in accordance with the manufacturer's assembly instructions. If the product design employs secondary support bars or straps beneath the changing surface that are not factory preassembled in their intended use position, this test is to be conducted without the support bars/straps installed. Place the unit on the test floor, center a 6 by 6 in. (150 by 150 mm) wood block on the changing surface and gradually apply a 100 lb (45.4 kg) weight onto the wood block within a period of 5 s. Maintain the weight for an additional period of 60 s.

(2) [Reserved]

(h) Instead of complying with section 7.4 of ASTM F2388-16, comply with the following:

(1) 7.4 *Barrier Structural Integrity and Retention Tests:*

(i) 7.4.1 *Test Equipment and Test Set Up*

(A) 7.4.1.3 *Test Set Up*—Assemble the unit in accordance with the manufacturer's assembly instructions. If the product design employs secondary support bars or straps beneath the changing surface that are not factory preassembled in their intended use position, this test is to be conducted without the support bars/straps installed.

(B) [Reserved]

(ii) [Reserved]

(2) [Reserved]

(i) In addition to complying with section 7.7 of ASTM F2388-16, comply with the following:

(1) 7.8 *Restraint System*—

(i) 7.8.1 Secure the unit in its recommended use position so that it cannot move in the direction of the force being applied.

(ii) 7.8.2 Secure a CAMI Infant Dummy, Mark II on the changing surface in accordance with the manufacturer's instructions.

(iii) 7.8.3 Adjust the restraint, using the webbing tension pull device shown in Figure 1, below, so that a force of 2 lbf (9 N) applied to the restraint will provide a 1⁄4 in. (6 mm) space between the restraint and the CAMI Dummy.

(iv) 7.8.4 Using the webbing tension pull device shown in Figure 1, below, perform the following tests without readjusting the restraint system.

(A) 7.8.4.1 Within 5 s, gradually apply a pull force of 30 lbf (200 N) on the restraint strap and maintain for an additional 10 s. Release the restraint strap. Repeat this test for a total of four pulls in the following directions: horizontally away from the table in the direction an occupant could roll, in a direction that is 45 degrees from the horizontal changing surface towards the head

of the changing pad, in a direction that is 45 degrees from the horizontal changing surface towards the foot of the changing pad, and vertically straight up away from the changing pad.

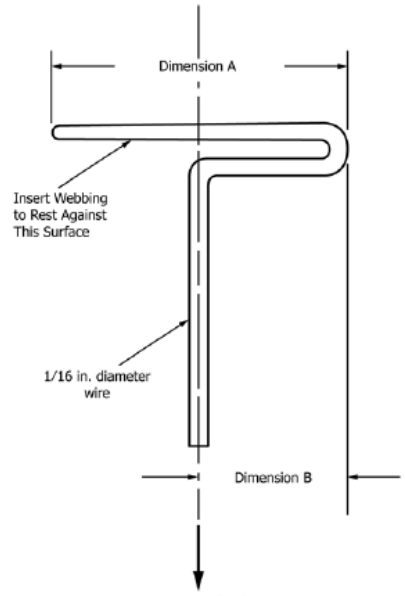

FIGURE 1.—*Webbing Tension Pull Device*

(B) [Reserved]

(2) [Reserved]

(j) Instead of complying with sections 9.1.1 and 9.1.2 of ASTM F2388-16, comply with the following:

(1) 9.1.1 The name, place of business (mailing address, including city, state, and zip code), and telephone number of the manufacturer, distributor, or seller.

(2) 9.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

NOTE 3—Add-on changing units, non-rigid add-on changing unit accessories, or contoured changing pads sold with non-full size cribs and play yards are exempt from the

labeling requirements of 9.1.1 and 9.1.2, as labeling requirements for these accessories are included in Consumer Safety Specification F406.

(k) Instead of complying with section 9.3 of ASTM F2388-16, comply with the following:

(1) 9.3 The marking and labeling on the product shall be permanent.

(2) [Reserved]

(l) In addition to complying with section 9.3, as revised in paragraph (k) of this section, comply with the following:

(1) 9.4 *Warning Design for Product*

(i) 9.4.1 The warning shall be easy to read and understand and be in the English language at a minimum.

(ii) 9.4.2 Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer.

(iii) 9.4.3 The warnings shall be conspicuous and permanent.

(iv) 9.4.4 The warnings shall conform to sections 6.1-6.4, 7.2-7.6.3, and 8.1 of ANSI Z535.4-2011, Product Safety Signs and Labels, approved on July 19, 2011, which is incorporated by reference herein, with the changes indicated in paragraph (l)(1)(iv)(A), (B), and (C) of this section. 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 American National Standards Institute, Inc., 1899 L Street, NW, 11th Floor, Washington, DC 20036; https://www.ansi.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814,

telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.

(A) 9.4.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”

(B) 9.4.4.2 In section 7.6.3, replace “should (when feasible)” with “shall.”

(C) 9.4.4.3 Strike the word “safety” when used immediately before a color (*e.g.*, replace “safety white” with “white”).

(v) 9.4.5 The safety alert symbol and the signal word “WARNING” shall not be less than 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified.

NOTE 4—For improved warning readability, the warning designer should avoid the use of typefaces with large height-to-width ratios, which are commonly identified as “condensed,” “compressed,” “narrow,” or similar.

(vi) 9.4.6 *Message Panel Text Layout*

(A) 9.4.6.1 The text shall be left aligned, ragged right for all but one-line text messages, which can be left aligned or centered.

NOTE 5—Left aligned means that the text is aligned along the left margin, and, in the case of multiple columns of text, along the left side of each individual column.

(B) 9.4.6.2 The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

(vii) 9.4.7 An example warning in the format described in this section is shown in Figure 2, below.

FIGURE 2.—*Example Warning*

(2) 9.5 *Warning Statements*—Each product shall have warnings statements to address the following, at a minimum:

(i) 9.5.1 The following warning statements shall be placed on all changing tables, including add-on changing units and contoured changing pads that are sold separately:

Fall Hazard. Children have suffered serious injuries after falling from changing [tables/pads/areas]. Falls can happen quickly.

- **STAY** in arm's reach.

NOTE 6—The words in brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.

(ii) 9.5.2 Removable pads that are included with changing tables, contoured pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately that are intended to be physically attached to the support surface shall have a warning on the pad or changing unit, and its retail packaging, to address the following:

- **ALWAYS** secure this [unit/pad] to the support [surface/frame] by (manufacturer's instructions for securing the changing unit). See instructions.

NOTE 7—The words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.

(iii) 9.5.3 Non-rigid add-on changing unit accessories, changing pads, and contoured changing pads, whether sold with the changing table or sold separately, shall include the following additional warning statements:

Suffocation Hazard. Babies have suffocated while sleeping [in/on] changing [tables/pads/areas]. Changing [table/pad/area] is not designed for safe sleeping.

- **NEVER** allow baby to sleep [in/on] changing [table/pad/area].

NOTE 8—The words in brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.

(iv) 9.5.4 Contoured changing pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately shall include additional warnings addressing either: (a) The specific products to attach the contoured changing pad or add-on unit to; or (b) That the surface used should be level, stable, and structurally sound with minimum surface dimensions of "X" by "Y."

(m) Instead of complying with section 10.1.1 of ASTM F2388-16, comply with the following:

(1) 10.1.1 The instructions shall contain the warnings as specified in 9.5 and address the statements in 10.1.1.1 through 10.1.1.8. These required warning statements shall meet the requirements described in 9.4, except for the color requirements provided in ANSI Z535.4,

Product Safety Signs and Labels (*e.g.*, the background of the signal word panel need not be a specific color).

NOTE 9—For additional guidance on the design of warnings for instructional literature, please refer to the most-recent edition of ANSI Z535.6, *Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials,* American National Standards Institute, Inc., available at http://www.ansi.org/.

(2) [Reserved]

Dated: _____

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

Staff Briefing Package

Notice of Proposed Rulemaking for Baby Changing Tables and Certain Changing Table Products for Domestic Use

August, 2016

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OR ACCEPTED BY THE COMMISSION.

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Briefing Memorandum

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

This document has been electronically approved and signed.

Memorandum

August 16, 2016

TO: The Commission
Todd Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel
DeWane Ray, Deputy Acting Executive Director

FROM: Duane Boniface
Acting Assistant Executive Director
Office of Hazard Identification and Reduction

Shaina Donahue and Mark Kumagai
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

SUBJECT: Notice of Proposed Rulemaking for Changing Tables and Certain Changing Table Products for Domestic Use

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act (Act). This Act requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to: (1) examine and assess voluntary safety standards for certain infant or 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 products in section 104 include durable infant or toddler products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. Although the list of products in section 104 does not include changing tables, the Commission specifically identified "changing tables" as a "durable infant or toddler product" in the product registration card rule that the Commission issued under section 104(d). 16 C.F.R. § 1130.2(a)(14).

The Act also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to

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examine and assess the effectiveness of the relevant voluntary standards. This consultation process has been ongoing, with staff's participation in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.[1] In April 2014, staff began this consultation process for domestic changing tables and became involved in changing table task groups.

This briefing package pertains to products included within the scope of the current voluntary standard, ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use* (ASTM F2388-16). This standard applies to changing tables, contoured changing pads, and add-on changing units sold separately for use with furniture that are used in the home. Changing tables used in public facilities, such as in public restrooms, are covered by ASTM F2285, *Standard Consumer Safety Performance Specification for Diaper Changing Tables for Commercial Use* and are not the subject of this briefing package. This briefing package reviews the relevant incident data and assesses the standard's effectiveness. Throughout this memorandum, the term "baby changing products" refers to changing tables and other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables. In addition, the briefing package discusses the potential impact of staff's recommendations on small businesses and reviews recent recalls associated with baby changing products. Finally, this briefing package recommends that the Commission publish a notice of proposed rulemaking (NPR) incorporating by reference the voluntary standard, ASTM F2388-16, with certain modifications to improve requirements addressing collapse, restraint, and warning labels, to serve as the new consumer product safety standard for baby changing products for domestic use.

II. BACKGROUND

A. Product Review

The scope of ASTM F2388-16 includes changing products, such as changing tables, contoured changing pads, and add-on changing units sold separately for use with furniture products other than changing tables.

F2388-16 defines a "changing table" as:

> *An elevated, freestanding structure generally designed to support and retain a child with a body weight of up to 30 lb (13.6 kg) in a horizontal position for the purpose of allowing a caregiver to change the child's diaper. Changing tables may convert from or to other items of furniture, such as, but not limited to, a dresser, desk, hutch, bookshelf, or play yard, may have pull-out or drop-down changing surfaces, and may provide storage for diapers and diaper products.*

[1] ASTM International website: www.astm.org, About ASTM International.

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F2388-16 defines a “contoured changing pad” as:

> *A changing pad designed for use on an elevated surface which incorporates barriers to prevent a child from rolling off the changing surface.*

F2388-16 defines an “add-on changing unit” as:

> *A rigid addition to or separate product used in conjunction with an item of furniture that provides a changing surface or barriers, or both, to prevent the infant from rolling off the product when a diaper is being changed.*

The majority of currently available changing tables and add-on changing units are constructed of wood. Some of these changing tables come with drawers, cabinets, and even retractable stairs. Contoured changing pads are typically some combination of synthetic-covered foam with contoured edges to prevent children from rolling off an elevated surface during a diaper change. Commercial-use changing tables are covered by ASTM F2285 – 04, *Standard Consumer Safety Performance Specification for Diaper Changing Tables for Commercial Use* and are excluded from ASTM F2388. See Figure 1 for a variety of currently available changing products.

Changing Table with storage

Changing Tables with steps

Add-On Changing Unit,

Changing Pad/ Contoured Pad

Commercial use changing table (not in scope - Covered by ASTM F2285 **)**

Figure 1: Changing Tables, Add-On Changing Unit, and Changing Pad

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B. Incident Data

1. Reported Incidents

The Directorate for Epidemiology's Division of Hazard Analysis (EPHA) staff identified 182 incidents, including 30 injuries and five fatalities involving baby changing productss reported to CPSC between January 1, 2005 and December 31, 2015 (Tab A). To identify these incidents, EPHA staff searched the Consumer Product Safety Risk Management System (CPSRMS).[2] Four fatalities occurred when a child was sleeping on the changing table or changing table pad. One fatality occurred when a child was strangled by a strap that was hanging from a changing table accessory on a play yard.

2. National Injury Estimates (NEISS data)

From January 1, 2005, through December 31, 2014, U.S. hospital emergency departments treated an estimated total of 31,780 injuries to victims younger than 3 years of age (sample size=1305, coefficient of variation=0.1533) related to changing tables. Staff observed a statistically significant increasing trend for injuries associated with changing tables over the 2005-2014 period (p-value = 0.0120). EPHA staff limited the search of the NEISS database to the years 2005-2014 because, at the time of preparing their memorandum, the NEISS database was not updated for the year 2015; and thus, reliable estimates could not be obtained for that year.

C. Hazard Patterns

Staff considered the 182 incident reports received to characterize the hazard patterns associated with the use of a domestic baby changing products. EPHA staff identified two hazard patterns associated with more general problems with baby changing productss: (1) one hazard pattern associated with a specific changing table component; and (2) one catch-all hazard pattern that involved miscellaneous incidents that did not fit into the three more specific hazard patterns. In addition, EPHA staff characterized as "unknown," incidents in which the hazard pattern could not be clearly identified (Tab A). The hazard patterns identified by staff are listed below, in descending order of frequency:

1. General product-related:
    a. Issues with ***structural integrity*** were described in 119 (or 65%) of the incident reports related to changing tables. Nearly half of the incidents in this category (55 reports) mentioned changing tables or changing table parts collapsing. Other incidents included: issues with changing table stability, hardware issues (defective screws and bolts), and assembly problems. Additionally, this hazard category

[2] CPSRMS combines the data from IPII (Injury or Potential Injury Incidents), DTHS (Death Certificates), and INDP (In-Depth Investigations) into one searchable incident database.

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includes consumer concerns about a possibility for changing tables collapsing or changing tables appearing unsteady.

b. There were 38 (or 21%) reports of faulty ***design***. The reports were comprised of: children's legs/arms getting trapped in the gaps between slats/rails; pinching of children's fingers by drawers/doors of changing tables; unstable steps; a child hitting his/her head on metal parts of a changing table attached to a play yard; problems with the finish of changing tables (wood or paint chipping); and a strangulation in a restraint strap hanging from a changing table accessory into the play yard the victim was occupying.

2. Specific component-related:

a. Issues with a ***restraining system*** included: straps breaking, the buckle coming loose, restraints detaching from changing tables, creating a choking (small parts) or pinching hazard, and consumer concerns about a lack of restraining straps. There were 14 (or 8%) incidents in this category.

3. Other

a. There were eight (or 4%) ***miscellaneous*** incident reports. The reports included chemical odor such as formaldehyde, and using a changing table for unintended purposes (sleeping).

b. Three reports (or 2%) did not have enough information to determine what caused the incidents. Those cases are categorized as ***unknown***.

D. ASTM F2388, Standard Consumer Safety Specifications for Baby Changing Tables for Domestic Use

ASTM first approved F2388 in 2004. The most recently approved version, F2388-16 (approved July 2016), addresses numerous hazards with several general requirements, most of which are also found in the other ASTM juvenile product standards. A more complete history of ASTM F2388 can be found in the Division of Mechanical and Combustion Engineering (ESMC) Memorandum (Tab B). The following are the general requirements contained in ASTM F2388-16:

- Sharp points and edges
- Small parts
- Lead paint
- Wood parts
- Openings
- Toy accessories
- Protective components

In addition to the general requirements listed above, ASTM F2388-16 contains requirements for marking, labeling, and instructional literature. The standard also contains several performance requirements and test methods specific to baby changing products. Below is a discussion of each performance requirement.

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- Structural integrity

  A 100 pound load (three times the intended occupant weight) is applied to the center of the changing surface for one minute. The purpose of this performance requirement is to reduce the likelihood of a table collapsing or a child breaking through the changing surface while he or she is being changed.

- Stability

  A 45 pound downward force is applied vertically to the edge of the support surface and held for ten seconds. The purpose of this performance requirement is to reduce the likelihood of falls by testing whether the changing surface will remain upright even when an off-center load is applied to the edge of the product.

- Barriers

  Barriers are required to be provided with changing products. Products with flat changing surfaces must have barriers on all four sides, while products with a contoured changing surface are only required to have barriers on the two opposing long sides. The provided barriers must remain intact and be capable of retaining a 12 inch long, 33 pound cylinder with an eight inch diameter (representative of the largest anticipated occupant) when the changing product is tipped to a 15˚ incline and the cylinder rolls into the provided barriers. Each barrier must be capable of retaining the cylinder at this tilted angle for one minute. (Contoured changing pads must first undergo a preconditioning step wherein the cylinder is rolled back and forth 100 times across the surface to "age" the product prior to barrier testing.) These provisions were added to address the fall incidents associated with children rolling off the sides of baby changing products. The requirements also help reduce injuries associated with barriers degrading or splintering after repeated use.

- Retention of contoured changing pads and add-on changing units

  Contoured changing pads and other add-on changing units must not slide more than one inch in any direction while the barrier test is being conducted. This test is meant to reduce the chance of a fall by ensuring pads and other add-on units (sold with or separately from a changing table) remain securely in place even while an occupant rolls back and forth on the changing surface.

- Entrapment in enclosed openings

  All completely bounded openings in areas accessible to an occupant or accessible to a child around the base of a changing unit must comply with probe test requirements. The purpose of this provision is to reduce the likelihood of children getting injured or dying because of suffocation due to getting their heads trapped in an opening.

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- Entrapment by shelves

  Any shelf above 4.3 inches from the floor is subjected to a probe test wherein the small head probe is pushed against the underside of the shelf with a force of 25 pounds and sustained for 10 seconds. This requirement was originally developed to address an incident where a child was found trapped between shelves of a changing table. (Excluded from this requirement are shelves and drawers enclosed within a cabinet equipped with doors.)

Descriptions of these requirements and their associated test methods can also be found in Tab B, the Mechanical and Combustion Engineering Memorandum.

E. Other relevant standards

Staff found one other international standard that addresses baby baby changing products for domestic use in a fashion similar to ASTM F2388-16:

The European standard, EN 12221:2008, *European/British Standard for Changing units for domestic use - Safety requirements and Test methods* ("EN standard")

Tab B provides a detailed comparison of this standard to ASTM F2388. Based on a comparison of the standards in relation to the available incident data, staff concludes that the ASTM standard is more stringent in most areas and addresses the hazard patterns seen in the incident data reported to the CPSC.

F. Compliance Recalls

The memorandum from the Office of Compliance in Tab C discusses the recalls related to baby changing products for domestic use since January 2005. During this time frame, there have been two changing product recalls, covering a total of about 425,000 products. Nearly all of the recalled products involved one company's play yard that had a changing accessory associated with the death of a child. The changing accessory attached to the top of the play yard. The restraint strap of that accessory baby changing product hung down beneath the changing accessory and into the play yard area, where an occupant died after being strangled in the loop formed by the restraint.

The other recalled product (only affecting a total of 130 units) was a cloth, folding changing table secured in place by zippers. If a zipper was misaligned during installation, the product posed a fall hazard, although no falls were reported.

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III. ADEQUACY OF THE CURRENT ASTM F2388 REQUIREMENTS

Staff believes that F2388-16 adequately addresses many of the baby changing product hazards identified in section II of this memorandum. However, ESMC staff found that the current F2388-16 standard is not stringent enough to address the hazards associated with collapse and restraints, and Engineering Sciences Human Factors (ESHF) found inadequacies in the warnings and instructional literature requirements. Staff has been working with the ASTM changing table subcommittee to improve the standard in all three of these areas, as detailed below.

A. Collapse

The current ASTM F2388-16 standard contains a stability and structural integrity performance requirement, but ESMC staff analysis indicates these have not been adequate to address the known incidents of baby changing products collapsing. A review of the incident data by Health Sciences staff (Tab D) revealed that falls from changing products made up the majority of injuries reported through NEISS; and of those hospital reports containing enough detail to determine root cause, table collapse was a reccurring hazard pattern. Additionally, 80 percent of the injuries captured in non-NEISS incidents reported to the CPSC resulted from children falling after structural collapse of changing products. Even though these incident reports included only minor injuries, staff notes that such falls have the potential to result in severe head injuries that could have long-term effects for the victims.

To address the issue of collapsing baby changing products, ASTM established a task group in April 2014 to review the incident reports and begin discussion on how F2388 could be modified to address specific issues found in the incident reports. The current structural integrity test involves gradually loading the center of a changing surface with a 100-pound static load and observing whether the baby changing product is capable of bearing that load for one minute. The stability test requires a table to remain upright when a 45-pound load is applied down on the edge deemed most likely to cause tip over. Based on a review of the incident data, ESMC staff's testing of various models of changing tables, including those reported to be involved in collapse incidents, as well as those not reported in collapse incidents, and finally, after evaluating design features common to tables known to have collapse issues, the task group developed two additional provisions to increase the stringency of ASTM structural integrity performance testing.

First, ESMC staff noted that three of the changing table models most frequently appearing in the collapse incident reports require assembly using self-tapping threaded fasteners, such as wood screws. Staff recommended to the task group certain requirements that prohibit the use of self-tapping threaded fasteners such as wood screws into key wood structural elements assembled by consumers similar to the requirements for cribs. Staff is also recommended means

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to impede loosening and detaching of metal inserts with external wood screw threads for screwing into a wood component and machine screws.

Second, ESMC staff found photographs included in several incident reports and actual incident sample tables in CPSC inventory with either misinstalled or no installation of the secondary support strap under the changing surface. This band or strap is typically one of the last components a consumer is expected to install under the changing surface. Manufacturers typically make changing surfaces out of a thin, light-weight material (like medium-density fiberboard, MDF), and the secondary support strap is intended to add an extra band of support under the center of the changing surface. If the strap is either misinstalled, or, if consumers simply do not install them, the structural integrity of the table is compromised. Therefore, staff recommended that the task group keep all existing performance tests as they are, but suggested adding a provision that simulates this foreseeable misuse (or misassembly) pattern, and also recommended requiring all structural integrity-related testing to be completed *without* the installation of any consumer-installed secondary support straps. Staff's testing showed that most of current changing table construction will meet these requirements.

Staff believes these two modifications will strengthen the structural integrity-related performance testing already existing in the F2388 standard, and staff also believes that these modifications will help identify potentially structurally unsound products. A ballot containing both the self-tapping threaded fastener and the secondary support strap provisions closed on June 15, 2016. Negative responses were found persuasive. The task group will address the negative comments and work to resolve them. After the task group agrees on draft requirements, the proposal will be balloted.

Because the requirements have not been approved by ASTM, staff is recommending that the Commission propose to include these additional requirements as modifications to ASTM F2388-16 for the NPR. The exact language for the provisions can be found in Appendices A and B of the Mechanical and Combustion Engineering memorandum (Tab B). Staff will continue to work with ASTM on resolving this issue before developing a briefing package for a final rule.

B. Restraints

The EPHA memorandum (Tab A) shows that restraint-related incident reports include straps or buckles breaking or detaching. Currently, there is no requirement in the ASTM F2388-16 standard for a restraint to be included as a mandatory feature. If the manufacturer chooses to fabricate a baby changing product with a restraint, ASTM F2388-16 does not contain requirements for the strength of the strap, attachment or buckle. ESHF's review of the incident data showed 10 of the 14 restraint-related reported incidents involved a fall or potential fall, due to a restraint detaching, a buckle releasing, or the restraint straps otherwise failing to function as a method of restraining a child. The restraint-related incidents suggest that consumers expect that when a restraint is provided, it will effectively restrain the child; otherwise, consumers are not likely to report an issue. For this reason, staff believes that a restraint integrity requirement is needed.

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In September 2015, ASTM established a task group to address the pattern of restraint failures found in the incident data. Based on a review of the incident data, a review of ASTM standards covering other durable juvenile products with restraint straps, as well as lab testing completed by ESMC staff, the task group developed a restraint integrity test. The test calls for any restraint provided on a changing product to be secured on an infant CAMI dummy and then pulled in four directions that would be anticipated for a restraint strap to undergo during normal usage. The strap is pulled in each direction with a 30-pound force, and the strap and buckles must not detach from the changing product, release, or loosen more than 1 inch from their initial adjustment position.

Staff testing indicates this additional performance requirement is sufficiently stringent to fail products involved with restraint failure incidents. Staff believes that the new provision will strengthen the F2388 standard and that it will help ensure that restraint straps provided with changing products will function as expected by consumers who choose to use them. The task group discussed an updated version of the restraint integrity test during a July 2016 ASTM task group meeting. Because the requirements have not yet been balloted and approved by ASTM, staff is recommending that the Commission propose to include these additional requirements as modifications to ASTM F2388-16 for the NPR. The exact language that staff recommends for the new restraint performance requirement can be found in Appendix C of the ESMC memorandum (Tab B).

C. Warnings/Labeling

The current ASTM standard contains requirements for warnings and instructional literature, but ESHF staff believes these requirements are not adequate to address the known incidents.

A review of the incident data by Health Sciences (HS) staff (Tab D) revealed that the most commonly reported incidents are falls from a baby changing product. HS also found the most common cause of fatalities related to changing products was caretakers putting/allowing children to sleep on changing products (a usage these products were not intended or designed for).

Based on the frequency of these incidents and the potential severity, ESHF staff does not believe the on-product warning requirements in ASTM F2388 – 16 adequately address the risk of injuries and deaths associated with changing products.

The following warning language is specified in section 9 of the current ASTM F2388 – 16 standard:

> FALL HAZARD – To prevent death or serious injury, always keep child within arm's reach. (§ 9.3.2.1)

Staff recommends that these requirements be replaced or revised with warning requirements that would produce the following warning label for changing tables:

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⚠WARNING

Fall hazard
Children have suffered serious injuries after falling from changing tables. Falls can happen quickly.
- **ALWAYS** keep child within arm's reach.

The requirements recommended by staff would also produce the following warning label for contoured changing pads that attach to a support surface and changing products that attach to play yards:

⚠WARNING

Fall hazard
Children have suffered serious injuries after falling from changing pads. Falls can happen quickly.
- **STAY** in arm's reach.
- **ALWAYS** secure this pad to the support surface by (manufacturer's instructions for securing the changing product).

Suffocation hazard
Babies have suffocated while sleeping on changing pads. Changing pad is not designed for safe sleeping.
- **NEVER** allow child to sleep on changing pad.

* Note that the language "changing pad" will vary slightly from product to product (*e.g.*, changing table, changing area)

The rationale behind these proposed revisions to label content and form can be found in the ESHF memorandum Tab E. The ESHF memorandum also details additional changes to improve readability and consistency among this standard, other ASTM standards, and the work of the ASTM Ad Hoc Wording Task Group, whose purpose is to develop recommended wording for sections of the ASTM standards that are common to multiple juvenile product standards.

ESHF staff finds that the instructional requirements in ASTM F2388 – 16 are similarly inadequate in addressing the risk of injuries and deaths associated with baby changing products. The instructions' inadequacy is primarily due to their lack of any design or form requirements for the required warning statements.

ESHF staff, therefore, recommends that the Commission propose requirements in addition to those in ASTM F2388-16 to require that warnings in the instructional literature meet the same form requirements as the on-product warnings, except that the warnings need not be in color. The rationale behind the proposed revisions to the instructional requirements can also be found in the ESHF Memorandum Tab E.

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V. POTENTIAL IMPACT ON SMALL BUSINESS

Staff identified 85 firms supplying baby changing products to the U.S. market. The majority of these firms (81 firms) supply products marketed to consumers; however, seven firms also market their products to commercial daycares. Most firms (56 firms) supply multiple baby changing products across a variety of product types. Based on U.S. Small Business Administration guidelines, 59 of the 85 firms are small domestic businesses, including 49 manufacturers, nine importers, and one wholesaler.

As described in Tab F, staff cannot rule out a significant economic impact for 40 of the 59 (68 percent) known small suppliers of baby changing products to the U.S. market. Accordingly, staff prepared an Initial Regulatory Flexibility Analysis (IRFA).

Of the 49 small manufacturers, it appears that 17 are unlikely to experience significant economic impacts. However, we could not rule out a significant economic impact for the remaining 32 small manufacturing firms. Based on a review of firm revenues for small importers and wholesalers, as well as the options available to each firm, the impact of the staff-recommended proposed rule may not be significant for two small importers. However, staff cannot rule out a significant economic impact on the remaining eight small importers and wholesalers.

VI. NOTICE OF REQUIREMENTS

Section 14(a) of the CPSA requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. The children's product certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party test laboratories to determine compliance with a children's product safety rule to which a children's product is subject. A proposed rule for baby changing products for domestic use, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission published a final rule regarding *Requirements Pertaining to Third Party Conformity Assessment Bodies*, codified in 16 C.F.R. part 1112 (part 1112). 78 Fed. Reg. 15836 (March 12, 2013). This rule became effective on June 10, 2013. Part 1112 establishes the requirements for accreditation of third party testing laboratories to test for compliance with a children's product safety rule. The final rule also codifies all of the NORs that the CPSC has published, to date, for children's product safety rules. All new children's product safety rules, such as the proposed standard for baby changing products for domestic use, would require an amendment to part 1112 to create an NOR. Therefore, staff recommends that the Commission propose to amend part 1112 to include baby changing products for domestic use in the list of children's product safety rules for which the CPSC has issued NORs.

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VII. EFFECTIVE DATE

Staff is recommending that the Commission propose an effective date of 6 months following publication of the final rule to allow baby changing product manufacturers time to bring their products into compliance after the final rule is issued. A 6-month effective date is consistent with the amount of time that has been given to a number of other section 104 rules. Although staff recommends proposing incorporation of the voluntary standard, with changes, manufacturers who already comply with the voluntary standard, and who routinely comply with changes to the voluntary standard will be in compliance with the regulation (assuming that the voluntary standard ultimately incorporates staff's modifications). Forty-four percent of small suppliers (45 percent of small manufacturers and 40 percent of small importers/wholesalers) already comply with the voluntary standard currently in effect for testing purposes. It is expected that they will remain compliant with the voluntary standard as the standard evolves because these manufacturers follow, and in five cases, actively participate in the standard development process. Six months will also allow time for manufacturers and importers to arrange for third party testing, which is expected to be the most time-consuming component.

VIII. STAFF RECOMMENDATIONS

Staff recommends that the Commission publish an NPR that proposes to incorporate by reference ASTM F2388 – 16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use,* with the modifications to:

1. Add threaded fastner requirments as described in Tab B, Appendix A that:
    - prohibit of the use of self-tapping screws, such as wood screws, for consumer assembly into key structural wood components as described in Tab B, Appendix A,

    - require baby changing products that use metal inserts, with external wood screw threads for screwing into a wood component and providing internal machine threads to accommodate a machine screw, that are used to secure key structural elements shall be glued or include other means to impede loosening or detaching as described in Tab B, Appendix A.

    - require baby changing products that use metal threaded fasteners, such as sheet metal screws and machine screws, secured into metal components and used to attach key structural elements shall have lock washers, self-locking nuts, or other means to impede loosening or detaching as described in Tab B, Appendix A.

- Add the structural integrity requirement (testing carried out *without* the addition of the often misassembled/omitted consumer-installed secondary support strap) as described in Tab B, Appendix B.

- Add a restraint integrity requirement as described in Tab B, Appendix C.

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- Modify the warnings and labeling requirements, as described in the Division of Human Factors memorandum, Tab E.

Staff also recommends that the NPR propose to amend 16 C.F.R. part 1112, which establishes requirements for testing laboratories, to include baby changing products.

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TAB A: Changing Table-Related Deaths, Injuries, and Potential Injuries; January 1, 2005 – December 31, 2015

TAB A

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

Memorandum

Date: March 4, 2016

TO : Shaina Donahue, Project Manager, Changing Tables
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka, Associate Executive Director
Directorate for Epidemiology

Stephen Hanway, Division Director
Division of Hazard Analysis

FROM : Wioletta Szeszel-Fedorowicz, Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Estimated Number of Injuries and Reported Incidents Associated with Changing Tables, 2005-2015[3]

I. Introduction

This memorandum provides information about the estimated number of emergency department-treated injuries associated with changing tables in the years 2005–2014. It also contains information about incidents reported to the CPSC associated with changing tables in the years 2005–2015. For this memorandum, CPSC staff searched two CPSC databases: the National Electronic Injury Surveillance System (NEISS) and the Consumer Product Safety Risk Management System (CPSRMS).[4] CPSC staff limited the search of the NEISS database to the years 2005–2014 because, at the time of preparing this memorandum, the NEISS database was not updated for the year 2015, and thus, reliable estimates could not be obtained for that year.

The ASTM voluntary standard F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, covers "baby changing tables and other changing surfaces,

[3] This analysis was prepared by CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

[4]The NEISS database contains the emergency department-treated injuries in a sample of hospitals nationwide. CPSRMS combines the data from IPII (Injury or Potential Injury Incidents), DTHS (Death Certificates), and INDP (In-Depth Investigations) into one searchable incident database. Staff's search of the NEISS database and the CPSRMS' database included product codes: 1502 (changing table), 1513 (playpens and play yards), 1529 (portable cribs), 1537 (bassinet or cradles), 1542 (baby mattresses or pads), 1543 (cribs), 1544 (baby bath or bathinettes), 1545 (cribs, not specified), and 0604 (desks, dresser, chest, bureaus or buffets). Staff extracted the NEISS reports on April 24, 2015; whereas, staff extracted the CPSRMS data on January 4, 2016. Upon joint review of the NEISS and CPRMS' data with CPSC's Directorate for Economic Analysis, Division of Human Factors, Division of Mechanical Engineering, Division of Pharmacology and Physiology Assessment, Office of the General Counsel, and Office of Compliance, some incidents were considered out of scope for the purpose of this memorandum. For example, staff excluded incidents involving children hitting their heads on changing tables when running.

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such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables . . . sold for domestic use for children up to a weight of 30 lbs. (13.6 kg)." This memorandum includes incidents associated with domestic- and day care-setting use of changing tables and other add-on changing products used with play yards and dressers. To comply with the weight restriction in the ASTM standard, the memorandum covers only injuries and incidents among children younger than 3 years of age. According to the Center for Disease Control and Prevention (CDC), the weight of 30 lbs. corresponds to the 50th percentile (median) weight for boys at age 31 months and to the median weight for girls at age 34 months.[5] For that reason, staff decided to focus on the incidents involving children younger than 3 years of age.

II. Injury Estimates[6]

1. Overview

There were an estimated 31,780 emergency department-treated injuries associated with changing tables to victims younger than 3 years of age from January 1, 2005 to December 31, 2014. The 95 percent confidence interval (C.I.) for this estimate is 22,240 to 41,350, based on a coefficient of variation (C.V.) of 0.1533.

2. Yearly Injury Estimates

Staff generated yearly estimates of emergency department-treated injuries associated with changing tables for 2005 through 2014 (Table 1). The yearly estimates ranged from 2,340 in 2005, to 4,140 in 2013. The yearly estimates for the early years were below 3,000 emergency department-treated injuries. In more recent years, starting from the year 2009, the yearly estimates were higher than 3,000. There was a statistically significant increasing trend for injuries associated with changing tables over the studied period (p-value = 0.0120).

[5] http://www.cdc.gov/growthcharts/data/set1clinical/cj41l017.pdf.
http://www.cdc.gov/growthcharts/data/set1clinical/cj41c018.pdf.
[6]The injury estimates are based on NEISS data.

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Table 1: Estimated Emergency Department-Treated Injuries Associated with Changing Tables to Victims Under 3 Years of Age, 2005–2014

Year	Observations	Estimate	95% C.I.	C.V.
2005	97	2,340	1,620–3,070	0.1584
2006	108	2,700	1,510–3,900	0.2251
2007	102	2,530	1,440–3,610	0.2188
2008	100	2,460	1,440–3,480	0.2110
2009	146	3,510	2,110–4,910	0.2034
2010	144	3,710	2,630–4,800	0.1492
2011	145	3,310	2,070–4,540	0.1903
2012	176	4,050	2,850–5,250	0.1512
2013	145	4,140	2,270–6,000	0.2304
2014	142	3,060	1,130–4,990	0.3211
Total	1,305	31,780	22,240–41,350	0.1533

Source: NEISS, April 2015
The estimates may not sum to the totals due to rounding.

3. Injury Characteristics

Staff characterized the injuries treated in emergency departments involving changing tables by victim age and gender, the body part injured, the injury diagnosis and the disposition.

The estimated emergency department-treated injuries involving changing tables by age category are shown in Table 2. Seventy-six percent of the estimated injuries were in the 0 to 11 months age group, and 94 percent of the estimated injuries involved children under the age of 2.

Table 2: Estimated Emergency Department-Treated Injuries Associated with Changing Tables by Age Category, 2005–2014

Age (months)	Estimate	% Total
0 to 11	24,290	76%
12 to 23	5,760	18%
24 to 35	1,750	6%
Total	31,780	100%

Source: NEISS, April 2015
The estimates may not sum to the totals due to rounding.

Further analysis of victim age within the 0-11-month age category is presented in Figure 1. Children ages 6 months to 8 months old had the highest percentage (44%) of emergency

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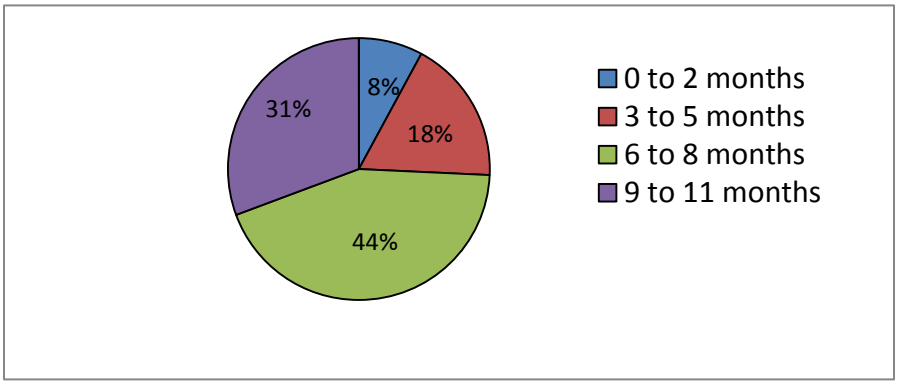
department-treated injuries among children under 1-year old, followed by children age 9-11 months old (31%).

Figure 1: Percentage of Estimated Annual Emergency Department-Treated Injuries for Children Younger than 1 Year Old.



Source: NEISS, April 2015
The percentages may not sum to the totals due to rounding.

The estimated emergency department-treated injuries by body part associated with changing tables involving children younger than 3 years old are presented in Table 3. The majority of the injuries were to the head (71%) or the face (13%).

Table 3: Estimated Emergency Department-Treated Injuries Associated with Changing Tables to Victims Under 3 Years of Age by Body Part Injured, 2005-2014

Body Part*	Estimate	% Total
Head	22,450	71%
Face	4,060	13%
Arm	2,210	7%
Leg	1,510	5%
Other	1,580	5%
Total	31,780	100%

Source: NEISS, April 2015
**The body part groups were based on NEISS body part codes; the face includes eyelid, eye area, and nose.*
The estimates may not sum to the totals due to rounding.

In the years 2005 to 2014, the most common estimated injury diagnosis for emergency department-treated visits related to changing tables for children under 3 years old was internal organ injury (50%). Contusions/abrasions accounted for 27 percent of the estimated injuries, fractures for 9 percent, and lacerations for 5 percent.

Most of the internal organ injury diagnoses associated with changing tables were head injuries—specifically, more than 99 percent of all estimated cases of internal organ injury diagnoses associated with changing tables were head injuries. In more than 83 percent of estimated cases with a contusions/abrasions diagnosis, the head or face were the affected body parts.

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The NEISS data showed that males younger than 3 years old (50%) were injured with the same frequency as females of the same age (50%).

In 94 percent of the estimated emergency department-treated injuries, the child was treated and released, and in 5 percent of the cases, the child was hospitalized.

III. Review of Incident Data[7]

1. Overview

CPSC staff is aware of 182 incidents associated with changing tables that occurred in the years 2005 to 2015. The reported incidents include: five fatalities, 30 injuries/adverse health problems, 113 non-injury incidents, and 34 incidents that did not have enough information to determine if an injury occurred. Among the injury incidents, cuts, lacerations, and scratches and bruises were the most frequently mentioned injuries. Two injuries (skull fracture and lower leg fracture) resulted in hospitalizations, and one leg injury resulted in an emergency department visit. Staff's review of incidents reported to CPSC revealed that 118 reports mentioned either children falling from changing tables, or a potential risk for falling from changing tables. In six cases, caregivers caught falling children, possibly preventing more injuries.

2. Deaths

CPSC staff is aware of five deaths involving changing tables that occurred sometime between January 1, 2005 and December 31, 2015. Four fatalities occurred as a child was sleeping on the changing table or changing table pad. One fatality occurred when a child was strangled by a strap that was hanging from a changing table accessory on a play yard. All victims were under 1 year old. The fatal incidents are described in more detail below.

There were two reports of fatal incidents associated with changing tables in 2007. A 10-month-old male was left unattended for 5 minutes in his play yard with the changing table accessory attached to the top of the rails of the play yard. The victim's mother found him hanging with the strap from the changing table accessory around his neck. The victim was transported to a local hospital. The victim did not have any brain activity and was taken off of the life support system 2 days later. Another fatal incident occurred in 2007, when a 2-month-old female was sleeping in the changing table accessory attached to a play yard. The victim's mother found the victim face down with her face pushed up against one of the changing table's ends. Based on the autopsy report, the incident was ruled an accident, with the official cause of death listed as positional asphyxia.

Two deadly incidents reported to CPSC occurred in 2008. A 6-week-old female was sleeping on a changing table accessory that was attached to a play yard. Her father found her face down in the changing table, which was centrally depressed, creating a "v shape" form. The cause of death was asphyxia due to mechanical compression. The second fatal report in 2008, involved a 4-

[7]CPSC staff searched the CPSRMS

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month-old male. He was positioned on his back on a changing table pad, which was placed on the top of a mattress in the victim's crib. The pad was smaller than the area of the crib. The victim rolled over. The mother found him with his head hanging over the side of the changing pad and the raised side of the pad was across his neck. The cause of death was determined to be positional asphyxia due to the victim's neck pressing on the raised side edge of the changing table pad.

In 2013, a 2-month-old girl and her parents were having a sleepover at a friend's house. The girl was placed to sleep on a "fluffy" blanket in the changing table accessory attached to the play yard. She was positioned on her left side with her back towards the high side of the changing area attachment. The victim rolled onto her stomach and was found the next morning by her parents face down in the "fluffy" blanket. The girl's death was ruled as accidental positional asphyxia. A coroner's report stated that the changing area had a sloped surface.

IV. Hazard Patterns

1. Emergency Department-Treated Cases (NEISS Data)

NEISS data revealed that a majority (94%) of the emergency-department treated injuries associated with changing tables were attributed to a child falling/rolling off of a changing table. Three percent of the estimated injuries involved an impact on the changing table. NEISS data, with a few exceptions, did not provide enough scenario-specific information on the cause of the falls. From among the injury reports with sufficient detail available, CPSC staff identified the following hazard categories (in order of descending frequency):

- Problem with changing table ***design***. These included injuries associated with children's legs/feet being entrapped in a changing table slat/rail, legs caught in a hinged door on a changing table, and fingers getting caught in the changing table.

- Lack of changing table ***structural integrity***. These included reports of changing tables collapsing, and consequently, causing children to fall.

2. Incident Data

Staff examined the 182 reports of incidents associated with changing tables to determine the hazard that lead to the reported incidents. Staff categorized the hazards into five groups, presented in Figure 2.

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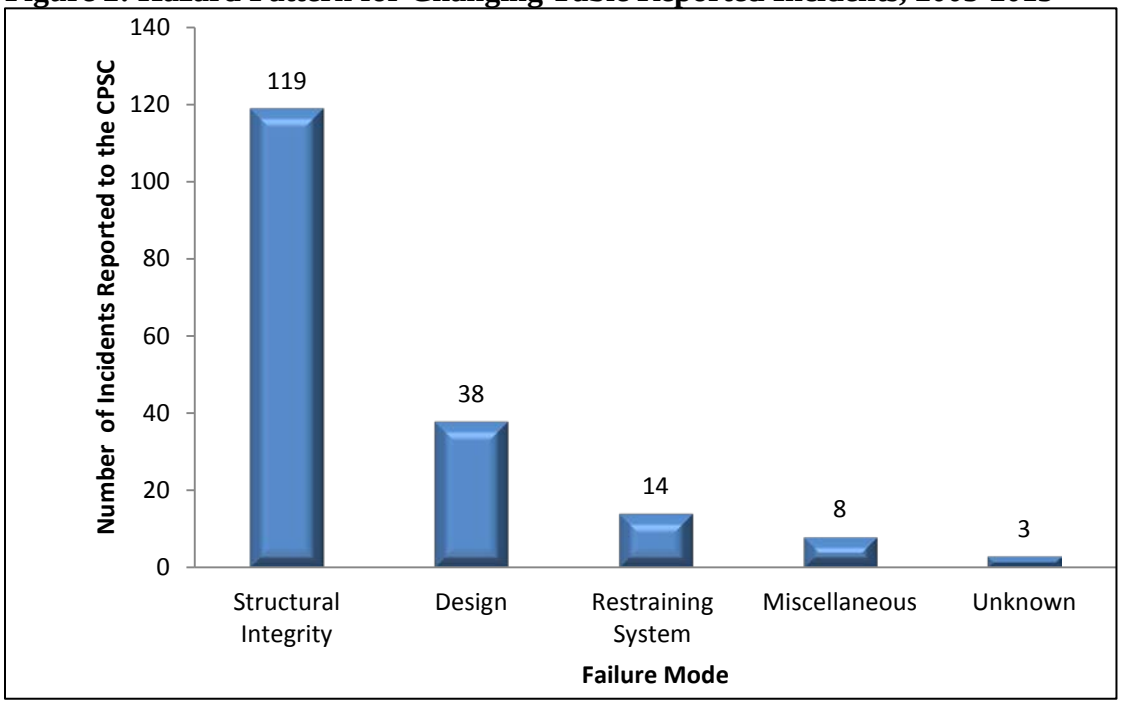
Figure 2: Hazard Pattern for Changing Table Reported Incidents, 2005-2015



Source: CPSRMS, January 2016

- Issues with ***structural integrity*** were described in 119 (or 65%) of the incident reports related to changing tables. Nearly half of the incidents in this category (55 reports) mentioned changing tables or changing table parts collapsing. Other incidents included: issues with changing table stability, hardware issues (defective screws and bolts), and assembly problems. Additionally, this hazard category includes consumer concerns about a possibility for changing tables collapsing or changing tables appearing unsteady.

- There were 38 (or 21%) reports of faulty ***design***. The reports were comprised of: children's legs/arms getting trapped in the gaps between slats/rails; pinching of children's fingers by drawers/doors of changing tables; unstable steps; a child hitting his/her head on metal parts of a changing table attached to a play yard; problems with a changing table finish (wood or paint chipping); and a strangulation in a restraint strap hanging from a changing table accessory into the play yard the victim was occupying.

- Issues with a ***restraining system*** included: straps breaking, coming loose out of the buckle, detaching from changing tables, creating a choking (small parts) or pinching hazard, and consumer concerns about lack of restraining straps. There were 14 (or 8%) incidents in this category.

- There were 8 (or 4%) ***miscellaneous*** incident reports. The reports included chemical odor such as formaldehyde, and using a changing table for an unintended purpose (sleeping).

- Three reports (or 2%) did not have enough information to determine what caused the incidents. Those cases were categorized as ***unknown***.

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V. Summary

Analysis of NEISS data associated with changing tables showed:

- There were an estimated 31,780 emergency department-treated injuries in the years 2005-2014 to victims younger than age three.
- There was a statistically significant increasing annual trend of estimated emergency department-treated injuries over the years 2005-2014.
- The majority of emergency department-treated injuries involved children under the age of 1 year, with the head as the most frequently injured body part.
- A child falling/rolling off of a changing table was the most frequently reported event associated with an injury.

In the incident data:

- There were five reports of deaths in the years 2005-2015: four due to asphyxia, one due to strangulation.
- Structural integrity failure and faulty design were the most frequently reported hazards.

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TAB B: ESMC Staff's Review and Evaluation of ASTM F2388-16, Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use

TAB B

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

Memorandum

August 4, 2016

TO: Mark Kumagai, P.E., Director
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

FROM: Shaina Donahue
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

SUBJECT: ESMC Staff's Review and Evaluation of ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, for Incorporation by Reference into Staff's Draft Proposed Rule

I. INTRODUCTION

CPSC's Directorate for Engineering Sciences, Division of Mechanical and Combustion Engineering (ESMC) staff was tasked to assess the effectiveness of ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, for rulemaking activity under section 104 of the Consumer Product Safety Improvement Act. This standard applies to baby changing products of various styles that are used in the home. Changing tables used in public facilities, such as in public restrooms, are covered by ASTM F2285, *Standard Consumer Safety Performance Specification for Diaper Changing Tables for Commercial Use* and are not the subject of this briefing package. This evaluation covers the evolution of the F2388 standard and how effectively the current edition addresses common hazard patterns found in reported incident data (most of which relate to falls and table collapses). The assessment also compares the ASTM standard to other international baby changing product standards. This memorandum substantiates ESMC staff's recommendation to incorporate by reference the F2388-16 standard into the proposed mandatory rule, with several modifications to strengthen the standard. Throughout this memorandum, the term "baby changing products" refers to changing tables and other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables.

II. PRODUCTS

ASTM F2388-16 defines a changing table as:

> *an elevated, freestanding structure generally designed to support and retain a child with a body weight of up to 30 lb (13.6 kg) in a horizontal position for the purpose of allowing a caregiver to change*

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the child's diaper. Changing tables may convert from or to other items of furniture, such as, but not limited to, a dresser, desk, hutch, bookshelf, or play yard, may have pull-out or drop-down changing surfaces, and may provide storage for diapers and diaper products.

The F2388 standard covers baby changing products including changing tables, contoured changing pads, and add-on changing units sold separately for use with furniture products other than changing tables. The majority of currently available baby changing products and add-on changing units are constructed of wood. Some of these tables come with drawers, cabinets, and even retractable stairs. Contoured changing pads are typically some combination of synthetic-covered foam with contoured edges to prevent children from rolling off. They can be used anywhere for the purpose of changing a baby's diaper on an elevated surface. See Figure 1 for a variety of currently available changing products.

Changing Table with storage

Changing Tables with steps

Add-On Changing Unit,

Changing Pad/ Contoured Pad

Commercial use changing table (covered by ASTM F2285, *Standard Consumer Safety Performance Specification for Diaper Changing Tables for Commercial Use*)

Figure 1: Changing Tables, Add-On Changing Unit, and Changing Pad

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III. SIGNIFICANT PROVISIONS OF ASTM F2388-16

ASTM F2388-16 addresses numerous hazards with several general requirements, most of which are also found in the other ASTM juvenile product standards. The following are the general requirements contained in ASTM F2388-16:

- Sharp points and edges
- Small parts
- Lead paint
- Wood parts
- Openings
- Toy accessories
- Protective components

In addition to the general requirements listed above, ASTM F2388-16 contains requirements for marking, labeling, and instructional literature. The standard also contains several performance requirements and test methods specific to baby changing product products. Below is a discussion of each performance requirement.

- **Structural integrity**
  A 100 pound load (three times the intended occupant weight) is applied to the center of the changing surface for one minute. The purpose of this performance requirement is to reduce the likelihood of a table collapsing or a child breaking through the changing surface while he or she is being changed.

- **Stability**
  A 45 pound downward force is applied vertically to the edge of the support surface and held for ten seconds. The purpose of this performance requirement is to reduce the likelihood of falls by testing whether the changing surface will remain upright even when an off-center load is applied to the edge of the product.

- **Barriers**
  Barriers are required to be provided with changing products. Products with flat changing surfaces must have barriers on all four sides, while products with a contoured changing surface are only required to have barriers on the two opposing long sides. The provided barriers (including contoured sides) must remain intact and be capable of retaining a 12 inch long, 33 pound cylinder with an eight inch diameter (representative of the largest anticipated occupant) when the changing product is tipped to a 15˚ incline and the cylinder rolls into the provided barriers. Each barrier must be capable of retaining the cylinder at this tilted angle for one minute. (Contoured changing pads must first undergo a preconditioning step wherein the cylinder is rolled back and forth 100 times across the surface to “age” the product prior to barrier testing.) These provisions were added to address the fall incidents associated with children rolling off the sides of baby changing products. The requirements also help reduce injuries associated with barriers degrading or splintering after repeated use.

- **Retention of contoured changing pads and add-on changing units**
  Contoured changing pads and other add-on changing units must not slide more than one inch in any direction while the barrier test is being conducted. This test is meant to reduce the chance of a fall by ensuring pads and other add-on units (sold with or separately from a

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changing table) remain securely in place even while an occupant rolls back and forth on the changing surface.

- **Entrapment in enclosed openings**
  All completely bounded openings in areas accessible to an occupant or accessible to a child around the base of a changing unit must comply with this probe testing requirement. No such openings shall allow the free passage of the five inch torso probe, unless they also allow passage of the nine inch head probe (probes shown in Figure 2). The purpose of this provision is to reduce the likelihood of children getting injured or dying because of suffocation due to getting their heads trapped in an opening.

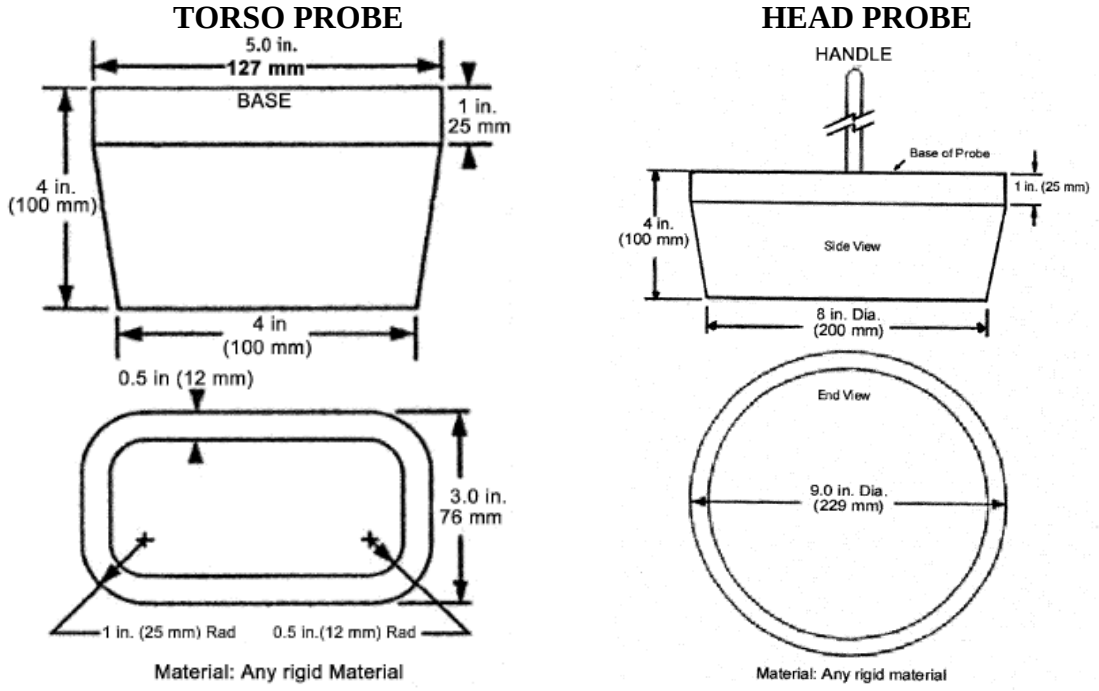

Figure 2: Small Torso and Large Head Probes

- **Entrapment by shelves**
  Any shelf above 4.3 inches from the floor is subjected to a probe test wherein the small head probe (Figure 3) is pushed against the underside of the shelf with a force of 25 pounds and sustained for 10 seconds. This requirement was originally developed to address an incident where a child was found trapped between shelves of a changing table. (Excluded from this requirement are shelves and drawers enclosed within a cabinet equipped with doors.)

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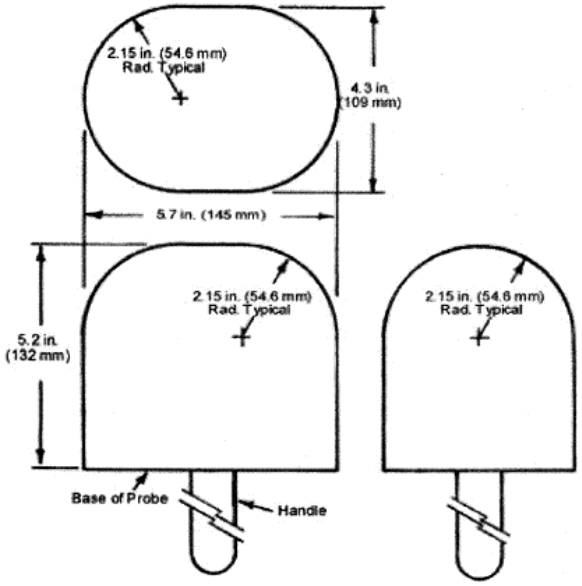

Figure 3: Small Head Probe

IV. ADEQUACY OF ASTM F2388-16 REQUIREMENTS

This section reviews the identified hazard patterns associated with the incident data collected by the CPSC between January 1, 2005 and December 31, 2015, and the applicable requirements found in ASTM F2388-16. The hazard patterns found in the incident reports are summarized in Table 1 and are presented in order of frequency.[8]

TABLE 1: Hazard Patterns Found in Incident Data

	Hazard	Total CPSRMS Incidents
A	Structural Integrity	119
B	Design	38
C	Restraining System	14
D	Miscellaneous	8
E	Unknown	3

After reviewing the incident data, staff considered each pattern in assessing the adequacy of ASTM F2388-16 and developing recommended requirements. Beginning in September 2014, CPSC staff suggested improvements to the ASTM changing tables subcommittee to address the common hazard patterns apparent in the incident data. Specifically, at the September 2014 ASTM subcommittee meeting, staff presented a pattern of table collapse incidents, and at the October 2015 ASTM subcommittee meeting, the pattern of issues related to restraint failures was presented. Since CPSC staff presented these safety hazard patterns, ASTM subcommittee task groups have been working cooperatively with staff to improve the effectiveness of ASTM F2388. Each identifiable hazard pattern found in the incident data, along with the applicable ASTM F2388-16 requirements, and CPSC staff's recommendations, are presented below.

Structural Integrity: The majority of NEISS injuries were due to falls from a baby changing product (Tab A). However, because of the limited information in the NEISS reports, it is difficult

[8] Data source: Memorandum from the Directorate for Epidemiology (Tab A).

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to determine the cause of the fall for most of the injuries. Nevertheless, there were a number of emergency department-treated injuries in CPSC's NEISS system that specifically mentioned the falls were a result of a collapse.

The CPSRMS incident reports indicating structural integrity issues commonly involved tables collapsing or being unstable. Nearly half (55) of the structural integrity incidents reported to the CPSC involved the top changing surface cracking or collapsing, with more than 50 percent of these reports involving just three particular changing table models manufactured in 2009-2010. There were only a few injury reports describing minor injuries, such as scrapes and bumps, associated with these collapsing tables. The other main structural integrity hazard pattern was table instability, of which half of these reports were consumer observations that the cantilevered changing accessory on their play yards tilted downward with the weight of their occupants. No injuries resulted.

ASTM F2388-16 contains several provisions that address these structural integrity hazards: the stability test (the table must remain upright when a 45 pound load is applied to the edge deemed most likely to cause a tip-over incident), as well as the structural integrity test (changing units must be capable of holding a 100 pound load for a minute without sustaining damage). However, these tests have not changed significantly since 2004, when the initial standard was published. Therefore, the number of structural integrity incidents reported to the CPSC indicates that the existing provisions, thus far, have been inadequate in addressing these hazard patterns.

Therefore, staff recommends adding in the NPR, two modifications to strengthen the existing structural integrity provisions in ASTM F2388-16:

1. Threaded fasteners installed by the consumer into key structural componets shall have means to impede loosening or detaching. Specificly:
    - Baby changing products shall **not** require consumer assembly of key structural elements using self-tappping screws (wood screws or sheet metal fasteners) directly into wood components. Three of the models involved in collapse incidents required consumer assembly with wood screws. Wood screws are not always installed properly on the first attempt, and second tries can lead to stripped or less secure connections. It is also not always obvious when a wood screw is "tight enough" and consumers may err on the side of overtightening (which can crack the component being attached, leading to an unstable joint). Or the opposite may happen, and the consumer may attempt to avoid cracks by under-tightening screws, also leading to less stable joints. Since changing tables are pieces of juvenile "furniture" used only for certain periods of time, consumers may also disassemble them for storage and then reassemble later for use with a second child. At that time, all the screws may be reconnected into the same, pre-existing holes left from the initial assembly and reconnecting a wood screw into a previously used hole typically leads to a less structurally sound connection.

    - Baby changing products that use metal inserts, with external wood screw threads for screwing into a wood component and providing internal machine threads to accommodate a machine screw, that are used to secure key structural elements shall be glued or include other means to impede loosening or detaching.

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- Baby changing products that use metal threaded fasteners, such as sheet metal screws and machine screws, secured into metal components and used to attach key structural elements shall have lock washers, self-locking nuts, or other means to impede loosening or detaching.

2. Tables must be capable of supporting the 100 pound load, as outlined in the existing structural integrity test, *without* any consumer-installed secondary support straps. Many stand-alone changing tables utilize a metal strap, rod or other type of component under the changing surface to provide added support. See Figure 4 for examples of these secondary support components. As part of staff's testing program, staff purchased used, exemplar changing tables directly from consumers. Some of these tables were observed to have a secondary support component that was either misinstalled by the consumer or not installed at all. In addition, incident changing tables collected as samples, or viewed in incident report photos, were also observed to have issues with the consumer installed support component. Therefore, staff concludes that it is foreseeable misuse for secondary support components to not be used in the manner intended by the manufacturer. See Appendix B for a draft of this proposed provision.

Figure 4: Examples of Secondary Support Straps Beneath Changing Surfaces

Based on the analysis above, staff concludes the existing ASTM F2388-16 performance requirements, in combination with the recommended additional requirements and modifications, will adequately address the various structural integrity hazard patterns (See Appendix A, B for a draft of this proposed provision).

Design: The product design-related incidents included:

- issues with finish (*i.e.*, chipping surface coatings).
- Side railings that allow the child's leg/arm to become entrapped in the gaps between the slats
- Storage compartments that allow the child's fingers/hands to become entrapped or pinched in drawers or door hinges.

Many of the issues captured in this category are addressed through ASTM F2388-16's general requirements, such as openings, protective components, sharp edges, small parts, and

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wood parts/finishes. ASTM F2388-16 also includes provisions to reduce the likelihood of hazardous head entrapments in enclosed openings or in shelf features.

Currently, staff is not recommending any changes to address reports of limbs or fingers getting entrapped in the slat openings of the side rail. The opening requirements are intended to prevent potentially fatal head entrapment incidents. These requirements are the same for crib slats and have been effective in addressing fatal head entrapments.

At this time, staff is not recommending requirements to address incidents involving finger and hand pinches, lacerations and amputations in drawers, doors and door hinges of the storage components. The drawers, cabinet doors and hinge components are not hazards accessible to children occupying changing tables. Incidents have occurred to children who were not on the changing surface. These components are not unique to changing tables and are commonly used in other types of furniture, such as dressers and cabinets. Therefore, requirements to address these incidents, such as a finger pinch in a drawer, may not be feasible without eliminating the function of the furniture.

Staff has determined that the finger amputation and lacerations occurred in a particular-style hinge mechanism for a cabinet door on a particular model-changing table. At this time, staff has not been able to determine exactly how the incidents occurred and whether these incidents are isolated to one manufacturer. CPSC staff will continue to analyze these incident reports, monitor the incidents, and, if necessary, staff will make recommendations to the subcommittee for requirements to address these issues.

Based on the analysis above, staff believes that the existing performance requirements adequately address the serious and known hazard patterns associated with design issues. Staff is concerned with the incidents of amputation and lacerations from hinge mechanisms. However, staff does not have enough information to determine whether requirements in the standard are feasible. Staff will continue to analyze these incident reports, monitor the incidents, and, if necessary, staff will make recommendations to the subcommittee for requirements to address these issues.

Restraining System: This hazard category includes incident reports regarding broken straps, straps pulling loose from their attachments, and buckles cracking or failing to remain secure. In addition, consumers have observed the lack of a restraint altogether.

Currently, the ASTM F2388-16 standard contains no provisions to address restraints. In fact, there is no requirement in the standard for restraints to be included as a mandatory feature. During past discussions where such a requirement was considered, it was rejected on the basis that requiring restraints provides a level of perceived safety that might encourage caregivers to be less attentive to the child on the table. Hazards associated with a child rolling off the table are currently addressed with the barrier performance requirement. The standard does not prohibit restraint straps; on the other hand, because there is no requirement mandating their existence, there are no restraint system performance tests.

ASTM established a task group to review the data and provide a recommendation to the subcommittee. The task group is currently working on the revision and the revision includes a restraint integrity test that would require restraints to remain attached and secure when pulled with a specified force. The current draft requirement developed by the task group is captured in

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Appendix C. At the task group meeting on July27, 2016, the draft revision was discussed; however, more revisions were needed to the test method. The task group intends to revise the draft and submit a ballot to the main committee in the future.

ESHF review of the incident data in Tab E, showed 10 of the 14 reported restraint-related incidents involved a fall or potential fall, due to a restraint detaching, a buckle releasing, or the restraint straps otherwise failing to function to restrain a child. The restraint-related incidents suggest that consumers expect that when a restraint is provided, it will effectively restrain the child. Otherwise, consumers are not likely to report an issue. For this reason, staff believes that a restraint-integrity requirement is needed.

Based on the analysis above, ESMC staff concludes that the task group's proposed restraint integrity test (Appendix C) would adequately address this hazard pattern. For this reason, staff is recommending adding this requirement to the standard in the NPR.

Miscellaneous: This category includes miscellaneous issues found in the incident reports, including using a baby changing product for unintended purposes (sleeping), or concerns of tables having unsafe levels of chemical content. All of the deaths associated with baby changing products involved occupants left to sleep on or below baby changing products. The memorandum from the Division of Human Factors, Tab E, outlines proposed requirements for labeling and instructional literature, which are intended specifically to reduce these unsafe sleeping incidents. The ASTM subcommittee has already proposed many of these requirements for ballot. The chemical concerns are addressed through ASTM F2388-16's general requirement for compliance with 16 C.F.R. part 1303.

ESMC staff's analysis indicates that the existing performance requirements, in combination with the proposed warning/labeling updates included in the Division of Human Factors memorandum, adequately address the miscellaneous hazard patterns captured in this category.

Unknown: Some reports did not include enough information for CPSC staff to determine how the incidents occurred. The lack of information available in these incident reports made it impossible to do an adequacy assessment for these cases.

V. HISTORY OF F2388

ASTM has published seven versions of F2388, starting with the first standard in 2004. The history of the recent revisions is captured below, beginning with F2388-04 (published July 2004), through the most recently approved version, F2388-1 (published July 2016).

1. ASTM F2388-04 (approved on July 1, 2004) contained requirements to address the following topics:
    - Sharp points and edges
    - Small parts
    - Surface coatings (lead paint)
    - Wood surface finishes
    - Openings
    - Protective components
    - Structural integrity (to ensure changing units can support up to a 100 lb load)

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- Stability (to help prevent tip overs when up to a 45 lb load is applied to the most unstable edge)
- Barriers (to test whether barriers can retain a maximum weight occupant when he/she rolls into the barrier)
- Entrapment in enclosed openings (to help prevent suffocation by limiting the completely bounded openings a child may get his or her head caught in)
- Entrapment by shelves (to help prevent suffocation by checking that a shelf cannot be pushed up and then trap a head in an enclosed opening).

2. ASTM F2388-04$^{\varepsilon 1}$ (correction approved October 2004) included a minor editorial correction to a figure.

3. ASTM F2388-06 (approved on November 1, 2006) added requirements, including:
   - Expansion of the scope, definitions, test methods, and warning/labeling requirements to cover changing products beyond just changing tables: now includes contoured changing pads and add-on changing units
   - A pre-conditioning (aging) test for contoured changing pads to undergo before barrier testing
   - A requirement for retail packaging to indicate the maximum occupant weight for which the product is designed
   - Minor revisions to instructional literature requirements.

4. ASTM F2388-08 (approved on May 1, 2008) added requirements to address the following:
   - All units provided in inch-pounds are to be taken as standard while the SI units provided parenthetically are for information only (not standard)
   - Toy accessories provided with the changing product must meet applicable requirements of F963, *Standard Consumer Safety Specification for Toy Safety*
   - For add-on or sold-separately changing products, warnings must be visible on or through packaging to address product compatibility.

5. ASTM F2388-08a (approved on July 1, 2008) included:
   - A rationale to explain why flat changing surfaces need barriers on four sides, while contoured changing surfaces only need barriers on two sides.

6. ASTM F2388-09 (approved on August 1, 2009) included a clarification:
   - Changing pads secured by straps or tabs shall not slip more than one inch in the direction opposite from the side the straps or tabs are anchored.

7. ASTM F2388-15 (approved on April 1, 2015) included minor editorial revisions and the following new definition:
   - For *support surface,* to clarify the component on which changing pads or add-on units are mounted.

8. ASTM F2388-16 (approved July 1, 2016) included:
   - A new definition for *self-folding steps,* which are held open by an adult caregiver and, when released, automatically fold into the changing table.

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- An exemption from the entrapment in enclosed openings requirements when the self-folding steps are in the open position.

VI. OTHER RELEVANT STANDARDS

Staff found one other standard, an international standard, which addresses baby changing products in a fashion similar to ASTM F2388-16: the European Standard BS EN 12221:2008, *Changing units for domestic use – Safety requirements and test methods*. The most recent version of EN 12221 was approved on February 18, 2008.

The EN 12221:2008 standard has general and accessory component requirements to address:

- Materials, including decay-free wood surfaces and coatings/chemical restrictions
- General construction, such as openings, sharp edges, small parts, and use of self-tapping screws
- Other components/accessories, including changing board flaps, castors/wheels, table folding mechanisms, extension elements, and child bath tubs.

In summary, the relevant differences between the ASTM standard and the European standard, as well as their relative merits, are:

- Both ASTM and EN require changing tables to be able to withstand supporting a load of about three times the intended occupant weight, without breaking. ASTM requires that a load be placed on a 6-inch square block in the middle of the changing surface. EN requires the load to be distributed uniformly across the entire changing surface. Typically, the weakest point on the changing table is the center of the table. Therefore, the concentrated load in the middle of the changing table, as specified by the ASTM standard, is a more stringent test than a distributed load, as specified in the EN standard. Staff is also recommending that the requirements be met without assembling the secondary support strap to address incidents due to misassembly. The recommended modification to this static load test (which will leave the secondary support strap disassembled) will further render ASTM the more stringent test.

- The EN standard stability test differs from the ASTM test procedure in several ways. In the EN requirement, stability is tested by attaching a beam to the top of the changing table and applying a downward force across a specified distance along that beam outward from the table. The EN test is repeated with the table loaded with both the minimum and maximum intended occupant weights. Because the ASTM standard simply calls for a downward force to be applied right on the edge "deemed most likely to fail" on an unloaded table, there is no clear basis for comparison between the EN and ASTM standards. However, incident data do not indicate that table tip-over incidents are a factor in hazard patterns. Therefore, staff believes that the ASTM requirement is adequate.

- To address a serious incident that occurred when a barrier failed to contain an occupant, at the time of its inception, ASTM adopted the barrier durability test method from the EN standard. Although the test methods remain nearly equivalent, the EN standard requires barriers to be provided on "at least 2 or 3 sides." Meanwhile, the ASTM standard requires that flat changing surfaces must have barriers on all four sides. ASTM also requires contoured changing pads to undergo an aging/pre-conditioning step before

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being subjected to the barrier test procedure. In addition, ASTM requires that they shift less than 1 inch at the conclusion of the barrier test. These additional requirements make the ASTM test requirements more stringent than the EN standard.

- Both ASTM and EN have provisions to address completely bounded openings. However, ASTM is considered the more stringent standard because ASTM prohibits a much wider range of opening dimensions than the EN standard; Additionally, ASTM prohibits these openings *anywhere* in the structure, except for retractable stairs in the open position of the changing table. In contrast, EN only puts a limitation on enclosed openings within specified zones considered accessible to the occupant.

- The EN standard includes provisions to limit the dimensions of any free-hanging cords or loops being created by changing table features. The only known loop incident reported to the CPSC involved a play yard, and that hazard has since been addressed with the addition of provisions in the ASTM play yard standard.

- The EN standard includes a provision for parts that move in relation to one another within the area deemed accessible to the occupant. Because the CPSC incident data show no pattern of scissoring or pinching injuries being sustained by changing table occupants, staff considers the existing ASTM requirement to be adequate.

- The EN standard prohibits the use of self-tapping screws on any components designed to be removed or loosened when dismantling changing units. This is a more stringent requirement than ASTM, and staff believes that this prohibition also should be a requirement for changing tables. Therefore, staff is recommending a draft provision (see appendix A) that would prohibit the use of self-tapping screws (such as wood screws and sheetmetal screws) on *any* key structural elements of a changing unit, regardless of whether it would be dismantled or loosened during transport or storage.

Staff compared the requirements of the EN standard that are relevant to the hazard patterns in the 2005 to 2015 incident data, to the equivalent ASTM requirements. Although there are differences, ESMC staff concludes that the ASTM standard is more stringent in most areas and believes that the ASTM standard addresses the hazard patterns seen in the incident data reported to the CPSC.

VIII. CONCLUSION

ESMC staff recommends that the Commission propose to incorporate by reference, ASTM F2388-16, as the mandatory safety standard for baby changing products for domestic use, with additional or modified requirements, as follows:

1. Add threaded fastener requirements as described in Appendix A of this memorandum that:
    - prohibit of the use of self-tapping screws, such as wood screws, for consumer assembly into key structural wood components,

    - require metal inserts, with external wood screw threads for screwing into a wood component and providing internal machine threads to accommodate a machine screw, that are used to secure key structural elements shall be glued or include other means to impede loosening or detaching,

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- require metal threaded fasteners, such as sheet metal screws and machine screws, secured into metal components and used to attach key structural elements shall have lock washers, self-locking nuts, or other means to impede loosening or detaching.

2. Modifications to the structural integrity requirement (testing carried out *without* the addition of the often misassembled/omitted consumer-installed secondary support strap), as described in Appendix B of this memorandum.

3. The addition of a restraint-integrity requirement, as described in Appendix C of this memorandum.

4. The warnings and labeling modifications, as described in the Division of Human Factors memorandum, TAB E

Staff recommends that the NPR include the additions and modifications to the requirements in ASTM F2388-16 set forth above, to address the frequency of injuries and deaths related to baby changing product collapses, restraint system problems, and unsafe sleeping hazards found in the incident data. The exact language of the staff-recommended modifications are in Appendices A, B, C of this memorandum and in the Division of Human Factors memorandum, TAB E.

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APPENDIX A: Threaded Fasteners

3.1.X *key structural elements, n*—side assemblies, end assemblies, base assemblies, leg assemblies, primary changing surface supports, or other components designed to support the weight of the occupant, or a combination thereof.

5.X *Threaded Fasteners:*

5.X.1 *Wood Screws and Sheet Metal Screws:*

5.X.1.1 No changing table shall require consumer assembly of key structural elements using wood screws or sheet metal fasteners directly into wood components. This shall not apply to non-key structural elements such as drawers, secondary support straps, other storage components, or accessory items.

5.X.1.2 Metal inserts, with external wood screw threads for screwing into a wood component and providing internal machine threads to accommodate a machine screw, that are used to secure key structural elements shall be glued or include other means to impede loosening or detaching.

5.X.1.3 Metal threaded fasteners, such as sheet metal screws and machine screws, secured into metal components and used to attach key structural elements shall have lock washers, self-locking nuts, or other means to impede loosening as defined in 6.2 or detachment during the testing required by this specification.

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APPENDIX B: Structural Integrity

6.2 Structural Integrity—When tested in accordance with 7.2, there shall be no breakage of the unit, nor shall it fail to conform with any other requirements in this specification before and after all testing. Components attached by screws shall not have separated by more than 0.04 in. (1 mm) upon completion of testing

NOTE 1—Contoured changing pads and add-on changing units that are sold separately are exempt from this requirement.

7.2 Structural Integrity—Assemble the unit in accordance with the manufacturer's assembly instructions. If the product design employs secondary support bars or straps beneath the changing surface that are not factory preassembled in their intended use position, this test is to be conducted without the support bars/straps installed. Place the unit on the test floor, center a 6 by 6 in. (150 by 150 mm) wood block on the changing surface and gradually apply a 100 lb (45.4 kg) weight onto the wood block within a period of 5 s. Maintain the weight for an additional period of 60 s.

7.4 *Barrier Structural Integrity and Retention Tests:*

7.4.1 *Test Equipment:*

7.4.1.1 Rigid cylinder with a diameter of 8 in. (200 mm), a length of 12 in. (300 mm), and a mass of 33 lb (15 kg).

7.4.1.2 Timing device capable of displaying seconds.

7.4.2 *Test Set Up:* Assemble the unit in accordance with the manufacturer's assembly instructions. If the product design employs secondary support bars or straps beneath the changing surface that are not factory preassembled in their intended use position, this test is to be conducted without the support bars/straps installed.

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APPENDIX C: Restraint Integrity

6.X *Restraint System:*

Note – A restraint system may be provided to restrict upward or lateral movement of the occupant's torso. Inclusion of a restraint system is not mandatory.

6.X.1 If a restraint system is installed on the product or available as an option, it shall meet the following:

6.X.1.1 A restraint system and its closing means (for example, buckle) shall not break or separate when tested in accordance with 7.X.

6.X.1.2 The anchorages shall not separate from the unit when tested in accordance with 7.X.

6.X.1.3 Restraints shall be capable of adjustment with a positive, self-locking mechanism that is capable, when locked, of withstanding the forces of tests in 7.X without allowing restraint movement or slippage of more than 1 in. (25.4 mm).

Note – Non-full-size cribs/play yards are exempt from these requirements.

7.X *Restraint System Tests:*

7.X.1 Secure the unit in its recommended use position so that it cannot move in the direction of the force being applied.

7.X.2 Secure a CAMI Infant Dummy, Mark II on the changing surface in accordance with the manufacturer's instructions.

7.X.3 Adjust the restraint, using the webbing tension pull device shown in Fig. Y, so that a force of 2 lbf (9 N) applied to the restraint will provide a 1⁄4 in. (6 mm) space between the restraint and the CAMI Dummy.

7.X.4 Perform the following tests without readjusting the restraint system.

7.X.4.1 Apply a pull force of 30 lbf (133 N) that is 45 degrees from the horizontal changing surface in the direction an occupant would roll sideways off the changing surface. Gradually apply the force within 5 s and maintain for an additional 10 s.

7.X.4.2 Release the restraint strap.

7.X.4.3 Repeat this test in the opposite direction an occupant would roll sideways off of the changing surface.

7.X.4.4 Apply a force of 30 lbf (133 N) in a direction that is 45 degrees from the horizontal changing surface towards the head of the changing pad. Gradually apply the force within 5 s and maintain for an additional 10 s.

7.X.4.5 Release the restraint strap.

7.X.4.6 Apply a force of 30 lbf (133 N) in a direction that is 45 degrees from the horizontal changing surface towards the foot of the changing pad. Gradually apply the force within 5 s and maintain for an additional 10 s.

7.X.4.7 Release the restraint strap.

7.X.4.8 Apply a force of 30 lbf (133 N) in a direction that is vertically straight up from the changing pad. Gradually apply the force within 5 s and maintain for an additional 10 s.

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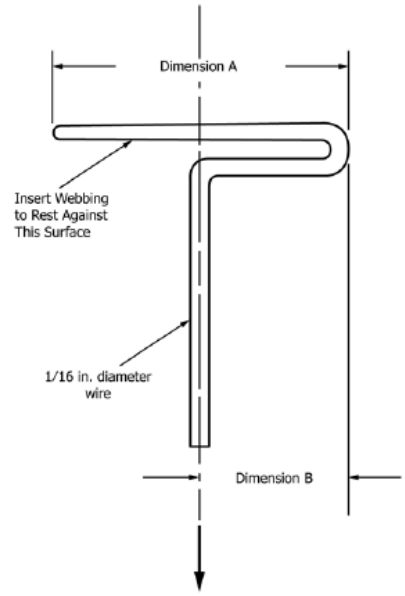

NOTE 1—Dimension A—Width of webbing plus ¼ in.
NOTE 2—Dimension B—One half of Dimension A.

Figure Y. Webbing Tension Pull Device

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TAB C: Summary of Changing Table Recalls from January 2005 to Present

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

Memorandum

Date: August 4, 2016

TO : Shaina Donahue, Project Manager,
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

THROUGH: DeWane Ray, Deputy Executive Director, Safety Operations
Mary F. Toro, Director, Division of Regulatory Enforcement, EXC
Carolyn Manley, Team Lead, Division of Regulatory Enforcement, EXC

FROM : Skordian Alaj, Compliance Officer,
Division of Regulatory Enforcement, EXC

SUBJECT : Durable Nursery Products: Summary of Recalls for Changing Tables from January 2005 to Present

PURPOSE

This memorandum responds to a request from the Project Manager seeking information on product safety recalls related to changing tables, conducted by the Office of Compliance and Field Operations (Compliance). The information is being provided to support CPSC staff in drafting a proposed mandatory rule for changing tables for the U.S. Consumer Product Safety Commission's consideration. The information only covers recalls conducted on changing tables from January 2005 to present.

COMPLIANCE ACTIVITIES

Since January 1, 2005, there have been two recalls involving changing tables. About 425,000 products were covered by these recalls.

On September 27, 2007, Kolcraft recalled about 425,000 infant play yards following the death of a child. The play yards were sold from January 2001 through September 2007. The play yards contained raised changing tables with a restraint strap that formed a loop beneath the changing table, posing a strangulation hazard to a child in the play yard.

On October 12, 2006, Scandinavian Child recalled about 130 units of its Cariboo Folding Changing Tables and Cariboo Bassinet Changers. The products were sold from September 2005

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through September 2006. The cloth supporting the child was secured by zippers. If a zipper was misaligned, the zipper could come apart and allow the cloth surface to separate, posing a fall hazard.

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TAB D: Health Sciences Assessment of Changing Table-Related Injuries

TAB D

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

Memorandum

Date: August 4, 2016

TO : Shaina Donahue
Changing Tables Project Manager
Directorate for Engineering Sciences

THROUGH: Alice Thaler, Associate Executive Director
Directorate for Health Sciences

Jacqueline Ferrante, Ph.D., Division Director
Division of Pharmacology and Physiology
Directorate for Health Sciences

FROM : Stefanie Marques, Ph.D., Physiologist
Division of Pharmacology and Physiology
Directorate for Health Sciences

SUBJECT : Health Science Analysis of Changing Table-Related Deaths and Injuries

I. Introduction

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the U.S. Consumer Product Safety Commission (CPSC) to assess the effectiveness of voluntary consumer product safety standards for durable infant and toddler products and to promulgate mandatory safety standards.

The scope of the current ASTM voluntary standard F2388-16 *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use* includes "baby changing tables and other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables." This memorandum provides Health Sciences (HS) staff's analysis of deaths and injuries associated with the use of changing tables from 2005 to 2015.

II. Health Sciences Analysis of Changing Table-Related Deaths and Injuries

Epidemiology staff's search of the CPSC database resulted in 182 changing table-related incidents that occurred between January 1, 2005 and December 31, 2015. Five incidents involved infant deaths, and 30 incidents resulted in injuries.

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A. Health Sciences Analysis of Changing Table-Related Deaths

There were five deaths related to changing tables that occurred from January 1, 2005 to December 31, 2015. They are described below in chronological order:

1) In March 2007, a 2-month-old girl was placed face up on the changing table accessory of a play yard to sleep. Three hours later, the victim's mother found her face down on the changing table and unresponsive. The cause of death was positional asphyxia.

2) In May 2007, a 10-month old boy was sleeping in the play area of a play yard with a changing table accessory. The mother of the infant checked on him and left the room. Upon returning approximately 5 minutes later, the victim's mother found him with his neck entangled on the changing table strap as his knees dangled near the bottom of the play yard. The infant was gasping for air and had a faint pulse; emergency personnel attempted life-saving techniques, and the baby was admitted to the pediatric intensive care unit of a local hospital. Two days later the baby was taken off life support systems and pronounced dead. The cause of death was strangulation.

3) In May 2008, a 4-month-old boy was put down for a nap on a portable changing pad that had been placed in his crib. The mother placed the infant on the pad face up so he would not turn over. Less than an hour later, the victim's mother found him in the prone position with his head hanging off the edge of the changing pad and unresponsive. The cause of death was positional asphyxia.

4) In November 2008, a 7-week-old girl was placed on the changing table accessory of a play yard to sleep. Approximately 1 hour later, the infant's father found her unresponsive. The changing table accessory was depressed in the center, which created a "V-" shaped contour; the infant was found at the bottom of this "V-" shaped depression. The cause of death was asphyxia due to mechanical compression.

5) In February 2013, the father of a 2-month-old girl placed the child on her side to sleep on the changing table accessory of a play yard. The surface of the changing table was covered by a fluffy baby blanket. Approximately 6 and half hours later, the parents discovered that the infant had rolled onto her stomach and was face down in the fluffy blanket, unresponsive. The cause of death was positional asphyxia.

HS staff observed that all of the deaths described above were due to a changing table accessory, changing pad, or play yard (with a changing table accessory) being used as a sleep product, which is not its intended use, which created a hazardous sleep environment. Four of the fatalities mentioned above involved play yards with changing table attachments; in three of these incidents, the changing table attachment was used as the sleep product; and in one incident, the play area of the play yard (with a changing table accessory attached above) was used as the sleep product, which caused the victim to become entangled on the straps hanging from the changing table attachment. There was only one fatality that involved an infant being placed in a crib; however a portable changing pad was used incorrectly as a sleep positioner product to prevent the infant from turning over.

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B. Health Sciences Analysis of Changing Table-Related Injuries

There were 177 nonfatal incidents related to changing tables from January 1, 2005 to December 31, 2015; 30 incidents resulted in injuries.

Based on the incident data, HS staff finds most concerning the incidents involving an infant falling from or through the changing table because those incidents have the greatest potential for a serious injury because of the relative height of the changing table surface. According to HS staff's analysis, 114 of the 177 nonfatal incidents involved an infant falling from or through the changing table (64%); 10 incidents resulted in an injury. Eight of the injuries sustained in falls were due to the collapse of the changing table surface or other supporting structure; seven of these incidents resulted in minor injuries, such as bruises, scratches and lacerations that did not require medical attention; (there is not sufficient information reported in the eighth incident to determine the injury severity). In the two remaining fall injuries, one involved a 4-month-old boy who fell from a changing table attachment of a play yard and sustained a fractured leg; the infant's caregiver noted that there was not a restraining system present on the changing table. The last fall injury involved a 9-month-old girl who fell from the changing table and sustained a fractured skull requiring hospitalization. The incident happened at a day care facility, and the child was left unsupervised. Accordingly, there is insufficient information to determine what caused the infant to fall from the changing table.

According to Epidemiology staff, the majority (94%) of emergency-department treated injuries associated with changing tables were attributed to the infant falling from the changing table. According to HS staff's analysis of these emergency-department treated injuries, a number of the fall injuries resulted in a serious head injury, such as a concussion or fractured skull. Due to the limited information reported in the emergency department incidents, staff could not determine the cause of the falls that resulted in serious head injuries.

III. Conclusion

HS staff observed that the contributing factor in changing table deaths is the use of the changing table as a sleep product; using the product that way creates a hazardous sleep environment. The incidents that resulted in death demonstrate this risk. Engineering Sciences Human Factors (ESHF) staff discussed in their memorandum (Tab E) that caregivers appeared to have confused the changing table accessory on play yards as a crib or bassinet and have made recommendations to add warnings on these products to clarify that they are not to be used as sleeping products.

The injuries treated in the emergency room strongly suggest that the most common cause of changing table injuries is falls from the changing table. HS staff noted that a number of the emergency room-treated injuries resulted in serious head injuries. Serious head injuries, such as concussions and fractured skulls, could cause extensive brain damage and affect the infant's motor development, emotional development, speech, ability to think and learn, and overall quality of life, long after the incident has occurred.

The reported incident data suggest that falls through the changing table are most often the result of the changing table surface or other supporting structure collapsing. Some falls from the changing table may be associated with the restraining system. Engineering Sciences Mechanical and Combustion Engineering

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(ESMC) staff has recommended two modifications to strengthen the structural integrity requirements in ASTM F2388-16. ESMC staff has also recommended adding a restraint-integrity test to ASTM F2388-16, to ensure that restraint straps provided with changing products are capable of withstanding the forces associated with normal usage (Tab B).

HS staff's analysis indicates the structural integrity test and warning label changes to ASTM F2388-16 recommended by ESHF and ESMC staff (Tabs E and B respectively), and currently being balloted, have great potential to reduce the number of head injuries and deaths associated with changing tables.

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TAB E: Human Factors Assessment of ASTM F2388 – 15 Requirements for Changing Tables (CPSIA Section 104)

TAB E

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

Memorandum

DATE: August 4, 2016

TO: Shaina Donahue, Project Manager, Changing Tables Rulemaking,
Division of Mechanical and Combustion Engineering,
Directorate for Engineering Sciences

THROUGH: Rana Balci-Sinha, Director,
Division of Human Factors, Directorate for Engineering Sciences

FROM: Hope E J. Nesteruk, Human Factors Engineer, and
Timothy P. Smith, Senior Human Factors Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of ASTM F2388 – 15 Requirements for Changing Tables and Changing Products (CPSIA Section 104)

Background

The ASTM International (ASTM) voluntary standard ASTM F2388, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, establishes requirements for changing tables and other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables in the United States. The standard is intended to minimize the hazards associated with the reasonably foreseeable use and misuse, or abuse, of these products. ASTM developed this voluntary standard in response to incident data supplied by staff of the U.S. Consumer Product Safety Commission (CPSC or Commission). The most recent, published version of the voluntary standard is ASTM F2388 – 16.

Section 9 of the voluntary standard specifies marking and labeling requirements, which include warning statements that must appear on each changing table, add-on changing unit, or changing pad.[9] Section 10 specifies the instructional literature that must be provided with each changing product. This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), assesses the adequacy of these sections of the voluntary standard in addressing the risk of injuries and deaths associated with the use of changing

[9] ESHF staff will use the term "changing products" throughout this memorandum to signify requirements that apply to all changing tables, add-on changing units, and changing pads. When the discussion applies to a specific subset of changing products, the name of the specific product-type will be used.

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products, and recommends revised requirements that staff concludes will further reduce the risk of injury or death associated with these products.

ESHF staff has worked closely with the warning and labeling task group for the ASTM F15.18 Changing Table subcommittee to discuss the changes to the warning labels, including task group teleconference calls on March 23, 2016, May 25, 2016, June 9, 2016, and June 30, 2016, in addition to full F15.18 subcommittee meetings on April 12, 2016 and June 15, 2016. The recommendations for warning label content and format contained in this memorandum are equivalent to what is expected to be balloted by the F15.18 subcommittee in the near future.

DISCUSSION

ESHF STAFF REVIEW OF INCIDENT DATA

REPORTED INCIDENTS

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA) discusses in Tab A, staff has identified 182 changing product-related incidents reported to have occur from January 1, 2005 through December 31, 2015. These incidents consist of five fatalities, 30 injuries/adverse health problems, 113 non-injury incidents, and 34 incidents that did not have enough information to determine whether an injury occurred.

For the reported incidents, EPHA found that the most frequent hazard pattern was structural integrity (65% of reported incidents), followed by design issues (21% of reported incidents), and then restraining system issues (8%). The design-related incidents included limb entrapment between vertical slats and underneath horizontal rails, as well as incidents related to drawers and doors on changing tables, along with consumer complaints about paints and finishes. Restraining system incident reports included broken straps, straps pulling loose from their attachments, and buckles cracking or failing to remain secure, along with consumer complaints that the product did not include restraint straps.

Among the design-related incidents, ESHF staff noted incidents related to a child's feet or legs becoming entrapped under a horizontal rail at the end of a changing table. Upon examining changing table samples, staff found the openings are roughly the same size and shape as the space between crib slats. Previous analysis of limb entrapment has revealed that limb entrapment is a difficult issue to address because simply reducing the size of the opening could result in limb entrapments of smaller infants or entrapment of smaller body parts.

Regarding the reported restraining system incidents, although restraints are not required by ASTM F2388, 10 of the 14 restraint-related reported incidents involved a fall or potential fall because a restraint detached, a buckle released, or the restraint straps otherwise failed to function as a method of restraining the child. Only one of these fall-related restraint incidents resulted in injury. One incident report[10] noted that the caregiver was standing "right near" the changing table when the strap detached and the child rolled off, but the caregiver was unable to catch the

[10] IPII I1180012A.

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child. Overall, only six of the 118 fall-related incidents specifically noted that the child was caught during a fall. The restraint-related incidents suggest that consumers expect that when a restraint is provided, the restraint will effectively restrain the child. Otherwise, staff suggests, consumers are not likely to report an issue. Moreover, the fall-related incidents, in general, suggest that falls occur even when a caregiver is nearby. ESHF staff recognizes the difficulty in designing a restraint that not only fully restrains the child, but also allows the caregiver to remove a child's clothing and diaper for a diaper change because the expected use of the product precludes using a crotch-strap. However, if only a 2-point restraint is provided, staff concludes that consumers will expect the strap to remain functional.

FATALITIES

ESHF staff reviewed the five fatal incidents that were reported to CPSC between January 1, 2005 and December 31, 2015.

In one fatal incident,[11] a 10-month-old child was in the lower area of a play yard that had a changing accessory attached. The restraint system on the changing accessory formed a loop underneath the changing table accessory. The child was able to access the loop and was strangled. This incident occurred in May 2007, and led directly to the addition of a new requirement in F406-08a, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, prohibiting hazardous loops formed by straps that hang from an attachment inside the play yard enclosure.

In three cases, an infant less than 3 months old was put to sleep in the changing accessory of a play yard. The infant died due to positional asphyxia. The reports from these incidents indicate that consumers might view play yard changing accessories as similar to play yard bassinet accessories or other sleeping surfaces. For example, in one of these three cases,[12] the police report quoted both parents referring to the changing accessory as a "bassinet." In the second case,[13] the coroner's report refers to the area as a "crib," but the report later clarified that the product was "actually a [play yard] changing area not really a crib." The police report in the third play yard changing accessory case[14] also refers to the child being placed in a crib. However, further analysis showed that all three products were play yard changing table accessories.

The fifth fatality involved a contoured changing pad that was placed inside a crib. The 4-month-old infant was placed on the pad to "prevent him from turning over." The infant was found with his head hanging over one of the raised sides of the changing pad, and the infant died due to positional asphyxia.

Analysis of the four incidents related to positional asphyxia and the terms used to describe the changing products suggest that some consumers might view changing accessories as similar to

[11] IDI number 070508HWE5897.
[12] IDI number 071129HCC3212.
[13] IDI number 140902HCC1909.
[14] IDI number 090331HCC1565.

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bassinets and sleep positioners. For this reason, ESHF staff concludes that changing products should be marked with a strong statement that a changing product is not a sleeping environment. Specific recommendations are discussed later in this memorandum.

NEISS INCIDENTS

From National Electronic Injury Surveillance System (NEISS) data, EPHA staff estimates that 31,780 changing product-related injuries to victims younger than 3 years of age were treated in U.S. hospital emergency departments from 2005 through 2014. Seventy-six percent of these injuries involved children younger than 12 months of age. Ninety-four percent of the emergency-department treated injuries resulted from the child falling or rolling off the changing product. The NEISS data provide very limited details about the circumstances surrounding these incidents. Although, ESHF staff noted that in a number of cases, a caregiver caught the child while falling, often resulting in an arm injury, such as nursemaid's elbow. In most cases, the NEISS narrative did not identify the type of changing product in use.

CURRENT ASTM WARNING AND INSTRUCTIONAL REQUIREMENTS

ON-PRODUCT WARNING REQUIREMENTS

Section 9 of ASTM F2388 – 16 specifies labeling and warning requirements for changing products. In short, all changing products must include warnings on the products about the risk of serious injury or death from falls. Removable changing pads and add-on changing units that are sold separately must also include a warning to secure the pad or add-on unit to the support surface. The specific warning language that must be addressed for all changing products is:

> FALL HAZARD – To prevent death or serious injury, always keep child within arm's reach. (§ 9.3.2.1)

Removable pads and add-on changing units that are sold separately must also include a message that addresses the following:

> Always secure this pad to the support surface by (manufacturer insert appropriate words on how to secure the changing pad). See instructions. (§ 9.3.2.2)

Finally, as part of the warning, contoured changing pads and add-on changing units sold separately are required to either identify the specific product they are designed to be attached to, or they must identify "that the support surface used should be level, stable, and structurally sound with minimum support surface dimensions of 'X' by 'Y'." (§ 9.3.3.1). Whichever message is appropriate, the message must be visible either on or through the retail packaging and during the product assembly. (§ 9.3.3)

The warning label is required to be "conspicuous" on the product, which is defined in § 3.1.6 as a "label that, when the changing table, changing pad, or add-on changing unit is in a manufacturer's recommended use position, is visible to a person standing in front of the table in a position normally associated with the task of changing a child's diaper."

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In terms of their design, or form, the warning statements must be "in contrasting colors," permanent, and in sans serif type (§ 9.3). The safety alert symbol (⚠)[15] and the signal word, "WARNING," must be at least 0.2 inches (5 mm) high, and the remainder of the warning message text must be in characters whose uppercase is at least 0.1 inches (2.5 mm) high (§ 9.3.1).

Figure 1 illustrates the types of warning labels that currently appear on changing products, all containing the required "fall hazard" warning language. However, not all of the labels conform to the formatting requirements of section 9.3.1, primarily due to type size. As illustrated in the figure, there is little consistency regarding color, typeface, signal word, or other format and design characteristics.

Figure 1. Example fall hazard warning labels

INSTRUCTIONAL REQUIREMENTS

Section 10 of ASTM F2388 – 16 specifies the instructional literature that must be provided with changing products. Section 10.1.1 states that the instructions must include the warning statements in section 9.3. Section 10 of the standarddoes not specify any design or form requirements for the warning statements in the instructional literature.

[15] The version of the safety alert symbol shown here is based on the default symbol used in the ANSI Z535 series of standards. For consistency, CPSC staff uses this version throughout the memorandum for all instances of the safety alert symbol.

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ASTM AD HOC WORDING TASK GROUP TO ADDRESS WARNING FORM AND FORMAT

As CPSC has proceeded through the mandate of CPSIA section 104, promulgating mandatory standards for durable nursery products that are the same or more stringent than industry voluntary standards, several of the subcommittee members associated with the ASTM F15 juvenile product/durable nursery product subcommittees have raised concerns about consistency of warnings among various durable nursery product rules. For this reason, the ASTM Ad Hoc Wording Task Group (ad hoc task group), consisting of members of the various standards groups affected by the durable nursery products rules, was formed to harmonize the wording and language used across nursery product standards. This ad hoc task group also took on the responsibility of developing recommendations for harmonizing the warning format across standards. The Human Factors Division hazard communication subject matter expert,[16] who is the CPSC staff representative on the ANSI Z535 committee, also represents CPSC staff on this task group. CPSC staff has worked closely with this group to develop recommendations that are based largely on the requirements of the ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, while also accounting for the wide range and unique nature of durable nursery products, the concerns raised by industry representatives, and ESHF staff recommendations associated with durable nursery product rulemaking projects over the past several years.

The task group presented their recommendations to the F15 juvenile product subcommittees via ASTM letter ballot F15 (16-04). On April 12, 2016, approximately halfway through the 30-day balloting period, the ad hoc task group met to discuss initial ballot results. The discussion resulted in several editorial changes to the balloted language. These editorial changes, along with the concerns expressed in a CPSC staff ballot comment dated April 21, 2016, are included in staff's final recommendations, which appear in the Appendix.

The ad hoc task group's work should result in permanent, conspicuous, and consistently formatted on-product warning labels across juvenile products. On-product warning labels that meet the requirements in the task group proposal would address numerous warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior. The proposal, which is incorporated in ESHF staff recommendations, includes requirements for:

- English language that is "easy to read and understand" and not contradicted elsewhere on the product;
- Certain sections of ANSI Z535.4 – 2011, American National Standard for Product Safety Signs and Labels, specifically
    - ANSI Z535.4, sections 6.1-6.4, which includes warning format requirements, such as the safety alert symbol, signal word selection, and warning panel format, arrangement, and shape;
    - ANSI Z535.4, sections 7.2-7.6.3, which includes color requirements for each panel;
    - ANSI Z535.4, section 8.1, which addresses letter style;

[16] Timothy P. Smith.

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- Minimum text size and alignment;
- The use of bullets, lists, outline, and paragraph form for hazard avoidance statements.

In addition, the task group developed recommended text for the general labeling section that appears in ASTM F2388, section 9.1, and covers labeling permanency and content related to manufacturer contact information and date of manufacture. Staff agrees with the task group recommendations and has included them in the Appendix under section 9.1.

ESHF Staff Assessment of Warning and Instructional Requirements

On-Product Warning Requirements

Summary of ESHF Staff Recommendations

ESHF staff does not believe that the on-product warning requirements in ASTM F2388 – 16 adequately address the risk of injuries and deaths associated with changing products. Accordingly, ESHF staff recommends that these requirements be replaced or revised with warning requirements that would produce the following warning label for changing tables:

⚠WARNING

Fall hazard
Children have suffered serious injuries after falling from changing tables. Falls can happen quickly.
- **STAY** in arm's reach.

The recommended requirements would produce the following warning label for contoured changing pads that attach to a support surface and changing products that attach to play yards. Note that the language "changing pad" will vary slightly from product to product (*e.g.*, changing table, changing area):

⚠WARNING

Fall hazard
Children have suffered serious injuries after falling from changing pads. Falls can happen quickly.
- **STAY** in arm's reach.
- **ALWAYS** secure this pad to the support surface by (manufacturer's instructions for securing the changing product).

Suffocation hazard
Babies have suffocated while sleeping on changing pads. Changing pad is not designed for safe sleeping.
- **NEVER** allow baby to sleep on changing pad.

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The following subsections detail the rationale behind these recommended revisions, and the appendix to this memorandum shows the revised section 9 that would be needed to produce the recommended warnings above. The section 9 that is presented in the Appendix also includes additional changes to improve readability and consistency within this standard, with other ASTM standards, and the work of the ASTM ad hoc task group, whose purpose is to develop recommended wording for sections of the ASTM standards that are common to multiple juvenile product standards. ESHF staff participated in this task group.

General warning effectiveness

For a warning to be effective, the consumer must do three things:

a) Notice the warning – Conspicuity is essential to getting a warning noticed. Signal words, colors, graphics, and placement all increase conspicuity; however, the ASTM standards related to durable nursery products define conspicuity to be related to placement only.

b) Read the warning – The consumer must read the label. Many things affect the likelihood of a consumer reading the label, such as familiarity with a product and perceived hazard, along with visual display issues, such as font size and text alignment. Studies have found that the more familiar a consumer is with a product, the less likely he or she will look for or read a warning (*e.g.*, Wogalter and Leonard, 1999).

c) Heed the warning – When personal experience conflicts with a warning message, it is generally the warning message that is discredited and ignored (Ayers, Gross, Wood, Horst, Beyer, and Robinson, 1986). However, providing more explicit or detailed information in a warning has been found to increase warning effectiveness (Laughery & Smith, 2006), and vividness has been found to increase message salience, which triggers one's motivation to act (Murray-Johnson & Witte, 2003).

A breakdown in any of these three areas will diminish the effectiveness of a warning. ESHF staff's recommendations below are intended to increase the likelihood that consumers will notice, read, and heed the warning, thereby further reducing the risk of injury or death associated with changing products.

Content

The primary U.S. voluntary consensus standard for product safety signs and labels, ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, as well as other literature and guidelines on warnings (*e.g.*, Robinson, 2009; Wogalter, 2006; Wogalter, Laughery, & Mayhorn, 2012) consistently recommends that on-product warnings include:

- a description of the hazard,
- information about the consequences of exposure to the hazard, and
- instructions regarding appropriate hazard-avoidance behaviors.

ESHF staff does not believe that the requirements in ASTM F2388 – 16 adequately address these warning elements for fall or suffocation hazards.

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Fall Hazard

The current requirements identify the hazard and consequences as "FALL HAZARD – To prevent death or serious injury," which, although accurate, is theoretical and vague about the nature of the injuries. Moreover, the warning does not identify that injuries have occurred. Providing more explicit or detailed information in a warning has been found to increase warning effectiveness (Laughery & Smith, 2006). Additionally, vividness has been found to increase message salience, which triggers one's motivation to act (Murray-Johnson & Witte, 2003). Thus, ESHF staff believes that a more explicit description indicating that injuries have occurred will increase the likelihood that consumers will comply with the recommended hazard-avoidance behavior.[17]

Moreover, the available incident data suggest that incidents can happen quickly, noting that several have occurred when a caregiver briefly turns away from the child or a caregiver has been close enough to catch a falling child, but still resulted in an injury. Although a restraint system could reduce the likelihood of a child falling off the table, restraints are not required by F2388 for two primary reasons: (1) the close proximity of the caregiver to the child during the act of a diaper change, and (2) because most effective restraints are 3-point or 5-point restraints, which are not practical for diaper change activities. However, consumers might be unaware of the speed with which incidents can occur, and therefore, might overestimate their ability to prevent an incident by their mere presence. Despite the presence of a caregiver, falls are the most common hazard pattern, which suggests that the presence of a caregiver alone does not prevent a fall incident. Thus, staff believes that a statement describing the speed at which incidents can occur is necessary and would further reduce the risk of injury.

The current warning requirements specify one hazard-avoidance behavior with which consumers should comply to avoid the fall hazard: always keep child within arm's reach. This statement is a positive description of the actions that a consumer should take to properly attend to the child. Therefore, ESHF staff does not recommend modifying the statement.

The table below shows the warning element, ESHF staff's recommended warning language, and the rationale for the language.

[17] Injury severity strongly determines perceived hazard or risk (Wogalter, Brelsford, Desaulniers, & Laughery, 1991; Wogalter, Brems, & Martin, 1993; Young & Wogalter, 1998), which research has found to increase warning effectiveness by affecting a consumer's motivation, or intent, to comply (DeJoy, 1999; Murray-Johnson & Witte, 2003; Riley, 2006).

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Table 1. Fall Hazard Warning Language Recommendations

Elements of a warning	Recommended warning language	Rationale
Description of the hazard	**Fall hazard.** … Falls can happen quickly.	Contains a hazard statement and statement about the speed at which incidents occur
Consequences of exposure to the hazard	Children have suffered serious injuries after falling from changing [tables/pads/areas].	Explicit, vivid statement supported by incident data.
Appropriate hazard-avoidance behaviors	**STAY** in arm's reach. **ALWAYS** secure this [table/pad/area] to the support [surface/frame] by (manufacturer's instructions for securing the changing product).	Strong statement as to how to avoid the hazard.
	Note: The words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.	

Suffocation Hazard

Currently, no warning related to a suffocation hazard is required for changing products. However, incident data show four deaths related to suffocation or positional asphyxia associated with changing products. In each of these cases, an infant was placed to sleep in or on a changing product and left unattended.[18] This suggests that the current statement "always keep child within arm's reach," which is associated with the fall hazard warning, was insufficient to instruct caregivers that the changing product was not intended as a sleeping product. As discussed above, police, coroners, and caregivers misidentify play yard changing accessories as bassinets; and, in one case, a caregiver used a changing pad as a sleep positioner. Therefore, ESHF staff concludes that changing products require a strong warning that alerts caregivers to the hazards associated with sleeping in or on changing products. This message must contain all the recommended elements of a warning to motivate consumers to heed the warning's guidance and overcome consumer perceptions that the changing product is like other products intended for infant sleep.

The table below shows the warning element, ESHF staff's recommended warning language, and the rationale for the language. These recommendations were discussed with the ASTM changing table subcommittee and associated task group meetings on February 17, 2016, March 23, 2016, and April 12, 2016.

[18] Including with a caregiver sleeping nearby.

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Table 2. Suffocation Hazard Warning Language Recommendations

Element of a warning	Recommended warning language	Rationale
Description of the hazard	**Suffocation hazard.** Changing [table/pad/area] is not for sleeping.	Contains a hazard statement and further information differentiating the changing product from sleeping products that might be similar in appearance.
Consequences of exposure to the hazard	Babies have suffocated while sleeping [in/on] changing [tables/pads/areas].	Explicit, vivid statement supported by incident data.
Appropriate hazard-avoidance behaviors	**NEVER** allow baby to sleep [in/on] changing [table/pad/area].	Strong statement as to how to avoid the hazard.
	Note: The words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.	

Form

When assessing the adequacy of a warning, the content of a warning, and also its design or "form" must be considered (Laughery & Wogalter, 2006; Madden, 1999; Madden, 2006). ESHF staff regularly uses ANSI Z535.4, *American National Standard for Product Safety Signs and Labels* — the primary U.S. voluntary consensus standard for the design, application, use, and placement of on-product warning labels—when developing or assessing the adequacy of warning labels. Human factors and warnings literature regularly cite ANSI Z535.4, when discussing the design and evaluation of on-product warning labels, and the standard is identified as the minimum set of requirements that products containing such labels that are sold in the United States should meet (*e.g.*, Vredenburgh & Zackowitz, 2005; Wogalter & Laughery, 2005). Hellier and Edworthy (2006) and Peckham (2006) report that this has been reaffirmed by the U.S. courts, that have accepted the ANSI Z535 series of standards, in general, and the ANSI Z535.4 standard, in particular, as the benchmark against which warning labels are evaluated for adequacy because these standards are seen as the state of the art (also see Laughery & Wogalter, 2006). Furthermore, the scope of ANSI Z535.4 is broad enough to encompass nearly all products, including children's products and toys (see Kalsher & Wogalter, 2008; Rice, 2012).

Given ESHF staff's involvement in the ad hoc task group and the similarity of the task group's recommendations to a recognized voluntary standard for product safety signs and labels (ANSI Z535.4), with modifications to make the ad hoc task group's recommendations more stringent, ESHF staff concludes that the warning design requirements for changing products should be revised to meet the recommendations developed by the ad hoc task group. Because the ad hoc task group's recommendations have not yet been published as part of the F2388 standard, ESHF staff has incorporated the warning format recommendations developed by the ad hoc task group per the March 24, 2016, ASTM letter ballot F15 (16-04), with editorial changes suggested in the April 21, 2016 CPSC staff ballot comment letter.

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Placement

ESHF staff is not recommending any modifications to the placement (*i.e.*, conspicuity) requirements in ASTM F2388 – 16. Based on the placement requirements of ASTM F2388 – 16, a single warning label that includes all of the warning statements would have to meet the placement requirements specified in the standard. In other words, the label would have to be visible to the caregiver standing in front of the changing product in a position normally associated with the task of changing a child's diaper. This existing recommendation is consistent with ANSI Z535.4, which states that warnings must be placed so that they are readily visible to the intended viewer and will alert the viewer in time enough to take appropriate action (§ 9.1).[19] As the recommended warnings describe, avoiding the fall and suffocation hazards associated with changing products demands that caregivers always stay near the child during use of the product. Thus, ideal placement of a warning that instructs caregivers to perform these behaviors must be readily visible to the caregiver:

- just before, or immediately after, the child is placed on the changing product; and
- just before the caregiver would leave the prone child on the changing product (to remind consumers that a changing product is not a sleeping surface).

ESHF staff concludes that the current placement requirements in ASTM F2388 – 16 are sufficient.

INSTRUCTIONAL REQUIREMENTS

Summary of ESHF Staff Recommendations

ESHF staff does not believe that the instructional requirements in ASTM F2388 – 16 adequately address the risk of injuries and deaths associated with changing tables, primarily because of their lack of any design or form requirements for the required warning statements. Staff, therefore, recommends that ASTM F2388 be revised to require that warnings in the instructional literature meet the same form requirements as the on-product warnings, except that the warnings need not be in color. The appendix to this memorandum includes staff's specific recommended revisions to address this issue and related issues. The recommended changes to section 9 have been discussed with the ASTM task group on changing table warnings and are understood to be consistent with the most recent task group version, although there is no planned ballot date for these changes. Note that the recommended content changes discussed earlier will be carried over into the instructions, via section 10.1.1, which states: "[t]he instructions shall contain the warning statements in 9.3."

Form

As staff noted earlier in this memorandum, Section 10 of the standard does not specify any design or form requirements for the required warning statements. In much the same way that ANSI Z535.4 sets forth minimum performance requirements for on-product warning labels,

[19] But not presented so far in advance of a hazard that the consumer might forget the warning when presented with the hazard.

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ANSI Z535.6, *American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials,* sets forth requirements for the design and location of product safety messages in instructional literature and similar materials for a wide variety of products. This standard is the primary U.S. voluntary consensus standard of its kind, and ESHF staff regularly relies upon this standard when assessing the adequacy of instructional materials. For the above reasons, and for reasons similar to those previously discussed in this memorandum regarding ANSI Z535.4, ESHF staff concludes that warnings in instructional literature for changing products ideally should meet or exceed the requirements outlined in ANSI Z535.6. However, product instructions can vary substantially in terms of their purpose, content, length, and other characteristics, and depend on the specific product in question. Thus, for simplicity, staff recommends that Section 10 of the standard state that the required warnings in the instructional literature must meet the same form requirements as the on-product warnings (Section 9, discussed earlier), except that the warnings need not be in color. In addition, to be consistent with staff's proposed revisions to Section 9, staff recommends that Section 10 include a note referencing ANSI Z535.6 to provide additional guidance. The Appendix to this memorandum includes staff's recommended revisions to address the issues above.

CONCLUSIONS

ESHF staff does not believe that the warning and instructional requirements specified in Sections 9 and 10 of ASTM F2388 – 16, adequately address the risk of injuries and deaths associated with the use of changing products. Consequently, staff recommends that the Commission propose the revised requirements shown in the Appendix of this memorandum to further reduce the risk of injury or death associated with these products.

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Appendix: Proposed modifications to sections 9 and 10 for ASTM F2388 – 16, consistent with ad hoc task group work

CURRENT	PROPOSED	RATIONALE
	3.1.X Non-rigid add-on changing unit accessory – a supported changing unit that attaches to a crib or play yard designed to convert the product into a changing table typically having a rigid frame with soft fabric or mesh sides and/or bottom surface.	New definition is needed to address warnings needed for play yard changing table accessories. This is a task group developed definition.
9. Marking and Labeling	9. Marking and Labeling	
9.1 Each changing table and add-on changing unit or contoured changing pad, sold separately, and its retail package shall be marked or labeled clearly and legibly to indicate the following:	9.1 Each changing table and add-on changing unit or contoured changing pad, sold separately, and its retail package shall be marked or labeled clearly and legibly to indicate the following:	Ad Hoc Wording Task Group
9.1.1 Name ~~and~~ place of business (city, state, and mailing address, including zip code) ~~or~~ telephone number of either the manufacturer, distributor, or seller.	9.1.1 The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.	Ad Hoc Wording Task Group
9.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture.	9.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture.	Ad Hoc Wording Task Group
NOTE 5—Add-on changing units or contoured changing pads sold with non-full-size cribs and play yards are exempt from the labeling requirements of 9.1.1 and 9.1.2 as labeling requirements for these accessories are included in Consumer Safety Specification F406.	Note 5—Add-on changing units, non-rigid add-on changing unit accessories, or contoured changing pads, sold with non-full-size cribs and play yards are exempt from the labeling requirements of 9.1.1 and 9.1.2 as labeling requirements for these accessories are included in Consumer Safety Specification F406.	Addresses play yard changing table accessories
9.1.3 The retail package must indicate the manufacturer's recommended maximum weight of the occupant for which the changing table or contoured changing pad is intended.	9.1.3 The retail package must indicate the manufacturer's recommended maximum weight of the occupant for which the changing table or contoured changing pad is intended.	
	9.2 The marking and labeling on the product shall be permanent.	Ad Hoc Wording Task Group
9.~~2~~ Any upholstery label required by law shall not be used to meet the requirements in 9.1.	9.3 Any upholstery label required by law shall not be used to meet the requirements of this section.	Ad Hoc Wording Task Group

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CURRENT	PROPOSED	RATIONALE
~~9.3 Each changing table, add-on changing unit or contoured changing pad shall be labeled with warning statements. The warning statements shall be in contrasting colors, permanent, and in sans serif font.~~	9.4 – Warning Design for Product	Ad Hoc Wording Task Group
	9.4.1 - The warning shall be easy to read and understand and be in the English language at a minimum.	Ad Hoc Wording Task Group
	9.4.2 - Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer.	Ad Hoc Wording Task Group
	9.4.3 - The warnings shall be conspicuous and permanent.	Ad Hoc Wording Task Group
	9.4.4 - The warnings shall conform to ANSI Z535.4 – 2011, American National Standard for Product Safety Signs and Labels, sections 6.1-6.4, 7.2-7.6.3, and 8.1, with the following changes.	Ad Hoc Wording Task Group
	9.4.4.1 - In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace "should" with "shall."	Ad Hoc Wording Task Group
	9.4.4.2 - In section 7.6.3, replace "should (when feasible)" with "shall."	Ad Hoc Wording Task Group
	9.4.4.3 - Strike the word "safety" when used immediately before a color (*e.g.*, replace "safety white" with "white").	Ad Hoc Wording Task Group
~~9.3.1 In the warning statements,~~ the safety alert symbol "!" and the word "WARNING" shall not be less than 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm) high.	9.4.5 - The safety alert symbol and the signal word "WARNING" shall not be less than 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified. NOTE: For improved warning readability, the warning designer should avoid the use of typefaces with large height-to-width ratios, which are commonly identified as "condensed," "compressed," "narrow," or similar.	Ad Hoc Wording Task Group
	9.4.6 - Message Panel Text Layout	Ad Hoc Wording Task Group

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CURRENT	PROPOSED	RATIONALE
	9.4.6.1 - The text shall be left-aligned, ragged right for all but one-line text messages, which can be left aligned or centered. NOTE: Left-aligned means that the text is aligned along the left margin, and, in the case of multiple columns of text, along the left side of each individual column.	Ad Hoc Wording Task Group
	9.4.6.2 - The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.	Ad Hoc Wording Task Group
	9.4.7 An example warning in the format described in this section is shown in Fig. X.  	Ad Hoc Wording Task Group and example label for changing tables. Label not shown actual size.
~~9.3.2 Warning statements shall be conspicuous and~~ address the following:	9.5 Warning Statements—Each product shall have warning statements to address the following, at a minimum:	Ad Hoc Wording Task Group

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CURRENT	PROPOSED	RATIONALE
~~9.3.2.1~~ FALL HAZARD~~— To prevent death or serious injury, always keep child with~~in arm's reach.	9.5.1 The following warning statements shall be placed on all changing tables, including add-on changing units and contoured changing pads that are sold separately: Fall Hazard. Children have suffered serious injuries after falling from changing [table/pad/area]. Falls can happen quickly. • STAY in arm's reach. Note: The words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.	Increases warning effectiveness through: • Strong statement about how to avoid the hazard. • Hazard statement and statement about the speed at which incidents occur Explicit, vivid statement supported by incident data.
~~9.3.2.2 For changing tables sold with a removable pad included, or contoured changing pads or~~ Removable pads that are included with changing tables, contoured pads, and add-on changing units sold separately that are intended to be physically attached to the changing surface, support surface shall have a warning on the pad or changing unit, and its retail packaging, to address the following: Always secure this pad to the support surface by (manufacturer insert appropriate words on how to secure the changing ~~pad~~). See instructions.	9.5.2 Removable pads that are included with changing tables, contoured pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately that are intended to be physically attached to the support surface shall have a warning on the pad or changing unit, and its retail packaging, to address the following: • **ALWAYS** secure this [unit/pad] to the support [surface/frame] by (manufacturer's instructions for securing the changing unit). See instructions. Note: The words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.	Addresses play yard changing table accessories

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CURRENT	PROPOSED	RATIONALE
	9.5.3 Non-rigid add-on changing unit accessories, changing pads, and contoured changing pads, whether sold with the changing table or sold separately, shall include the following additional warning statements: Suffocation Hazard. Babies have suffocated while sleeping [in/on] changing [tables/pads/areas]. Changing [table/pad/area] is not designed for safe sleeping. NEVER allow baby sleep [in/on] changing [table/pad/area] Note: The words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.	New warning to address suffocation incidents.
~~9.3.3 The following warning must be visible on or through the retail packaging and visible on the product during assembly and address the following:~~		
9.~~3.3.1 For~~ contoured changing pads and add-on changing units sold separately ~~the warnings shall address either~~ (a) identify specific products to attach the product to or (b) that the support surface used should be level, stable, and structurally sound with minimum support surface dimensions of "X" by "Y".	9.5.4 Contoured changing pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately shall include additional warnings addressing either: (a) The specific products to attach the contoured changing pad or add-on unit to; or (b) That the surface used should be level, stable, and structurally sound with minimum surface dimensions of "X" by "Y".	Addresses play yard changing table accessories
10.1 Instructions shall be provided with or permanently attached or printed on the changing table, add-on changing unit, or contoured changing pad and shall be easy to read and understand. These instructions shall include information regarding assembly, maintenance, cleaning, and use of the product.	10.1 Instructions shall be provided with or permanently attached or printed on the changing table, add-on changing unit, or contoured changing pad and shall be easy to read and understand. These instructions shall include information regarding assembly, maintenance, cleaning, and use of the product.	

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CURRENT	PROPOSED	RATIONALE
10.1.1 The instructions shall contain the warning statements in 9.~~3~~ and address the following:	10.1.1 The instructions shall contain the warnings as specified in 9 and address the following: NOTE: For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, *American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials*, or equivalent.	Addresses the lack of any design or form requirements for the required warning statements in the instructions by providing a guidance note.

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TAB F: Initial Regulatory Flexibility Analysis of the Staff-Recommended Proposed Standard for Changing Tables and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Changing Tables Standard

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

Memorandum

Date: May 31, 2016

TO : Shaina E. Donahue
Project Manager, Changing Tables
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

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

Robert L. Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

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

SUBJECT : Initial Regulatory Flexibility Analysis of the Staff-Recommended Proposed Standard for Changing Tables and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Changing Tables Standard[20]

I. Introduction

ASTM F2388-16 is the current ASTM International (ASTM) standard for baby changing tables for domestic use. Staff recommends that the U.S. Consumer Product Safety Commission (CPSC or Commission) issue a proposed rule under the requirements of the Danny Keysar Child Product Safety Notification Act (section 104) of the Consumer Product Safety Improvement Act (CPSIA) that incorporates by reference the most recent ASTM standard for baby changing tables for domestic use (changing tables or changing products), with modifications to the warning labels and instructional literature, an added test for restraint effectiveness, a modification to the structural integrity test procedures for products with user-installed secondary supports for the changing surface, and a ban on using self-tapping screws such as wood screws, sheet metal screws and the like for key structural elements requiring user assembly, as well as requiring a

[20] Industrial Economics, Incorporated (IEc) served as a consultant on this project, performing research and analysis to support Directorate for Economic Analysis (EC) staff.

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means to impede loosening or detachment of metal inserts and metal threaded fasteners used to secure key structural elements.

This memorandum evaluates the potential economic impact on small entities, including small businesses, of the staff-recommended changing table standard, as required by the Regulatory Flexibility Act (RFA).[21] Section 603 of the RFA requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the general notice of proposed rulemaking (NPR) is published, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained below, at this time, staff cannot rule out a significant economic impact for 40 of the 59 (68 percent) known small suppliers of changing tables to the U.S. market. Accordingly, we have prepared an IRFA and pose several questions for public comment to help us with our assessment.

The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objective and minimize any significant economic impact. Specifically, the IRFA must contain:

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

II. The Product

The scope of ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, covers "baby changing tables and other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables." The changing products that fall within the scope of this standard are listed below:

1. Standalone changing tables typically used in homes range widely in price (from $35 to $1,400). (See Figure 1)

[21] 5 U.S.C. §§ 601-612.

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Figure 1. Home-Use Standalone Changing Table

2. Standalone changing tables typically used in daycare and educational settings also range widely in price ($270 to $1,650) and complexity (some have stairs to assist children in getting onto them). (See Figure 2)

Figure 2. Daycare/Educational Setting Standalone Changing Table

3. Home-use, wall-mounted changing units are uncommon in the U.S. market. However, the units found by staff range in price from $380 to $1,330. (See Figure 3)

Figure 3. Home-Use Wall-Mounted Changing Table

4. Changing trays, although sometimes sold attached to furniture pieces, are also sold separately to be used on any flat surface along with a changing pad (either flat or contoured). These range widely in price, with some as inexpensive as $12 and high-end models selling for as much as $1,050. (See Figure 4)

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Figure 4. Changing Trays

5. Contoured changing pads may be used alone on any flat surface or in conjunction with a changing tray.[22] They have higher sides on at least the long ends to prevent children from rolling out. They tend to be fairly inexpensive (about $7 to $100); although contoured pads, intended for a specific changing product only, may be more expensive. (See Figure 5)

Figure 5. Contoured Changing Pads

6. Cribs with attached changing tables tend to be relatively inexpensive, possibly because their dual usage appeals mostly to those on tighter budgets (from $177 to $330). The cribs themselves may be full-sized or mini-cribs. (See Figure 6)

Figure 6. Crib with Attached Changing Table

[22] Flat changing pads are also a changing product, but have no separate requirements within the voluntary or staff-recommended proposed standard. Rather, the flat pads are used in conjunction with changing products with built-in barriers, such as changing trays or home-use standalone changing tables. It is these latter products that have requirements in the standard. Because the standard does not cover flat changing pads, they were not included in the market research.

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7. Changing table attachment accessories are units that become a changing table only when attached to a specific product, such as a crib, play yard, or bassinet. These products may be sold separately or only with the base product. The price range is similar to the pricing of the base products; however, the attachments sold separately tend to be for more high-end products than attachments that are sold with the base product (about $100 to $300). (See Figure 7)

Figure 7. Changing Table Attachment Accessories

8. Bathing stations with changing capabilities look similar to home-use, standalone changing tables, until the changing table top is removed or lifted up, uncovering a baby bath tub. There are only a few of these products sold in the U.S. marketplace at this time. These products appear to be more popular in Europe, perhaps due to their space-saving nature. They typically cost around $100 to $200. (See Figure 8)

Figure 8. Bathing Station with Changing Capabilities

9. Furniture pieces sold with an attached changing tray, rather than a removable changing tray, are essentially pieces of furniture where the top incorporates rails or barriers of some sort to hold a changing pad and prevent a child from rolling over while being changed. Some look very similar to home-use, standalone changing tables; except that home-use, standalone changing tables have open, rather than closed, storage spaces. Others resemble a dresser with a changing tray placed on top. These products vary widely in price, from $150 to $4,500. (See Figure 9)

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Figure 9. Furniture with Attached Changing Tray

As noted in the scope of the standard, furniture pieces may become changing tables with the use of contoured changing pads or add-on pieces like changing trays. Although furniture pieces that come with an attached tray would fall under the scope of the rule, a dresser that only becomes a changing table with the consumer's addition of a changing tray or contoured changing pad would not fall within the scope of the rule. Therefore, these furniture products are not included in the IRFA market research.

Also not included within the scope of the voluntary standard (or the staff-recommended proposed standard) are commercial wall-mounted changing tables, such as those frequently seen in public restrooms. Commercial changing products are wall mounted and are subject to a separate voluntary standard (ASTM F2285-04, reapproved in 2010, *Standard Consumer Safety Performance Specification for Diaper Changing Tables for Commercial Use*). There is no reason to believe that commercial changing tables are being used in homes. An example of a commercial wall-mounted changing table, for comparison, is shown in Figure 10.

Figure 10. Commercial Wall-Mounted Changing Table

III. The Market for Changing Tables

At least 85 firms supply changing tables to the U.S. market. The majority of these firms (81 firms) supply products marketed to consumers; however seven firms also market their products to commercial daycares. Most firms (56 firms) supply multiple changing table products across a variety of product types. The majority of the 85 known firms are domestic (including 57

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manufacturers, 12 importers, one wholesaler, and one retailer). The remaining 14 firms are foreign (including 12 manufacturers, one importer, and one retailer).[23]

IV. Reason for Agency Action and Legal Basis for the Draft Proposed Rule

Based on National Electronic Injury Surveillance System (NEISS) injury estimates[24] and data on the number of changing tables in use from CPSC's Durable Nursery Product Exposure Survey (DNPES),[25] staff found that the risk associated with changing table use in homes is approximately 4.96 emergency department-treated injuries per 10,000 changing tables in use annually [(3,060 injuries[26] ÷ 6.17 million changing tables in use in U.S. households) x 10,000].

Section 104 of the CPSIA requires the CPSC to examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products and promulgate 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 requirements would further reduce the risk of injury associated with the products. Changing tables were not expressly mentioned as a durable infant or toddler product in section 104(f)(2). However, the Commission specifically identified "changing tables" as a "durable infant or toddler product" in the product registration card rule that the Commission issued under section 104(d). 16 C.F.R. § 1130.2(a)(14).

CPSC staff recommends that the Commission propose to incorporate by reference the voluntary ASTM standard for changing tables for domestic use (F2388-16), with modifications to the warning labels and instructional literature, an added test for restraint effectiveness, a modification to the structural integrity test procedures for products with user-installed secondary supports for the changing surface, and a ban on wood screws for key structural elements requiring user assembly, and a means to impede loosening or detachment of metal inserts or metal threaded fasteners used to secure key structural elements.

All of the staff-recommended changes to the existing ASTM standard would address fall hazards. Based on a review of NEISS cases from January 1, 2005 to December 31, 2014, staff from the Directorate for Epidemiology (EPHA) concluded that cases where a child fell or rolled off of a changing table were the most common injury incidents.[27] The Directorate for Health Science staff (HS) found in their analysis of the incidents reported to CPSC over the same period from the Consumer Product Safety Risk Management System (CPSRMS) database that 114 of

[23] Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.
[24] Memorandum from Wioletta Szeszel-Fedorowicz, Division of Hazard Analysis, Directorate for Epidemiology, dated March 4, 2016, Subject: Estimated Number of Injuries and Reported Incidents Associated with Changing Tables, 2005–2015.
[25] Melia, K.L. and J.L. Jenkins (November 2014). *Durable Nursery Products Exposure Survey (DNPES): Final Summary Report*. U.S. Consumer Product Safety Commission, prepared by Westat.
[26] Given the statistically significant increase in annual injuries over the period of time examined, the annual injuries from the most recent year of data (2014) were used.
[27] Szeszel-Fedorowicz (2016).

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the 177 nonfatal incidents "involved an infant falling from or through the changing table"; although "only 10 of these incidents resulted in an injury."[28] Additionally, a new suffocation warning would address four of the five deaths associated with changing products used for sleeping.[29]

V. Requirements of the Draft Proposed Rule

The draft proposed rule would incorporate by reference the voluntary ASTM standard for changing tables (F2388-16), with modifications to the warning labels and instructional literature, an added test for restraint effectiveness, a modification to the structural integrity test procedures for products with user-installed secondary supports for the changing surface, and a ban on wood screws for key structural elements requiring user assembly and a means to ensure that key structural components do not become loose or detached. This would make it a mandatory product safety rule under the Consumer Product Safety Act (CPSA). Firms whose changing tables do not comply will need to evaluate their products, determine what changes would be required to meet the standard, and decide how to proceed. Noncompliant products would need to be removed from the U.S. market or modified to meet the staff-recommended proposed standard.

A. ASTM F2388-16

The major requirements from ASTM F2388-16 are presented below:[30]

- Stability—intended to reduce the likelihood of falls by addressing changing table tip overs. The test does not apply to contoured changing pads or add-on changing units that are sold separately.
- Entrapment in enclosed openings—intended to ensure that neither the occupant nor a child outside the changing unit can slip through an opening and have his or her head entrapped. The test essentially checks that if the child's torso would pass through the opening, so would his or her head.
- Entrapment by shelves—intended to prevent open shelves on changing units from entrapping a child's head.
- Structural integrity—intended to ensure that the changing table remains intact after static testing, thereby reducing the likelihood of a table collapsing or a child breaking

[28] Memorandum from Stefanie Marques, Division of Pharmacology and Physiology, Directorate for Health Sciences, dated April 8, 2016, Subject: Health Science Analysis of Changing Table-Related Deaths and Injuries.
[29] Memorandum from Hope E. J. Nesteruk and Timothy P. Smith, Division of Human Factors, Directorate for Engineering Sciences, dated August 4, 2016, Subject: Human Factors Assessment of ASTM F2388 – 15 Requirements for Changing Tables and Changing Products (CPSIA section 104).
[30] Additional information on the ASTM standard and how it addresses various hazard patterns can be found in the memorandum from Shaina Donahue, Division of Mechanical Engineering and Combustion, Directorate for Engineering Sciences, dated August 4, 2016, Subject: ESMC Staff's Review and Evaluation of ASTM F2388-15, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, for Incorporation by Reference into Staff's Draft Proposed Rule.

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through the changing surface while he or she is being changed. The test does not apply to contoured changing pads or add-on changing units that are sold separately.

- Barriers—intended to prevent children from falling off the sides of changing tables, as well as reducing injuries associated with barriers degrading or splintering after repeated use. Barriers are required for all changing table products, but the test method varies for each type of changing product.
- Retention—intended to prevent contoured changing pads and add-on changing units, like trays, from slipping, thereby reducing the fall risk. The barriers test method is applied to this requirement. Add-on changing unit accessories for play yards and non-full-size cribs are not subject to this requirement, as changing unit retention is addressed in the voluntary ASTM standard (F406) and the mandatory CPSC standards (16 C.F.R part1221 and 16 C.F.R. part 1220) for these products.

The voluntary standard also includes various general requirements common to most other voluntary children's product standards: (1) torque and tension tests to ensure that components cannot be removed; (2) requirements to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and smoothness of wood parts; (3) marking and labeling requirements, including permanency requirements; (4) requirements for instructional literature; and (5) toy accessory requirements. ASTM F2388-16 includes no reporting or recordkeeping requirements.

B. Staff-Recommended Changes

Staff is recommending four changes to the ASTM voluntary standard, F2388-16: (1) modifications to the warning labels and instructional literature; (2) a new restraint-effectiveness test; (3) a modification to the structural integrity test procedures for products with user-installed secondary supports for the changing surface; and (4) a ban of wood screws for key structural elements requiring user assembly and a means to impede loosening or detachment of metal inserts and metal threaded fasteners used to secure key structural elements.

To assist in the evaluation of the economic impact of the draft proposed rule, EC staff contacted several ASTM members and supplier representatives. We contacted nine firms (three responded).

1. Warning Labels and Instruction Manuals

As noted in the Division of Human Factors (ESHF) memorandum (Tab E), ESHF staff does not believe that the existing on-product warning requirements or the instruction manual requirements adequately address the risk of injuries and death associated with changing products. To address fall and suffocation hazards better, as well as hazards associated with misusing changing products for sleep, staff is recommending changes to the format and the wording of these warnings.

To address the four deaths associated with the use of play yard changing table attachments and contoured changing pads for sleep, ESHF staff recommends adding a "strong warning alerting caregivers to the hazards associated with sleeping in or on changing products." Staff also

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recommends modifying the existing fall hazard warning to: (1) emphasize the speed with which these incidents can occur; and (2) include a more explicit description of the injuries that have occurred with falls.

For formatting, staff recommends that on-product warnings meet the recommendations developed by the ASTM Ad Hoc Wording Task Group (ad hoc task group),[31] with a few editorial changes identified by CPSC staff. The ad hoc task group's recommendations incorporate accepted ANSI labeling requirements. Staff recommends that the formatting of instructional warnings be the same, except that coloration associated with warning symbols would not be required.

All firms would be affected by the staff-recommended warning label changes. Each firm would need to modify the formatting and wording of the warnings for the product and the instruction manual. Generally, these kinds of straightforward modifications to the format and content of an existing label would not generate costs that would be considered significant, relative to any of the changing product firms' revenues. The firms contacted for this rulemaking said that factors such as stock levels that would need to be scrapped and the number/size of the labels that need to be replaced would influence costs. One firm estimated that it might cost up to $10,000 and take about 3 months to accomplish. A second firm estimated that it would take them closer to 6 months to make the labeling changes.

Additionally, one firm noted that the timing of changes to the warning label and instructional manual requirements can affect costs and also impact retailers. This is because warning labels and instruction manuals are keyed to model and SKU numbers, which means that changing them can cause inventory issues, particularly when the changes take place during a busy time of the year for retailers. The firm noted that enacting the changes to coincide with periods where models are typically changed (*i.e.*, January), would reduce these costs. This comment responded to an inquiry about developing a briefing package for a notice of proposed rulemaking for inclined sleepers, However, it seems likely that a similar pattern might exist in the changing table market, as well.

Staff requests comments on whether the timing of changes to the warning/instruction requirements for changing products would impact compliance costs. Staff also requests comments on the cost and time required to modify warning labels and instruction manuals.

2. Restraint Effectiveness

The voluntary standard for changing tables, ASTM F2388-16, does not require that restraints be included with each product. Nevertheless, staff found that about 21 percent of the changing table products in the U.S. marketplace came with restraints. Restraints may serve a useful purpose, preventing falls, holding the child relatively still, and making it easier for the caregiver to change the child. However, restraints also have the potential to give caregivers a false sense

[31] The composition, intent, and recommendations of the ad hoc task group are described more fully in the ESHF memorandum.

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of security. The EPHA memorandum found several instances in the incident data of restraints breaking, detaching, or coming loose. In some cases, falls occurred.

Based on the hazard pattern seen in the incident data, staff recommends adding a restraint effectiveness test.[32] Including this test would reduce the risk of changing tables with ineffective restraints entering the U.S. market in the future, as well as decrease the hazard of falls associated with ineffective restraints.

Limited initial testing indicates that some changing table products may require modifications to meet the staff-recommended restraint effectiveness requirement. Division of Mechanical and Combustion Engineering (ESMC) staff found that some contoured changing pads were unable to pass the proposed test procedure because the stitching used to attach the straps to the product was insufficient. Staff believes that extra reinforcement of the stitching would effectively address the new requirement. Similarly, changing table products (other than contoured changing pads) that screw through the webbing without additional reinforcement also failed the proposed test. However, products that used washers or metal straps, in addition to the screws through the restraint webbing, passed the test procedure easily.[33] Therefore, the methods that suppliers are likely to use to bring any noncompliant restraints into compliance appear to be low cost, consisting primarily of additional support from stitching, washers, or metal straps. It is possible, however, that some suppliers may opt to remove their restraints altogether. None of the firms that responded to staff's questions would be affected by the proposed restraint effectiveness test.

Staff requests information on the methods that might be employed to bring existing restraints into compliance and the costs associated with them. Staff is also interested in how feasible (and likely) it is that suppliers will remove the restraints instead.

3. User-Installed Secondary Changing Surface Supports

Staff's review of the emergency department-treated injury cases in NEISS-member hospitals showed that falls were the most common cause of injury incidents. Similarly, a review of the incidents reported to CPSC showed that the majority (65%) resulted from problems with structural integrity; nearly half mentioned a collapse.[34] Product testing of incident and non-incident products identified two places where a modification to the voluntary standard would help address these incidents: (1) wood screws for user-assembled key structural elements (covered in the next section), and (2) user-installed secondary supports.

Preliminary testing by staff revealed that certain types of changing tables (particularly home-use, standalone changing tables with open shelves) tended to use secondary support straps to support the changing surface. In all cases, these secondary support straps required consumer installation. Some changing tables that staff tested were unable to pass the structural integrity test procedures required by the current ASTM standard without those secondary straps installed. Additional incident review showed that, in some cases, these secondary supports were not

[32] Tested using a pull force of 30 lbf, without the strap or buckle detaching.
[33] Kumagai (2016) and email correspondence with Shaina Donahue.
[34] Szeszel-Fedorowicz (2016).

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installed or were misinstalled. However, staff was unable to identify any products currently on the market that failed the structural integrity tests when secondary supports were not installed.

Based on this evidence, staff recommends that all changing tables be tested to the structural integrity test procedures without user-assembled secondary support straps in place. Essentially, this means that the changing table must be able to support the intended child's weight, even if the user neglects to assemble or misassembles secondary supports.

It is unclear precisely how many changing tables will require modifications to meet the revised testing requirements. Similarly, it is unclear how many firms might be impacted. However, it seems likely that, at minimum, some subset of suppliers of home-use, standalone changing tables with open shelves would be affected. Although it is possible that some other types of changing products may use secondary supports that require user assembly, as well (staff did not find any in their preliminary testing). A review of the changing table products in the U.S. marketplace led staff to believe that less than half of the known suppliers would require modifications to their changing tables to meet the staff-recommended test procedure.

Possible changes that firms might make to achieve compliance include sturdier primary supports or manufacturer-installed secondary supports. It is likely that the cost would vary, depending upon the method chosen to meet the requirement. In many cases, it could be a simple material change, which suppliers have reiterated many times tends to be lower cost than design changes. However, it is possible that some firms may redesign their changing surface support system as well. In that case, the cost is likely to be greater and take a longer time. The three firms that responded to staff's questions all indicated that their changing products do not employ user-installed secondary supports.

Staff requests information on the types of changing products that have user-assembled secondary supports and the prevalence of these products in the market. Staff also requests input on the types of modifications that affected suppliers might make to their changing tables to bring them into compliance with the revised test method. Information on the cost and time frame of these alternatives is likewise requested.

4. Wood Screws and Other Fasteners in Key Structural Elements

While testing changing tables to identify potentially addressable causes of fall hazards, staff noted that many of the incident products used wood screws (*i.e.*, screws used in wood components) in user-assembled key structural elements. When used by consumers, consumers run the risk of installing these products incorrectly on the first try, requiring a second attempt, which weakens the connection. Additionally, for products like changing tables, which may be disassembled and then reassembled for additional children, the use of wood screws makes the connection weaker each time the changing product is reassembled.[35]

Most voluntary juvenile product standards for wooden children's products, as well as most CPSC mandatory juvenile product standards for those products, ban the use of wood screws that

[35] See Kumagai (2016) for a more detailed explanation.

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require consumer assembly in key structural elements. Therefore, this is a requirement that juvenile product suppliers are familiar with, and based on the market review, there are no more than half a dozen firms that might not be familiar with this type of ban. Additionally, there is general support among ASTM members for adding this ban to the standard.

CPSC testing indicates that most products on the market do not require consumers to assemble key structural elements using wood screws. None of the responding firms employ wood screws for user-assembled key structural components. Therefore, the overall impact on the market from this requirement is believed to be small. However, it is possible that there may be a few firms that do use these elements in their designs, and therefore, these firms would be affected by the staff-recommended ban. Possible methods of complying include pre-assembling the relevant key structural elements, which could increase the package size and resulting shipping costs, and redesigning the product, possibly using non-wood materials. Perhaps alternative fastening devices are possible as well. They are likely to be less costly than the other two options mentioned.

At this time, we do not know how affected firms will respond, and we have no basis for estimating the costs associated with the recommended ban on wood screws. We welcome comments on this issue, and, in particular, request comments on possible methods of complying, in addition to comments on estimates of the costs of making these changes. We are additionally interested in receiving comment on whether the costs would be considered "economically significant," meaning an impact greater than 1 percent of revenue (or a similar economic benchmark or criteria).

Staff also recommends requiring firms to use a means to impede loosening or detachment of metal inserts and metal threaded fasteners used to secure key structural elements as part of their changing table designs. Staff believes that these methods may consist of lock washers, self-locking nuts, and glue, none of which are believed to add significant costs to firm or to require product redesign. However, staff requests comments from industry representative regarding the methods that may be required to meet this requirement, the likely costs, and the time frame necessary to achieve compliance.

VI. Other Federal or State Rules

CPSC staff has not identified any federal or state rule that overlaps or conflicts with the staff-recommended proposed rule.

VII. Impact on Small Businesses

CPSC staff is aware of approximately 85 firms currently marketing changing tables in the United States; 71 are domestic. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of changing tables is considered "small" if it has 500 or fewer employees; and importers, wholesalers; and retailers are considered "small" if they have 100 or fewer employees. Our analysis is limited to domestic firms because SBA guidelines and definitions pertain to U.S.-

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based entities. Based on these guidelines, about 59 of the 71 firms are small—49 domestic manufacturers, nine domestic importers, and one domestic wholesaler. Additional unknown small domestic changing table suppliers may be operating in the U.S. market. Table 1 describes the identified firms in the changing table market.

Table 1. Identified Firms in the U.S. Changing Table Market

CATEGORY	NUMBER OF FIRMS
Total Firms	**85**
Domestic	71
Small	**59**
Manufacturers	**49**
Compliant with ASTM Voluntary Standard	22
Not Compliant with ASTM Voluntary Standard	27
Importers or Wholesalers	**10**
Compliant with ASTM Voluntary Standard	4
Not Compliant with ASTM Voluntary Standard	6
Large	**12**
Foreign	14
Highlighted categories are the focus of this analysis.	

A. Small Manufacturers

1. Small Manufacturers with Compliant Changing Tables

Of the 49 small manufacturers, 22 produce changing tables that comply with ASTM F2388-16. In general, staff expects that small manufacturers with changing tables that already comply with the voluntary standard currently in effect, for testing purposes, will remain compliant with the voluntary standard as it evolves. That is because these manufacturers follow, and in five cases, actively participate in the standard development process. Therefore, compliance with the voluntary standard is part of an established business practice for these manufacturers. ASTM F2388-16, the version of the voluntary standard upon which the staff-recommended mandatory standard is based, is already in effect for testing purposes; therefore, these firms are expected to be in compliance already.

As described above, the costs associated with three of the four staff-recommended changes to the ASTM voluntary standard (modifications to the format and wording of on-product warning labels and instructional warnings, new restraint effectiveness requirements, and a ban on the use of wood screws in user-assembled key structural elements, as well as methods to prevent

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loosening) are expected to be small for the 22 small domestic manufacturers supplying compliant changing tables to the U.S. market. These firms are all familiar with the production of warning labels and instruction manuals. Therefore, costs to modify the format of existing labels and manuals are expected to be small, with one firm putting the cost at $10,000 total. These firms are also unlikely to manufacture products that rely on wood screws for user assembly because all of these firms are familiar with bans on the use of wood screws, which is common in voluntary and mandatory juvenile product standards. About half of the compliant manufacturers (10 firms) supply at least one changing table model with restraints. If restraints are found to be noncompliant, the restraints could be reinforced with low-cost methods, such as extra stitching or adding washers or metal straps. Alternatively, firms could choose to remove restraints.

The staff-recommended revision to the structural integrity test procedures for changing tables with user-installed secondary supports may result in more significant costs. Only five of the compliant manufacturers supply changing tables that may have user-installed secondary supports. It is difficult to determine the magnitude of costs associated with design changes needed to achieve compliance with the staff-recommended revised test method. Costs could be minimal, if a simple material change is sufficient to pass the test; however, if a redesign of the changing surface support system is required, costs could be greater. Firms indicated that a complete redesign could range from $25,000 to $200,000, depending upon the changing table product type. Therefore, staff cannot rule out a significant economic impact on the five manufacturers of compliant changing tables that may have user-installed secondary supports. Staff requests comment on the types of changing products that employ user-installed secondary supports and the costs associated with modifications necessary to bring these products into compliance with the revised test method.

2. Small Manufacturers with Noncompliant Changing Tables

Twenty-seven small manufacturers produce changing tables that do not comply with the voluntary standard. Staff cannot rule out a significant economic impact for any of these 27 small manufacturers. These firms may not be aware of the ASTM voluntary standard. All 27 firms' changing tables are likely to require modifications; some modifications may be significant simply to meet the base requirements of the voluntary standard. Additional modifications may be required to comply with staff-recommended changes, especially for changing tables with restraints (16 manufacturers); changing tables likely to have user-installed secondary supports (three manufacturers); and changing tables with wood screws in user-assembled key structural elements (number of affected firms unknown). It is expected that all of these products have instruction manuals and some on-product warnings; staff is unaware of any changing table products that do not have instruction manuals; and such products would likely be perceived as less desirable by consumers. The extent and cost of the changes required cannot be determined. Consequently, staff cannot rule out a significant economic impact.

Staff requests information on the changes that may be required to meet the voluntary standard, ASTM F2388-16; and, in particular, whether redesign or retrofitting would be necessary, and the associated costs and time frame. We also request information on the degree to which the staff-recommended changes may add to a firm's costs.

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3. Third Party Testing Costs for Small Manufacturers

Under section 14 of the CPSA, once new changing table requirements become effective, all manufacturers will be subject to the third party testing and certification requirements under the *Testing and Labeling Pertaining to Product Certification* rule ("1107 rule"). Third party testing will include any physical and mechanical test requirements specified in the final changing table rule. Manufacturers and importers should already be conducting required lead testing for changing tables. Third party testing costs are in addition to the direct costs of meeting the changing table standard.

Almost half of small changing table manufacturers (22 out of 49) are already testing their products to verify compliance with the ASTM standard, although, their testing is not necessarily by a third party.[36] For these manufacturers, the impact to testing costs will be limited to the difference between the cost of third party tests and the cost of current testing regimes. Contacted suppliers estimate that third party testing of changing tables to the ASTM voluntary standard would cost about $300-$1,200 per model sample, depending upon whether the tests are conducted in the United States or overseas. For manufacturers that are already testing, the incremental costs will be lower than that and are unlikely to be economically significant.

For the 27 small manufacturers that are not currently testing their products to verify compliance with the ASTM standard, the impact of third party testing, by itself, could result in significant costs for five firms. Although it is unknown how many samples will be needed to meet the "high degree of assurance" criterion required in the 1107 rule, testing costs could exceed 1 percent of gross revenue with five or fewer samples tested for these firms (assuming high-end U.S.-based testing costs of $1,200 per model sample). Revenue information was not available for six of the small manufacturers with noncompliant changing tables; therefore, no impact evaluation could be made.[37]

We welcome comments regarding overall testing costs and incremental costs for third party testing (*i.e.*, how much does moving from a voluntary to a mandatory third party testing regime add to testing costs, in total and on a per test basis). In addition, staff seeks comments regarding the number of changing table units that typically need to be tested to provide a "high degree of assurance."

B. Small Importers and Wholesalers

1. Small Importers and Wholesalers with Compliant Changing Tables

[36] Determinations about a firm's compliance were made based on the following factors: (1) certification by the Juvenile Products Manufacturers Association (JPMA); (2) claims of compliance with the voluntary standard; (3) active participation in the ASTM rulemaking process; or (4) testing to the ASTM standard by CPSC staff.
[37] These determinations were made based on an examination of firm revenues from recent Dun & Bradstreet or ReferenceUSAGov reports.

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The economic impact to importers and wholesalers are considered together because both rely on outside firms to supply the products that they distribute to the U.S. market. Importers distribute products made by foreign firms and are often closely related to the firm producing their product. Staff was unable to determine the source of the changing tables distributed by wholesalers. However, staff believes that they are likely purchased from other suppliers that may be foreign or domestic.

Without a mandatory regulation, the four small importers of changing tables currently in compliance with the voluntary standard would likely remain in compliance with new versions of the standard. However, the changing tables supplied by these firms would require modifications to meet the staff-recommended proposed rule. There are two firms supplying models that may require restraint reinforcement; but as already noted, these costs are likely to be low. The cost of modifications to the format and wording of the warnings, as well as the ban on the use of wood screws and means to prevent other fasteners from becoming loose or detached, should be small, as well, given that these requirements are familiar to firms supplying compliant products.

Modifications to pass the revised structural integrity test procedures for changing tables with user-installed secondary supports, however, could be more costly, and could possibly require retrofitting or redesign. Two of the four importers supply models that may require physical modifications to pass the structural integrity test procedures. Finding an alternative supply source would not be a viable alternative for these firms, due to the close relationships they have with their supplier. Both firms supply a sufficient number of other products, so that they could probably eliminate changing tables from their product line entirely, without a significant adverse impact. Staff requests information on how importers will respond to the proposed rule, as well as what importers estimate the costs of developing a compliant product will be.

2. Small Importers and Wholesalers with Noncompliant Changing Tables

There is insufficient information to rule out a significant impact for any of the six firms (five importers and one wholesaler) with noncompliant changing tables. Whether there will be a significant economic impact will depend upon the extent of the changes required to come into compliance and the responses of their supplying firms. Any increase in production costs experienced by suppliers from changes to meet the mandatory standard may be passed on to the importers and wholesalers. These costs would include costs associated with coming into compliance with the voluntary standard, as well as costs associated with the staff-recommended modifications to the voluntary standard.

Four of the six importers/wholesalers with noncompliant changing tables do not appear to have direct ties to their product suppliers. These firms may opt to switch to alternative suppliers (or, in some cases, alternative products), rather than bear the cost of complying with the standard. However, it is unclear whether the costs associated with such a change and/or any associated changes in revenue would be significant for these firms. Changing products are the only wares supplied by one of these firms. Therefore, it is unlikely that this firm would exit the changing tables market, unless it is unable to find alternative suppliers with compliant changing products, or cannot bear the cost of complying with the standard. If this firm did exit the changing table market, the economic impact would be significant. The other three firms supply

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many children's products, in addition to changing tables. Therefore, dropping noncompliant changing tables for another product, or using compliant changing tables from another supplier may be a reasonable alternative for these firms. However, sales revenue for changing tables was not available. We cannot determine whether exiting the changing table market would generate significant economic impacts.

The remaining two firms are directly tied to their foreign suppliers, and finding an alternative supply source would not be a viable alternative. However, the foreign suppliers of these firms may have an incentive to work with their U.S. subsidiaries/distributors to maintain an American market presence. It is also possible that these firms may discontinue the sale of changing tables altogether because changing tables are not a large component of their firm's product lines. Again, we cannot determine whether exiting the changing table market would generate significant economic impacts, given the lack of sales revenue for changing tables.

3. Third Party Testing Costs for Small Importers and Wholesalers

As with manufacturers, all importers will be subject to third party testing and certification requirements. Wholesalers, if their products are obtained from foreign sources, may be subject to these testing requirements as well. Consequently, importers will be subject to costs similar to manufacturers' costs, if their supplying foreign firm(s) does not perform third party testing. For the four importers already testing their products to verify compliance with the ASTM standard, any costs would be limited to the incremental costs associated with third party testing over the current testing regime.

For firms with changing tables that are not believed to be compliant with the ASTM standard, moving to third party certification of the staff-recommended proposed rule could result in significant costs for two or three firms. Testing costs could exceed 1 percent of gross revenue with as few as two units per model tested for two of those firms. A third firm would need to test about nine units per model, before testing costs would exceed 1 percent of gross revenue. There was no revenue data available for one small wholesaler of changing products that are believed to be noncompliant with the voluntary ASTM standard. Therefore, we had no basis for examining the size of the impact on that firm.

C. Summary of Impacts

CPSC staff is aware of 59 small firms, 49 domestic manufacturers and 10 domestic importers/wholesalers, currently marketing changing tables in the United States. Of the 49 small manufacturers, 17 are unlikely to experience significant economic impacts. However, we could not rule out a significant economic impact for the remaining 32 small manufacturing firms. Based on a review of firm revenues for small importers and wholesalers, as well as the options available to each firm, the impact of the staff-recommended proposed rule may not be significant for two small importers. However, staff cannot rule out a significant economic impact on the remaining eight small importers and wholesalers. Therefore, based upon current information, we cannot rule out a significant economic impact for 40 of the 59 firms (68 percent) operating in the U.S. market for changing tables.

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VIII. Alternatives

At least three alternatives are available to minimize the economic impact on small entities supplying changing tables, while also being able to meet the statutory objectives: (1) adopt ASTM F2388-16, with no modifications; (2) adopt ASTM F2388-16, with the staff-recommended modifications, except for the revision to the structural integrity test procedures for changing tables with user-installed secondary supports; and (3) allow a later effective date.

First, section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent if the Commission determines that more stringent standards would further reduce the risk of injury. Therefore, adopting ASTM F2388-16 with no modifications is the least stringent rule that could be promulgated. This alternative would reduce the impact on all of the known small businesses supplying changing tables to the U.S. market. Although this option would not reduce the testing costs triggered by the rule, this alternative would eliminate any economic impact related directly to complying with the staff-recommended proposed rule for the 22 small domestic manufacturers and the four small importers that comply with the voluntary standard. However, the staff-recommended modifications are intended to reduce the risk of fall and suffocation incidents associated with product misuse, fall incidents where restraints have failed, and fall incidents where the user has assembled the product in a manner that decreases the structural integrity. Adopting ASTM F2388-16 with no modifications may not meet these objectives.

Second, the Commission could reduce impacts to small businesses by adopting ASTM F2388-16 with the staff-recommended modifications, except for the revision to the structural integrity test procedures for changing tables with user-installed secondary supports. This staff-recommended modification is likely to have the largest economic impact, possibly resulting in redesign of the changing surface support system in a subset of suppliers of home-use standalone changing tables with open shelves. This alternative would help reduce the impact on these small suppliers (nine small manufacturers and two small importers). However, eliminating this staff-recommended modification could increase the possibility of future fall incidents, due to improperly installed supports, relative to the staff-recommended proposed rule.

Third, the Commission could also reduce the staff-recommended proposed rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. First, firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third party test within the required timeframe. Second, firms could spread costs over a longer time period, thereby reducing their annual costs and the present value of their total costs. Staff specifically requests comments on the 6-month effective date and seeks feedback on how firms would likely address the proposed rule. Staff would appreciate input on the recommended effective date.

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IX. Small Business Impacts of the Accreditation Requirements for Testing Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a CPSC-accepted third party conformity assessment body (*i.e*., testing laboratory) for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the NOR pertaining to third party conformity testing. NORs have been codified for existing rules at 16 C.F.R. part 1112. Consequently, staff recommends that the Commission propose an amendment to 16 C.F.R. part 1112 that would establish the NOR for those testing laboratories that want to test for compliance with the changing products final rule. This section assesses the impact of the amendment on small laboratories.

Staff conducted a Final Regulatory Flexibility Analysis (FRFA) as part of promulgating the original 1112 rule (78 FR 15836, 15855-58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the rule to include the NOR for the changing products standard will 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 changing products standard. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards. The only costs to them would be the cost of adding the changing products standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. Consequently, the Commission could certify that the NOR for the changing products standard will not have a significant impact on a substantial number of small entities.

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