



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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This document has been electronically
approved and signed.

DATE: June 13, 2018

BALLOT VOTE SHEET:

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Patricia H. Adkins, Executive Director

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

SUBJECT: Final Rule: Safety Standard for Baby Changing Products

BALLOT VOTE DUE: Tuesday, June 19, 2018

Staff is forwarding to the Commission a briefing package recommending that the Commission publish in the *Federal Register* the attached draft final rule concerning baby changing products. Pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008, the draft final rule would incorporate by reference the voluntary standard, ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*, as the mandatory federal safety standard for baby changing products. Additionally, the draft final rule would amend the Commission's regulation regarding third party conformity assessment bodies to include the mandatory standard for baby changing products in the list of notices of requirements in 16 C.F.R. part 1112. The Office of the General Counsel is providing the attached draft final rule for Commission consideration.

Please indicate your vote on the following options:

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

(Signature)

(Date)

II. Approve publication of the attached document in the *Federal Register*, with the specified changes.

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action specified below.

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Final Rule to Establish a Safety Standard for Baby Changing Products

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1235

[Docket No. CPSC-2016-0023]

Safety Standard for Baby Changing Products

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the United States Consumer Product Safety Commission (CPSC) to adopt consumer product safety standards for durable infant or toddler products. To comply with the CPSIA, the Commission is issuing a safety standard for baby changing products. This rule incorporates by reference ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use* (ASTM F2388-18). In addition, this rule amends the regulations regarding third party conformity assessment bodies to include the safety standard for baby changing products in the list of Notices of Requirements (NORs).

DATES: The rule will become effective on [INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Keysha Walker, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission; 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-6820; email: KWalker@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Congress enacted the CPSIA (Pub. L. 110-314, 122 Stat. 3016), as part of the Danny Keysar Child Product Safety Notification Act, on August 14, 2008. Section 104(b) of the CPSIA 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 mandate must be substantially the same as the applicable 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. Section 104(f)(1) of the CPSIA defines the term “durable infant or toddler product” as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,” and the Commission identified baby changing tables as a durable infant or toddler product in the product registration card rule codified in 16 CFR 1130.2(a)(14).

On September 29, 2016, the Commission issued a notice of proposed rulemaking (NPR), proposing to incorporate by reference the then-current voluntary standard for baby changing products, ASTM F2388-16, with more stringent requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature. 81 FR 66881. After the Commission issued the NPR, ASTM revised the voluntary standard several times, as discussed in section V of this preamble, and published the current version of the standard, ASTM F2388-18, in March 2018.

In this final rule, the Commission is incorporating by reference ASTM F2388-18, with no modifications, as the mandatory safety standard for baby changing products. As section 104(b)(1)(A) of the CPSIA requires, CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this standard, largely through the ASTM standard-development process. In addition, this final rule amends the list of NORs in 16 CFR part 1112 to include the standard for baby changing products. This rule is based on information CPSC staff provided in its briefing package, “Draft Final Rule for Baby Changing Products for Domestic Use under the Danny Keysar Child Product Safety Notification Act,” which is available on CPSC’s website at: [\[REDACTED\]](#).

II. Product Description

ASTM F2388-18 defines a “changing product” as “one of the following: changing table, changing table accessory, add-on changing unit, contoured changing pad.” The standard defines each of those terms, as follows:

- a changing table is “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”;
- a changing table accessory is “an accessory 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 or bottom surface, or both”;

- an add-on changing unit is “a rigid addition to or separate product used in conjunction with an item of furniture that provides barriers to prevent the infant from rolling off the product when a diaper is being changed”; and
- a contoured changing pad is “a changing pad designed for use on an elevated surface which incorporates barriers to prevent a child from rolling off the changing surface.”¹

Changing tables used in public facilities, such as public restrooms, are covered by ASTM F2285, *Standard Consumer Safety Performance Specification for Diaper Changing Tables for Commercial Use*, and are not subject to ASTM F2388-18 or this final rule.

Most changing tables and add-on changing units are constructed of wood; contoured changing pads often consist of synthetic-covered foam with contoured edges; and changing table accessories that attach to a play yard or crib generally are constructed of plastic or wood with a foam pad. Changing tables come in various designs, some of which include drawers, cabinets, or retractable stairs to assist children getting onto them.

III. Market Description

CPSC staff has identified 102 domestic firms that currently supply baby changing products to the U.S. market. Eighty-four of the firms (61 manufacturers and 23 importers or wholesalers) are small, according to the U.S. Small Business Administration’s (SBA) standards,² and the remaining 18 firms are large. In addition, staff identified 17 foreign firms that supply baby changing products to the U.S. market, and one additional firm for which staff lacked sufficient information to determine a location or supply source. Staff also identified numerous

¹ ASTM F2388-18 defines a “changing pad” as: “a flat or contoured pad specifically designed for the purpose of changing the diaper of a child with a body weight of up to 30 lb (13.6 kg) on an elevated surface. The child is placed on the pad during the process of changing.”

² Under SBA size standards, a baby changing product manufacturer is “small” if it has 500 or fewer employees, and an importer is “small” if it has 100 or fewer employees.

baby changing products that are manufactured outside the United States and bought domestically through online sales.

At the time CPSC staff assessed the baby changing products market, staff identified 22 of the 61 small domestic manufacturers, and 10 of the 23 small domestic importers and wholesalers, as compliant with the ASTM standard for baby changing products (based on firms' assertions of compliance, certifications from the Juvenile Products Manufacturers Association, or participation in the development of the ASTM changing products standard).

IV. Incident Data

A. Summary

CPSC receives data regarding product-related injuries from several sources. One source is the National Electronic Injury Surveillance System (NEISS), from which CPSC can estimate, based on a probability sample, the number of injuries that are associated with specific consumer products that are treated in U.S. hospital emergency departments (U.S. EDs) nationwide. 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—CPSC refers to these sources collectively as Consumer Product Safety Risk Management System data (CPSRMS).

For this rulemaking, CPSC staff reviewed the NEISS and CPSRMS databases for incidents involving baby changing products and children younger than 3 years old because that age corresponds with the 30-pound weight limit in the ASTM standard. *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 Apr. 9, 2018).

The preamble to the NPR summarized reports of incidents involving baby changing products that occurred between January 1, 2005 and December 31, 2015, which CPSC received through CPSRMS sources. For the final rule, CPSC staff has updated this information to reflect one reported changing product incident that occurred between January 1, 2005 and December 31, 2015, but was not included in the NPR, as well as new incidents that occurred between January 1, 2016 and November 30, 2017. In total, CPSC has received 188 reports of incidents involving baby changing products that occurred between January 1, 2005 and November 30, 2017. These incidents involved 7 fatalities, 31 injuries or adverse health problems, 116 incidents that did not result in injuries, and 34 incidents for which CPSC did not receive sufficient information to determine whether an injury occurred.³

The preamble to the NPR also summarized NEISS estimates for baby changing product incidents that occurred between January 1, 2005 and December 31, 2014. After the Commission issued the NPR, complete injury data became available for 2015 and 2016, and CPSC staff has updated this information for the final rule. Including this new data and extrapolating from the probability sample, CPSC staff estimates that there were 39,010 baby changing product-related injuries to children under 3 years old that were treated in U.S. EDs between January 1, 2005 and December 31, 2016. There was a statistically significant increasing linear trend for injuries associated with baby changing products over this period. Seventy-six percent of the estimated injuries involved children between 0 and 11 months old, and 94 percent of the estimated injuries involved children under 2 years old.

³ The NPR indicated that CPSC had received 182 reports of baby changing product-related incidents that occurred between January 1, 2005 and December 31, 2015, of which 5 were fatal, 30 reported injuries, 113 did not result in injuries, and 34 did not provide sufficient information to determine whether an injury occurred. Since the NPR, CPSC staff identified one additional fatality that occurred in 2010, and CPSC received an additional five reports of incidents that occurred between January 1, 2016 and November 30, 2017, of which one was fatal, one reported injuries, and three did not result in injuries.

B. Fatalities

CPSC is aware of seven fatal incidents to children under 3 years old that occurred between January 1, 2005 and November 30, 2017, involving baby changing products. One death involved a 10-month-old male who was strangled by a strap hanging from a changing table accessory in a play yard while the child was in the play yard beneath. Another death involved a 3-month old female who rolled over and compressed her neck on the changing table ledge, resulting in suffocation. The remaining five reported deaths involved children sleeping on baby changing products, which is not their intended use. All of the victims in these incidents were younger than 1 year old.

One of these incidents involved a 4-month-old male who was sleeping on a changing pad in a crib and died from positional asphyxia when his head hung over the raised side of the changing pad. Another incident involved a 3-day-old female, who died while sleeping on the changing portion of a play yard; her death was determined to be the result of mechanical asphyxia from being swaddled too tightly in a sleep sack. The remaining three sleep-related deaths involved babies (ages 6 weeks, 2 months, and 2 months) sleeping in the changing accessory portion of a play yard.

C. Nonfatal Injuries

The injuries and treatments reported through NEISS for 2015 and 2016 were consistent with those for 2005 through 2014, described in the NPR. In 94 percent of cases between 2005 and 2016, the patient was treated in the U.S. ED and released; in 5 percent of cases, the child was hospitalized. The most commonly injured body parts were the head (71 percent for 2005-2014; 73 percent for 2015-2016) and face (13 percent for 2005-2014; 12 percent for 2015-2016). The most common types of injuries were injuries to internal organs (50 percent for 2005-2014; 53

percent for 2015-2016), contusions and abrasions (27 percent for 2005-2014; 29 percent for 2015-2016), and fractures (9 percent for 2005-2014; 8 percent for 2015-2016).

D. Hazard Patterns

The hazards reported in the new incidents are consistent with the hazard patterns staff identified in the incidents presented in the NPR. The fatal incidents are discussed above, and primarily involved suffocation or asphyxia when babies were sleeping on baby changing products.

As reported in the NPR, structural integrity issues were the primary hazard associated with nonfatal incidents. Incident reports CPSC received after the NPR, for incidents that occurred between January 1, 2016 and November 30, 2017, also involved structural integrity issues. Three of the four nonfatal incidents that occurred between January 1, 2016 and November 30, 2017, were related to structural integrity. These incidents involved: a wooden shelf on the bottom of the changing table that fell because the small pins were too weak to keep the shelf in place; drawers falling out of a changing table; and bolts falling out. The fourth incident involved an 11-month-old male who fell off of a changing table when his caregiver was distracted.

V. ASTM F2388-18

In this final rule, the Commission incorporates by reference ASTM F2388-18. The Commission is incorporating by reference ASTM F2388-18 because it includes provisions that are the same as, or consistent with, the requirements proposed in the NPR, and CPSC staff believes that the standard addresses the hazards associated with baby changing products.

A. History of ASTM F2388

ASTM F2388, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*, is the voluntary standard that addresses the hazard patterns associated with the

use of baby changing products (in domestic settings). ASTM first approved and published the standard in 2004, as ASTM F2388-04, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*. ASTM has revised the standard several times since then. In the NPR, the Commission proposed to incorporate by reference ASTM F2388-16, with modifications.

After the Commission issued the NPR, ASTM revised ASTM F2388 three times. CPSC staff worked with representatives of manufacturers, consumer groups, retailers, and other industry members and groups on the ASTM subcommittee for baby changing products to develop requirements to address the hazards associated with baby changing products, including issues raised in the NPR. CPSC staff also participated in the ASTM Ad Hoc Committee on Standardized Wording for Juvenile Product Standards (Ad Hoc TG) to finalize recommendations for warning labels, entitled, “Recommended Language Approved by Ad Hoc Task Group, Revision C” (November 10, 2017), to provide consistent and effective warnings for juvenile product standards. The most recent version of the standard, ASTM F2388-18, reflects the work of these groups. ASTM approved ASTM F2388-18 on February 15, 2018, and published it in March 2018.

B. ASTM F2388-18: Comparison with the NPR and Assessment of Requirements

In the NPR, the Commission proposed to incorporate by reference ASTM F2388-16, which addressed many of the hazard patterns associated with baby changing products, with modifications to four areas of the standard. Specifically, the Commission proposed more stringent requirements than those in ASTM F2388-16 for structural integrity, restraint systems, warnings on labels, and instructional literature.

The requirements in ASTM F2388-18 are largely the same as those the Commission proposed in the NPR. ASTM F2388-18 includes the same scope, definitions, general requirements (*e.g.*, small parts; openings), performance requirements, and test methods that the Commission proposed incorporating by reference from ASTM F2388-16. In addition, ASTM F2388-18 includes modifications to reflect the more stringent requirements the Commission proposed in the NPR, to address comments filed in response to the NPR, and to provide additional detail and clarity. The following discussion compares the areas in which the NPR and ASTM F2388-18 differ, describes the more stringent requirements in the NPR and ASTM F2388-18, and provides CPSC staff's assessment of the ASTM F2388-18 provisions.

1. Definitions

ASTM F2388-18 includes six definitions that were not in ASTM F2388-16, two of which are consistent with definitions the Commission proposed in the NPR. In the NPR, the Commission proposed to define “key structural elements” and “non-rigid add-on changing unit accessory.” ASTM F2388-18 includes these definitions, but uses the term “changing table accessory” instead of “non-rigid add-on changing unit accessory.” In addition, ASTM F2388-18 defines the terms “changing product,” “protective component,” “secondary support component,” and “threaded fastener.” As explained below, the Commission concludes that these definitions are appropriate and provide additional clarity.

ASTM F2388-18 defines “changing product” to clarify that this general term, used in the title of the standard and throughout the standard, encompasses changing tables, changing table accessories, add-on changing units, and contoured changing pads. Although the Commission did not propose to define this term in the NPR, the NPR did use “changing products” as the general term encompassing all products subject to the standard and the proposed rule, which included

each of the products listed in the ASTM F2388-18 definition. Accordingly, this definition is appropriate and provides clarity about the products that are subject to the standard.

ASTM F2388-16 (and the NPR, through proposed incorporation by reference) used the term “protective component,” although that version of the standard did not define it. ASTM F2388-16 described protective components as “caps, sleeves, or plugs used for protection from sharp edges, points or entrapment of fingers and toes.” The definition in ASTM F2388-18 is nearly identical to this description, stating “any component used for protection from sharp edges, points or entrapment of fingers or toes.” Consequently, this definition is accurate and adds clarity to the standard.

Although the Commission did not propose to define “secondary support component” in the NPR, the NPR did propose requirements regarding secondary support straps, and the preamble to the NPR described the feature as “a metal band that runs under the center of the changing surface to provide additional support” that is installed by consumers when assembling a baby changing product. 81 FR at 66888. ASTM F2388-18 defines a “secondary support component” as “a strap, bar, rod, or other component that is consumer installed and provides added support, to the changing surface of the changing table.” Because these descriptions are consistent, this definition is appropriate, and it provides added clarity to include an explicit definition in the standard.

Similarly, the Commission did not propose to define “threaded fastener” in the NPR, but the NPR did describe threaded fasteners as products, such as wood or sheet metal screws, metal inserts, and machine screws, which allow consumers to assemble and disassemble products. 81 FR at 66887. ASTM F2388-18 defines a “threaded fastener” as “a discrete piece of hardware that has internal or external screw threads which is used for the assembly of multiple parts and

facilitates disassembly.” This definition is consistent with the NPR description, indicating that the definition is accurate, and including it in the standard provides clarity.

2. Scissoring, Shearing, and Pinching

ASTM F2388-18 requires baby changing products to be designed to prevent injuries from scissoring, shearing, or pinching, and includes a method of assessing compliance with this requirement (which consists of admitting a probe of particular dimensions). ASTM F2388-16 did not include requirements regarding scissoring, shearing, and pinching, and the Commission did not propose additional requirements to address these hazards in the NPR. However, these requirements are appropriate in light of other durable infant and toddler product standards. The scissoring, shearing, and pinching provisions in ASTM F2388-18 are identical to those in other ASTM durable infant and toddler product standards (*e.g.*, high chairs, infant walkers, full-size baby cribs, play yards) that have the potential for these injuries. Accordingly, these requirements are appropriate to address a hazard common across products.

3. Self-Folding Steps

ASTM F2388-18 includes two distinct methods of assessing the single action release mechanism on self-folding steps, depending on the type of action necessary to release the mechanism. In ASTM F2388-16, the test for assessing self-folding steps on a baby changing product applied to all products with self-folding steps that had a “single action release mechanism.” The test involved applying a force of 10 lbf (45 N) to the locking or latching mechanism. The NPR proposed to incorporate this requirement by reference, without modification. ASTM F2388-18 retains this test for mechanisms that require a “pull or push action,” and adds a duration for applying the force. Specifying a test duration is helpful to provide clarity about the test procedure.

ASTM F2388-18 also includes a different test for self-folding steps with a release mechanism that requires a “twist or turn action” to release, which was not in ASTM F2388-16 and was not proposed in the NPR. For steps with this mechanism, testers must apply a torque of 4 lb-in. (0.5 N-m) to the mechanism. This separate test is appropriate to better reflect and assess the different types of release mechanisms on self-folding steps.

4. Structural Integrity Requirements

In the NPR, the Commission proposed more stringent requirements in two areas to address structural integrity issues—threaded fasteners and secondary support straps. First, the Commission proposed requirements for threaded fasteners, to provide secure connections between fasteners and key structural elements of changing tables and products. Specifically, the Commission proposed to:

- prohibit the use of threaded fasteners, such as wood screws or sheet metal fasteners, directly into wood components that are 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 proposed 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.

ASTM F2388-18 includes the same requirements regarding threaded fasteners as the Commission proposed in the NPR, as well as two additions. As one minor addition, ASTM

F2388-18 includes additional detail about the features that are “non-key structural elements,” and therefore, not subject to the threaded fastener requirements. Specifically, where the NPR listed drawers, secondary supports, storage components, and accessory items, ASTM F2388-18 lists these as well as other examples, such as fasteners that attach contoured pads and add-on changing units to supporting furniture (section 5.8.1.1). This additional detail is consistent with the requirements proposed in the NPR, which will improve the structural integrity of baby changing products. ASTM F2388-18 also specifies that the prohibition of threaded fasteners on key structural elements assembled by consumers does not apply to products that are also clothing storage units, because those products fall under the scope of ASTM F2057, *Safety Specification for Clothing Storage Units*. This added exemption is acceptable because incident data indicate that the products that were involved in structural integrity incidents associated with fasteners were traditional stand-alone changing products, and not clothing storage units, such as dressers.

Second, the Commission proposed to adopt the structural integrity testing required in ASTM F2388-16, but modified the test to specify that consumer-installed secondary support straps must not be installed for the test. This would reflect the less-structurally sound condition the product may be in when consumers use it without installing the secondary support strap or install the strap incorrectly.

ASTM F2388-18 includes the same provisions proposed in the NPR. The only minor difference is that where the NPR used the term “secondary support straps or bars,” ASTM F2388-18 uses “secondary support components.” The meaning of these terms is the same, and these requirements are appropriate to provide greater product stability.

5. Restraint System Requirements

ASTM F2388-16, the NPR, and ASTM F2388-18 do not require baby changing products to include restraint systems. However, to ensure that restraints function effectively if provided, in the NPR, the Commission proposed to require testing of restraint systems. The proposed test required 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 were required not to break or separate from baby changing products more than 1 inch from their initial adjustment positions.

ASTM F2388-18 includes the same restraint system testing requirements as those proposed in the NPR. Accordingly, these requirements are appropriate to reduce the hazards associated with ineffective restraints.

6. Warning Label Requirements

In the NPR, the Commission proposed more stringent warning label content and format requirements than those in ASTM F2388-16. With respect to content, the NPR proposed to require on-product warning labels specifically addressing fall hazards, proper securement of attachable changing products, and the suffocation hazard if babies sleep on a changing product. With respect to form, the NPR proposed to include form requirements for warnings, to increase the likelihood that consumers would notice, read, and follow the warnings. The requirements for warning format proposed in the NPR were drawn from the Ad Hoc TG recommendations, which were under development at the time.

ASTM F2388-18 includes labeling requirements that are the same as those proposed in the NPR. ASTM F2388-18 includes some minimal modifications that do not notably alter the requirements. For example, ASTM F2388-16 and the NPR specified that changing accessories

sold with non-full-size cribs and play yards were exempt from the requirement to mark manufacturer and manufacturing date information on the product and retail package because they were subject to another ASTM standard with similar requirements. ASTM F2388-18 extends this exemption to accessories sold with full-size cribs, as well. This does not reduce the stringency of the requirement because full-size cribs are also subject to another ASTM standard that addresses this information. As another example, ASTM F2388-18 includes more example figures of warnings than the NPR provided, which clarify the meaning of some requirements and provide examples of additional combinations of warning statements. Additionally, ASTM F2388-18 includes a note, explaining what “address” means in the requirement that product warnings “address” specified information. The NPR also required warnings to “address” specific information, but did not explicitly define that term. This explanatory note is useful and including it aligns with the Ad Hoc TG recommendations.

7. Instructional Literature Requirements

In the NPR, the Commission proposed more stringent requirements for instructional literature, including format requirements consistent with those for on-product warnings, a requirement that instructions be in English (at a minimum), and that additional labels must not contradict the meaning of required information. Additionally, the Commission proposed 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.

The instructional literature requirements in ASTM F2388-18 are consistent with those in the NPR, with minor adjustments to align with the Ad Hoc TG recommendations. For example,

where the NPR required warnings in instructions to align with the on-product warning format requirements generally, ASTM F2388-18 includes an equivalent requirement, but exempts warnings in instructions from distinctiveness and color requirements. These requirements are appropriate because they are consistent with the NPR and the Ad Hoc TG recommendations.

VI. Comments Filed in Response to the NPR

CPSC received nine comments in response to the NPR. The comments are available in the docket for this rulemaking, CPSC-2016-0023, at: www.regulations.gov. A summary of the comments, grouped by topic, and CPSC staff's responses are below.

A. Postpone Rulemaking

Summary of Comment: Comments recommended that the Commission delay issuing a final rule or issue a supplemental NPR because ASTM's then-upcoming 2017 revisions to the standard likely would address the concerns raised in the NPR.

Response: ASTM has updated its standard several times since the NPR, and approved ASTM F2388-18 on February 15, 2018. ASTM F2388-18, which the Commission is incorporating by reference without modification, addresses the issues raised in the NPR. As discussed in section V of this notice, the requirements in ASTM F2388-18 align with the requirements in the NPR, making a supplemental NPR unnecessary.

B. Wood Screws

Summary of Comment: Comments requested that the Commission only apply the wood screw restriction to "open frame" products, or exclude from the wood screw restrictions furniture, such as dressers, that include barriers or a changing pad. Commenters stated that incident data does not indicate that these types of products are involved in incidents.

Commenters stated that furniture is often sold unassembled and consumers use wood screws to

assemble it, making it difficult for such products to comply with the wood screw restriction. Commenters noted that the ASTM subcommittee considered excluding these types of furniture from the wood screw restriction. One commenter recommended removing the wood screw restriction and, instead, relying on the structural performance tests in the standard.

Response: Consistent with these comments, ASTM F2388-18 excludes changing tables that are also clothing storage units (such as dressers) from the wood screw restriction. This exclusion is reasonable because incident data indicate that fastener failures occur in open-frame changing tables, rather than changing tables that are also clothing storage units. In addition, changing tables that are also clothing storage units are subject to requirements in ASTM F2057, *Safety Specification for Clothing Storage Units*. For all other changing tables, ASTM F2388-18 prohibits the use of wood screws on key structural elements, consistent with requirements in other ASTM durable infant or toddler product standards, such as cribs and high chairs. This requirement is good engineering practice and addresses incidents in which a changing product collapsed due to wood screws coming out or missing from the product.

C. Metal Inserts

Summary of Comment: Comments opposed the proposal to require glue or other locking means for metal inserts. Commenters stated that glue inside the insert can result in assembly difficulties for consumers, is design restrictive, and unnecessary. In addition, one commenter requested definitions of “key structural elements” and “threaded fasteners” to clarify which products and features would be subject to the requirement.

Response: This requirement is similar to requirements in other ASTM durable infant or toddler product standards (such as cribs and high chairs), is good engineering practice, and addresses structural integrity issues identified in incident data. CPSC staff does not consider the

wording “. . . shall be glued or include other means to impede loosening or detaching” to be design restrictive because it provides manufacturers with flexibility to meet the requirements by any means (glue is just an example of how the requirement can be met). In addition, to provide clarity about the features subject to this requirement, ASTM F2388-18 includes definitions for “key structural elements” and “threaded fasteners.”

D. Restraints

Summary of Comment: A comment requested that the Commission require baby changing products to include restraint straps, rather than allow them to be optional. The commenter stated that barriers are not sufficient to prevent children from rolling off of products and that there are restraint designs that would not interfere with changing a diaper.

Response: Restraints may give caregivers a sense of safety, diminishing their attentiveness, and increasing potential hazards. For example, if caregivers believe that restraint straps provide safety, they may leave a child unattended on a changing table, and an unattended child in a restraint consisting of a single waist strap is exposed to a potential strangulation hazard. As such, the Commission does not believe it is appropriate to require restraints at this time. Moreover, incident data indicate that restraint failures involve restraints detaching from the product, or straps or buckles breaking. The final rule addresses these demonstrated hazards by requiring that if restraints are provided, they must be tested to ensure they are effective.

E. Warnings

Summary of Comment: A comment suggested that the Commission require pictograms in warnings to convey the hazards associated with baby changing products.

Response: The commenter did not provide recommended pictograms for staff to evaluate. CPSC’s Division of Human Factors staff believes that a well-developed and tested pictogram can

increase comprehension, but designing effective, understandable graphics can be difficult. Readers do not properly understand some seemingly obvious graphics, which can result in misinterpretations.

F. Effective Date

Summary of Comment: CPSC received comments about the proposed 6-month effective date. One comment, submitted by three consumer advocate groups, supported the 6-month effective date. Two commenters requested a longer effective date (one firm requested 1 year and the other at least 1 year). The latter two commenters expressed concern that six months would not provide adequate time for producers to modify their products, and one of the commenters noted that some manufacturers “purchase their materials as a single order to cover an entire year,” which would be problematic if these firms need to change their products sooner than that.

Response: The Commission generally considers 6 months an appropriate effective date for rules issued under section 104 of the CPSIA, but recognizes that longer effective dates minimize the impact on affected firms. As the final regulatory flexibility analysis for this rule explains, the final rule could have a significant economic impact on as much as 43 percent of the small firms that supply baby changing products to the U.S. market. Many of those firms may not be aware of the ASTM voluntary standard for changing products or this rulemaking. Accordingly, the Commission is providing a longer effective date for the final rule than proposed in the NPR. The rule will take effect 12 months after publication of this final rule.

G. Miscellaneous

Summary of Comment: A comment stated that a mandatory standard for baby changing products would not reduce the risk of fatalities because the fatalities reported to CPSC involved babies sleeping on products, which is not their intended use.

Response: As the Division of Human Factors memorandum in the NPR briefing package explained, the fatal incidents involving baby changing products suggest that caregivers may mistake changing accessories for sleep surfaces. To address this issue and reduce the risk associated with babies sleeping on baby changing products, the NPR proposed and the final rule requires baby changing products to bear warnings specifically cautioning against allowing babies to sleep on the products. The Commission believes that this will reduce the risk of such foreseeable misuse and the resulting injuries and deaths.

VII. Incorporation by Reference

The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. These regulations require the preamble to a final rule to summarize the material and discuss the ways in which the material the agency incorporates by reference is reasonably available to interested persons, and how interested parties can obtain the material. 1 CFR 51.5(b). In accordance with the OFR regulations, this section summarizes ASTM F2388-18, and describes how interested parties may obtain a copy of the standard.

ASTM F2388-18 contains requirements concerning:

- sharp points and edges;
- small parts;
- surface coatings;
- wood parts;
- openings;
- toys;
- threaded fasteners;
- protective components;

- scissoring, shearing, and pinching;
- structural integrity;
- stability;
- barriers;
- retention of contoured changing pads and add-on changing units;
- entrapment in shelves and in enclosed openings;
- self-folding steps;
- restraint systems;
- warnings and labels; and
- instructional literature.

The standard also includes test methods to assess conformance with these requirements.

Interested parties may obtain a copy of ASTM F2388-18 from ASTM, through its website (<http://www.astm.org>), or by mail from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428. Alternatively, interested parties may inspect a copy of the standard at CPSC's Office of the Secretary.

VIII. Final Rule

Section 1235.2(a) of the final rule requires baby changing products to comply with ASTM F2388-18 and incorporates the standard by reference. Section VII of this preamble describes the OFR requirements for incorporating material by reference. In accordance with those requirements, section VII summarizes ASTM F2388-18, explains how the standard is reasonably available to interested parties, and how interested parties may obtain a copy of the standard.

The final rule also amends 16 CFR part 1112 to add a new section 1112.15(b)(45) that lists 16 CFR part 1235, *Safety Standard for Baby Changing Products*, as a children's product safety rule for which the Commission has issued an NOR. Section XIV of this preamble provides additional information about certifications and NORs.

IX. Effective Date

The Administrative Procedure Act (5 U.S.C. 551-559) generally requires that agencies set an effective date for a final rule that is at least 30 days after the *Federal Register* publishes the final rule. 5 U.S.C. 553(d). The NPR proposed that the final rule for baby changing products, and the amendment to part 1112, would take effect 6 months after publication. CPSC received comments requesting an implementation date of 1 year, asserting that additional time would be necessary for firms to modify products to meet the standard. CPSC believes that 1 year is sufficient for firms to modify their products to meet the new standard. Therefore, this rule will take effect 1 year after publication in the *Federal Register*, and will apply to products manufactured or imported on or after that date.

X. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and Office of Management and Budget (OMB) review under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501-3521). Under the PRA, CPSC must estimate the "burden" associated with each "collection of information." 44 U.S.C. 3506(c).

In this rule, section 9 of ASTM F2388-18 contains labeling requirements that meet the definition of "collection of information" in the PRA. 44 U.S.C. 3502(3). In addition, section 10 of ASTM F2388-18 requires instructions to be provided with baby changing products; however, CPSC believes this requirement can be excluded from the PRA burden estimate. OMB allows

agencies to exclude from the PRA burden estimate any “time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities,” if the disclosure activities required to comply are “usual and customary.” 5 CFR 1320.3(b)(2). Because baby changing products generally require use and assembly instructions, and CPSC is not aware of baby changing products that generally require instructions but lack them, CPSC believes that providing instructions with baby changing products is “usual and customary.” For this reason, the burden estimate includes only the labeling requirements.

The preamble to the NPR discussed the information collection burden of the proposed rule and requested comments on the accuracy of CPSC’s estimates. 81 FR 66893 to 66894. CPSC did not receive any comments about the information collection burden of the proposed rule. However, the information collection burden has changed since the NPR because CPSC staff has identified 120 baby changing product suppliers (102 domestic firms, 17 foreign firms, and 1 firm of unknown location), rather than the 85 firms identified in the NPR, that it estimates will be subject to the information collection burden. Accordingly, the estimated burden of this collection of information is as follows:

TABLE 1.—*Estimated Annual Reporting Burden*

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1231.2	120	6	720	1	720

The estimated reporting burden is based on CPSC staff’s expectation that all 120 baby changing product suppliers known to CPSC will need to modify their labels to comply with the final rule. CPSC staff estimates that it will take about 1 hour per model to make these modifications and, based on staff’s evaluation of product lines, that each supplier has an average

of 6 models of baby changing products. Consequently, CPSC estimates that the burden associated with the labeling requirements is: 120 entities \times 1 hour per model \times 6 models per entity = 720 hours. CPSC staff estimates that the hourly compensation for the time required to create and update labels is \$34.21 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” Sept. 2017, 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 labeling requirements is: \$34.21 per hour \times 720 hours = \$24,631.20. CPSC staff does not expect there to be operating, maintenance, or capital costs associated with this information collection.

As the PRA requires, CPSC has submitted the information collection requirements of this final rule to OMB. 44 U.S.C. 3507(d). OMB has assigned control number 3041-0175 to this information collection.

XI. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601-612) requires agencies to consider the potential economic impact of a proposed and final rule on small entities, including small businesses. Section 604 of the RFA requires agencies to prepare and publish a final regulatory flexibility analysis (FRFA) when they issue a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The FRFA must discuss:

- the need for and objectives of the rule;
- significant issues raised in public comments about the initial regulatory flexibility analysis (IRFA), a response to comments from the Chief Counsel for Advocacy of the

SBA, the agency's assessment of the comments, and any changes made to the rule as a result of the comments;

- the description and estimated number of small entities that will be subject to the rule;
- the reporting, recordkeeping, and other compliance requirements of the rule, as well as the small entities that would be subject to those requirements, and the types of skills necessary to prepare the reports or records;
- steps the agency took to minimize the significant economic impact on small entities; and
- the factual, policy, and legal reasons the agency selected the alternative in the final rule, and why it rejected other significant alternatives.

5 U.S.C. 604.

Based on an assessment by CPSC's Directorate for Economic Analysis staff, CPSC cannot certify that this rule will not have a significant economic impact on a substantial number of small entities. As a result, staff has prepared a FRFA. This section summarizes the FRFA for this final rule. The complete FRFA is available as part of CPSC staff's briefing package at:

[\[REDACTED\]](#).

B. Comments Relevant to the FRFA

CPSC did not receive any comments specifically addressing the IRFA that accompanied the proposed rule or from the Chief Counsel for Advocacy of SBA. However, CPSC received comments about the effective date of the final rule, which are relevant to the FRFA insofar as they address the costs associated with the rule. These comments are discussed in section VI.F. of this preamble. After considering these comments, and the potential economic impact of the rule on small firms, the Commission is extending the effective date for the final rule to 1 year, rather

than the proposed 6 months. CPSC believes that this longer effective date will reduce the economic impact of the rule on firms, some of which may not be aware of the ASTM standard or this rulemaking, by reducing the potential for a lapse in production or imports while bringing products into compliance with the rule, and spreading the costs of compliance over a longer period.

C. Description of Small Entities Subject to the Rule

CPSC staff identified 120 firms that supply baby changing products to the U.S. market, consisting of 102 domestic firms, 17 foreign firms, and 1 firm for which staff could not determine the location. Of the 102 domestic firms, 84 are small entities, according to SBA's standards, and 18 are large. Of the 84 small domestic entities, 61 are manufacturers, and 23 are importers or wholesalers. It is possible that there are additional baby changing product suppliers in the U.S. market that staff has not identified.

D. Description of the Final Rule

Sections V and VII of this preamble describe the requirements in the final rule, which incorporates by reference ASTM F2388-18. In addition, the final rule amends the regulations regarding third party conformity assessment bodies to include the safety standard for baby changing products in the list of NORs.

E. Impact on Small Businesses

For the FRFA, staff limited its analysis to the 84 small domestic firms staff identified as supplying baby changing products to the U.S. market because SBA guidelines and definitions apply to domestic entities. In assessing whether a rule will have a significant economic impact on small entities, staff generally considers impacts "significant" if they exceed 1 percent of a firm's revenue. This section provides details about staff's assessment of the economic impact of the

final rule on small domestic entities. To summarize, staff believes that it is unlikely that the final rule will have a significant economic impact on 22 of the 61 small manufacturers and 10 of the 23 small importers and wholesalers, all of which already comply with a version of the ASTM standard. Of the remaining firms, which do not already comply with the voluntary standard, staff does not expect the final rule to have a significant economic impact on 13 of the 39 small manufacturers and 3 of the 13 small importers and wholesalers because most of these firms supply products that staff does not expect will require changes to conform to the rule. Staff could not rule out a significant economic impact on the remaining 26 small manufacturers and 10 small importers and wholesalers.

1. Small Manufacturers

At the time staff prepared the FRFA, 22 of the 61 small manufacturers reported that their baby changing products complied with the then-current ASTM standard. Staff believes that firms that report complying with the voluntary standard will continue to comply with the standard as it evolves, as part of an established business practice. Staff does not expect the final rule to have a significant economic impact on any of these 22 firms because ASTM F2388-18 was published well before the effective date of this rule. Staff expects third party testing costs to be minimal because these firms already test their products for compliance with the voluntary standard.

The remaining 39 small manufacturers produce baby changing products that do not comply with the voluntary standard. Seven of these firms manufacture only wooden changing trays that are sold separately from furniture, which are subject to few requirements other than side height, labeling, and instructions. Staff does not expect changes to warnings, instructions, or side heights to create significant costs. An additional 12 firms manufacture only contoured changing pads, which are also subject to minimal requirements, primarily including barrier and

retention requirements, labels, and instructions. Staff believes that firms will not have to modify most of these changing pads to meet these requirements, but it is possible that a few firms would need to modify their products to meet the barrier and retention requirements. These modifications could be costly because firms would need new molds for foam products. For purposes of the FRFA, staff assumed that two firms would need to modify their contoured changing pads to comply with the final rule.

The remaining 20 firms manufacture a variety of changing products. Firms staff interviewed before the Commission issued the NPR indicated that the cost of completely redesigning a product could range from \$25,000 to \$200,000, depending on the type of changing product. It is likely that the final rule will have a significant impact on nine of these firms (and possibly one more) based on their revenue levels; it is unlikely the rule will have a significant economic impact on three of these firms, based on their revenues; and staff could not determine the revenues of the remaining seven firms.

Staff believes that third party testing costs are not likely to have a significant economic impact on 21 of the 39 small domestic noncompliant manufacturers, but could exceed 1 percent of revenues for the remaining 18 firms, with varying degrees of likelihood. Staff also believes that third party testing costs could result in significant economic impacts for 7 of the 20 small domestic noncompliant manufacturers that are not likely to experience significant economic impacts from the requirements in ASTM F2388-18.

2. Small Importers and Wholesalers

At the time staff prepared the FRFA, 10 of the 23 small importers and wholesalers reported that their baby changing products complied with the then-current ASTM standard. Staff 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. Like small, compliant manufacturers, staff expects that these importers and wholesalers will comply with ASTM F2388-18 before the effective date of the final rule. Therefore, staff does not expect the final rule to have a significant economic impact on any of these firms. Likewise, staff expects third party testing costs to be minimal because costs would be limited to the difference between the cost of current testing regimes and third party testing costs.

The remaining 13 small importers and wholesalers supply baby changing products that do not comply with the voluntary standard. The economic impact of the rule on these importers and wholesalers depends on the extent of the changes needed for their products to comply with the rule and the response of their suppliers. Staff generally cannot determine this information for importers and wholesalers that do not comply with the voluntary standard.

Nevertheless, staff anticipates that the rule could have a significant economic impact on some of these firms. Staff estimates that the rule will not have a significant economic impact on one importer that supplies only wooden changing trays. The rule also may not have a significant economic impact on two importers and one wholesaler that provide only contoured changing pads. However, one of these firms may need to redesign its product, which would have a significant economic impact on the firm. Each of these firms has wide enough product lines that it could stop supplying changing products, although the impact of that on revenue is unclear.

Of the remaining six importers and three wholesalers, four firms have low enough revenues that they are likely to experience a significant economic impact, regardless of how their suppliers respond, as their suppliers are not likely to absorb any of the costs and finding alternative suppliers can be costly. Three of these firms may be able to stop supplying changing products, but it is not clear what impact this would have on their revenues. Staff does not have

revenue information for the remaining five firms. As a result, staff cannot rule out the possibility that the rule will have a significant economic impact on these five firms. However, one of these firms appears to be tied to its suppliers, who may absorb some of the costs, and another firm has a wide enough product line that it could stop supplying changing products.

Staff believes that third party testing could result in significant costs for three of the firms that import noncompliant baby changing products. For two of these firms, testing costs could exceed 1 percent of gross revenue if the firm tests only one unit per model. A third firm would need to test about three units per model before testing costs would exceed 1 percent of its gross revenue. Staff did not have access to revenue data for seven of the small noncompliant importers and wholesalers to determine the potential economic impact of the rule.

3. Accreditation Requirements for Testing Laboratories

Section 14 of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089) requires all children's products that are subject to a children's product safety rule to be tested by a third party conformity assessment body (*i.e.*, testing laboratory) that has been accredited by CPSC. Testing laboratories that want to conduct this testing must meet the NOR for third party conformity testing. The final rule amends 16 CFR part 1112 to establish an NOR for testing laboratories to test for compliance with the baby changing product rule.

In the IRFA for this rule, staff anticipated that the accreditation requirements would not have a significant economic impact on a substantial number of small laboratories because: (1) the rule imposed requirements only on laboratories that intended to provide third party testing services; (2) laboratories would assume the costs only if they anticipated receiving sufficient revenue from the testing to justify accepting the requirements as a business decision; and (3) most laboratories would already have accreditation to test for conformance to other juvenile

product standards, thereby limiting the costs to adding the baby changing product standard to their scope of accreditation. CPSC has not received any information to date that contradicts this assessment. Therefore, staff believes that the NOR for the baby changing product standard will not have a significant economic impact on a substantial number of small entities.

F. Alternatives and Steps to Minimize Economic Impacts

In response to comments, the Commission is providing a 1 year effective date, rather than the proposed 6 months. This should reduce the economic impact of the rule for small entities. Setting a later effective date reduces the likelihood of a lapse in production or imports if firms cannot comply with the standard or obtain third party testing within the time provided. In addition, a later effective date spreads the costs of compliance over a longer period, reducing annual costs and the present value of total costs.

XII. Environmental Considerations

CPSC's regulations list categories of agency actions that "normally have little or no potential for affecting the human environment." 16 CFR 1021.5(c). Such actions qualify as "categorical exclusions" under the National Environmental Policy Act (42 U.S.C. 4321-4370m-12), which do not require an environmental assessment or environmental impact statement. One categorical exclusion listed in CPSC's regulations is for rules or safety standards that "provide design or performance requirements for products." 16 CFR 1021.5(c)(1). Because the final rule for baby changing products creates design or performance requirements, the rule falls within the categorical exclusion.

XIII. 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). However, states or political subdivisions of states may apply to CPSC for an exemption, allowing them to establish or continue such a requirement if the state requirement “provides a significantly higher degree of protection from [the] risk of injury” and “does not unduly burden interstate commerce.” *Id.* 2075(c).

Section 104 of the CPSIA requires the Commission to issue consumer product safety standards for durable infant or toddler products. As such, consumer product safety standards that the Commission creates under CPSIA section 104 are covered by the preemption provision in the CPSA. As a result, the preemption provision in section 26 of the CPSA applies to the mandatory safety standard for baby changing products.

XIV. Testing, Certification, and Notification of Requirements

Section 14(a) of the CPSA requires the manufacturer or private labeler of a children’s product that is subject to a children’s product safety rule to certify that, based on a third party conformity assessment body’s testing, the product complies with the applicable children’s product safety rule. 15 U.S.C. 2063(a)(2)(A), 2063(a)(2)(B). Section 14(a) also requires the Commission to publish an NOR for a third party conformity assessment body (*i.e.*, testing laboratory) to obtain accreditation to assess conformity with a children’s product safety rule. 15 U.S.C. 2063(a)(3)(A). Because this safety standard for baby changing products is a children’s product safety rule, it requires the Commission to issue an NOR.

On March 12, 2013, the Commission published a final rule in the *Federal Register*, entitled *Requirements Pertaining to Third Party Conformity Assessment Bodies*, establishing 16 CFR part 1112, which sets out the general requirements and criteria concerning testing laboratories. 78 FR 15836. Part 1112 includes procedures for CPSC to accept a testing

laboratory's accreditation and lists the children's product safety rules for which the Commission has published NORs. When the Commission issues a new NOR, it must amend part 1112 to include that NOR. Accordingly, the Commission is amending part 1112 to include the baby changing products standard.

Testing laboratories that apply for CPSC acceptance to test baby changing products for compliance with the new baby changing product rule would have to meet the 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 include 16 CFR part 1231, *Safety Standard for Baby Changing Products*, in the laboratory's scope of accreditation of CPSC safety rules listed on the CPSC website at: www.cpsc.gov/labsearch.

As the RFA requires, CPSC staff conducted a FRFA for the rulemaking in which the Commission adopted part 1112. 78 FR 15836, 15855 (Mar. 12, 2013). To summarize, the FRFA concluded that the accreditation requirements would not have a significant economic 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 CPSC 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.

By the same reasoning, adding an NOR for the baby changing product standard to part 1112 will not have a significant economic impact on small test laboratories. A relatively small number of laboratories in the United States have applied for accreditation to test for conformance to existing juvenile product standards. Accordingly, CPSC expects that only a few laboratories will seek accreditation to test for compliance with the baby changing product standard. Of those that seek accreditation, CPSC expects that most will have already been accredited to test for

conformance to other juvenile product standards. The only costs to those laboratories will be the cost of adding the baby changing product standard to their scopes of accreditation. For these reasons, CPSC certifies that amending 16 CFR part 1112 to include an NOR for the baby changing products standard will not have a significant economic impact on a substantial number of small entities.

XV. Consumer Registration of Durable Infant or Toddler Products

As section 104(d) of the CPSIA requires, regulations in 16 CFR part 1130 require manufacturers of durable infant or toddler products to provide registration forms with each product, maintain the contact information consumers submit on these forms, and mark manufacturer and model information on products. Section 1130.2(a)(14) lists “changing tables” as one of the products subject to the registration card requirements. However, “changing tables” is no longer used as the general term to encompass all baby changing products that are subject to ASTM F2388-18 and this final rule, and this term may create confusion since it is only one type of baby changing product. Because all of the baby changing products subject to this rule are “durable infant or toddler products,” section 104(d) of the CPSIA requires the registration card requirements to apply to all of these products.

Accordingly, the Commission anticipates issuing a notice proposing to amend 16 CFR part 1130 to clarify that “changing tables” include all changing products identified in ASTM F2388-18, which includes changing tables, contoured changing pads, changing table accessories, and add-on changing units.

List of Subjects in

16 CFR Part 1112

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

16 CFR Part 1231

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

For the reasons discussed in the preamble, the Commission amends 16 CFR Chapter II 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: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

- 2. Amend § 1112.15 by adding paragraph (b)(45) to read as follows:

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

* * * * *

(b) * * *

(45) 16 CFR part 1235, Safety Standard for Baby Changing Products.

* * * * *

- 3. Add part 1235 to read as follows:

PART 1231-SAFETY STANDARD FOR BABY CHANGING PRODUCTS

Sec.

1235.1 Scope.

1235.2 Requirements for baby changing products.

Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (August 14, 2008); Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

§ 1235.1 Scope.

This part establishes a consumer product safety standard for baby changing products.

§ 1235.2 Requirements for baby changing products.

Each baby changing product shall comply with all applicable provisions of ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*, approved on February 15, 2018. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

<https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Dated: _____

Alberta E. Mills,
Secretary,
Consumer Product Safety Commission.



Staff Briefing Package

**Draft Final Rule for Baby Changing Products for
Domestic Use under the Danny Keysar Child Product
Safety Notification Act**

June 2018

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

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Briefing Memorandum



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically
approved and signed.

Memorandum

June 13, 2018

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Patricia H. Adkins, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

FROM: George A. Borlase, Assistant Executive Director,
Office of Hazard Identification and Reduction

Mark Kumagai, Director,
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

SUBJECT: Draft Final Rule for Changing Products for Domestic Use under the Danny
Keysar Child Product Safety Notification Act

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act. This Act requires the U.S. Consumer Product Safety Commission (CPSC) 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.

Section 104 defines “durable infant or toddler products” as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,” and provides a list of examples. Although the list of products in section 104 does not include changing products, the Commission specifically identified “changing tables” as a “durable infant or toddler product” in the product registration card rule issued by the Commission under section 104(d). 16 CFR § 1130.2(a)(14). Staff will be preparing a briefing package later in fiscal year 2018, to amend 16 CFR part 1130, *Requirements for Consumer Registration of Durable Infant or Toddler Products*, to clarify that the registration rule covers all changing products identified in ASTM F2388-18. As explained below, ASTM F2388-18 includes changing tables, contoured

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changing pads, changing table accessories, and add-on changing units, which can be sold separately from the furniture to which it attaches, or with which it is used.

Section 104 also requires CPSC to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. This consultation process has been ongoing, with staff participating 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 baby changing products and became involved in changing product task groups.

This briefing package pertains to products included within the scope of the current voluntary standard, ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use* (ASTM F2388-18). Changing tables used in public facilities, such as 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 provides staff's responses to nine comments received in response to the Commission's notice of proposed rulemaking (NPR) on a *Safety Standard for Baby Changing Products*.² This package also assesses the current voluntary standard; reviews relevant incident data; discusses the potential impact on small business; and provides staff's recommendation that the Commission issue a final rule that would incorporate by reference the voluntary standard, ASTM F2388-18, with no modifications.

II. BACKGROUND

A. Product Review

The scope and definition of "changing product" in ASTM F2388-18 indicate that baby changing products include: changing tables, changing table accessories, add-on changing units, and contoured changing pads, as defined below.

changing product - one of the following: changing table, changing table accessory, add-on changing unit, contoured changing pad.

changing table, n - 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.

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

² 81 FR 66881, September 29, 2016.

changing table accessory—an accessory 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 or bottom surface, or both.

add-on changing unit, n- a rigid addition to or separate product used in conjunction with an item of furniture that provides barriers to prevent the infant from rolling off the product when a diaper is being changed.

contoured changing pad, n - a changing pad designed for use on an elevated surface which incorporates barriers to prevent a child from rolling off the changing surface.

The majority of currently available changing tables and add-on changing units are constructed of wood. Some changing tables come with drawers, cabinets, and retractable stairs. Contoured changing pads are typically some combination of synthetic-covered foam with contoured edges to prevent children from rolling off of an elevated surface during a diaper change. Changing table accessories that attach to a play yard or crib can be constructed of plastic or wood with a foam pad. Figure 1 shows a variety of currently available changing products.

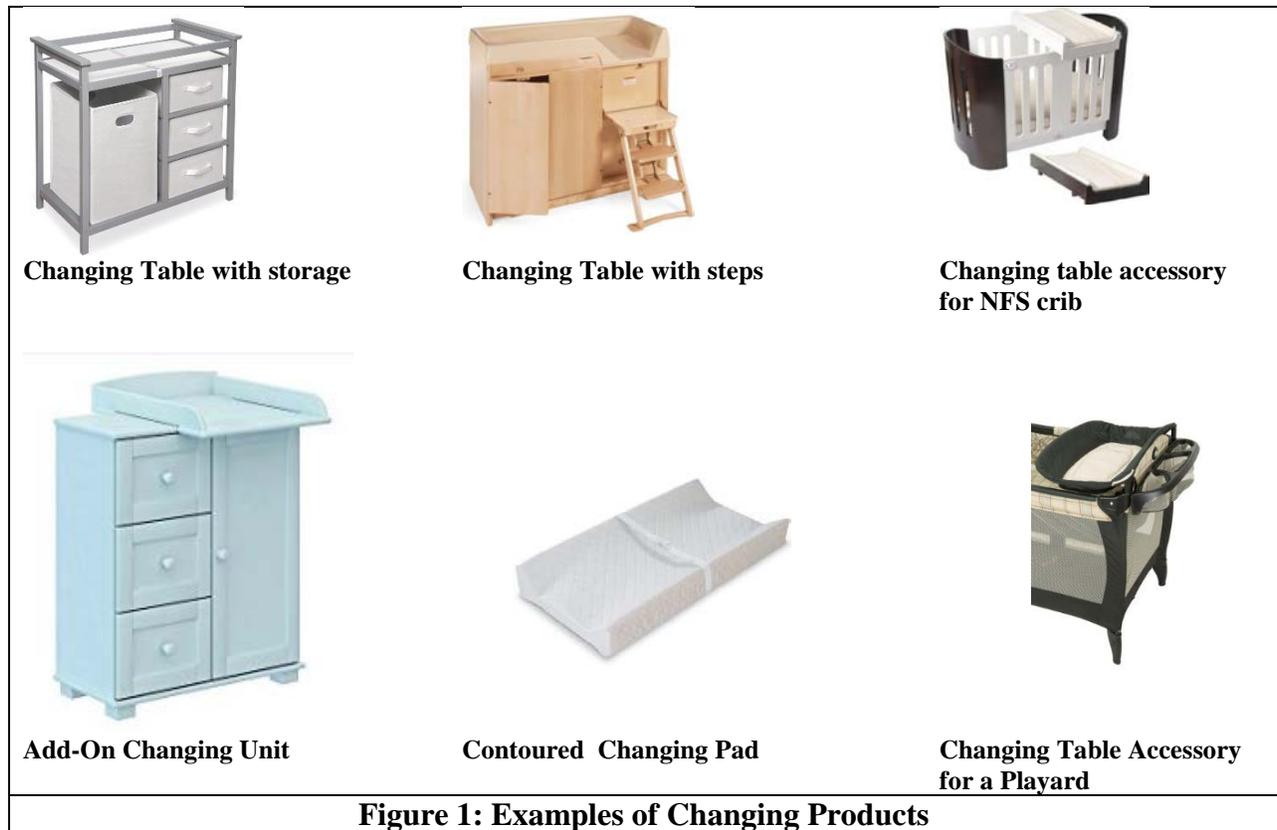


Figure 1: Examples of Changing Products

B. Rulemaking History

In September 2016, the Commission issued an NPR for baby changing products (81 FR 66881, published on September 29, 2016). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, with modifications. Specifically, the NPR proposed more stringent requirements for structural integrity, restraints, warning labels, and instructional literature. CPSC received nine comments on the NPR.³ Staff's responses to these comments are discussed in section III. C. of this memorandum.

III. DISCUSSION

A. Overview of Incident Data (Tab A)

In the NPR briefing package, the Directorate for Epidemiology (EP) staff searched the National Electronic Injury Surveillance System (NEISS) and determined that there were an estimated 31,780 emergency department-treated injuries associated with changing products from January 1, 2005 to December 31, 2014, involving victims younger than 3 years of age.⁴

For this briefing package, EP staff updated the estimate to include NEISS data from January 1, 2005 to December 31, 2016. There were an estimated 39,010 emergency department-treated injuries associated with changing products from January 1, 2005 to December 31, 2016 involving victims younger than 3 years of age.⁵ Staff generated yearly estimates of emergency department-treated injuries associated with baby changing products for the years 2005 to 2016 (Table 1, Tab A). The yearly estimates ranged from 2,340 in 2005 to 4,140 in 2013. For the years before 2009, the yearly estimates were below 3,000 emergency department-treated injuries. In more recent years, starting from 2009, the yearly estimates were higher than 3,000. There was a statistically significant increasing linear trend for injuries associated with baby changing products over the studied period (p-value = 0.0048).

Staff examined data sources other than NEISS. EP staff searched the Consumer Product Safety Risk Management System (CPSRMS).⁶ Using these databases for the NPR briefing package, EP staff identified 182 incidents, including 30 injuries and five fatalities⁷ involving baby changing products reported to CPSC between January 1, 2005 and December 31, 2015.⁸ Four fatalities occurred as a child was sleeping on the changing table or changing table pad. One

³ Submitters included individuals, manufacturers, industry associations, and consumer advocacy groups. The China WTO submitted one comment.

⁴ Sample size=1305, coefficient of variation=0.1533.

⁵ The 95 percent confidence interval ("C.I.") for this estimate is 27,570–50,450, based on a coefficient of variation ("C.V.") of 0.1496.

⁶ CPSRMS combines the data from IPII (Injury or Potential Injury Incidents), DTHS (Death Certificates), and INDP (In-Depth Investigations) into one searchable incident database.

⁷ CPSC staff found one death that occurred in 2010, but was not reported in the baby changing tables NPR briefing package. In 2010, a 3-day-old female died while sleeping on the changing portion of the play yard. The death was determined to be the result of mechanical asphyxia caused by swaddling too tightly in the sleep sack.

⁸ Tab A of NPR.

fatality occurred when a child was strangled by a strap that was hanging from a changing table accessory on a play yard.

Since the NPR, five incidents associated with changing products were reported to CPSC through CPSRMS. These five incidents occurred between January 1, 2016 and November 30, 2017, and include: one fatality, three non-injury incidents, and one incident that resulted in medical treatment. The death in 2016 involved a 3-month-old female. The girl was left unattended on the changing table for a few minutes. She rolled over and compressed her neck on the changing table ledge, resulting in suffocation.

In the NPR briefing package, staff identified structural integrity as the major hazard in the incidents associated with changing products. Incidents that occurred between January 1, 2016 and November 30, 2017, similarly included reports of structural integrity as the changing product hazard.

B. Updates to ASTM F2388 and Adequacy of the Current Requirements

The NPR proposed to incorporate by reference ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, with certain modifications. In the NPR briefing package, staff concluded that ASTM F2388-16 was not stringent enough to address hazards associated with structural integrity and restraints that can result in fall injuries. Engineering Sciences (ES) staff recommended additional requirements for structural integrity (threaded fasteners, and more stringent tests for structural integrity), and a more stringent requirement for restraint systems. ES staff found inadequacies in the warnings and instructional literature requirements that address the fall hazard and suffocation hazard. ES recommended more stringent requirements for warnings and instructional literature.

Since 2016, ASTM has revised ASTM F2388 three times (ASTM F2388-17, ASTM F2388-17a, and ASTM F2388-18). CPSC staff worked with the ASTM subcommittee on these updates to the standard. ASTM F2388-18 addresses all of staff's concerns, as explained in the NPR and deals with all comments submitted in response to the NPR, by adding requirements to improve structural integrity, restraints, and warnings and instructional literature. During the revision process, the ASTM subcommittee identified some minor discrepancies and inconsistencies with wording throughout the standard and has corrected those errors in ASTM F2388-18.

In addition, after the NPR was published, the ASTM Ad Hoc Committee on Standardized Wording for Juvenile Product Standards (Ad Hoc TG) finalized its recommendations for warning labels, titled, "Recommended Language Approved by Ad Hoc Task Group, Revision C" (November 10, 2017). CPSC staff participated in the Ad Hoc TG and helped develop the finalized recommendations. The goal of the recommendations was to provide consistent and effective warnings for juvenile product standards. ASTM F2388-18 reflects the work of this group and includes revisions consistent with the Ad Hoc TG recommendations.

The major requirements from ASTM F2388-18 are presented below. Changes made since the NPR are in italics:

- 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 product, 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 products from entrapping a child’s head.
- Structural integrity—intended to ensure that the changing product remains intact after static testing, thereby reducing the likelihood of a product collapsing or a child breaking 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. *The structural integrity section now includes an additional requirement for threaded fasteners. Also, the test must be conducted without any secondary support components beneath the changing surface, unless they are factory preassembled. This addresses collapses seen in the incident data⁹ and was proposed by the Commission as part of the NPR.*
- Barriers—intended to prevent children from falling off the sides of changing products, as well as reduce injuries associated with barriers degrading or splintering after repeated use. Barriers are required for all baby changing products, but the test method varies for each type of changing product. *The test procedure has been clarified to indicate more clearly what tests should be performed on the different types of changing products. Additionally, the standard now specifies a test surface for contoured changing products sold separately and add-on changing units sold separately.*
- Retention—intended to prevent contoured changing pads and add-on changing units, like trays, from slipping, thereby reducing the fall risk. The standard applies the barriers test method for 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 CFR part 1221 and 16 CFR part 1220) for these products.
- Self-folding steps—intended to prevent a child from activating the steps. *The test for units with a single-action release mechanism has been updated to specify how to apply the force and how long it should be maintained.*
- *Threaded fasteners—intended to prevent the loosening of key structural elements. Wood screws and sheet metal screws cannot be used in key structural components requiring consumer assembly. These requirements and test procedures were proposed by the Commission as part of the NPR.*

⁹ NPR (81 FR 66881, published on September 29, 2016), *Staff’s Briefing Package, TAB B*, p.34, *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.*

- *Restraint system—intended to ensure that if a restraint system is provided as part of the changing product, it is effective. This requirement and test procedure were proposed by the Commission as part of the NPR.*
- *Scissoring, Shearing, and Pinching – intended to prevent injuries to the occupant when components rotate about a fixed point, causing a scissoring or clamping action. This is a general requirement found in most ASTM juvenile product standards and was inadvertently omitted in previous versions of the ASTM standard. It was not proposed by the Commission as part of the NPR.*
- *Marking and labeling requirements, including permanency requirements, which have been updated to incorporate the Commission’s NPR proposals.*
- *Requirements for instructional literature, which have been updated to incorporate the Commission’s NPR proposals.*

ASTM F2388 has also been modified to address more clearly changing products of all types, rather than just changing tables; and this has led to numerous language changes and two new definitions (“changing product” and “changing table accessory”). CPSC staff determined these editorial modifications clarify the requirements and test procedures in the standard.

Staff has assessed the requirements in ASTM F2388-18 and determined that ASTM F2388-18 adequately addresses all of the baby changing product hazards identified in the NPR, as well as warnings and instructional literature requirements consistent with the Ad Hoc TG recommendations. The NPR proposed additional requirements to address hazards the staff identified. ASTM F2388-18 includes the following provisions that the Commission had proposed or otherwise addresses the hazards.

- Threaded fasteners and metal inserts. The NPR proposed adding requirements that would provide for secure connections between fasteners and key structural elements. ASTM F2388-18 includes requirements that are equivalent to the requirements proposed in the NPR.
- Restraint systems. The NPR proposed strength requirements for products that include restraints. ASTM F2388-18 includes requirements that are equivalent to the requirements proposed in the NPR.
- Warnings in labels and instructions. The NPR proposed labeling and instruction requirements to address falls and suffocation hazards. ASTM F2388-18 includes requirements that are equivalent to the requirements proposed in the NPR.

C. Staff Responses to NPR Comments

CPSC received nine comments from eight commenters in response to the NPR. Several commenters expressed support for the proposed requirements in the NPR, and others raised objections to the NPR. A summary of the comments and staff’s responses are below.

Warnings: Several commenters recommended adding pictogram warnings to convey the hazards more effectively.

Response: Commenters did not provide specific pictograms with their comments. Human Factors (ESHF) staff acknowledges that a well-developed and tested pictogram could increase

comprehension. However, designing effective, well understood graphics can be difficult. Some seemingly obvious graphics are poorly understood and can lead to interpretations that are opposite of the intended meaning. Thus, although staff may recommend action in the future if graphic symbols are needed to further reduce the risk of injury associated with changing products, at this time, staff does not support mandating graphics for changing products.

Delay the Final Rule: Several commenters recommended delaying the final rule until ASTM could complete their revisions to the voluntary standard in 2017. The commenters expressed the belief that ASTM would address concerns raised in the NPR. One commenter recommended issuing a “new NPR” based on a revised ASTM standard so that the public could comment on the latest standard.

Response: On February 15, 2018, ASTM approved the new standard, ASTM F2388-18. This standard addressed the concerns raised in the NPR and includes provisions that are equivalent to ones the Commission proposed in the NPR. This Briefing Package and draft final rule are based on ASTM F2388-18. Because ASTM F2388-18 aligns with the requirements proposed in the NPR, it is not necessary to issue a “new NPR.”

Effective Date: CPSC received three comments on the proposed 6-month effective date. One comment, submitted by three consumer advocate groups, supported the 6-month effective date. Two commenters requested a longer effective date (one firm requested 1 year and the other at least 1 year). Both of the latter two commenters are concerned about producers having inadequate time to make changes to their products with a 6-month effective date, with one commenter citing the tendency for some manufacturers to “purchase their materials as a single order to cover an entire year,” which could lead to hardship and waste, if these firms needed to make changes to their products sooner than that.

Response: Staff generally considers 6 months to be an appropriate effective date, but recognizes that longer effective dates minimize the impact on affected firms. The final regulatory flexibility analysis found that as many as 43 percent of small changing products suppliers could be significantly impacted by the draft final rule. Many of those firms may not be aware of the ASTM voluntary standard for changing products or this rulemaking. Given the potential for a significant economic impact, as well as the concerns expressed by two commenters about a short effective date, staff now recommends a 12-month effective date to reduce the impact on small businesses. Meanwhile, ongoing compliance activities would be available to address unsafe changing products on the market.

Wood Screws: Several commenters recommended excluding furniture, such as dressers that include barriers, or a changing pad, from the wood screw restriction or limiting the wood screw restriction to “open frame” products. The commenters stated that it would be difficult to comply with the requirement because this type of furniture is often sold unassembled, and consumers use wood screws to complete the assembly. The commenters stated that data do not show that these types of products were involved in incidents. The commenters noted that the ASTM subcommittee proposed to exclude these types of furniture from the wood screw restriction. One commenter recommended removing the wood screw restriction entirely and relying on the structural performance tests in ASTM F2388-16.

Response: ASTM F2388-18 excludes dressers with changing tables from the wood screw restriction. CPSC staff agrees with this exclusion because the incident data show that fastener failures occur in the open-frame changing tables rather than dressers. Additionally, the stability requirements for furniture, such as dressers that incorporate changing products, are covered by ASTM F2057, *Safety Specification for Clothing Storage Units*. For all other wood changing tables, the ASTM F2388-18 prohibits the use of wood screws on key structural elements. This is similar to requirements in the ASTM crib and high chair standards. CPSC staff believes this requirement is good engineering practice and addresses some incidents of collapse due to wood screws coming out or missing from the changing table.

Metal Inserts: Many commenters recommended removing the requirement to glue or provide other locking means for metal inserts. The commenters stated that this is unnecessary, design restrictive, and that glue can inadvertently seep inside the insert resulting in assembly difficulties for the consumer. In addition, one commenter requested definitions of “key structural elements” and “threaded fasteners,” to clarify which products and features would be subject to the requirement.

Response: Consistent with the NPR, ASTM F2388-18 requires “metal inserts, with external wood screw threads for screwing into a wood component and providing internal threads to accommodate a machine screw, that are used to secure key structural elements” to have a means (such as glue) to prevent loosening. This is similar to requirements in the ASTM crib and high chair standards. CPSC staff believes this requirement is good engineering practice, consistent with other ASTM standards. CPSC staff does not consider the wording “. . . shall be glued or include other means to impede loosening or detaching” to be design restrictive. Glue is an example of how the requirement can be met. The ASTM F2388-18 requirement allows the manufacturer design freedom to meet the requirement by any means. In addition, to provide clarity on the features subject to this requirement, ASTM F2388-18 includes definitions for “key structural elements” and “threaded fasteners.”

Restraints: One commenter recommended requiring restraint straps, rather than allowing them to be optional. The commenter stated that barriers are not enough to prevent children from rolling off products, and CPSC should develop performance requirements for restraint systems. The commenter referenced medical pediatric immobilizer restraints that are not 3-point restraint design and can be used while changing a child’s diaper.

Response: CPSC staff believes that restraints may give caregivers a sense of safety that diminishes caregivers’ attentiveness. Specifically, staff is concerned that the use of restraint straps could result in increased incidents where a child is left unattended on the changing product. A child left unattended in a restraint consisting of a single waist strap is exposed to a potential strangulation hazard. CPSC staff was not aware of medical pediatric immobilizer restraints mentioned by the commenter. The commenter’s Internet link showed a restraint that consists of a wide band that wraps around the baby’s torso. CPSC staff believes that this type of restraint strap could also give caregivers a sense of safety that diminishes their attentiveness; however, the product should meet the ASTM F2888-18 restraint requirement, if it is sufficiently strong.

CPSC staff agrees with the commenter that performance requirements should be developed for restraints, as recommended in the NPR. Staff's review of the incident data indicates that restraint failures are due to detachment from the product, breakage of the strap, or the buckle breaking. ASTM F288-18 has incorporated strength requirements for restraints and that should address these incidents.

Miscellaneous: One commenter stated that a mandatory standard for baby changing products would not reduce the risk of fatalities because all of the fatalities reported to CPSC involved babies sleeping in the product, which is not its intended use.

Response: As the ESHF memorandum in the NPR briefing package explained, the fatal incidents involving baby changing products suggest that changing accessories may be mistaken for sleep surfaces. To address this issue, and to reduce the risk associated with babies sleeping on baby changing products, the NPR proposed, and ASTM F288-18 requires, baby changing products to bear warnings specifically cautioning against allowing babies to sleep on the product. Staff believes that this will reduce the risk of such foreseeable misuse and the resulting injuries and deaths.

D. Impact on Small Businesses

Staff identified 102 domestic firms supplying changing products to the U.S. market. Based on U.S. Small Business Administration guidelines, 84 of the 102 domestic firms are "small businesses," including 61 manufacturers and 23 firms that we believe to be importers. Additionally, staff identified 17 foreign suppliers and one firm of unknown type and location, as well as numerous changing products entering the U.S. market via online firms that act as brokers between buyers and sellers.

As described in Tab C, although it appears unlikely that the draft final rule would impose a significant economic impact on the 22 small manufacturers, nine small importers, or one small wholesaler of *compliant* changing products (or 20 of the small manufacturers and three of the small importers of *noncompliant* changing products), the rule could potentially have a significant economic impact on 19 of the small manufacturers and 10 of the importers/wholesalers of noncompliant changing products. Additionally, third party testing costs could be significant for seven of the small manufacturers of noncompliant changing products that are not significantly impacted by the draft final rule, for a total of 26 small firms significantly impacted. Accordingly, staff prepared a Final Regulatory Flexibility Analysis.

E. Effective Date of Final Rule

The Administrative Procedure Act generally requires that the effective date of the rule be at least 30 days after publication of the final rule (5 U.S.C. 553(d)). In the NPR, CPSC proposed a 6-month effective date. CPSC received two comments requesting at least a 1-year effective date to allow manufacturers sufficient time to make changes to their products. 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 and importation, which could result if they are unable to

comply with the draft final rule and obtain third party testing within the required timeframe. Second, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. Given the potential for a significant economic impact on some small firms, staff now recommends a 12-month effective date to help reduce the impact on affected firms.

IV. STAFF'S CONCLUSION and RECOMMENDATION

CPSC staff has reviewed and participated in the revision of ASTM F2388-18 to address concerns and recommendations stated in the NPR. CPSC staff determined that ASTM F2388-18 adequately addresses the hazards presented in the incident data. Therefore, CPSC staff recommends that the Commission issue a final rule that would incorporate by reference the voluntary standard, ASTM F2388-18, with no modifications. Staff recommends that the rule take effect 12 months after the final rule is published in the *Federal Register*. Staff also recommends that the Commission amend 16 CFR part 1112, which would establish the Notice of Requirements (NOR) for testing laboratories that want to test baby changing products for compliance with the baby changing products final rule.

TAB A: Estimated Number of Injuries Associated with Baby Changing Products in the Years 2005-2016 and Reported Incidents that Occurred Between January 1, 2016 and November 30, 2017

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**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

Memorandum

Date: December 13, 2017

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

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

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

SUBJECT : Estimated Number of Injuries Associated with Baby Changing Products in the
Years 2005-2016 and Reported Incidents that Occurred between January 1,
2016 and November 30, 2017.¹⁰

I. Introduction

This memorandum updates the data in the baby changing products notice of proposed rulemaking (NPR) briefing package presented to the Commission in September 2016. The time frame covered in the previous data extraction was January 1, 2005 to December 31, 2014, for the National Electronic Injury Surveillance System (NEISS) and January 1, 2005 to December 31, 2015, for the Consumer Product Safety Risk Management System (CPSRMS).¹¹ This memorandum includes updated estimates for injuries associated with baby changing products that occurred in the years 2005 to 2016. It also includes baby changing product-related incidents

¹⁰ This analysis was prepared by CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

¹¹The National Electronic Injury Surveillance System (NEISS), database contains the emergency department-treated injuries in a sample of hospitals nationwide. The Consumer Product Safety Risk Management System (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 (baby 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, 2017, and CPSRMS reports on December 5, 2017. Upon joint review of the NEISS and the 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 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 baby changing tables when running.

reported to CPSC that occurred between January 1, 2016 and November 30, 2017. This memorandum includes incidents among children younger than 3 years of age that are associated with domestic and day care setting use of baby changing products and other add-on baby changing products used with play yards and dressers.

II. Injury Estimates Based on NEISS Data

1. Overview

There were an estimated 39,010 emergency department-treated injuries associated with baby changing products from January 1, 2005 to December 31, 2016, to victims younger than 3 years of age. The 95 percent confidence interval (CI) for this estimate is 27,570–50,450, based on a coefficient of variation (CV) of 0.1496.

2. Yearly Injury Estimates

Staff generated yearly estimates of emergency department-treated injuries associated with baby changing products for the years 2005 to 2016 (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 linear trend for injuries associated with baby changing products over the studied period (p-value = 0.0048).

Table 1: Estimated Emergency Department-Treated Injuries Associated with Baby Changing Products to Victims Under 3 Years of Age, 2005–2016

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
2015	146	3,380	2,040–4,720	0.2024
2016	158	3,830	2,480–5,180	0.1792
Total	1,609	39,010	27,600–50,400	0.1496

Source: NEISS, April 2017

The estimates may not sum to the totals due to rounding.

3. Injury Characteristics

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

The estimated emergency department-treated injuries for baby changing products 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 years.

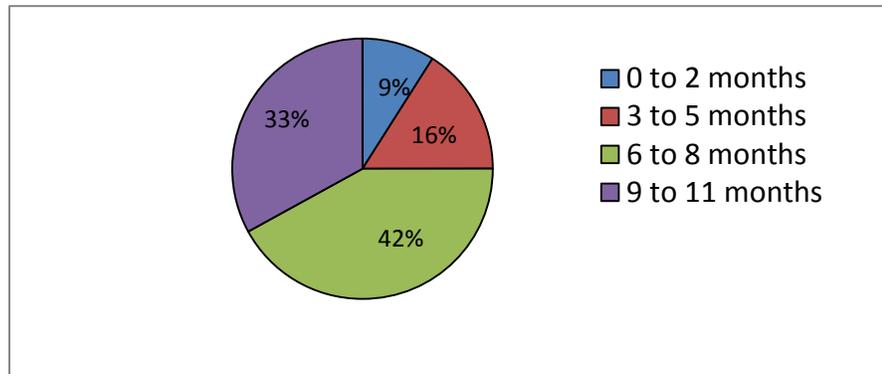
Table 2: Estimated Emergency Department-Treated Injuries Associated with Baby Changing Products by Age Category, 2005–2016

Age (months)	Estimate	% Total
0 to 11	29,570	76%
12 to 23	7,220	19%
24 to 35	2,230	6%
Total	39,010	100%

Source: NEISS April 2017. The estimates may not sum to the totals due to rounding.

Further analysis of victim age within the 0-11-months age category is presented in Figure 1. Children ages 6 to 8 months old had the highest percentage (42%) of emergency department-treated injuries among children under 1-year-old, followed by children ages 9-11 months old (33%).

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



Source: NEISS, April 2017

The percentages may not sum to the totals due to rounding.

The estimated emergency department-treated injuries by body part that are associated with baby changing products involving children younger than 3 years old are presented in Table 3. The majority of the injuries were to the head (73%) or the face (12%).

Table 3: Estimated Emergency Department-Treated Injuries by Body Part Associated with Baby Changing Products to Victims Under 3 Years of Age , 2005-2016

Body Part*	Estimate	% Total
Head	28,400	73%
Face	4,570	12%
Arm	2,590	7%
Leg	1,680	4%
Other	1,780	5%
Total	39,010	100%

Source: NEISS, April 2017

*The body part groups were based on NEISS body part codes; face includes eyelid, eye area, and nose.

The estimates may not sum to the totals due to rounding.

In the years 2005 to 2016, the most common estimated injury diagnosis for emergency department-treated visits related to baby changing products for children under 3 years old was internal organ injury (53%). Contusions/abrasions accounted for 29 percent of the estimated

injuries, fractures for 8 percent, contusion/strains for 5 percent, and other injuries accounted for 5 percent.

The NEISS data showed that equal proportions of emergency-department injuries were to males younger than 3 years old (50%) 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 from CPRMS

1. Overview

CPSC staff also reviewed data from CPRMS. From these sources, CPSC staff is aware of five incidents associated with baby changing products that occurred between January 1, 2016 and November 30, 2017. The reported incidents include: one fatality, three non-injury incidents, and one incident that resulted in medical treatment. Additionally, CPSC staff found one death that occurred in 2010, which was not reported in the baby changing products notice of proposed rulemaking (NPR) briefing package.

2. Deaths

A death in 2016 involved a 3-month-old female. The girl was left unattended on the baby changing product for a few minutes. She rolled over and compressed her neck on the baby changing product's ledge, resulting in suffocation. In 2010, a 3-day old female died while sleeping on the changing portion of a play yard. The death was determined to be the result of mechanical asphyxia caused by swaddling too tightly in the sleep sack.

IV. Hazard Patterns

There were five incidents, reported to CPSC, associated with a baby changing product that occurred between January 1, 2016 and November 30, 2017. The incident involving a death is described above. Three incidents were related to a *structural integrity* problem. These incidents included: a report of a wooden shelf, located on the bottom of the baby changing table, falling because the small pins were too weak to keep the shelf in place; a report of baby changing product drawers falling out; and a report of bolts falling out. No injury was reported for the incidents that involved a falling baby changing table shelf or falling bolts. The incident associated with falling drawers resulted in an unspecified injury and subsequent medical treatment. One incident involved an 11-month-old boy who fell off a baby changing table when his mother got distracted by her 6-year-old son. No injury occurred because the boy's 9-year-old brother was able to catch him. It is not known if the baby changing table had restraining straps.

In the NPR briefing package, staff identified structural integrity as the major hazard in the incidents associated with the baby changing products. Incidents that occurred between January 1, 2016 and November 30, 2017, similarly included reports of structural integrity as changing product hazards.

TAB B: ES Staff's Review and Evaluation of ASTM F2388-18, Standard Consumer Safety Specification for Baby Changing Products for Domestic Use

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

March 4, 2018

TO: Joel Recht, Ph.D.
Associate Executive Director
Directorate for Engineering Sciences

FROM: Mark Kumagai, P.E., Director
Hope Nesteruk, General Engineer
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

SUBJECT: ES Staff's Review and Evaluation of ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*

I. INTRODUCTION

CPSC's Directorate for Engineering Sciences (ES) staff was tasked with assessing the effectiveness of ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products 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 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 F2388-18 standard and how effectively the current edition addresses staffs' recommendations in the NPR briefing package. This memorandum supports ES staff's recommendation to incorporate by reference ASTM F2388-18, without modifications, into the draft final rule.

II. PRODUCTS

The scope of ASTM F2388-18 includes changing products, which include changing tables, changing table accessories, contoured changing pads, and add-on changing units. F2388-18 definitions for "changing product," "changing table," "changing table accessory," "add-on changing units," and "contoured changing pad," are provided below:

changing product - one of the following: changing table, changing table accessory, add-on changing unit, or contoured changing pad.

changing table, n - 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

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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.

changing table accessory—an accessory 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 or bottom surface, or both.

add-on changing unit, n - a rigid addition to or separate product used in conjunction with an item of furniture that provides barriers to prevent the infant from rolling off the product when a diaper is being changed.

contoured changing pad, n - a changing pad designed for use on an elevated surface which incorporates barriers to prevent a child from rolling off the changing surface.

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. Changing table accessories that attach to a play yard or to cribs can be constructed of plastic or wood with a foam pad. See Figure 1 for a variety of currently available changing products.



III. ASTM F2388

A. Overview

ASTM first approved F2388, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*, in 2004. ASTM has revised the voluntary standard many times since this original version. ASTM F2388-16 is the version the Commission proposed to incorporate by reference, with modifications, in the NPR. Since the NPR, ASTM has revised the standard three times, publishing ASTM F2388-17, ASTM F2388-17a, and ASTM F2388-18. The current voluntary standard is ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*, which includes the structural integrity, restraints, warning labels and instructional literature improvements proposed in the NPR.

The major requirements from ASTM F2388-18 are presented below. Changes made since the NPR are in italics:

- 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 product 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 products from entrapping a child’s head.
- Structural integrity—intended to ensure that the changing product remains intact after static testing, thereby reducing the likelihood of a product collapsing or a child breaking 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. *The structural integrity section now includes an additional requirement for threaded fasteners. Additionally, the test must be conducted without any secondary support components beneath the changing surface, unless they are factory preassembled. This addresses collapses seen in the incident data¹² and was proposed by the Commission as part of the NPR.*
- Barriers—intended to prevent children from falling off the sides of changing products, as well as reduce injuries associated with barriers degrading or splintering after repeated use. Barriers are required for all baby changing products, but the test method varies for each type of changing product. *The test procedure has been clarified to indicate more clearly what tests should be performed on the various types of changing products. Additionally, the standard now specifies a test surface for contoured changing products sold separately and add-on changing units sold separately.*

¹² NPR (81 FR 66881, published on September 29, 2016), *Staff’s Briefing Package, TAB B*, p.34, *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.*

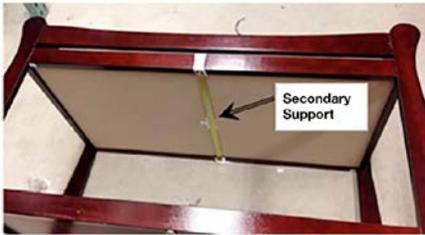
- Retention—intended to prevent contoured changing pads and add-on changing units, like trays, from slipping, thereby reducing the fall risk. The standard applies the barriers test method for this requirement. Add-on changing unit accessories for play yards and non-full-size cribs are not subject to this requirement, as changing unit retention is addressed in the voluntary ASTM standard (F406) and the mandatory CPSC standards (16 CFR part 1221 and 16 CFR part 1220) for these products.
- Self-folding steps—intended to prevent a child from activating the steps. *The test for units with a single-action release mechanism has been updated to specify how to apply the force and how long it should be maintained.*
- Threaded fasteners—intended to prevent the loosening of key structural elements. *Wood screws and sheet metal screws cannot be used in key structural components requiring consumer assembly. These requirements and test procedures were proposed by the Commission as part of the NPR.*
- Restraint system—intended to ensure that if a restraint system is provided as part of the changing product, it is effective. *This requirement and test procedure were proposed by the Commission as part of the NPR.*
- Scissoring, Shearing, and Pinching – *intended to prevent injuries to the occupant when components rotate about a fixed point, causing a scissoring or clamping action. This is a general requirement found in most ASTM juvenile product standards and was inadvertently omitted in previous revisions. Labeling, Warnings, and Instructions – intended to incorporate the ASTM Ad Hoc Committee on Standardized Wording for Juvenile Product Standards (Ad Hoc TG) to provide consistent and effective warnings for juvenile product standards. These requirements and example labeling were proposed by the Commission as part of the NPR.*

B. Adequacy of ASTM F2388-18 Requirements

Staff believes that ASTM F2388-18 adequately addresses all of the baby changing product hazards identified in the NPR and incident data. In the NPR, ES staff concluded that ASTM F2388-16 was not stringent enough to address the hazards associated with baby changing products, which include structural integrity issues (such as collapses), falls, and suffocations. ES staff recommended additional requirements for restraint systems, and to address structural integrity issues, including requirements for threaded fasteners, and more stringent tests for structural integrity (*i.e.*, secondary support straps). ES staff found inadequacies in the warnings and instructional literature requirements and recommended that the Commission propose more stringent requirements to address the fall and suffocation hazards.

The ASTM subcommittee on baby changing products has addressed the concerns raised in the NPR by adding requirements into ASTM F2388-18 to improve structural integrity, restraints, warnings, and instructions. ASTM F2388-18 includes the more stringent requirements the Commission proposed in the NPR for these areas. Table 1 shows the proposed mechanical requirements in the NPR, the corresponding and additional requirements in ASTM F2388-18, and staff's assessment of the requirements. Table 2 shows the proposed warning, labeling, and instructional literature requirements in the NPR; the corresponding requirement in ASTM F2388-18; and staff's assessment of the requirements.

Table 1. Comparison Between the More-Stringent Mechanical Requirements in the NPR and ASTM F2388-18 and CPSC Staff’s Assessment of the ASTM Requirements (additions in red underline, deletions in strikeouts)

Definitions		
NPR (underlined text show additions to ASTM F2388-16)	ASTM F2388-18	CPSC staff Assessment
<u>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.</u>	<u>3.1.11 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 (see Fig. 1).</u>	ASTM F2388-18 has incorporated the definition proposed in the NPR for <i>key structural elements</i> . CPSC staff agrees with this definition
<u>3.1.15 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.</u>	<u>3.1.7 changing table accessory—an accessory 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 or bottom surface, or both.</u>	In ASTM F2388-18, the term “ <i>changing table accessory</i> ” is essentially the same as the proposed term and definition in the NPR for a <i>Non-rigid add-on unit accessory</i> CPSC staff agrees with this definition
Additional definition not proposed in the NPR	<u>3.1.4 changing product—one of the following: changing table, changing table accessory, add-on changing unit, contoured changing pad.</u>	CPSC staff agrees with this definition
Additional definitions not proposed in the NPR	<u>3.1.16 secondary support component, n—a strap, bar, rod, or other component that is consumer installed and provides added support, to the changing surface of the changing table.</u>	CPSC staff agrees with this definition
	 <p>FIG. 1 Example of Secondary Support Component</p>	
Additional definition not proposed in the NPR	<u>3.1.15 protective component, n—any component used for protection from sharp edges, points, or entrapment of fingers or toes.</u>	CPSC staff agrees with this definition
Additional definition not proposed in the NPR	<u>3.1.19 threaded fastener, n—a discrete piece of hardware that has internal or external screw threads which is used for the assembly of multiple parts and facilitates disassembly.</u>	CPSC staff agrees with this definition

Threaded Fasteners and Metal Inserts

NPR	ASTM F2388-18	CPSC staff Assessment
<p><u>5.8 Threaded Fasteners:</u></p> <p><u>5.8.1 Wood Screws and Sheet Metal Screws:</u></p> <p><u>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.</u></p> <p><u>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.</u></p> <p><u>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 as defined in 6.2 or detachment during the testing required by this specification.</u></p>	<p><u>5.8 Threaded Fasteners:</u></p> <p><u>5.8.1 Wood Screws and Sheet Metal Screws:</u></p> <p><u>5.8.1.1 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 components, other storage components, accessory items and the fasteners used for attaching contoured pads and add-on changing units to other supporting furniture. This shall also not apply to the fasteners used for changing tables which are also clothing storage units which fall under the scope of Safety Specification F2057.</u></p> <p><u>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.</u></p> <p><u>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 as defined in 6.2 or detachment during the testing required by this specification.</u></p>	<p>ASTM F2388-18 has incorporated requirements for use of threaded fasteners and metal inserts. These requirements are equivalent to the proposed requirements in the NPR.</p> <p>ASTM F2388-18 clarifies that clothing storage units are exempt from the threaded fastener requirements since these products are covered by ASTM F2057 <i>Safety Specification for Clothing Storage Units</i>. Consumer assembled furniture such as dressers that incorporate a changing table commonly use wood screws. Incident data showed that fastener issues involved the traditional standalone changing tables and not the clothing storage units.</p> <p>This exemption for clothing storage units was not in the NPR but a suggestion for it was made by a commenter. CPSC staff agrees with this provision.</p>

Structural Integrity

NPR	ASTM F2388-18	CPSC staff Assessment
<p>6.2 <i>Structural Integrity</i>—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. <u>Components attached by screws shall not have separated by more than 0.04 in. (1 mm) upon completion of testing</u></p> <p>NOTE 1—Contoured changing pads and add-on changing units that are sold separately are exempt from this requirement.</p> <p>7.2 <i>Structural Integrity</i>—Assemble the unit in accordance with the manufacturer's assembly instructions. <u>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.</u> 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.</p>	<p>6.2 <i>Structural Integrity</i>—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. <u>Threaded fasteners used for key structural elements shall not have separated by more than 0.04 in. (1 mm) upon completion of testing.</u></p> <p>NOTE 1—Contoured changing pads and add-on changing units that are sold separately are exempt from this requirement.</p> <p>7.2 <i>Structural Integrity</i>—Assemble the product in accordance with the manufacturer's assembly instructions. <u>If the product design employs secondary support components beneath the changing surface that are not factory preassembled in their intended use position, this test is to be conducted without the secondary support components installed.</u> Place the product 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.</p>	<p>The Structural Integrity requirements in ASTM F2388-18 are equivalent to the proposed Structural Integrity requirements in the NPR</p> <p>The Structural Integrity test method in ASTM F2388-18 are equivalent to the proposed Structural Integrity test in the NPR</p>

Restraint Integrity		
NPR	ASTM F2388-18	CPSC staff Assessment
<p><u>6.9 Restraint System:</u></p> <p><u>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.</u></p> <p><u>6.9.1 If a restraint system is installed on the product or available as an option, it shall meet the following:</u></p> <p><u>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.</u></p> <p><u>6.9.1.2 The anchorages shall not separate from the unit when tested in accordance with 7.8.</u></p> <p><u>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).</u></p>	<p><u>6.9 Restraint System:</u></p> <p><u>NOTE 4—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.</u></p> <p><u>6.9.1 If a restraint system is installed on the product or available as an option, it shall meet the following:</u></p> <p><u>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.</u></p> <p><u>6.9.1.2 The anchorages shall not separate from the product when tested in accordance with 7.8.</u></p> <p><u>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).</u></p>	<p>The restraint system requirements in ASTM F2388-18 are equivalent to the proposed restraint system requirements in the NPR</p>

7.8 Restraint System Tests:

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

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

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.

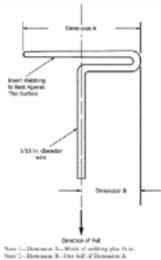


FIGURE 1.—Webbing Tension Pull Device

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

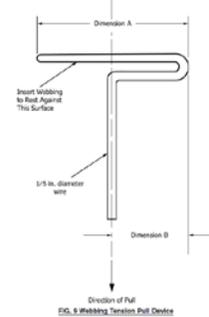
7.8.4.1 Within 5 s, gradually apply a pull force of 30 lbf (200 N) on the restraint strap and maintain for an additional 10 s. Release the restraint strap. Repeat this test for a total of four pulls in the following directions: Horizontally away from the table in the direction an occupant could roll, 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. Within 5 s, gradually apply a pull force of 30 lbf (133 N) that is 5 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.

7.8 Restraint System Tests:

7.8.1 Secure the product in its recommended use position so that it cannot move in the direction of the force being applied.

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

7.8.3 Adjust the restraint, using the webbing tension pull device shown in Fig. 9, 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.



7.8.4 Perform the following tests without readjusting the restraint system.

7.8.4.1 Apply a pull force of 30 lbf (133 N) on the restraint strap in the direction an occupant would roll sideways off the changing surface at a 45° angle from the horizontal changing surface (see Fig. 10). Gradually apply the force within 5 s and maintain for an additional 10 s.

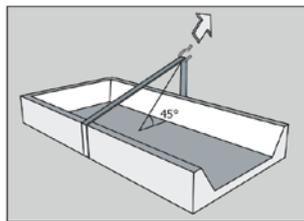


FIG. 10 Restraint Strap Directional Pull Force

7.8.4.2 Release the restraint strap.

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

7.8.4.4 Apply a force of 30 lbf (133 N) in a direction that is 45° 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.

7.8.4.5 Release the restraint strap.

7.8.4.6 Apply a force of 30 lbf (133 N) in a direction that is 45° 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.

7.8.4.7 Release the restraint strap.

7.8.4.8 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 10s.

Restraint Integrity (continued)		
NPR	ASTM F2388-18	CPSC staff Assessment
Additional rationale for restraint requirements not proposed in the NPR	<u>X1.2 Subsection 7.8, Restraint System Tests:</u> <u>X1.2.1 30 lbf is the approximate forward push force of a 95th percentile 3 year old. The 5 directions of the force applications are intended to simulate the forces that could be applied on the straps when a child attempts to escape the restraint system.</u>	ASTM F2388-18 provided the rationale for the restraint system tests. CPSC staff agrees with the rationale.
Requirements in ASTM F2388-18 that were not proposed in the NPR		
NPR	ASTM F2388-18	CPSC staff Assessment
Additional requirement not proposed in the NPR	<u>6.87 Self-folding Steps</u> —Self-folding steps shall be secured in their closed position by either a double action release mechanism, or a single action locking or latching device that <u>by one of the following latching or locking mechanisms:</u> <u>6.7.1 The latching or locking mechanism must be a double action release system, or</u> <u>6.7.2 The latching or locking mechanism</u> shall require a minimum force of 10 lbf (45 N) to activate the release mechanism when tested in accordance with 7.7.	This clarifies the intent of this requirement. CPSC staff agrees with this requirement.
Additional test method not proposed in the NPR	<u>7.7 Self-folding Steps with Single Action Release Mechanism</u> —With the self-folding steps in their closed position, <u>test the mechanism using one of the following test methods.</u> <u>7.7.1 If the mechanism requires a pull or push action,</u> gradually apply a force of 10-lbf (45-N) to the locking or latching mechanism in the direction tending to release it. <u>Apply the force within 5 s and maintain for an additional 10 s.</u> <u>7.7.2 If the mechanism requires a twist or turn action,</u> gradually apply a torque of 4 lb-in. (0.5 N-m) to the locking or latching mechanism in the direction tending to release it. <u>Apply the torque within 5 s and maintain for an additional 10 s.</u>	This clarifies the test method for this requirement. CPSC staff agrees with this test method.
Additional requirement not proposed in the NPR	<u>5.11 Scissoring, Shearing, and Pinching</u> — <u>The product, when in the manufacturer’s recommended use position(s), shall be designed and constructed to prevent injury to the occupant from any scissoring, shearing, or pinching when members or components rotate about a common axis or fastening point, slide, pivot, fold, or otherwise move relative to one another. Scissoring, shearing, or pinching that may cause injury exists when the edges of the rigid parts admit a probe greater than 0.210 in. (5.33 mm) and less than 0.375 in. (9.53 mm) in diameter at any accessible point throughout the range of motion of such parts.</u>	This requirement is a general requirement in most ASTM standards for juvenile products. CPSC staff believes these requirements are appropriate

Table 2. Comparison Between the Labeling, Warnings and Instructions More-stringent Requirements in the NPR and ASTM F2388-18 and CPSC Staff’s Assessment of ASTM Requirements (additions in red underline)

NPR Proposal	ASTM F2388-18	CPSC staff Assessment
9. Marking and Labeling	9. Marking and Labeling	Identical
9.1 Each <u>changing table and add-on changing unit or contoured changing pad, sold separately</u> , and its retail package shall be marked or labeled clearly and legibly to indicate the following:	9.1 Each <u>product</u> and its retail package shall be marked or labeled clearly and legibly to indicate the following:	ASTM F2388 – 18 is functionally equivalent to the proposal because it more clearly and succinctly applies the requirement to all products covered by the standard.
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.	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.	Identical
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.	Identical
Note 5— <u>Add-on changing units, non-rigid add-on changing unit accessories, or contoured changing pads</u> , 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— <u>Changing table accessories</u> sold with <u>full size cribs</u> , 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 Specifications <u>F1169</u> and F406 <u>respectively</u> .	ASTM F2388 – 18 includes all accessories, including those sold with full-size crib in this exemption. Because the full-size crib will be required to be labeled with manufacturer and model information (9.1.1 and 9.1.2), this exemption does not reduce stringency.
9.1.3 The retail package must indicate the manufacturer’s recommended maximum weight of the occupant for which the <u>changing table or contoured changing pad</u> is intended.	9.1.3 The retail package must indicate the manufacturer’s recommended maximum weight of the occupant for which the <u>product</u> is intended.	ASTM F2388 – 18 is functionally equivalent to the proposal because it more clearly and succinctly applies the requirement to all products covered by the standard.
9.2 The marking and labeling on the product shall be permanent.	9.2 The marking and labeling on the product shall be permanent.	Identical
9.3 Any upholstery label required by law shall not be used to meet the requirements of this section.	9.3 Any upholstery label required by law shall not be used to meet the requirements of this section.	Identical
9.4 – Warning Design for Product	9.4 Warning Design for Product:	Identical
9.4.1 - The warning shall be easy to read and understand and be in the English language at a minimum.	9.4.1 The warnings shall be easy to read and understand and be in the English language at a minimum.	Identical
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.	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.	Identical

NPR Proposal	ASTM F2388-18	CPSC staff Assessment
9.4.3 - The warnings shall be conspicuous and permanent.	9.4.3 The warnings shall be conspicuous and permanent.	Identical
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.	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.	Identical
9.4.4.1 - In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”	9.4.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”	Identical
9.4.4.2 - In section 7.6.3, replace “should (when feasible)” with “shall.”	9.4.4.2 In section 7.6.3, replace “should (when feasible)” with “shall.”	Identical
9.4.4.3 - Strike the word “safety” when used immediately before a color (<u>e.g.</u> , replace “safety white” with “white”).	9.4.4.3 Strike the word “safety” when used immediately before a color (<u>for example</u> , replace “safety white” with “white”).	ASTM F2388 – 18 is equivalent to the proposal because “e.g.” is the Latin abbreviation for “for example.”
<p>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), <u>except where otherwise specified.</u></p> <p>NOTE: For improved warning readability, <u>the warning designer should avoid the use of</u> typefaces with large height-to-width ratios, which are commonly identified as “condensed,” “compressed,” <u>“narrow,”</u> or similar.</p>	<p>9.4.5 The safety alert symbol “ ” and the signal word “WARNING” shall be at least 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.</p> <p>NOTE 6—For improved warning readability, typefaces with large height-to-width ratios, which are commonly identified as “condensed”, or “compressed”, or similar <u>should be avoided.</u></p>	<p>ASTM F2388 – 18 is functionally equivalent to the proposal. Although the ad hoc consensus is to include “except where otherwise specified,” ASTM F2388-18 does not contain any requirements that differ from those specified. Therefore the statement is unnecessary.</p> <p>In addition, the wording of NOTE 6 is harmonized with the most recent ad hoc warning recommendations.</p>
9.4.6 - Message Panel Text Layout	9.4.6 <i>Message Panel Text Layout:</i>	Identical
<p>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.</p> <p>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.</p>	<p>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.</p> <p>NOTE 7—Left aligned means that the text is aligned along the left margin, and, in case of multiple columns of text, along the left side of each individual column. <u>Please see Fig. 11 for examples of left aligned text.</u></p>	ASTM F2388 – 18 is functionally equivalent to the proposal. The additional language adds an example figure requested by some members of the subcommittee clarify the meaning of “left aligned”

NPR Proposal	ASTM F2388-18	CPSC staff Assessment
<p>9.4.6.2 - The text in each column should be arranged in list <u>or outline</u> format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.</p>	<p>9.4.6.2 The text in each column should be arranged in list format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.</p>	<p>Although the ASTM F2388 – 18 requirement does not include the language “or outline,” staff believes the requirement is functionally equivalent to the proposal. ANSI Z535.4, which is the standard the forms the basis of the ASTM ad hoc warning formatting requirements, refers only to “outline” format; however, concerns were raised that outline format implies a numbered hierarchy. CPSC human factors staff and the ad hoc wording task group intended the terms “list” to be synonymous with “outline,” as used in ANSI Z535.4 to capture the concepts overarching goal of including one hazard concept per bullet item or list item. The changing table subcommittee chose to ballot this as list format only. No difference in effectiveness is expected in a warning that arranges text in “list” format as opposed to “outline” format. In addition, section 9.4.6.2 is a “should” requirement, meaning it is intended to be guidance and to represent best practices. Therefore, staff concluded that there is no meaningful difference.</p>

9.4.7 An example warning in the format described in this section is shown in Fig. X.

⚠ WARNING
<p style="text-align: center;">Fall hazard</p> <p>Children have suffered serious injuries after falling from changing pads. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY in arm's reach. • ALWAYS secure this pad to the support surface by (manufacturer's instructions for securing the changing product).
<p style="text-align: center;">Suffocation hazard</p> <p>Babies have suffocated while sleeping on changing pads. Changing pad is not designed for safe sleeping.</p> <ul style="list-style-type: none"> • NEVER allow child to sleep on changing pad.

9.4.7 Example warning labels for various changing products and in the format described in this section are shown in Figs. 11-16.

⚠ WARNING
<p>FALL HAZARD: Children have suffered serious injuries after falling from changing tables. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY in arm's reach of your child.

FIG. 11 Sample Label – e.g. Changing Table

⚠ WARNING
<p>FALL HAZARD: Children have suffered serious injuries after falling from changing tables. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY in arm's reach of your child. • ALWAYS secure this unit to the support surface by (manufacturer's instructions for securing the changing unit). See instructions.

FIG. 12 Sample Label – e.g. Add-on Changing Unit Intended to be Attached to Support Surface

⚠ WARNING
<p>FALL HAZARD: Children have suffered serious injuries after falling from changing tables. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY in arm's reach of your child. <p>SUFFOCATION HAZARD: Babies have suffocated while sleeping on changing pads. Changing pads are not designed for safe sleeping.</p> <ul style="list-style-type: none"> • NEVER allow baby to sleep on changing pad.

FIG. 13 Sample Label – e.g. Contoured Changing Pad

⚠ WARNING
<p>FALL HAZARD: Children have suffered serious injuries after falling from changing tables. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY in arm's reach of your child. • ALWAYS secure this pad to the support surface by (manufacturer's instructions for securing the changing pad). See instructions. <p>SUFFOCATION HAZARD: Babies have suffocated while sleeping on changing pads. Changing pads are not designed for safe sleeping.</p> <ul style="list-style-type: none"> • NEVER allow baby to sleep on changing pad.

FIG. 14 Sample Label – e.g. Contoured Changing Pad Intended to be Attached to Support Surface

⚠ WARNING
<p>FALL HAZARD: Children have suffered serious injuries after falling from changing tables. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY in arm's reach of your child. • ALWAYS secure this product to the support frame by (manufacturer's instructions for securing the changing table accessory). See instructions. <p>SUFFOCATION HAZARD: Babies have suffocated while sleeping in changing areas. Changing areas are not designed for safe sleeping.</p> <ul style="list-style-type: none"> • NEVER allow baby to sleep in changing area.

FIG. 15 Sample Label – e.g. Changing Table Accessory

9.5 Warning Statements—Each product shall have warning statements to address the following, at a minimum:

9.5 *Warning Statements*—Each product shall have warning statements to address the following at a minimum:

NOTE 8—Address means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product specific is presented.

NOTE 9—For 9.5.1 – 9.5.3, the words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product or may substitute another term that is consistent with the product's marketing and instructions.

ASTM F2388 – 18 is functionally equivalent to the proposal. The NPR showed only one example containing all potential hazard avoidance statements. Consensus in the ASTM subcommittee was to show multiple example warnings to address different combinations of required statements.

ASTM F2388 – 18 is functionally equivalent to the proposal.

The addition of NOTE 8 was in harmonization with the ad hoc recommendations and is explanatory.

The text in NOTE 9 is identical to that proposed in the NPR as three separate notes in section 9.5.1, 9.5.2, and 9.5.3. Consensus in the subcommittee was to use one note to apply to all three sections.

NPR Proposal	ASTM F2388-18	CPSC staff Assessment
<p>9.5.1 <u>The following warning statements shall be placed on all changing tables, including add-on changing units and contoured changing pads that are sold separately:</u></p> <p>Fall Hazard. Children have suffered serious injuries after falling from changing [table/pad/area]. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY in arm’s reach. <p><u>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.</u></p>	<p>9.5.1 <u>Warning addressing fall hazards</u></p> <p>Fall Hazard Children have suffered serious injuries after falling from changing [tables/pads/areas]. Falls can happen quickly.</p> <ul style="list-style-type: none"> • STAY within arm’s reach. 	<p>ASTM F2388 – 18 is functionally equivalent to the proposal, as it applies to all products covered by ASTM F2388 – 18.</p>
<p>9.5.2 <u>Removable pads that are included with changing tables, contoured pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately</u> that are intended <u>to be</u> physically attached to the support surface shall have a warning <u>on the pad or changing unit, and its retail packaging, to address the following:</u></p> <ul style="list-style-type: none"> • ALWAYS secure this [unit/pad] to the support [surface/frame] by (manufacturer’s instructions for securing the changing unit). See instructions. <p><u>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.</u></p>	<p>9.5.2 <u>Products</u> that are intended <u>for the consumer</u> to physically attach to the support surface <u>or frame</u> shall include an <u>additional</u> warning statement under Fall Hazard:</p> <ul style="list-style-type: none"> • ALWAYS secure this [unit/pad] to the support [surface/ frame] by (manufacturer’s instructions for securing the changing unit/pad). See instructions. 	<p>ASTM F2388 – 18 is functionally equivalent to the proposal because it more clearly and succinctly describes the products to which this section applies.</p>

NPR Proposal	ASTM F2388-18	CPSC staff Assessment
<p>9.5.3 <u>Non-rigid add-on</u> changing unit accessories, <u>changing pads</u>, and contoured changing pads, <u>whether sold with the changing table or sold separately</u>, shall include the following additional warning statements:</p> <p>Suffocation Hazard. Babies have suffocated while sleeping [in/on] changing [tables/pads/areas]. Changing [table/pad/area] is not designed for safe sleeping.</p> <ul style="list-style-type: none"> • NEVER allow baby sleep [in/on] changing [table/pad/area] <p><u>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.</u></p>	<p>9.5.3 Changing table accessories and contoured changing pads shall include the following additional warning statements:</p> <p>Suffocation Hazard Babies have suffocated while sleeping [in/on] changing [tables/pads/areas]: changing [table/pad/area] is not designed for safe sleep.</p> <ul style="list-style-type: none"> • NEVER allow baby to sleep [in/on] changing [table/pad/ area]. 	<p>ASTM F2388 – 18 is functionally equivalent to the proposal because it more clearly and succinctly describes the products to which this section applies.</p>
<p>9.5.4 <u>Contoured changing pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately shall include additional warnings addressing either:</u></p> <p>(a) <u>The specific products to attach the contoured changing pad or add-on unit to; or</u></p> <p>(b) That the surface used should be level, stable, and structurally sound with minimum surface dimensions of “X” by “Y”.</p>	<p>9.5.4 <u>For changing products sold separately from a changing table and designed to be attached to furniture, the warning in either 9.5.4.2 or 9.5.4.3 shall be addressed and be visible on the product during assembly. The warning shall also either be visible on the product through the retail package or shall be located on the retail package.</u></p> <p><u>9.5.4.1 The warning on the product shall comply with the format and text requirements in 9.4 and 9.5 and shall either be displayed as a separate warning which includes the safety alert symbol and signal word or shown at the bottom of the combined warning.</u></p> <p><u>9.5.4.2 Identify specific furniture to attach the changing products to.</u></p> <p>9.5.4.3 That the support surface used should be level, stable, and structurally sound with minimum surface dimensions of “X” by “Y”.</p>	<p>ASTM F2388 – 18 is functionally equivalent to the proposal. The ASTM subcommittee revised this language to more clearly specific the products to which it applies while adding the requirement that such language must be visible on the retail packaging.</p>
<p>10.1 Instructions shall be provided <u>with or permanently attached or printed on the changing table, add-on changing unit, or contoured changing pad</u> and shall be easy to read and understand. These instructions shall include information regarding assembly, maintenance, cleaning, and use of the product.</p>	<p>Instructions shall be provided with <u>the product</u> and shall be easy to read and understand, <u>and shall be in the English language at a minimum</u>. These instructions shall include information regarding assembly, maintenance, cleaning, and use, <u>where applicable</u>.</p>	<p>ASTM F2388 – 18 is functionally equivalent to the proposal, as it applies to all products covered by ASTM F2388 – 18. In addition, ASTM F2388 – 18 added a requirement that all instructions shall be in English.</p>

NPR Proposal	ASTM F2388-18	CPSC staff Assessment
<p><u>10.1.1 The instructions shall contain the warnings as specified in 9 and address the following:</u></p> <p><u>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.</u></p>	<p><u>10.4 The warnings in the instructions shall meet the requirements specified in 9.4.4, 9.4.5, and 9.4.6 with the following two exceptions: (1) the background of the signal word panel need not be in color and (2) clause 6.4 on ANSI Z535.4 need not be applied. An example warning in the format described in this section is shown in Fig. 17. The warning statements' wording content, as well as the use of underlining capital lettering, italics, or bold typeface, or a combination thereof, are at the discretion of the manufacturer.</u></p>	<p>Since publication of the NPR, the Ad Hoc TG has developed, balloted, and published new, recommended requirements for the formatting of warnings in instructional literature. These requirements can be found in the latest revision to the "Ad Hoc Approved Language." and ASTM F2388 – 18 includes instructional literature requirements that are based on these recommendations. Staff continues to be involved in Ad Hoc TG activities and believes that the requirements that have been adopted by the current ASTM voluntary standard are more appropriate than the analogous requirements that appeared in the NPR for high chairs.</p>

C. Conclusion

The more stringent requirements proposed in the NPR were intended to address hazards associated with baby changing products that ASTM F2388-16 did not adequately address. ES staff determined that ASTM F2388-18 adequately addresses all of the baby changing product hazards identified in the NPR because it incorporates into ASTM F2388-18, the more stringent requirements proposed in the NPR. In addition, ASTM F2388-18 has addressed issues with warnings and instructional literature section, based on the Ad Hoc Language Task Group. ES staff recommends that the Commission propose to incorporate by reference, ASTM F2388-18, with no modifications, as the mandatory safety standard for baby changing products for domestic use.

TAB C: Final Regulatory Flexibility Analysis of the Draft Final Rule for Baby Changing Products and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Baby Changing Products Standard

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: March 12, 2018

TO : Mark Kumagai, P.E.
Project Manager, Baby Changing Products
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 : Final Regulatory Flexibility Analysis of the Draft Final Rule for Baby Changing Products and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Baby Changing Products Standard

I. Introduction

On September 29, 2016, the Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking (NPR) in the *Federal Register* (FR) (81 FR 66881). The NPR proposed to incorporate by reference the then-current voluntary ASTM International (ASTM) standard for baby changing products 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 the use of 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 means to impede loosening or detachment of metal inserts and metal-threaded fasteners used to secure key structural elements.

Since the NPR, ASTM has published an updated version of the standard, F2388-18, which incorporates all of the modifications proposed by the Commission in the NPR. Therefore, staff recommends adopting ASTM F2388-18, without modifications, as the final baby changing product standard.

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

As required by the Regulatory Flexibility Act (RFA), this memorandum evaluates the potential economic impact on small entities, including small businesses, that would result from adopting ASTM F2388-18 as a mandatory rule.¹³ Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis (FRFA) when the Commission promulgates a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained below, staff cannot rule out a significant economic impact for 36 of the 84 (43 percent) known small suppliers of changing products to the U.S. market. Accordingly, we have prepared a FRFA.

The FRFA must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the FRFA must contain:

1. a statement of the need for, and objectives of, the rule;
2. a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. the response of the agency to any comments filed by the Chief Council for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
4. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
5. a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
6. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

II. The Product

The scope of ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*, covers “baby changing products including changing tables, changing table accessories, contoured changing pads, and add-on changing units.” The changing products that fall within the scope of this standard, as presented in the Initial Regulatory Flexibility Analysis (IRFA), are described again below:

¹³ 5 U.S.C. §§ 601-612.

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



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)



Figure 4. Changing Trays

5. Contoured changing pads may be used alone on any flat surface or in conjunction with a changing tray.¹⁴ They have higher sides on at least the long sides 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 (from \$177 to \$330). The cribs themselves may be either full-sized or minicribs. (See Figure 6)



Figure 6. Crib with Attached Changing Table

¹⁴ 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 would have no impact on flat changing pads, they were not included in the market research.

7. Changing table 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, however, because the accessories sold separately tend to be for more high-end products than those sold with the base product (about \$100 to \$300). (See Figure 7)



Figure 7. Changing Table 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 on the U.S. market at this time. 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 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)



Figure 9. Furniture with Attached Changing Tray

As noted in the scope of the voluntary standard, however, 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 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 market research.

Also excluded from the scope of the voluntary standard (or the draft final rule) are commercial wall-mounted changing tables, such as those frequently seen in public restrooms. Commercial changing products are wall-mounted and subject to a separate voluntary standard (ASTM F2285-04, reapproved 2010, *Standard Consumer Safety Performance Specification for Diaper Changing Tables for Commercial Use*). Additionally, there is no reason to believe that commercial changing tables are being used in homes. An example of a commercial wall-mounted changing table is shown in Figure 10 for comparison.



Figure 10. Commercial Wall-Mounted Changing Table

III. Objectives of the Draft Final Rule

The objectives of the draft final rule are to comply with the CPSIA and address the risk of injury associated with baby changing products. Section 104 of the CPSIA requires the CPSC to promulgate mandatory standards for durable infant or toddler products that are substantially the same as the 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.¹⁵ Based on 2013 National Electronic Injury Surveillance System (NEISS) injury estimates¹⁶ and data on the number of changing tables in use from CPSC's Durable Nursery Product Exposure Survey (DNPES),¹⁷ also from 2013, staff found that the risk associated with changing product use in homes is approximately 7.58 emergency department-treated injuries per 10,000 changing products in use annually [(4,140 injuries ÷ 5.46 million changing products in use in U.S. households) x 10,000]. CPSC staff believes that the requirements, test procedures, warning labels, and instructional literature included in the draft final rule address the hazard patterns identified in the incident data.

IV. IRFA Issues Raised in the Public Comments

The IRFA requested public feedback on four major questions:

- What actions might firms take to bring their changing tables into compliance with the proposed rule? What costs might be associated with those actions? How might the timing of the rule affect compliance costs?

Staff received no public comments in response to these questions in the IRFA.

- What types of changing tables have user-assembled secondary supports and how prevalent are those products in the market?

Staff received no public comments in response to these questions in the IRFA.

- What are the total and incremental testing costs of the proposed rule? How many changing tables are typically required to provide a “high degree of assurance?”

Staff received no public comments in response to these questions in the IRFA.

- What is the appropriate effective date for the proposed rule?

Staff received three comments on CPSC's proposed 6-month effective date. One comment, submitted by three consumer advocate groups, supported the 6-month effective date. The other two comments requested at least a 1-year effective date to allow manufacturers sufficient time to make changes to their products.

¹⁵ Changing tables (or products) 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 CFR § 1130.2(a)(14).

¹⁶ Memorandum from Wioletta Szeszel-Fedorowicz, Ph.D., Division of Hazard Analysis, Directorate for Epidemiology, dated December 13, 2017, Subject: Estimated Number of Injuries Associated with Changing Tables in the Years 2005-2016 and Reported Incidents that Occurred between January 1st, 2016 and November 30th, 2017.

¹⁷ The number of changing tables in use was run from the Durable Nursery Products Exposure Survey (DNPES) on 4/10/18, to exclude households with no children under age of 3, the relevant age group for the incident data.

CPSC staff found that as many as 43 percent of small suppliers of changing products could be significantly impacted by the proposed mandatory standard. Given the potential for significant impact, as well as the concerns expressed by two commenters about a short effective date, staff now recommends a 12-month effective date to reduce the impact on small businesses. The complete comment and full response are part of the briefing memo.¹⁸

V. Requirements of the Draft Final Rule

The draft final rule would incorporate by reference the voluntary standard for changing products (F2388-18), with no modifications. If finalized, it would become a mandatory consumer product safety standard under section 104 of the CPSIA. If it becomes a mandatory standard, firms whose changing products 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 manufactured or imported after the effective date of the standard would be prohibited from distribution in commerce. Noncompliant products would need to be modified to meet the mandatory standard or removed from the market.

This section lays out the requirements for, and considers the implications on, all firms, large and small. Section VI then continues the discussion, focusing exclusively on the small business impacts.

A. *ASTM F2388-18*

The major requirements from ASTM F2388-18 are presented below. Changes made since the NPR are in italics:

- 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 through the changing surface while he or she is being changed. The test

¹⁸ Memorandum from George A. Borlase and Mark Kumagai, Office of Hazard Identification and Reduction, dated June 13, 2018, Subject: Draft Final Rule for Changing Products for Domestic Use, Section III.C., Staff Responses to NPR Comments.

does not apply to contoured changing pads or add-on changing units that are sold separately. *It now includes an additional requirement for threaded fasteners. Additionally, the test must be conducted without any secondary support components beneath the changing surface, unless they are factory preassembled. This addresses collapses seen in the incident data¹⁹ and was proposed by the Commission as part of the NPR.*

- *Barriers—intended to prevent children from falling off the sides of changing tables, as well as reduce 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. The test procedure has been clarified to indicate more clearly what tests should be performed on which types of changing products. Additionally, a test surface is now specified for contoured changing products sold separately and add-on changing units sold separately.*
- *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 CFR part 1221 and 16 CFR part 1220) for these products.*
- *Self-folding steps—intended to prevent a child from activating the steps. The test for units with a single-action release mechanism has been updated to specify how to apply the force and how long it should be maintained.*
- *Threaded fasteners—intended to prevent the loosening of key structural elements. Wood screws and sheet metal screws cannot be used in key structural components requiring consumer assembly. These requirements and test procedures were proposed by the Commission as part of the NPR.*
- *Restraint system—intended to ensure that if a restraint system is provided as part of the changing product, it is effective. This requirement and test procedure were proposed by the Commission as part of the NPR.*

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, smoothness of wood parts, *and scissoring, shearing, and pinching*); (3) marking and labeling requirements, including permanency requirements, *which have been updated to incorporate the Commission's NPR proposals*; (4) requirements for instructional literature, *which have been updated to incorporate the Commission's NPR proposals*; and (5) toy accessory requirements. *ASTM F2388 has been modified to more clearly address changing products of all types, rather than just changing tables, and this has led to numerous language changes and two new definitions (changing*

¹⁹ Memorandum from Wioletta Szeszel-Fedorowicz, Ph.D., Division of Hazard Analysis, Directorate for Epidemiology, dated August 16, 2016, Subject: Notice of Proposed Rulemaking for Changing Tables and Certain Changing Table Products for Domestic Use.

product and changing table accessory). ASTM F2388-18 includes no reporting or recordkeeping requirements.

B. Third Party Testing

Under section 14 of the CPSA, once the new changing product requirements become effective, all suppliers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR part 1107) (1107 rule), which requires that manufacturers and importers certify that their products comply with the applicable children's product safety standards, based on third party testing. Third party testing costs are in addition to the costs of modifying the changing products to meet the standard. For changing products, the third party testing costs are expected to be \$300 to \$1,200 per sample tested, depending upon whether the testing is conducted in the United States or overseas.²⁰ As allowed by the component part testing rule (16 CFR part 1109), importers may rely upon third party tests obtained by their suppliers, which could reduce the impact on importers. The incremental costs would also be lower for suppliers of compliant changing products if they are already obtaining third party tests to ensure conformance with the voluntary standard.

VI. The Market for Changing Products and the Impact on Small Businesses

Table 1 describes the U.S. market for changing products. Staff identified 120 firms supplying changing products to the U.S. market. Of these, 102 firms were domestic suppliers, 17 were foreign suppliers, and one supplier lacked sufficient information to determine a location or supply source. Staff limited our analysis of the impact of the draft final rule on small entities to domestic firms because SBA guidelines and definitions pertain to only to U.S.-based entities. Most firms supply a variety of changing products; however, staff identified 25 firms that supply only contoured changing pads to the market, 26 firms that supply only changing trays to the market, and one firm that supplies only changing pads and changing trays to the market.²¹ Staff also identified nine firms specializing in standalone changing tables for daycare and/or educational settings (although one of those firms also supplies contoured changing pads to go with their changing tables).

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of changing products is considered small if it has 500 or fewer employees; and importers are considered small if they have 100 or fewer employees. Of the 102 domestic firms that supply changing products to the U.S. market, 84 are small according to SBA guidelines. Among these 84 small

²⁰ These cost estimates are for testing compliance with the physical or mechanical requirements in the standard only. Manufacturers and importers of changing tables are already subject to third party testing requirements for lead content.

²¹ Due to the limited requirements these products are subject to, these firms are handled slightly differently in the analysis that follows, and therefore, are highlighted here.

firms, we identified 61 manufacturers and 23 that we believe to be importers.²² Among the small domestic firms, 22 small manufacturers, and 10 small importers have changing products that already comply with the voluntary standard. This is based on either Juvenile Products Manufacturers Association (JPMA) certification (5 firms) or claims of compliance and/or active participation in the development of the ASTM changing products standard (27 firms).

The remaining 18 firms are 16 foreign manufacturers, one foreign importer, and one firm for which a location and supply source could not be determined. Additionally, staff identified numerous foreign changing products entering the U.S. market via Amazon.com storefronts and other online firms acting as brokers between buyers and sellers. It is often impossible to determine whether these sellers are located domestically or overseas, making it difficult to categorize these companies for analysis. However, foreign suppliers are not considered in the regulatory flexibility analysis, and none of the suppliers specialize in changing products. Each sells a wide variety of products other than those for children. Therefore, the impact of a changing products mandatory standard on these firms would be small.

Table 1. Firms in the U.S. Changing Table Market²³

CATEGORY	NUMBER OF FIRMS SUPPLYING CHANGING PRODUCTS
Total Firms	120
<i>Total Domestic Firms</i>	<i>102</i>
<i>Large</i>	<i>18</i>
<i>Small</i>	<i>84</i>
Manufacturers	61
<i>Compliant with ASTM voluntary standard</i>	<i>22</i>
<i>Not compliant with ASTM voluntary standard</i>	<i>39</i>
Importers	23
<i>Compliant with ASTM voluntary standard</i>	<i>10</i>
<i>Not compliant with ASTM voluntary standard</i>	<i>13</i>
<i>Total Foreign Firms</i>	<i>17</i>
<i>Unknown Firms</i>	<i>1</i>
Highlighted categories are the focus of this analysis.	

²² Five of the firms that we believe to be importers were wholesalers, for which the original manufacturer of the changing products supplied (domestic or overseas) could not be identified. These firms will be grouped with importers in the analysis that follows. There may be additional small domestic changing product suppliers operating in the U.S. market that we have not identified.

²³ Staff made these determinations using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

A. Small Manufacturers

1. Small Manufacturers with Compliant Changing Products

Currently, 22 of the small manufacturers produce changing products that comply with the ASTM voluntary standard now in effect for testing purposes (ASTM F2388-17a).²⁴ Staff assumes that compliant firms will remain compliant with the voluntary standard as it evolves, because compliance is part of an established business practice. Given that the draft final rule incorporates by reference ASTM F2388-18, without modifications, and that the voluntary standard will be in effect for testing purposes several months before the mandatory rule becomes effective, the draft final rule is not expected to have a significant impact on any of the 22 firms with already compliant changing products. Additionally, because these firms are already testing to the ASTM standard, any third party testing costs are expected to be minimal.

2. Small Manufacturers with Noncompliant Changing Products

Thirty-nine small manufacturers produce changing products that do not comply with the voluntary standard. However, of those 39 firms, seven manufacture only wooden changing trays that are sold separately from a base piece of furniture. Such changing trays have few requirements beyond side height and labeling/instructions. Changes to warning labels and instruction manuals are not typically expected to result in significant costs. Similarly, additional materials to increase side height (should they be required) are not expected to result in significant cost increases, given that the material involved is wood. Therefore, no significant impact is expected for the seven small manufacturers supplying only noncompliant wooden changing trays.

Additionally, 12 of the 39 firms supplying noncompliant changing products supply only contoured changing pads. As with changing trays, these products are subject to few requirements, primarily the labeling/instructional and barrier/retention requirements. The labeling, instructional, and retention requirements are not expected to result in significant costs for these firms; and while no test results are available for the barrier requirements, it appears that all of these products are likely to pass the ASTM test.²⁵ Even allowing for some possibility that the contoured pads of one or more firms fail the barrier or retention test, it is unlikely that more than two firms would need to modify their products (20 percent). However, modifying the side height of a changing pad to address barrier problems would tend to result in significant costs, because new molds would need to be created for these foam products, an expensive and time consuming process.

²⁴ There is typically a 6-month delay between the publication of a new ASTM voluntary standard and its adoption for compliance testing. Published in October 2017, ASTM F2388-17a went into effect for testing purposes in April 2018. ASTM F2388-18 was published in March 2018, and will not be effective for testing purposes until September 2018. However, this is before the draft final rule would go into effect.

²⁵ It is relatively easy to make a determination on the likelihood of compliance based on a photograph comparing the side height of a known compliant contoured changing pad to one of unknown compliance.

The remaining 20 firms supply a variety of noncompliant changing products to the U.S. market. Firms interviewed before the NPR indicated that the cost of a complete redesign could range from \$25,000 to \$200,000, depending upon the changing table product type. Generally, staff considers impacts that exceed 1 percent of a firm's revenue to be potentially significant. Based on an evaluation of the revenue information of these 20 firms, it appears likely that the draft final rule will be significant for nine of these firms, due to low revenue levels, and may be significant for a tenth as well (1 percent of revenue is about \$140,000). There was no revenue information available for seven of the 20 firms; therefore, a significant impact could not be ruled out in those cases. However, it appears unlikely that the economic impact of the draft final rule would be significant for three of the 20 firms, based on their revenue levels.

As noted in Section V, firms interviewed said that testing costs were likely to be as high as \$1,200 for testing conducted in the United States. However, given the smaller number of tests conducted for contoured changing pads and changing trays sold separately, it is assumed that testing costs for those products might run as much as \$600 instead.²⁶ Of the 39 small domestic manufacturers of noncompliant changing products, third party testing costs are not expected to exceed 1 percent of revenue for 21 of those firms. Third party testing costs may exceed 1 percent of sales revenue for the remaining 18 firms, with varying degrees of likelihood. More tellingly, the third party testing costs could result in significant costs for seven of the 20 small domestic manufacturers of noncompliant changing products that *are not expected to experience significant economic impacts as a result of the draft final rule itself*. Three of these are very small firms operating on websites that bring together buyers and sellers of handmade goods. All three firms make changing trays that might reasonably be expected to experience high testing costs per model, relative to sales volume per model, although sales revenue is not typically available for these businesses. The remaining four firms have low enough revenue levels, relative to their changing product models, that, in one case, the cost of testing just one unit per model for a "high degree of assurance" would exceed 1 percent of its revenue.

B. Small Importers

1. Small Importers and Wholesalers with Compliant Changing Products

Staff identified nine changing product importers and one wholesaler currently in compliance with the voluntary standard. 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, whereas wholesalers supply products that may be supplied by foreign or domestic firms, or both. Staff was unable to determine the supply source for the wholesaler in this case.

As with small manufacturers of compliant changing products, these firms are expected to be in compliance with ASTM F2388-18 before the final changing product rule becomes effective. Therefore, under the draft final rule, the economic impact is unlikely to be significant for any of

²⁶ This lower testing cost is consistent with ASTM standards with fewer testing requirements, based on information collected from firms for numerous past rulemakings.

the nine small importers or one small wholesaler with compliant changing products. Any third party testing costs for importers of compliant changing products would be limited to the incremental costs associated with third party testing over their current testing regime.

2. Small Importers and Wholesalers with Noncompliant Changing Products

Staff identified nine small importers and four small wholesalers of noncompliant changing products. The economic impact on importers and wholesalers depends upon the extent of the changes required to come into compliance and the response of their supplying firms, which cannot generally be determined for noncompliant importers and wholesalers. However, one of the importers supplies only wooden changing trays that are sold separately, which (as discussed in Section VI.A.2.) are not expected to result in significant cost increases. The same is true for the two small importers and one small wholesaler supplying only contoured changing pads to the U.S. market; although using the same assumption as in the earlier analysis, it is possible that one of these firms might still require redesign, which would have a significant economic impact on that firm. However, each of these firms has wide enough product lines that dropping contoured changing pads might be a viable option, although it is not clear what impact this might have on their revenue.

For the remaining six small importers and three small wholesalers of noncompliant changing products, four firms have low enough revenue levels that they are likely to experience a significant economic impact, regardless of how their supplying firm responds; none has a subsidiary relationship with their supplier, and it is not expected that their supplier will help absorb any of the costs. Finding an alternative supplier might pose significant costs for these firms relative to their revenue levels as well. Dropping changing products from their product lines entirely would appear to be an option for at least three of these firms, but it is not clear what impact this might have on their revenue.

There is no revenue information available for the other five firms; therefore, there is insufficient information to rule out a significant economic impact. However one of the firms does appear to be tied to its foreign supplier, which may help it absorb some of the costs of compliance, and another firm has a wide enough product line that dropping changing products would be a viable alternative, if another source (or an alternative product) cannot be secured.

Third party certification of compliance with the draft final rule could result in significant costs for three firms with noncompliant changing products. For two of these firms, testing costs could exceed 1 percent of gross revenue if only one unit per model required testing for a “high degree of assurance.” A third firm would need to test about three units per model before testing costs would exceed 1 percent of gross revenue. There were no revenue data available for seven small importers/wholesalers of noncompliant changing products, and therefore, staff could not make a determination for these firms. It is unlikely that third party testing costs would be significant for the remaining three firms. However, it is uncertain whether any firms not significantly impacted by the draft final rule would experience significant third party testing costs.

C. Summary of Impacts

CPSC staff is aware of 84 small domestic firms (61 manufacturers, 18 importers, and five wholesalers) currently marketing changing products in the United States. It appears unlikely that there would be a significant economic impact on the 22 small manufacturers, nine small importers, or one small wholesaler of compliant changing products. There is also unlikely to be a significant economic impact on 13 of the small manufacturers or three of the small importers of noncompliant changing products, primarily because most of these firms supply changing trays or contoured changing pads exclusively and are not expected to require changes. However, we could not rule out a significant economic impact on 26 of the small manufacturers and 10 of the importers/wholesalers of noncompliant changing products.

VII. Efforts to Minimize the Impact on Small Entities

CPSC proposed a 6-month effective date for the proposed rule and requested public comments on the most appropriate effective date. A later effective date would reduce the economic impact on firms in two ways. 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. Additionally, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. Staff received two comments requesting at least a 1-year effective date to allow manufacturers sufficient time to make changes to their products, as well as a comment from three consumer advocate groups supporting CPSC's proposed 6-month effective date. Given the potential for a significant economic impact on some small firms, staff now recommends a 12-month effective date to help reduce the impact on affected firms.

VIII. 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 notice of requirements (NOR) pertaining to third party conformity testing. NORs have been codified for existing rules at 16 CFR part 1112 (1112 rule). Consequently, staff recommends that the Commission amend the 1112 rule to establish the NOR for 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.

CPSC certified in the notice of proposed rulemaking that the proposed NOR would not have a significant 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;

- Only firms that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements would provide testing services; and
- Most of these laboratories will already be accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the changing products standard to their scope of accreditation.

There have been no substantive changes in these facts since the NPR was published, and no staff received no public comments suggesting that the NOR could significantly impact a substantial number of small test laboratories. Therefore, there is no reason to alter CPSC's certification of the NOR's impact on small test laboratories.