

Ballot Vote Sheet

TO: The Commission DATE: April 13, 2022

Alberta E. Mills, Secretary

THROUGH: Austin C. Schlick, General Counsel Mary T. Boyle, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel,

Regulatory Affairs

Meridith L. Kelsch, Attorney, Regulatory Affairs

SUBJECT: ASTM's Revised Safety Standard for Baby Changing

Products

BALLOT VOTE DUE: Tuesday April 19, 2022

Staff is forwarding to the Commission a briefing memorandum recommending that the Commission issue a direct final rule to update the ASTM standard incorporated by reference in the Safety Standard for Baby Changing Products, codified in 16 CFR part 1235. In 2018, the Commission issued that mandatory standard under the Consumer Product Safety Improvement Act of 2008 (CPSIA), incorporating by reference ASTM F2388-18, Standard Consumer Safety Specification for Baby Changing Products for Domestic Use. Under the CPSIA, when ASTM revises a voluntary standard for a durable infant or toddler product that the Commission has incorporated by reference, the revised standard automatically becomes the mandatory standard, unless the Commission determines that the revised standard "does not improve the safety of the consumer product" and so notifies the voluntary standards organization. ASTM updated the voluntary standard for baby changing products, issuing ASTM F2388-21, and notified the Commission of the revised standard. Staff recommends that the Commission allow the revised voluntary standard to become the mandatory standard, and publish a direct final rule to revise part 1235 to reference ASTM F2388-21. Attached for Commission consideration is a draft Federal Register notice for that purpose. If approved by the Commission, the Office of the General Counsel will seek approval of the incorporation by reference from the Office of the Federal Register, in accordance with the requirements in 1 CFR part 51, and upon receiving approval of the incorporation by reference, will send the notice to the Federal Register for publication.

	Please indicate your vote on the followin	g options:
I.	Approve publication of the attached notice in the Federal Register, as drafted.	
	(Signature)	(Date)

U.S. Consumer Product Safety Commission4330 East-West Highway
Bethesda, MD 20814

National Product Testing and Evaluation Center 5 Research Place Rockville, MD 20850



Ballot Vote Sheet

(Signature)	(Date)
Do not approve publication of the attac	ned notice in the rederal Negister.
(Signature)	(Date)
(Signature) Take other action specified below.	(Date)
(Signature) Take other action specified below.	(Date)

Attachment: Draft *Federal Register* notice: Revisions to Safety Standard for Baby Changing Products

U.S. Consumer Product Safety Commission 4330 East–West Highway Bethesda, MD 20814 National Product Testing and Evaluation Center 5 Research Place Rockville, MD 20850 [Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1235

[Docket No. CPSC-2016-0023]

Revisions to Safety Standard for Baby Changing Products

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In June 2018, the U.S. Consumer Product Safety Commission (CPSC) published a consumer product safety standard for baby changing products under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The standard incorporated by reference the 2018 ASTM voluntary standard for baby changing products that was in effect at the time. The CPSIA sets forth a process for updating mandatory standards for durable infant or toddler products that are based on a voluntary standard, when a voluntary standards organization revises the standard. Consistent with the CPSIA update process, this direct final rule updates the mandatory standard for baby changing products to incorporate by reference ASTM's 2021 version of the voluntary standard.

DATES: The rule is effective on July 31, 2022, unless CPSC receives a significant adverse comment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. If CPSC receives such a comment, it will publish a notice in the Federal Register, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of July 31, 2022.

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ADDRESSES: You can submit comments, identified by Docket No. CPSC-2016-0023, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking

Portal at: https://www.regulations.gov. Follow the instructions for submitting comments. CPSC does not accept comments submitted by electronic mail (e-mail), except through https://www.regulations.gov, and as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/hand delivery/courier Written Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479. Alternatively, as a temporary option during the COVID-19 pandemic, you may e-mail such submissions to: cpscos@cpsc.gov.

Instructions: All submissions must include the agency name and docket number for this direct final rule. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to:

https://www.regulations.gov. Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: For access to the docket to read background documents or comments received, go to: https://www.regulations.gov, and insert the docket number, CPSC-2016-0023, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Keysha Walker, Compliance Officer, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-6820; e-mail: KWalker@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products and adopt mandatory standards for those products. 15 U.S.C. 2056a(b)(1). The mandatory standard must be "substantially the same as" the voluntary standard, or it may be "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. *Id*.

Section 104(b)(4)(B) of the CPSIA specifies the process for updating the Commission's rules when a voluntary standards organization revises a standard that the Commission incorporated by reference under section 104(b)(1). First, the voluntary standards organization must notify the Commission of the revision. Once the Commission receives this notification, the Commission may reject or accept the revised standard. The Commission may reject the revised standard by notifying the voluntary standards organization, within 90 days of receiving notice of the revision, that it has determined that the revised standard does not improve the safety of the consumer product and that it is retaining the existing standard. If the Commission does not take this action to reject the revised standard, the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (15

U.S.C. 2058), effective 180 days after the Commission received notification of the revision or on a later date specified by the Commission in the *Federal Register*. 15 U.S.C. 2056a(b)(4)(B).

2. Safety Standard for Baby Changing Products

Under section 104(b)(1) of the CPSIA, the Commission adopted a mandatory rule for baby changing products, codified in 16 CFR part 1235. The rule incorporated by reference ASTM F2388-18, *Standard Consumer Safety Specification for Baby Changing Products for Domestic Use*, with no modifications. 83 FR 29672 (June 26, 2018). At the time the Commission published the final rule, ASTM F2388-18 was the current version of the voluntary standard.

On February 1, 2022, ASTM notified CPSC that it had revised the voluntary standard for baby changing products, approving ASTM F2388-21 on November 15, 2021. As discussed below, based on CPSC staff's review of ASTM F2388-21, the Commission will allow the revised voluntary standard to become the mandatory standard because the revised requirements in the voluntary standard either improve the safety of baby changing products, or are neutral with respect to safety. Accordingly, by operation of law under section 104(b)(4)(B) of the CPSIA, ASTM F2388-21 will become the mandatory consumer product safety standard for baby changing products on July 31, 2022. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates 16 CFR part 1235 to incorporate by reference the revised voluntary standard, ASTM F2388-21.

B. Revisions to ASTM F2388

The ASTM standard for baby changing products includes performance requirements, test methods, and requirements for warning labels and instructional literature, to address hazards to children associated with baby changing products, including structural integrity, stability, barriers,

¹ ASTM published ASTM F2388-21 in January 2022.

² CPSC staff's briefing memorandum regarding ASTM F2388-21 is available at: TBD.

³ The Commission voted TBD-TBD to approve this notice.

retention of contoured changing pads and add-on changing units, entrapment, self-closing steps, and restraints. This section describes the changes in ASTM F2388-21, as compared to ASTM F2388-18, which is the current mandatory standard, and includes an assessment of those changes. ASTM F2388-21 contains substantive revisions, as well as editorial, non-substantive revisions.

1. Substantive Revisions

ASTM F238-21 includes two substantive changes. The first revision is in Figure 9, Webbing Tension Pull Device, which is in section 7 of the standard. Section 7 specifies test methods to address hazards associated with baby changing products. Section 7.8 provides tests to assess restraint systems, which include components of the baby changing product that contribute to the capability to restrict upward or lateral movement of an occupant's torso within the product. Part of the restraint system test involves using a webbing tension pull device to adjust the restraint before applying a specified pull force to the restraint. Figure 9 depicts the webbing tension pull device that must be used. In ASTM F2388-21, two notes have been added to Figure 9 to provide the overall width and length dimensions for the tool, and a metric equivalent dimension has been added for one of the dimensions shown in the figure. CPSC staff considers these revisions neutral with respect to the safety of baby changing products because they provide dimension notes and equivalent metric measurements, which clarify how to fabricate the test tool, but do not change the test tool or test procedure. Moreover, the revisions are consistent with figures of similar webbing tension devices used in other ASTM standards, such as ASTM F833-21, Standard Consumer Safety Performance Specification for Carriages and Strollers.

The second revision is in section 9.5 of the standard, which provides warning statements that must be addressed on product labels and requires that the warnings align with the format and

text requirements illustrated in the standard. The warning statements provided in section 9.5.1 address fall hazards, including the hazard statement, "Fall Hazard," at the beginning of the warning statement. In ASTM F2388-21, this hazard statement has been revised to be capitalized as "FALL HAZARD." Likewise, the warning statements provided in section 9.5.3 address suffocation hazards, including the hazard statement, "Suffocation Hazard," at the beginning of the warning statement. In ASTM F2388-21, this warning statement has also been revised to be capitalized as "SUFFOCATION HAZARD." CPSC staff considers these revisions an improvement to the safety of baby changing products because capitalization emphasizes the hazard statements and makes them more conspicuous, thereby increasing the likelihood that a caregiver will pay attention to the warning statements.

2. Non-Substantive Revisions

ASTM F2388-21 also includes minor revisions that are editorial and do not alter any substantive requirements in the standard. These changes are as follows:

- Footnote 1 has been revised to include "baby changing products," instead of "changing tables," as part of the correct name for the subcommittee that developed the standard and has been revised to include the approval and publication dates of the revised standard.
- Figure 11, which provides examples of left-aligned warning label text, has been renumbered as Figure X1.1 and relocated from section 9, *Marking and Labeling*, to section X1, *Rationale*. This revision has not changed the figure content or illustration. Although section 9 is a mandatory portion of the standard and section X1 is not mandatory, moving Figure 11 is a non-substantive change because the figure merely provides examples of the mandatory message panel text layout specified in section 9.4.6.1, and already was not mandatory.

- ASTM F2388-21 includes minor wording changes and grammatical corrections, including changing "example warning labels" to "example warning statements" (section 9.4.7); changing the warning label statement regarding fall hazards from "stay within arms reach" to "stay in arm's reach of your child" (section 9.5.1); and correcting the title of updated Figure X1.1 from "Example of Left Aligned Text" to "Example of Left-aligned Text."
- In section 9, *Marking and Labeling*, and section 10, *Instructional Literature*, several figure names have been revised, including changing "sample label" to "example warning statements" (revised Figures 11 through 15), and changing "Sample Warning in Instructions for example, Changing Table" to "Example Warning Statement in Instructions e.g., Changing Table" (updated Figure 16). These revisions are consistent with wording that was already in the standard, which describes these figures as "examples" (sections 9.4.7 and 10.4).

Because these revisions do not change any substantive requirements, they are neutral with respect to the safety of baby changing products.

C. Incorporation by Reference

Section 1235.2 of the direct final rule incorporates by reference ASTM F2388-21. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section **B. Revisions to ASTM F2388** of this preamble summarizes the major provisions of ASTM F2388-21 that the Commission here incorporates by reference into 16 CFR part 1235. The standard is reasonably available to interested parties. Until the direct final rule takes effect, a read-only copy of ASTM F2388-21 is available for viewing, at no cost, on ASTM's website at: https://www.astm.org/CPSC.htm. Once the rule takes effect, a read-only copy of the standard will be available for viewing, at no cost, on the ASTM website at: https://www.astm.org/READINGLIBRARY/. Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone: (301) 504-7479; e-mail: cpsc-gov. Interested parties can purchase a copy of ASTM F2388-21 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959 USA; telephone: (610) 832-9585; www.astm.org.

D. Certification

Section 14(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089) requires manufacturers of products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, to certify that the products comply with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or for children's products, on tests of a sufficient number of samples by a third party conformity assessment body accredited by CPSC to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA, such as the present rule on baby

changing products, are "consumer product safety standards." Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because baby changing products are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products. Products subject to part 1235 also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA,⁴ the phthalates prohibitions in section 108 of the CPSIA⁵ and 16 CFR part 1307, the tracking label requirements in section 14(a)(5) of the CPSA,⁶ and the consumer registration form requirements in section 104(d) of the CPSIA.⁷

E. Notice of Requirements

In accordance with section 14(a)(3)(B)(iv) of the CPSIA, the Commission previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies for testing baby changing products. 83 FR 29672 (June 26, 2018). The NOR provided the criteria and process for CPSC to accept accreditation of third party conformity assessment bodies for testing baby changing products to 16 CFR part 1235. The NORs for all mandatory standards for durable infant or toddler products are listed in the Commission's rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies," codified in 16 CFR part 1112. *Id*.

ASTM F2388-21 includes revised requirements for baby changing products. However, these revisions do not require additional equipment or test protocols beyond those that already exist in the standard. The revisions to the figure depicting the webbing tension pull device clarify the test equipment dimensions, without changing the specifications of the test tool or test method. The change to the capitalization of warning text does not necessitate a change in the

⁴ 15 U.S.C. 1278a.

⁵ 15 U.S.C. 2057c.

⁶ 15 U.S.C. 2063(a)(5).

⁷ 15 U.S.C. 2056a(d).

way that third party conformity assessment bodies test products. Accordingly, the revisions do not change the way that third party conformity assessment bodies test these products for compliance with the safety standard for baby changing products. Laboratories will begin testing to the new standard when ASTM F2388-21 goes into effect, and the existing accreditations that the Commission has accepted for testing to this standard will cover testing to the revised standard. Therefore, the Commission considers the existing CPSC-accepted laboratories for testing to ASTM F2388-18 to be capable of testing to ASTM F2388-21 as well. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected to update the scope of the testing laboratories' accreditations to reflect the revised standard in the normal course of renewing their accreditations.

F. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551-559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency, "for good cause finds," that notice and comment are "impracticable, unnecessary, or contrary to the public interest." *Id.* 553(b)(B). The Commission concludes that when it updates a reference to an ASTM standard that the Commission incorporated by reference under section 104(b) of the CPSIA, notice and comment are not necessary.

Specifically, under the process set out in section 104(b)(4)(B) of the CPSIA, when ASTM revises a standard that the Commission has previously incorporated by reference under section 104(b)(1)(B) of the CPSIA, that revision will become the new CPSC standard, unless the Commission determines that ASTM's revision does not improve the safety of the product and so notifies ASTM. Thus, unless the Commission makes such a determination, the ASTM revision

become CPSC's standard by operation of law. The Commission is allowing ASTM F2388-21 to become CPSC's new standard because its provisions either improve product safety or are neutral with respect to safety. The purpose of this direct final rule is to update the reference in the Code of Federal Regulations (CFR) so that it reflects the version of the standard that takes effect by statute. This rule updates the reference in the CFR, but under the terms of the CPSIA, ASTM F2388-21 takes effect as the new CPSC standard for baby changing products, even if the Commission does not issue this rule. Thus, public comments would not alter substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 104(b) of the CPSIA. Under these circumstances, notice and comment are unnecessary.

In Recommendation 95-4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and that are not expected to generate significant adverse comments. *See* 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the "unnecessary" prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective, by operation of law, on July 31, 2022. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be "one where the commenter explains why the rule would be inappropriate," including an assertion challenging "the rule's underlying premise or approach," or a claim that the rule "would be ineffective or unacceptable without a change." 60 FR 43108, 43111 (Aug. 18, 1995). As noted,

this rule merely updates a reference in the CFR to reflect a change that occurs by statute, and public comments should address this specific action.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601-612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section **F. Direct Final Rule Process** of this preamble, the Commission has determined that notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

H. Paperwork Reduction Act

The current mandatory standard for baby changing products includes requirements for marking, labeling, and instructional literature that constitute a "collection of information," as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501-3521). The revised mandatory standard does not alter these requirements. The Commission took the steps required by the PRA for information collections when it adopted 16 CFR part 1235, including obtaining approval and

a control number. Because the information collection is unchanged, the revision does not affect the information collection requirements or approval related to the standard.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision "consumer product safety standards." Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission notifies the standards organization that it has determined that the revision does not improve the safety of the product, or the Commission sets a later date in the *Federal*

Register. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the standard for baby changing products. Therefore, ASTM F2388-21 will take effect as the new mandatory standard for baby changing products on July 31, 2022, 180 days after February 1, 2022, when the Commission received notice of the revision.

L. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a "major rule."

Pursuant to the CRA, this rule does not qualify as a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1235

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

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1235 - SAFETY STANDARD FOR BABY CHANGING PRODUCTS

Revise the authority citation for part 1235 to read as follows:
 Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec 3, Pub. L. 112-28, 125 Stat. 273.

2. Revise § 1235.2 to read as follows:

§ 1235.2 Requirements for baby changing products.

Each baby changing product shall comply with all applicable provisions of ASTM

F2388-21, Standard Consumer Safety Specification for Baby Changing Products for Domestic

Use, approved on November 15, 2021. 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. A read-only

copy of the standard is available for viewing on the ASTM website at

https://www.astm.org/READINGLIBRARY/. You may obtain a copy from ASTM International,

100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; telephone (610)

832-9585; www.astm.org. You may inspect a copy at the Division of the Secretariat, U.S.

Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD

20814, telephone (301) 504-7479, e-mail cpsc-os@cpsc.gov, or at the National Archives and

Records Administration (NARA). For information on the availability of this material at NARA,

e-mail fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-

locations.html.

Alberta E. Mills,

Secretary,

Consumer Product Safety Commission.

15



Memorandum

DATE: April 13, 2022

TO: The Commission

Alberta E. Mills, Secretary

THROUGH: Austin C. Schlick, General Counsel

Mary T. Boyle, Executive Director

DeWane Ray, Deputy Executive Director for Safety Operations

FROM: Duane E. Boniface, Assistant Executive Director

Office of Hazard Identification and Reduction

Lawrence Mella, Mechanical Engineer

Division of Mechanical Engineering and Combustion Engineering

Directorate for Engineering Sciences

SUBJECT: Notice of Revision to the Safety Standard for Baby Changing Products

(16 CFR part 1235)

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), instructs voluntary standards organizations, such as ASTM International (ASTM), to notify the U.S. Consumer Product Safety Commission (CPSC) of revisions to voluntary standards that are a basis for a consumer product safety promulgated by the Commission. Section 104(b)(4)(B) of the CPSIA states:

COMMISSION ACTION ON REVISED VOLUNTARY STANDARD – If an organization revises a standard that has been adopted, in whole or in part, as a consumer product safety standard under this subsection, it shall notify the Commission. The revised voluntary standard shall be considered to be a consumer product safety standard issued by the Commission under section 2058 of this title [i.e., section 9 of the Consumer Product Safety Act (15 U.S.C. 2058)], effective 180 days after the date on which the organization notifies the Commission (or such later date specified by the Commission in the Federal Register) unless, within 90 days after receiving that notice, the Commission notifies the organization that it has determined that the proposed revision does not improve the safety of the consumer product covered by the standard and that the Commission is retaining the existing consumer product safety standard.

Bethesda, MD 20814

On June 26, 2018, the Commission published a final rule that incorporated by reference ASTM F2388 – 18, Standard Consumer Safety Specification for Baby Changing Products for Domestic Use, as the mandatory standard for baby changing products under section 104 of the CPSIA. 83 Fed. Reg. 29672. The final rule is codified at 16 CFR part 1235. The baby changing products standard applies to "changing tables, changing table accessories, contoured changing pads, and add-on changing units" that are "sold for domestic use for children up to a weight of 30 lb. (13.6 kg)." (ASTM F2388 – 18, sections 1.1-1.2).

On February 1, 2022, ASTM notified CPSC that it published a revised 2021 version of ASTM F2388 that affects the requirements for baby changing products. The revised standard is ASTM F2388 – 21, which ASTM approved on November 15, 2021, and published in January 2022. The revised standard will take effect as the new mandatory standard on July 31, 2022, unless the Commission specifies a later date in the *Federal Register* or notifies ASTM by May 2, 2022, that it has determined that the revision does not improve the safety of baby changing products.

The memorandum outlines the differences between ASTM F2388 – 21 and ASTM F2388 – 18, which is incorporated by reference into 16 CFR part 1235. Based on staff's evaluation of the revised voluntary standard, staff recommends that the Commission allow ASTM F2388 – 21 to be considered the new consumer product safety standard for baby changing products, effective July 31, 2022. Additionally, staff recommends that the Commission issue a direct final rule to update the incorporation by reference in part 1235 to reflect that ASTM F2388 – 21 will become the mandatory standard.

II. REVIEW AND COMPARISON OF STANDARDS

ASTM published ASTM F2388 - 18 in March 2018. On June 26, 2018, the Commission published a final rule that incorporated by reference ASTM F2388 - 18, with no modifications, into 16 CFR part 1235. 83 Fed. Reg. 29672. The rule took effect on June 26, 2019. ASTM F2388 - 21 is the first revision of ASTM F2388 since the Commission adopted ASTM F2388 - 18 as the mandatory standard.

Comparison of ASTM F2388 – 18 to ASTM F2388 – 21

Non-substantive changes

ASTM made several minor and editorial changes throughout ASTM F2388 - 21. These changes do not affect the safety of baby changing products, and include the following:

- Wording change in Note 1 for the subcommittee name from "Changing Tables" to "Baby Changing Products" and updated publication dates.
- Moving and renumbering Fig. 11, which provides examples of left-aligned text, from section 9, *Marking and Labeling*, to section X1, *Rationale*, and renumbering subsequent figures, accordingly. This revision did not change the figure content or illustration. Although section 9 is a mandatory portion of the standard, and section X1 is non-

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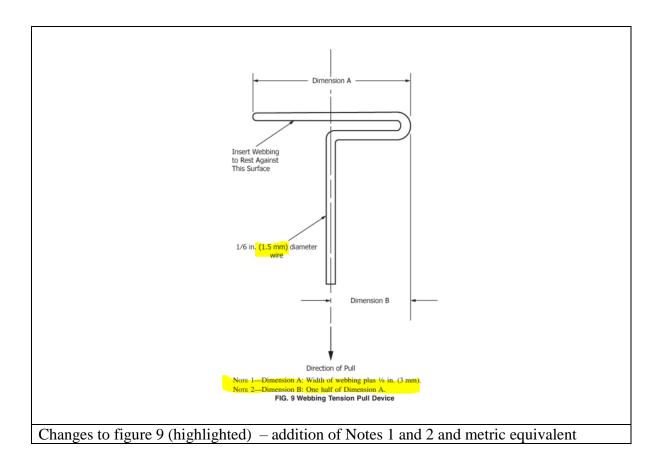
mandatory, moving Fig. 11 is a non-substantive change because it merely provides examples of the mandatory message panel text layout specified in Section 9.4.6.1, and already was not mandatory.

- Wording changes and grammatical corrections in the warning label regarding fall hazards (changing "stay within arms reach" to "stay in arm's reach of your child" (section 9.5.1)); changing "example warning labels" to "example warning statements" (section 9.4.7); and correcting the title of Fig. X1.1 from "Examples of Left Aligned Text" to "Example of Left-aligned Text."
- Renaming figures from "sample label" to "example warning statements" in section 9, *Marking and Labeling* (updated Figs. 11 through 15), and from "sample warning in instructions for example, changing table" to "example warning statements in instructions *e.g.*, changing table" in section 10, *Instructional Literature* (updated Fig. 16). These changes are consistent with wording that was already in the standard, which describes these figures as "examples" (sections 9.4.7 and 10.4).

Substantive changes

ASTM F2388 – 21 incorporated two substantive changes:

- Section 9.5 includes requirements for warning statements that must be addressed on product labels and requires that the warnings align with the format and text requirements illustrated in the standard. ASTM F2388 21 capitalized the hazard statement in these warnings from "Fall Hazard" to "FALL HAZARD" (section 9.5.1), and from "Suffocation Hazard" to "SUFFOCATION HAZARD" (section 9.5.3).
- Fig. 9 Webbing Tension Pull Device, in section 7, *Test Methods*, depicts the webbing tension pull device used for restraint system tests. Restraint systems include components of the changing product that contribute to the capability to restrict upward or lateral movement of the occupant's torso within the product. The webbing test device is used to adjust the restraint before a pull force is applied to the restraint straps. ASTM F2388 21 added two notes to the figure to provide the overall width and length dimensions for the tool and a metric equivalent dimension, as shown in the figure below. This is consistent with figures of similar webbing test devices used in other ASTM standards, such as ASTM F833, *Standard Consumer Safety Performance Specification for Carriages and Strollers*.



III. DISCUSSION

A. Staff's Assessment of the Revised Standard

Under CPSIA section 104(b)(4)(B), unless the Commission determines that ASTM's revision to a voluntary standard that is referenced in a mandatory standard "does not improve the safety of the consumer product covered by the standard," the revised voluntary standard becomes the new mandatory standard. Staff determined that the non-substantive editorial changes made to ASTM F2388 – 21 are neutral with respect to safety for baby changing products because they do not alter any requirements in the standard. Staff determined that the two substantive changes are collectively an improvement on safety. The first substantive change, changing the capitalization of the hazard statements, improves the safety of baby changing products by emphasizing and increasing the conspicuity of the hazard statement, thereby, increasing the likelihood that the caregiver will pay attention to the warning statement. The second substantive change provides dimension notes and equivalent metric measurements. These changes harmonize the webbing test tool figure with figures used in other standards. The change clarified how to fabricate the test tool, but it did not change the test tool or test procedure. Therefore, this second change is neutral regarding safety. Accordingly, staff recommends that the Commission allow the revised voluntary standard to become the consumer product safety standard for baby changing products, pursuant to section 104(b)(4)(B) of the CPSIA. Staff also recommends that the Commission

issue a direct final rule to revise the incorporation by reference in 16 CFR part 1235 to reflect this update.

B. Effect of the Changes on Third Party Testing

The notice of requirements (NOR), as set forth in the final rule for baby changing products, provides the criteria and process for the Commission's acceptance of accreditation of third party conformity assessment bodies for testing baby changing products to 16 CFR part 1235 (which incorporated by reference ASTM F2388 – 18). The NORs for children's product safety rules are listed in the Commission's rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies," at 16 CFR part 1112.

As discussed above, ASTM F2388 – 21 changes the capitalization of warning text, which does not necessitate a change in the way that third party conformity assessment bodies test these products. In addition, ASTM F2388 – 21 includes one change to clarify test equipment dimensions, which harmonizes the webbing test tool figure with the figures used in other standards, but it does not change the specifications of the test tool or test method. As such, the revisions do not require additional equipment or test protocols beyond those that exist in the standard. Therefore, testing laboratories that have demonstrated competence for testing in accordance with ASTM F2388 will have the competence to test in accordance with the revised standard.

For these reasons, staff recommends that the Commission accept the existing accreditations for testing to this standard as sufficient for testing to the revised standard as well. If the Commission follows this recommendation, the existing NOR for this standard would remain in place, and CPSC-accepted third party conformity assessment bodies would be expected, in the normal course of renewing accreditation(s), to update the scope of the testing laboratories' accreditation(s) to reflect the revised standard. If the Commission approves the draft direct final rule, CPSC staff will notify all CPSC-accepted laboratories by e-mail and will provide links to the *Federal Register* notice to explain the changes to the standard and the effective date.

C. Effective Date

Section 104(b)(4) of the CPSIA provides that the revised standard will become effective 180 days after the date on which an organization notifies the Commission of the revision, unless the Commission notifies an organization within 90 days of receiving the notification of the revision that it has determined that the proposed revision does not improve the safety of a consumer product covered by the standard, or the Commission specifies a later effective date in the *Federal Register*. Under this time frame, ASTM F2388 – 21 will become the new mandatory standard for baby changing products, effective on July 31, 2022, unless the Commission notifies ASTM by May 2, 2022, that it has determined that a proposed revision does not improve the safety of baby changing products, or the Commission specifies a later effective date in the *Federal Register*. Staff does not believe that specifying a later effective date is necessary. The Juvenile Products Manufacturers Association (JPMA) typically allows 6 months for products in their certification program to shift to a new voluntary standard once that new voluntary standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to a new voluntary

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standard within this time frame. As such, staff recommends that the Commission allow the updated standard to take effect as the new mandatory standard on the statutory effective date, July 31, 2022.

IV. RECOMMENDATION

Staff recommends that the Commission allow ASTM F2388 – 21 to be considered the revised consumer product safety standard issued by the Commission for baby changing products, because the revisions to the standard are neutral regarding safety or improve safety. Staff also recommends that the Commission issue a direct final rule to revise the incorporation by reference in 16 CFR part 1235 to reflect the revised voluntary standard. Staff recommends that the Commission allow the revised standard to take effect on the statutory 180-day effective date, of July 31, 2022.