



Ballot Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

DATE: November 6, 2024

THROUGH: Jessica L. Rich, General Counsel
Austin C. Schlick, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
Jane Rothstein, Attorney, Regulatory Affairs

SUBJECT: ASTM's Notice of a Revised Voluntary Standard for Soft Infant and Toddler Carriers

BALLOT VOTE DUE: November 13, 2024

Section 104(b)(4)(B) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) sets forth a procedure for updating mandatory standards to incorporate by reference, in whole or in part, a voluntary standard for a durable infant or toddler product. 15 U.S.C. § 2056a(b)(4)(B). This procedure applies to the Safety Standard for Soft Infant and Toddler Carriers, at 16 C.F.R. part 1226, which incorporates by reference ASTM F2236-14, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*.

On August 26, 2024, ASTM notified the Commission that it had approved and published ASTM F2236-24 as a revised version of this voluntary standard. Under CPSIA section 104(b)(4)(B), revised voluntary standards that the Commission has incorporated by reference into a mandatory standard automatically are considered consumer product safety standards, unless the Commission determines and notifies the voluntary standards organization that the revised voluntary standard "does not improve the safety of the consumer product." 15 U.S.C. § 2056a(b)(4)(B).

As indicated in the attached draft final rule, staff recommends that the Commission allow the revised ASTM standard to become the updated mandatory standard for soft infant and toddler carriers. Staff recommends that the Commission publish the attached draft direct final rule that revises the reference in CPSC's safety standard to refer to ASTM F2236-24.

Please indicate your vote on the following options:

- I. Accept ASTM F2236-24 as the new mandatory standard for soft infant and toddler carriers and approve publication of the attached notice in the *Federal Register*, as drafted.

(Signature)

(Date)

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

- II. Accept ASTM F2236-24 as the new mandatory standard for soft infant and toddler carriers and approve publication of the attached notice in the *Federal Register*, with specified changes.

(Signature)

(Date)

- III. Determine that ASTM F2236-24 does not improve the safety of soft infant and toddler carriers and direct staff to notify ASTM accordingly.

(Signature)

(Date)

- IV. Take other action specified below.

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Direct Final Rule; Revision to Safety Standard for Soft Infant and Toddler Carriers

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1226

[Docket No. CPSC-2013-0014]

Safety Standard for Soft Infant and Toddler Carriers

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In March 2014, the U.S. Consumer Product Safety Commission (CPSC or Commission) published a safety standard for soft infant and toddler carriers under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The standard incorporated by reference ASTM F2236-14, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*, the voluntary standard for soft infant and toddler carriers that was in effect at the time. ASTM has now issued a revised standard, ASTM F2236-24. Consistent with the CPSIA, this direct final rule updates the mandatory standard to incorporate by reference ASTM's 2024 version of the voluntary standard.

DATES: The rule is effective on February 22, 2025, 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 document 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 February 22, 2025.

ADDRESSES: You can submit comments, identified by Docket No. CPSC-2013-0014, 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 typically does not accept comments submitted by email, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504-7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. 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 through this website: 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/confidential 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-2013-0014, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Will Cusey, Small Business Ombudsman, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504-7945 or (888) 531-9070; email: sbo@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. 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 these products. 15 U.S.C. 2056a(b)(1). The mandatory standard must be “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. *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, then the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (CPSA; 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).

B. Safety Standard for Soft Infant and Toddler Carriers

Under section 104(b)(1) of the CPSIA, the Commission published a mandatory standard for soft infant and toddler carriers, codified in 16 CFR part 1226, “Safety Standard for Soft Infant and Toddler Carriers.” The rule incorporated by reference the then-current voluntary standard, ASTM F2236-14, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*, without alteration. 79 FR 17422 (Mar. 28, 2014). ASTM F2236 applies to soft infant and toddler carriers, defined as “a product, normally of sewn fabric construction, which is designed to contain a full term infant to a toddler, generally in an upright position, in close proximity to the caregiver.” The mandatory standard includes performance requirements and test methods, as well as requirements for warning labels and instructions, to address hazards associated with soft infant and toddler carriers.

After the Commission adopted the mandatory standard in 2014, ASTM approved two more revisions: ASTM F2236-16 and ASTM F2236-16a. However, ASTM did not notify CPSC of these revisions under CPSIA section 104(b)(4)(B). Consequently, the Commission did not update its mandatory standard to incorporate by reference either of these revised ASTM standards.

In July 2024, ASTM approved another revision to the voluntary standard for soft infant and toddler carriers, ASTM F2236-24. On August 26, 2024, ASTM notified CPSC of the revision. On September 10, 2024, the Commission published in the *Federal Register* a notice of availability of the revised voluntary standard and sought comments on the effect of the revisions. 89 FR 73320. CPSC received no comments on the notice of availability.

As discussed below, based on staff’s review of ASTM F2236-24, the Commission will allow the revised voluntary standard to become the mandatory standard for soft infant and

toddler carriers because the revised requirements in the voluntary standard improve the safety of soft infant and toddler carriers overall; and none of the revised requirements reduce safety.¹

Accordingly, by operation of law under section 104(b)(4)(B) of the CPSIA, ASTM F2236-24 will become the mandatory consumer product safety standard for soft infant and toddler carriers on February 22, 2025. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates part 1226 to incorporate by reference the revised voluntary standard, ASTM F2236-24.

II. Revisions to ASTM F2236

ASTM has revised the voluntary standard for soft infant and toddler carriers three times since its adoption of ASTM F2236-14, which is the current mandatory standard. This section describes the changes in these three versions of the standard – ASTM F2236-16, ASTM F2236-16a, and ASTM F2236-24. The newly revised 2024 version includes the revisions that ASTM made in the two 2016 versions of the standard.

A. *ASTM F2236-16 and ASTM F2236-16a*

On May 1, 2016, ASTM approved a revised version of the standard, ASTM F2236-16. On September 1, 2016, ASTM approved another revised version of the standard, ASTM F2236-16a. ASTM F2236-16 and ASTM F2236-16a included several substantive and clarifying additions and revisions, as well as editorial revisions that did not alter substantive requirements in the standard or affect safety.

1. Substantive and Clarifying Revisions

ASTM F2236-14 only provided a general definition for “fastener” in section 3.1.6.² ASTM F2236-16 included additions and revisions to the definition of “fastener” to clarify which

¹ The Commission voted TBD-TBD to approve this notice.

² ASTM F2236-14 and ASTM F2236-16 defined “fastener” as a “mechanical means of attachment that may also allow for adjustments of the product fit to wearer and occupant including, but not limited to, buckles, snaps, rings,

type of fastener, primary load bearing, secondary load bearing, or non-load bearing, is subject to each performance requirement. First, the Terminology section of ASTM F2236-16 added definitions for “primary load bearing fastener” (section 3.1.12) and “secondary load bearing fastener” (section 3.1.14).³ ASTM F2236-16a slightly modified these definitions for clarity.⁴

ASTM F2236-16 also included revisions to the performance requirements regarding fastener strength and strap retention (section 6.4) to clarify that primary load bearing fasteners are the type of fasteners that are subject to the performance requirements in section 6.4.1, which require an 80-pound load on the strap in accordance with sections 7.7.1 and 7.7.2; secondary load bearing fasteners are the type of fasteners that are subject to the performance requirements in section 6.4.2, which require a 45-pound load on the strap in accordance with sections 7.7.1 and 7.7.3; and non-load bearing fasteners intended to retain accessory items or fasteners which do not provide support or securement of the child’s torso within the carrier are exempt from the requirements in section 6.4.

ASTM was made aware of questions and varying interpretations of ASTM F2236-14 that could result in straps not being tested to their proper test method, which would make the testing less stringent in some cases (specifically, if a fastener that is meant to be tested to section 7.7.2 is instead tested to the less stringent 7.7.3). In response, ASTM made these revisions to ensure that fasteners are tested using the proper test method. These revisions do not change which fasteners

D-rings, hook-and-loop, etc., and excluding fabric-only means of attachment and fit adjustment such as, but not limited to, consumer-tied knots.”

³ ASTM F2236-16, in section 3.1.12, defined “primary load bearing fastener” as “any fastener used in the attachment of the product to the caregiver which provides support for the child or is used to attach that support of the child to the caregiver, or both, that is subject to the direct force of the occupant load, including those fasteners associated with positioning or supporting the child’s torso within the carrier.” Section 3.1.14 defined “secondary load bearing fastener” as “any fastener used in the attachment of the product to the caregiver which provides aid to the wearer for positioning primary load bearing components (for example, sternum strap fasteners). Such fasteners are subject to forces less than those exhibited by the direct occupant load in intended/foreseeable use.”

⁴ ASTM F2236-16a deleted “used in the attachment of the product to the caregiver” because it was not relevant to the definition of load bearing fasteners and could cause confusion.

should be subject to each performance requirement. However, the revisions improve the clarity of the standard and better ensure that third party laboratories consistently test fasteners using the proper test method. As a result, these revisions will improve the safety of soft infant and toddler carriers.

ASTM F2236-16a included further clarifying additions and revisions to test methods. ASTM F2236-14 included a Dynamic Load Test in which products are tested by repeatedly dropping a mass into the product in each of its carrying positions/configurations. This test is performed to evaluate the structural integrity of the product as it relates to occupant retention, as well as the slippage of the product's adjustable support/shoulder straps. This test is meant to ensure that products do not create a hazardous condition as defined by Section 5 (examples: sharp edges and small parts), do not fail structurally, and do not fall off the wearer during normal use. Section 7.2.1.1 specified that the test must be performed with either a 25 lb mass or a mass equal to the manufacturer's recommended maximum weight for the specific carrying position of the product, whichever is greater. ASTM F2236-16a, however, added the word "occupant" before "weight" to clarify that that the weight being referred to in this section is the maximum occupant weight. ASTM explained in the Rationale section (section X1.2.1) that the "occupant" weight clarification was made to be consistent with the terminology used in the Static Load Test in section 7.2.2.3. ASTM also explained that the maximum weight for load tests was always intended to be the recommended maximum occupant weight, and that any additional weight from accessory items that come with the product or are sold specifically for use with the product and stored in pockets or pouches is negligible and need not be considered in the recommended carry weight of the product. While these revisions improve the clarity of the test method and ensure that the test is applied consistently, they do not increase the stringency of the test method or

impact the outcome of performance testing because the accessory items generally consist of hoods, straps and similar components of the carrier that are stored in pockets or pouches and are not heavy enough to make a meaningful difference. Additionally, since neither version of the test specifies evaluating a product's pockets/pouches, this revision does not affect the structural integrity of pockets/pouches (which are not spaces that contain a child). Therefore, they are neutral regarding the safety of soft infant and toddler carriers.

In addition, ASTM F2236-16a included revisions to the Unbounded Leg Opening Test (section 7.6.2). This test involves securing a product to a test torso, placing a 17 lb shot bag, meant to represent the weight/size of an occupant into the product, placing the truncated test cone⁵ into a leg opening of the product, and applying a 5 lb force to the test cone for a minute to try to push the test cone through the leg opening. To meet the performance requirements, products shall not allow the truncated test cone to pass through any of the leg openings. This test is meant to evaluate the product's leg openings and ensure that occupants cannot slip through the leg openings. Section 7.6.2 of ASTM F2236-14 only instructed that adjustable leg openings should be adjusted to their "smallest size" as described in the manufacturer's literature or instructions. ASTM F2236-16a clarified that adjustable leg openings should be adjusted to "the size recommended for the smallest suitable occupant" as described in the manufacturer's literature or instructions. ASTM made this clarification to address products for which, when the seat width is configured to accommodate the smallest suitable occupant, the leg openings are not in their smallest possible configuration. In these instances, staff assesses that it is appropriate to test the leg openings based on the product configuration most appropriate for the smallest

⁵ The truncated test cone is 4.7 inches long, 4.7 inches in diameter at one end, and 3.0 inches in diameter at the other end. The 4.7-inch diameter is meant to simulate the 50th percentile hip circumference of the smallest child likely to use the carrier (*i.e.*, 7 to 8 lbs).

occupant, rather than the configuration that produces the smallest leg opening. Specifically, the smallest occupant could have a larger leg size than the smallest possible opening. As large leg openings are more likely than small leg openings to fail the Unbounded Leg Opening Test by allowing the test cone to pass through, this revision makes the test more stringent for products where a larger leg opening is appropriate for the smallest suitable occupant. Therefore, this revision is an improvement to safety.

2. Non-substantive Revisions

ASTM F2236-16 and ASTM F2236-16a also included several minor additions and revisions that were editorial in nature and did not alter any substantive requirements in the standard. For example, ASTM F2236-16 updated section and figure numbers to reflect the substantive and clarifying revisions. ASTM also updated the Rationale sections of both standards to provide explanatory information about the 2016 revisions. Because these revisions did not change any substantive requirements, they are neutral regarding the safety of soft infant and toddler carriers.

B. ASTM F2236-24

On July 1, 2024, ASTM approved a revised version of the standard, ASTM F2236-24. ASTM F2236-24 includes several substantive additions and revisions, revisions to clarify existing requirements, and editorial revisions that do not alter substantive requirements in the standard or affect safety. All the revisions in both 2016 ASTM versions of the standard are included in the newly revised version, ASTM F2236-24. Many of the changes in ASTM F2236-24 are intended to align with ASTM's Ad Hoc Wording Task Group (Ad Hoc TG) recommendations for durable infant and toddler product standards. In December 2013, ASTM convened the Ad Hoc TG, consisting of members of the various durable nursery products

voluntary standards committees, including CPSC staff. The purpose of the Ad Hoc TG is to harmonize the wording, as well as the warning format, across durable infant and toddler product voluntary standards. This latest revision to the Ad Hoc TG recommendations is in a reference document titled “Recommended Language Approved by Ad Hoc Task Group Revision H,” and is a part of the ASTM’s F15 Committee Documents.

1. Substantive and Clarifying Revisions

a. Terminology

In the Terminology section of ASTM F2236-24, the definition of “static load” is revised. ASTM F2236-14 defined the term as “vertically downward force applied by a calibrated force gage or by dead weights.” ASTM F2236-24 revises the term by replacing the word “force” with “load” and replacing “a calibrated force gage or by dead weight” with “weights or other means,” so that the definition is revised to state “vertically downward load applied by weights or other means.” These changes were made to align with Ad Hoc TG recommendations. Because these revisions simply modify wording and do not change the substantive meaning of the terms or change the stringency of the standard, they are neutral regarding the safety of soft infant and toddler carriers.

b. Flammability

ASTM F2236-24 makes revisions to section 5.7 regarding flammability, which include renaming the section to “Flammability of Soft Infant and Toddler Carriers” from “Flammability of Textile Products.” ASTM F2236-24 also replaces the word “product” with “fabrics” in section 5.7.1 to clarify that fabrics, rather than products, are subject to the flammability requirements in 16 CFR part 1610 – Standard for the Flammability of Clothing Textiles. In addition, section 5.7.2 of ASTM F2236-14 stated that “[i]f a soft infant and toddler carrier is incapable of being

evaluated to the requirements of 16 CFR 1610 due to construction characteristics, the product shall not be flammable as defined under 16 CFR 1500.3(c)(6)(vi) [“Flammable solid” definition] when tested in accordance with Consumer Safety Specification F963, Annex 5.” ASTM F2236-24 revises section 5.7.2 to clarify that “[c]omponents of the product that contain padding material(s) shall not be flammable as defined under 16 CFR 1500.3(c)(6)(vi) when tested in accordance with Consumer Safety Specification F963, Annex A5.” ASTM made these revisions in response to reports that several testing laboratories were not evaluating fabrics to 16 CFR 1610 and were instead evaluating them to 16 CFR 1500.3(c)(6)(vi). These revisions improve the clarity of the standard by specifying that all fabrics are subject to 16 CFR 1610, with the exception of padding components that are to be tested to 16 CFR 1500.3(c)(6)(vi) using the test method in Consumer Safety Specification F963, Annex A5. These revisions also ensure that fabrics and padding materials are consistently being tested to the flammability requirements/test method best suited for their characteristics. (Fabrics are generally not well-suited for testing to the F963, Annex A5 test method.) Therefore, these changes constitute an improvement to safety.

Also, the revised ASTM standard adds a note that the exemptions for flammability testing listed in 16 CFR 1610.1(d) and 1610.6(a)(1)(vi) apply when a fabric is subject to the requirements of 16 CFR part 1610. The exemptions include the following fabrics: plain surface fabrics, regardless of fiber content, weighing 2.6 ounces per square yard or more; all fabrics, both plain surface and raised-fiber surface textiles, regardless of weight, made entirely from any of the following fibers or entirely from combination of the following fibers: acrylic, modacrylic, nylon, olefin, polyester, and wool; and narrow fabrics and loose fibrous materials manufactured less than 50 mm (2 in) in width in either direction. Although only indirectly stated, these exemptions under 16 CFR 1610.1(d) and 1610.6(a)(1)(vi) previously were recognized as part of

the standard and applied by test laboratories assessing products to ASTM F2236-14. Because the additional note does not provide for any new exemptions that were not already in existence at the time of ASTM F2236-14, it is neutral regarding the safety of soft infant and toddler carriers.

Additionally, per the recommendation of the Ad Hoc TG, ASTM F2236-24 adds a requirement that non-toy accessories that are sold with and are intended to be attached to the product are also subject to the flammability requirements of section 5.7. ASTM made this new requirement to ensure that non-toy accessory products such as hoods and bibs that are commonly included with and attached to soft infant and toddler carriers are subject to flammability requirements as well. Because these accessory products attach to the soft infant and toddler carriers, they pose a foreseeable flammability hazard. Therefore, this change introducing a new requirement for non-toy accessories improves safety because it ensures that these accessory products are also subject to the flammability requirements of section 5.7.

c. Marking and Labeling

ASTM F2236-24 introduces an additional required warning statement for carriers that allow for nursing. This warning applies to all carriers except those that possess characteristics which render it impossible for the caregiver to nurse their baby while the baby is in the carrier. This warning instructs caregivers to reposition their baby after nursing so that the baby's face is not pressed against the caregiver's body. The new warning statement informs that if a baby's face is pressed against the caregiver's body while in the carrier, the baby could suffocate. The additional warning statement is an improvement to safety because it addresses a suffocation hazard pattern observed in soft infant and toddler carriers. There is no warning statement that addresses this suffocation hazard pattern in the 2014 version of the standard incorporated in 16 CFR part 1226.

In addition, section 8 of ASTM F2236-24 includes several revisions to the marking and labeling requirements to bring the standard into alignment with current Ad Hoc TG recommendations. These revisions include:

- requiring that the warnings be easy to read and understand and be in the English language at a minimum (section 8.4.1);
- requiring that any marking or labeling provided in addition to those required not contradict the meaning of the required information (section 8.4.2);
- requiring that the warnings conform to ANSI Z535.4-2011 and other sections of the standard, which provide guidance on formatting (font size, layout, use of signal words, colors, and etc.) of warning labels (section 8.4.4);
- adding a note that typefaces with large height-to-width ratios (*i.e.*, condensed, compressed, or narrow) should be avoided (Note 4);
- requiring that the message panel text layout be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered (section 8.4.6.1);
- adding Figure X1.1 in Appendix X1 to show examples of left-aligned text as described in section 8.4.6.1 (Note 5);
- updating Figure 5 to illustrate changes to section 8 and explaining that it is presented as an example for the display of the required warnings (section 8.5.3); and
- adding a note to section 8.5 explaining 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 6).

Because these revisions provide a consistent format for manufacturers to follow and improve messaging so that it is more conspicuous, clear, noticeable, easily readable, and understandable to the consumer, they are an improvement to safety. Other revisions include requiring that the marking and labeling on the product and its retail package include both the place of business and telephone number of the manufacturer, distributor, or seller (section 8.1.1); and requiring that the marking and labeling on the product be permanent (section 8.2). The revision in section 8.1.1 is an improvement to safety because it provides more information to the consumer, so that the consumer has more than one way of contacting the manufacturer, distributor, or seller if they have any safety-related questions or concerns. The revision in section 8.2 is also an improvement to safety because it ensures that marking and labeling will not fall off of the

product, so that marking and labeling would better be able to withstand normal wear and tear and remain visible to the consumer.

Also, in some places for warnings on the product, use of the words “infant,” “infants,” “child,” and “children” have been replaced with “baby” or “babies” (sections 8.5 and 8.6). Because these revisions don’t affect the substance of the messaging, they are neutral regarding the safety of soft infant and toddler carriers.

d. Instructional Literature

ASTM F2236-24 includes several revisions to the instructional literature requirements in section 9 for consistency with the current Ad Hoc TG recommendations and the revised warning label requirements in section 8. These revisions to the instructional literature requirements include adding requirements that instructions be in the English language at a minimum; that warnings in the instructions meet certain requirements specified in section 8 with regard to contrast with the background; and that any instructions provided in addition to those required shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer. These revisions also include a note referencing ANSI Z535.6 for additional guidance on the design of warnings for instructional literature. These revisions improve the safety of soft infant and toddler carriers by providing a consistent format for manufacturers to follow and providing messaging that is clear, noticeable, and consistent with the corresponding marking and labeling requirements to the consumer.

In addition, in some places, in the instructional literature, use of the words “infant,” “infants,” “child,” and “children” have been replaced with “baby” or “babies” (sections 9.2 and 9.3). Because these revisions don’t affect the substance of the messaging, they are neutral regarding the safety of soft infant and toddler carriers.

2. Non-substantive Revisions

ASTM F2236-24 also includes several minor additions and revisions that are editorial in nature and do not alter any substantive requirements in the standard. These revisions include formatting changes to align with ASTM form and style guidelines, and adjustments to section and figure numbers to reflect revised and new sections and figures. ASTM also updated the Rationale section in the standard to provide explanatory information about the revisions. Because these revisions do not change any substantive requirements, they are neutral regarding the safety of soft infant and toddler carriers.

III. Incorporation by Reference

Section 1226.2 of the direct final rule incorporates by reference ASTM F2236-24. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 16 CFR part 51. Under these regulations, agencies must discuss, in the preamble of the 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. 16 CFR 51.5(b).

In accordance with the OFR regulations, section II of this preamble summarizes the material in ASTM F2236-24 that the Commission incorporates by reference into 16 CFR part 1226. The standard is reasonably available to interested parties in several ways. Until the direct final rule takes effect, a read-only copy of ASTM F2236-24 is available for viewing on ASTM's website at: www.astm.org/CPSC.htm. Once the rule takes effect, a read-only copy of the standard will be available for viewing on the ASTM website at: www.astm.org/READINGLIBRARY/. Additionally, interested parties can purchase a copy of ASTM F2236-24 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West

Conshohocken, PA 19428-2959; telephone: (610) 832-9500; www.astm.org. Finally, interested parties can schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504-7479; email: cpsc-os@cpsc.gov. Interested parties can also schedule an appointment to inspect a copy of the standard at the National Archives and Records Administration by emailing fr.inspection@nara.gov, or going to: www.archives.gov/federal-register/cfr/ibr-locations.html.

IV. Certification

Section 14(a) of the CPSA (15 U.S.C. 2063(a)) requires manufacturers, including importers, 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 CPSC-accepted third party conformity assessment body accredited to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are "consumer product safety standards." Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because soft infant and toddler carriers are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products. Products subject to part 1226 must also comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA,⁶ the phthalates prohibitions in section 108 of the

⁶ 15 U.S.C. 1278a.

CPSIA⁷ and 16 CFR part 1307, the tracking label requirements in section 14(a)(5) of the CPSA,⁸ and the consumer registration form requirements in 16 CFR part 1130. ASTM F2236-24 makes no changes that would impact any of these existing requirements.

V. Notice of Requirements

In accordance with section 14(a)(3)(B)(vi) of the CPSA (15 U.S.C. 2063(a)(3)(B)(vi)), the Commission previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies (third party labs) for testing soft infant and toddler carriers. 79 FR 17433 (Mar. 28, 2014). The NOR provided the criteria and process for CPSC to accept accreditation of third party conformity assessment bodies for testing soft infant and toddler carriers to 16 CFR part 1226. 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. The NOR for accreditation of third party labs for testing soft infant and toddler carriers is codified at 16 CFR 1112.15(b)(37).

ASTM F2236-24 did not change the testing requirements, testing equipment, or testing protocols for soft infant and toddler carriers. Although ASTM F2236-16 and ASTM F2236-16a contained revisions relating to the testing requirements, these revisions served only to clarify previously existing requirements and did not require additional equipment or test protocols beyond those that already exist in the standard. Accordingly, the revisions in these versions of the standard have not changed the way that third party conformity assessment bodies test these products for compliance with the safety standard for soft infant and toddler carriers. Testing laboratories that have demonstrated competence for testing in accordance with ASTM F2236-14 will have the competence to test in accordance with the revised standard ASTM F2236-24.

⁷ 15 U.S.C. 2057c.

⁸ 15 U.S.C. 2063(a)(5).

Therefore, the Commission considers the existing CPSC-accepted laboratories for testing to ASTM F2236-14 to be capable of testing to ASTM F2236-24 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.

VI. Direct Final Rule Process

On September 10, 2024, the Commission published in the *Federal Register* a notice of availability regarding the 2024 revision to ASTM F2236 and requested comment on whether the revision improves the safety of soft infant and toddler carriers covered by the standard. 89 FR 73320. CPSC received no comments. 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 previously incorporated by reference under section 104(b) of the CPSIA, notice and comment are not necessary.

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 F2236-24 would take effect as the new CPSC standard for soft infant and toddler carriers in the absence of any action by the Commission. Thus, public comments would not lead to substantive changes to the

standard or to the effect of the revised standard as a consumer product safety rule 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. CPSC did not receive any adverse comments about the requirements in this update in response to the notice of availability published on September 10, 2024.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on February 22, 2025. 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 that undermines “the rule’s underlying premise or approach,” or a showing that the rule “would be ineffective or unacceptable without change.” 60 FR 43108, 43111. As noted, this rule updates a reference in the CFR to reflect a change that occurs by statute.

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.

VII. 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 VI of this preamble, the Commission has determined that further 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.

VIII. Paperwork Reduction Act

The current mandatory standard 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). While the revised mandatory standard adds marking, labeling, and instructional literature requirements for soft infant and toddler carriers, the new requirements would not materially add to the burden hours because the products already require marking, labeling, and instructional literature. The new requirements merely require revisions to the labeling language in addition to that already required by the standard. The Commission took the steps required by the PRA for information collections when it promulgated 16 CFR part 1226, and the marking, labeling, and instructional literature for soft infant and toddler carriers are currently approved under OMB Control Number 3041-0159. The agency will consider whether OMB Control Number 3041-0159 should be revised for soft infant and toddler carriers in the next scheduled update.

IX. Environmental Considerations

The Commission's regulations provide for a categorical exclusion 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). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

X. 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.

XI. 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 180 days after notification to the Commission, unless the Commission determines 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 revised standard for soft infant and toddler carriers. Therefore, ASTM F2236-24 automatically will take effect as the new

mandatory standard for soft infant and toddler carriers on February 22, 2025, 180 days after the Commission received notice of the revision. As a direct final rule, unless the Commission receives a significant adverse comment within 30 days of this document, the rule will become effective on February 22, 2025.

XII. 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 (OIRA) determines whether a rule qualifies as a “major rule.”

Pursuant to the CRA, OIRA has determined that 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 1226

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

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

PART 1226—SAFETY STANDARD FOR SOFT INFANT AND TODDLER CARRIERS

1. The authority citation for part 1226 is revised to read as follows:

Authority: 15 U.S.C. 2056a.

2. Revise § 1226.2 to read as follows:

§ 1226.2 Requirements for soft infant and toddler carriers.

Each soft infant and toddler carrier must comply with all applicable provisions of ASTM F2236-24, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*, approved on July 1, 2024. 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. This material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, telephone: (301) 504-7479, email: cpsc-os@cpsc.gov. For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. A read-only copy of the standard is available for viewing on the ASTM website at www.astm.org/READINGLIBRARY/. You may also obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959; telephone: (610) 832-9500; www.astm.org.

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



Memorandum

TO: The Commission
Alberta E. Mills, Secretary

DATE: November 6, 2024

THROUGH: Jessica L. Rich, General Counsel
Austin C. Schlick, Executive Director
DeWane Ray, Deputy Executive Director, Safety Operations

FROM: Duane E. Boniface, Assistant Executive Director,
Office of Risk Reduction

Zachary Foster, Project Manager,
Division of Human Factors, Directorate for Engineering Sciences

Daniel Taxier, Children's Program Manager,
Directorate for Engineering Sciences

SUBJECT: Staff's Draft Proposed Rule to Revise the Safety Standard for
Soft Infant and Toddler Carriers

In March 2014, the Commission published a mandatory standard for soft infant and toddler carriers, codified in 16 C.F.R. part 1226, "Safety Standard for Soft Infant and Toddler Carriers." The rule currently incorporates by reference ASTM F2236-14, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*. Soft infant and toddler carriers are defined in 16 C.F.R. part 1226 and ASTM F2236 as "a product, normally of sewn fabric construction, which is designed to contain a full-term infant to a toddler, generally in an upright position, in close proximity to the caregiver." Soft infant and toddler carriers are generally worn on the front, side, or back of the caregiver's body with the weight of the carrier and infant/toddler being supported by one or both of the caregiver's shoulders. Figure 1 below shows some examples of soft infant and toddler carriers.

In 2016, ASTM approved two revisions to the voluntary standard for soft infant and toddler carriers, ASTM F2236-16 and ASTM F2236-16a. However, ASTM did not notify CPSC of the changes until a revised version of the standard, ASTM F2236-24, was published in August 2024. On August 24, 2024, ASTM notified CPSC of this most recent revision. On September 10, 2024, the Commission provided notice in the *Federal Register* of the availability of the revised standard and sought comments on the effect of the revisions on the safety standard for infant bath seats. 89 Fed. Reg. 73,320. CPSC received no comments.



Figure 1: Examples of Soft Infant & Toddler Carriers

The revisions in F2236-24, including those originally adopted in F2236-16 and F2236-16a, are described in detail in Section II of the accompanying draft Direct Final Rule. Their substantive elements can be summarized as follows:

- Definitions for “primary load bearing fastener” and “secondary load bearing fastener” have been added to Terminology (Section 3.1). These definitions, when paired with the revisions to Fastener Strength and Strap Retention requirements (see below), better ensure that fasteners are subject to their appropriate performance requirement/test method. Specifically, this addition specifies that fasteners that are subject to the direct force of the occupant load (*i.e.*, primary load bearing fasteners) must be tested to the most stringent method. Therefore, staff considers this addition a safety improvement.
- The definition of “static load” (Section 3.1.15) has been revised to state that the load can be applied by “weights or other means,” rather than just by “a calibrated force gage (sic) or by dead weights.” This change was made to align with the current Ad Hoc Wording Task Group (Ad Hoc TG) recommendations.¹ Because this revision does not change the substantive meaning of the terms or the stringency of the standard, staff considers it neutral in terms of safety.
- Section 5.7 Flammability of Soft Infant and Toddler Carriers (formerly “Flammability of Textile Products”) has been revised to clarify that fabrics, rather than products, are subject to 16 C.F.R. part 1610 (with the exceptions listed in 16 C.F.R. 1610.1(d) and 1610.6(a)(1)(vi)) and that components of the product that contain padding material(s) shall not be flammable as defined under 16 C.F.R. 1500.3(c)(6)(vi) when tested in accordance with Consumer Safety Specification F963, Annex A5. This revision clarifies the flammability

¹ The purpose of the Ad Hoc TG is to harmonize the wording, as well as the warning format, across durable infant and toddler product voluntary standards. This latest revision to the Ad Hoc Language recommendations is in an ASTM F15 Committee reference document titled “Recommended Language Approved by Ad Hoc Task Group Revision H.”

requirements and ensures that fabrics and padding materials are consistently being tested to the flammability requirements/test method best suited for their characteristics. Therefore, staff views this revision as a safety improvement.

- Also, a requirement specifying that non-toy accessories, such as hoods and bibs, that are sold with and are intended to be attached to the product are also subject to the flammability requirements of Section 5.7 has been added. Because this revision introduces new requirements for non-toy accessories that provides for testing of the flammability of these accessory products, it is a safety improvement.
- Fastener Strength and Strap Retention performance requirements (Section 6.4) have been revised to clarify that primary load bearing fasteners are subject to Section 6.4.1 of the standard, which require an 80 lb. load on the strap in accordance with Section 7.7.2. Secondary load bearing fasteners are subject to Section 6.4.2 which require a 45 lb. load on the strap in accordance with Section 7.7.3. Non-load bearing fasteners that are intended to retain accessory items and fasteners which do not provide support or securement of the child's torso within the carrier are exempt from the requirements of Section 6.4. ASTM made this revision in response to concerns that the language used in ASTM F2236-14 could foreseeably be interpreted in a manner that would result in straps not being tested to their appropriate test method (specifically, straps that are meant to be tested to an 80 lb. load, as required by 7.7.2, could instead be tested to a 45lb. load, as required by 7.7.3). These revisions were made to clarify which types of fasteners are subject to which performance requirements and test methods and better ensures that fasteners that are subject to the direct force of the occupant load (*i.e.*, primary load bearing fasteners) are tested to the most stringent method.
- The Dynamic Load Test (Section 7.2.1) has been revised to clarify that the test is to be performed with either a 25 lb. mass or a mass equal to the manufacturer's recommended maximum occupant weight. This revision makes the language consistent with the language used for the Static Load Test in Section 7.2.2.3. It therefore clarifies the test method and promotes consistent application of the test. Furthermore, while the –24 revision of the standard does not include dynamic load testing of pockets and pouches, the same is true of the –14 version of the standard. Therefore, the revision of the Dynamic Load Test is neutral in terms of safety.
- The Unbounded Leg Opening Test (Section 7.6.2) assesses whether a test cone will pass through a leg opening when force is applied. Passage of the cone is a failure. This test has been revised to clarify that adjustable leg openings shall be adjusted to the size recommended for the smallest suitable occupant, rather than simply the smallest size, as described in the manufacturer's literature or instructions. This clarification was made because there are some products where adjustment of the seat width affects the size of the leg openings, and there are some instances where the seat width appropriate for the smallest occupant does not produce the smallest possible leg opening. Staff assesses that, in this scenario, performing the test with the seat width adjusted for the smallest occupant, even if the leg openings not necessarily at their smallest possible

configuration, is appropriate. Larger leg openings are more likely to fail the cone-passage test than smaller leg openings, and therefore the test is more stringent in cases where adjustment for the smallest suitable occupant enlarges the leg opening. Therefore, this revision is a safety improvement.

- Marking and Labeling requirements (Section 8) and Instructional Literature requirements (Section 9) have been revised to include requiring that the warnings conform to ANSI Z535.4-2011 and adding a warning statement instructing caregivers to reposition their baby after nursing so that the baby's face is not pressed against the caregiver's body. Figure 1 shows the current warning in 16 C.F.R. part 1226 (ASTM F2236-14) and Figure 2 shows the warning in ASTM F2236-24. This warning statement (see last statement in Figure 3 below) was added to address incidents of suffocation that have occurred while infants were nursing in soft infant and toddler carriers. This added warning statement will notify the caregiver of the suffocation hazard and instruct them to reposition the baby after nursing. Therefore, staff considers this additional statement a safety improvement.

▲ WARNING
FALL AND SUFFOCATION HAZARD
<p>FALL HAZARD - Infants can fall through a wide leg opening or out of carrier.</p> <ul style="list-style-type: none"> • Adjust leg openings to fit baby's legs snugly. • Before each use, make sure all ____ are secure. • Take special care when leaning or walking. • Never bend at waist; bend at knees. • Only use this carrier for children between ___ lb and ___ lb. <p>SUFFOCATION HAZARD - Infants under 4 months can suffocate in this product if face is pressed tight against your body.</p> <ul style="list-style-type: none"> • Do not strap infant too tight against your body. • Allow room for head movement. • Keep infant's face free from obstructions at all times.

FIG. 5 Warning Statements and Label Format

Figure 2: Warning Statement and Label Format in 16 C.F.R. part 1226 (ASTM F2236-14)

▲ WARNING
FALL AND SUFFOCATION HAZARD
<p>FALL HAZARD - Babies can fall through a wide leg opening or out of carrier.</p> <ul style="list-style-type: none"> • Adjust leg openings to fit baby's legs snugly. • Before each use, make sure all ____ are secure. • Take special care when leaning or walking. • Never bend at waist; bend at knees. • Only use this carrier for babies between ___ lbs and ___ lbs. <p>SUFFOCATION HAZARD - Babies under 4 months can suffocate in this product if face is pressed too tight against your body.</p> <ul style="list-style-type: none"> • Do not strap infant too tight against your body. • Allow room for head movement. • Keep baby's face free from obstructions at all times. • If you nurse your baby in carrier, always reposition after feeding so baby's face is not pressed against your body.

FIG. 5 Example of Warning Statements

Figure 3: Warning Statement and Label Format in ASTM F2236-24.

Other revisions to the Instructions, Marking and Labeling requirements include:

- Instructional literature must include the warning statements specified in Section 8.5; this statement is also required in the instructional literature (Section 9).
- Formatting requirements for warnings and instructional literature to bring the standard into alignment with the current Ad Hoc TG recommendations. These revisions include:
 - requiring that the marking and labeling on the product and its retail package include both the place of business and telephone number of the manufacturer, distributor, or seller;
 - requiring that the marking and labeling on the product be permanent;

- requiring that the warnings be easy to read and understand and be in the English language at a minimum;
 - requiring that any marking or labeling provided in addition to those required does not contradict the meaning of the required information;
 - adding a note that typefaces with large height-to-width ratios (i.e., condensed, compressed, or narrow) should be avoided;
 - adding formatting requirements for warnings on the product (in section 8.4.6);
 - adding Figure X1.1 in Appendix X1 to show examples of the formatting requirements described in section 8.4.6; and
 - adding a note to section 8.5 explaining 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.
- Replacing various use of the words “infant,” “infants,” “child,” and “children,” in warnings (Sections 8.5 and 8.6) and instructional literature (Sections 9.2 and 9.3) with consistent use of “baby” or “babies.”

In addition, several non-substantive revisions have been made, including:

- Updating dates and numbers associated with approval and publication of the revised standard;
- Updating formatting to align with ASTM form and style guidelines; and
- Adjusting section and figure numbers to reflect new and revised sections and figures.

Staff reviewed each of the changes to the standard, and as discussed in Section II of the draft Direct Final Rule, assessed that the substantive revisions in F2236-24, including those originally present in F2236-16 and F2236-16a improve the safety of soft infant and toddler carriers overall; and none of the revised requirements reduce safety.

Staff recommends the Commission accept the revised voluntary standard and publish the draft Direct Final Rule.