

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

This document has been electronically approved and signed.

DATE: May 30, 2018

BALLOT VOTE SHEET:

- TO: The Commission Alberta E. Mills, Secretary
- **THROUGH:** Patricia M. Hanz, General Counsel Patricia H. Adkins, Executive Director
- **FROM:** Patricia M. Pollitzer, Assistant General Counsel, Regulatory Affairs Meridith L. Kelsch, Attorney, Regulatory Affairs
- **SUBJECT:** Final Rule: Safety Standard for High Chairs

BALLOT VOTE DUE: <u>Tuesday</u>, June 5, 2018

Staff is forwarding to the Commission a briefing package recommending that the Commission publish in the *Federal Register* the attached draft final rule concerning high chairs. Pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008, the draft final rule would incorporate by reference the voluntary standard, ASTM F404-18, *Standard Consumer Safety Specification for High Chairs*, as the mandatory federal safety standard for high chairs. Additionally, the draft final rule would amend the Commission's regulation regarding third party conformity assessment bodies to include the mandatory standard for high chairs in the list of notices of requirements in 16 C.F.R. part 1112. The Office of the General Counsel is providing the attached draft final rule for Commission consideration.

Please indicate your vote on the following options:

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

(Signature)

(Date)

II. Approve publication of the attached document in the *Federal Register*, with changes. (Please specify.)

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

(Signature)		(Date)
Do not approve publicat	tion of the attached docu	ument in the Federal Register
(Signature)		(Date)
Take other action. (Plea	ase specify.)	

Attachment: Draft *Federal Register* Notice: Final Rule to Establish a Safety Standard for High Chairs

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1231

[Docket No. CPSC-2015-0031]

Safety Standard for High Chairs

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 (CPSIA) directs the Commission to issue standards for durable infant or toddler products. To comply with section 104 of the CPSIA, CPSC is issuing a safety standard for high chairs. This rule incorporates by reference ASTM F404-18, *Standard Consumer Safety Specification for High Chairs* (ASTM F404-18). In addition, this rule amends the regulations regarding third party conformity assessment bodies to include the safety standard for high chairs in the list of Notices of Requirements (NORs).

DATES: The rule will become effective on [INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. FOR FURTHER INFORMATION CONTACT: Keysha Walker, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission; 4330 East West Highway, Bethesda, MD 20814; email: KWalker@cpsc.gov; telephone: (301) 504-6820.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Congress enacted the CPSIA (Pub. L. No. 110-314, 122 Stat. 3016), as part of the Danny Keysar Child Product Safety Notification Act, on August 14, 2008. Section 104(b) of the CPSIA requires CPSC to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant or toddler product safety standards for durable infant or toddler product safety standards for durable infant or toddler products. Any standard CPSC adopts under this mandate must be substantially the same as the applicable voluntary standard, or more stringent than the voluntary standard if CPSC determines that more stringent requirements would further reduce the risk of injury associated with the product. Section 104(f)(1) of the CPSIA defines the term "durable infant or toddler product" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years," and section 104(f)(2)(C) specifically identifies high chairs as a durable infant or toddler product.

On November 9, 2015, the Commission issued a notice of proposed rulemaking (NPR), proposing to incorporate by reference the then-current voluntary standard for high chairs, ASTM F404-15, with more stringent requirements for rearward stability and warnings on labels and in instructional literature. 80 FR 69144; 81 FR 3354 (January 21, 2016) (correcting an error in the NPR). After the Commission issued the NPR, ASTM revised the voluntary standard several times, as discussed in section V of this preamble, and published the current version of the standard, ASTM F404-18, in March 2018.

In this final rule, the Commission is incorporating by reference ASTM F404-18, with no modifications, as the mandatory safety standard for high chairs. As section 104(b)(1)(A) of the CPSIA requires, CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this standard, largely through the ASTM standard-development process. In addition, this final rule amends the list of NORs in 16 CFR part 1112 to include the standard for high chairs.

II. Product Description

ASTM F404-18 defines a "high chair" as "a free standing chair for a child up to 3 years of age which has a seating surface more than 15 in. above the floor and elevates the child normally for the purposes of feeding or eating." The ASTM standard further specifies that a high chair may be sold with or without a tray, have adjustable heights, or recline for infants.¹

High chairs are available in various designs, including four-legged A-frame styles, single-leg pedestals, Z-frame styles, and restaurant-style. Construction materials often include a plastic, wood, or metal frame, and a padded fabric seat. Some designs include a tray or mounted toy accessories, fold for storage and transport, or convert for continued use as a child grows. ASTM F404-18 requires high chairs to have a passive crotch restraint (*i.e.*, two separate bounded openings for the occupant's legs) and a three-point restraint system; some designs also include a rigid front torso support or a five-point restraint system with shoulder harnesses.

¹ After the Commission issued the NPR, staff learned of a reclined infant seat accessory for a high chair product that is intended for young infants. The product consists of a high chair base that is sold separately from, but accommodates, several seat accessories that are appropriate for different ages and sizes of children. One of the seat accessories is a reclined seat that, when placed on the high chair base, allows infants to be raised to the height of a dining table. Based on the characteristics of the infant seat accessory, its intended use, and marketing materials, CPSC staff believes that these products also meet the definition of a high chair.

III. Market Description

CPSC staff has identified 59 domestic firms that currently supply high chairs to the U.S. market. Thirty-three of these firms manufacture high chairs and the remaining 26 firms are importers. Forty-three of the firms (26 manufacturers and 17 importers) are small, according to the U.S. Small Business Administration's (SBA) standards,² and the remaining 16 (7 manufacturers and 9 importers) are large. Of the 59 domestic firms, 43 market their high chairs only to consumers, and 4 sell their high chairs to both consumers and restaurants. In addition, staff identified 9 foreign firms that supply high chairs to the U.S. market, including 8 manufacturers and 1 importer. Staff also identified numerous high chairs that are manufactured outside the United States and bought domestically through online sales.

At the time CPSC staff assessed the high chairs market, 13 of the 26 small domestic manufacturers, and 9 of the 17 small domestic importers, reported that they complied with the ASTM standard for high chairs.

IV. Incident Data

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

² Under SBA size standards, a high chair manufacturer is "small" if it has 500 or fewer employees, and an importer is "small" if it has 100 or fewer employees.

The preamble to the NPR summarized reports of high chair-related incidents that occurred between January 1, 2011 and December 31, 2014, which CPSC received through CPSRMS sources. For the final rule, CPSC staff has updated this information to reflect newly reported high chair incidents that occurred between January 1, 2011 and December 31, 2014, as well as new incidents that occurred between January 1, 2015 and September 30, 2017. In total, CPSC has received 1,842 reports of high-chair related incidents that occurred between January 1, 2011 and September 30, 2017. These incidents involved 2 fatalities and 271 reported injuries.³ Of the incidents that reported the age of the child involved, the majority of incidents involved children between 7 and 18 months old.

The preamble to the NPR also summarized NEISS estimates for high chair-related incidents that occurred between January 1, 2011 and December 31, 2014. After the Commission issued the NPR, complete injury data became available for 2015 and 2016, and CPSC staff has updated this information for the final rule. Including this new data and extrapolating from the probability sample, CPSC staff estimates that there were 49,900 high chair-related injuries treated in U.S. EDs between January 1, 2011 and December 31, 2016. There were no deaths reported through NEISS for this period. There was no statistically significant increase or decrease in the estimated injuries from year-to-year between 2011 and 2016, and there was no statistically significant trend in the data over this period. Similarly to the CPSRMS data, of the incidents that reported the age of the child involved, most incidents involved children between 7 and 23 months old.

³ The NPR indicated that CPSC had received 1,296 reports of high chair-related incidents that occurred between January 1, 2011 and December 31, 2014, of which 1 was fatal and 138 reported injuries. Since the NPR, CPSC received an additional 546 reports of high-chair related incidents that occurred between January 1, 2011 and September 30, 2017, of which 1 was fatal and 133 reported injuries.

A. Fatalities

CPSC is aware of two fatal incidents that occurred between January 1, 2011 and September 30, 2017. As the NPR stated, CPSC staff has been unable to collect detailed information about the fatal incident that was reported in 2014. CPSC received another report of a high chair-related fatality in 2016; this incident involved strangulation, but CPSC staff was unable to obtain additional details about the incident.

B. Nonfatal Injuries

Of the total 271 nonfatal injuries reported to CPSC through CPSRMS sources that occurred between January 1, 2011 and September 30, 2017, 1 involved a child who was admitted to the hospital with a skull fracture and retinal hemorrhage; 15 were treated in U.S. EDs for injuries including a puncture wound to the forehead, a broken collarbone, a compound fracture of the finger, lacerations, and contusions; and 1 reported a head injury and broken wrist, but did not indicate the treatment the child received. The remaining injuries primarily consisted of contusions, abrasions, and lacerations, resulting from falls or entrapment of limbs or extremities.

The injuries and treatments reported through NEISS for 2015 and 2016 were consistent with those for 2011 through 2014, described in the NPR. In most cases, the patient was treated in the U.S. ED and released (94 percent for 2011-2014, and 95 percent for 2015-2016). The most commonly injured body parts were the head (65 percent for 2011-2016) and face (17 percent for 2011-2016). The most common types of injuries were injuries to internal organs (48 percent for 2011-2014, and 51 percent for 2015-2016), contusions and abrasions (22 percent for 2011-2014, and 16 percent for 2015-2016), and lacerations (11 percent for 2011-2014, and 16 percent for 2015-2016).

CPSC staff also assessed NEISS data to determine the hazards associated with high chairs in restaurants. There were an estimated 1,600 injuries treated in U.S. EDs between 2011 and 2016, which were related to high chairs in restaurant settings. Most incidents involved users falling from the high chair. Of the reports that indicated the cause of the fall, it commonly occurred when a child attempted to climb into or out of the high chair; the high chair tipped over; or consumers did not use restraints or the restraints failed or were defeated.

C. Hazard Patterns

The hazards reported in the new incidents are consistent with the hazard patterns staff identified in the incidents presented in the NPR. The hazard in nearly all reported incidents, both those discussed in the NPR (96 percent) and in the new incidents (95 percent), involved issues with specific components of the high chair, including the frame, seat, restraint system, armrest, tray, toy accessories, and footrest. Design, stability, and other general product issues accounted for 4 percent of incidents discussed in the NPR and 3 percent of the new incidents.

Most of the NEISS incidents reported for 2015 and 2016 involved falls from high chairs, often when a child attempted to climb into or out of the high chair; when the chair tipped over when a child pushed back or rocked while in the high chair; or when a component of the high chair (*e.g.*, restraint, tray, lock) failed or disengaged.

V. ASTM F404-18

In this final rule, the Commission incorporates by reference ASTM F404-18. The Commission is incorporating by reference ASTM F404-18 because it includes provisions that are the same as, or consistent with, the requirements proposed in the NPR, and CPSC staff believes that the standard addresses the hazards associated with high chairs.

A. History of ASTM F404

ASTM F404, *Standard Consumer Safety Specification for High Chairs*, is the voluntary standard that addresses the hazard patterns associated with the use of high chairs. ASTM first approved and published the standard in 1975, as ASTM F404-75. ASTM has revised the standard numerous times since then. In the NPR, the Commission proposed to incorporate by reference ASTM F404-15, with modifications.

After the Commission issued the NPR, ASTM revised ASTM F404 five times. CPSC staff worked with representatives of manufacturers, consumer groups, retailers, and other industry members and groups on the ASTM subcommittee on high chairs to develop requirements to address the hazards associated with high chairs, including issues and requirements raised in the NPR, concerns raised by members of the ASTM subcommittee, and comments on the NPR. CPSC staff also participated in the ASTM Ad Hoc Committee on Standardized Wording for Juvenile Product Standards (Ad Hoc TG) to finalize recommendations for warning labels, entitled, "Recommended Language Approved by Ad Hoc Task Group, Revision C" (November 10, 2017), to provide consistent and effective warnings for juvenile product standards. The most recent version of the standard, ASTM F404-18, reflects the work of these groups. ASTM approved ASTM F404-18 on February 15, 2018, and published it in March 2018.

B. ASTM F404-18: Comparison with the NPR and Assessment of Requirements

In the NPR, the Commission proposed to incorporate by reference ASTM F404-15, which addressed many of the hazard patterns associated with high chairs, with modifications to three areas of the standard. The Commission proposed more stringent requirements than those in

ASTM F404-15 for rearward stability, warnings on labels, and instructional literature.

Specifically, the Commission proposed:

- more stringent rearward stability requirements, including test procedures, a formula for determining a "rearward stability index" (RSI), and a requirement that high chairs have an RSI of at least 50;
- more stringent warning content, format, and placement requirements than those in ASTM F404-15; and
- warning content in instructional literature that aligned with the modified warning labels, as well as formatting requirements for warnings in instructions.

The requirements in ASTM F404-18 are largely the same as those the Commission proposed in the NPR. ASTM F404-18 includes the same scope, definitions, general requirements (*e.g.*, threaded fasteners; latching and locking mechanisms), performance requirements, and test methods that the Commission proposed to incorporate by reference from ASTM F404-15. In addition, ASTM F404-18 includes modifications to reflect the more stringent requirements the Commission proposed in the NPR, to address comments filed in response to the NPR, and to provide additional detail and clarity. The following discussion compares the areas in which the NPR and ASTM F404-18 differ, and describes CPSC staff's assessment of the ASTM F404-18 provisions.

1. Stability Requirements

In the NPR, the Commission proposed to require the forward and sideways stability requirements in ASTM F404-15 and more stringent rearward stability requirements, consisting of a test method and formula for determining the RSI for a high chair, and a minimum RSI of 50. ASTM F404-18 includes these requirements, with some additional details and minor changes for

clarification. First, ASTM F404-18 includes additional details about how to perform stability testing (*e.g.*, using a low stretch cord), and, in particular, how to perform stability testing when product features vary (*e.g.*, reclining seat backs; high chairs without trays; when test weights cannot be centered on the seat). Second, ASTM F404-18 includes minor wording changes to provide clarity, such as describing the point at which a high chair becomes unstable (for purposes of calculating the RSI) as the point where it "begins to tip over," instead of the point at which it is on "the verge of tipping over." This wording maintains the meaning in the NPR, but adds clarity, in response to comments requesting clarification.

CPSC staff in the Division of Mechanical and Combustion Engineering has reviewed the stability requirements in ASTM F404-18 and believes that they adequately address the stability issues associated with high chairs. The stability requirements in ASTM F404-18 are largely the same as the more-stringent stability requirements the Commission proposed in the NPR (maintaining the same test method, formula, and RSI limit), which staff believes are effective, and the minor modifications added to ASTM F404-18 add clarity and detail.

2. Warning Label Requirements

In the NPR, the Commission proposed more stringent warning label content, format, and placement requirements than those in ASTM F404-15. ASTM F404-18 also includes more stringent warning label requirements than those in ASTM F404-15, but the requirements are not identical to those in the NPR.

Content. The content of the warnings in ASTM F404-18 are nearly identical to those the Commission proposed in the NPR, with minor changes to some wording. For example, ASTM F404-18 requires the phrase "Fall Hazard" to appear before the warning statement. In addition, one of the NPR warnings stated: "children have suffered skull fractures after falling from high

chairs"; in contrast, ASTM F404-18 states: "children have suffered severe head injuries including skull fractures when falling from high chairs." ASTM F404-18 also includes some changes to how warnings are phrased, but conveys the same information as the wording in the NPR (*e.g.*, "falls can happen quickly," versus "falls can happen suddenly").

CPSC staff in the Division of Human Factors (HF) has reviewed the warning label content requirements in ASTM F404-18 and believes that the warning content is largely consistent with that in the NPR, addressing the same general information, and staff concludes that the changes do not undermine the effectiveness of the warnings. Staff believes that warning of severe head injuries, coupled with citing skull fractures as one possible example of such an injury, is an effective way to warn users about the potential consequences of the fall hazard. Moreover, staff believes that this warning avoids the impression that the NPR language may have given, which is that skull fractures are the only type of potential injury. In addition, staff believes that the phrase, "Fall Hazard," is unnecessary, but is not problematic.

Format. The NPR and ASTM F404-18 include the same requirements for size and organization of warning labels, but handle some other formatting requirements differently. After the Commission issued the NPR, the Ad Hoc TG finalized its recommendations for warning labels, which address warning format. The goal of the Ad Hoc TG recommendations is to provide consistent and effective warnings for juvenile products by addressing warning format issues that impact consumer attention, readability, hazard perception, and avoidance behaviors.

The Ad Hoc TG recommendations are based largely on the requirements of ANSI Z535.4, *American National Standard for Product Safety Signs and Labels* (ANSI Z535.4), with additional content to account for the wide range and unique nature of durable nursery products, the concerns of industry representatives, and CPSC staff's recommendations. ANSI Z535.4

addresses format topics, such as safety alert symbols, signal words, panel format, color, and letter style; and additional Ad Hoc TG recommendations address text size, alignment, and organization.

The warning format requirements in ASTM F404-18 align with the Ad Hoc TG recommendations. The warning format requirements in the NPR differ from ASTM F404-18 in the following ways.

- Where the NPR proposed a specific typeface and required certain words to be in bold, ASTM F404-18 only recommends avoiding certain kinds of typeface (*e.g.*, narrow).
- Where the NPR detailed specific requirements for colors, borders, typeface, and referred to ANSI Z535.4 for optional additional guidance, ASTM F404-18 simply requires conformance to ANSI Z535.4, which includes provisions on these topics.

HF staff has reviewed the warning label format requirements in ASTM F404-18 and believes that they are appropriate. The warning format requirements in ASTM F404-18 are largely consistent with the provisions in the NPR, because the NPR discussed the same format topics and referenced ANSI Z535.4; and the requirements resolve many of the comments filed in response to the NPR by clarifying conflicting or unclear provisions. Because the requirements align with the Ad Hoc TG recommendations, staff believes they are effective.

Placement. The NPR proposed requiring all warning content to appear on one label that was visible both when putting a child in the high chair and once a child was in the high chair. ASTM F404-18 allows the warning content to appear on two labels. One label, addressing fall injuries and restraints, must be visible when putting a child in the high chair; the second label, addressing attendance, must be visible when a child is in the high chair.

HF staff has reviewed the warning label placement requirements in ASTM F404-18 and believes that they are sufficient. In response to the NPR, commenters identified challenges the placement requirements in the NPR posed. For example, commenters noted that it would be difficult for high chair models with design or size limitations to meet the placement requirements proposed in the NPR because the proposal required a single label with more content that was visible during all stages of use. After considering these comments, staff agrees that the two warning labels ASTM F404-18 requires are justified. Staff believes that the placement requirements in ASTM F404-18 are adequate because they require each of the warnings to be visible at the time the information is most relevant.

First, ASTM F404-18 requires the fall-related warnings to be visible to caregivers when putting a child into the high chair. Warning caregivers of the hazard, potential injuries, and how to avoid the hazard is most relevant when they are placing the child into the high chair, because it informs them of the risks from the outset of use, and may motivate them to use restraints appropriately. Thus, it is likely more important to include these warnings on a label that is visible when placing a child in the high chair, than on a label that is visible during use. Second, ASTM F404-18 requires the warning to "stay near and watch child during use" to be visible when the child is in the high chair, and the caregivers to supervise children is most relevant when a child is already in the high chair, and the caregiver may become distracted or leave the child unattended. Accordingly, it is likely more important to include this warning on a label that is visible during use, rather than on a label that is visible when initially putting a child into the high chair. Thus, although staff believes it would be ideal to convey all warning information in a place that is visible during all stages of use, given design and space limitations, the placement requirements in ASTM F404-18 are appropriate.

3. Instructional Literature Requirements

In the NPR, the Commission proposed more stringent content and design requirements for warnings in instructional literature than those in ASTM F404-15. ASTM F404-18 also requires more stringent instructional literature requirements than ASTM F404-15, although the design requirements are not identical to those in the NPR.

The warning content requirements for instructional literature in ASTM F404-18 are consistent with those in the NPR. Both the NPR and ASTM F404-18 required instructional literature to contain the warning statements specified for on-product warning labels, by referencing the applicable sections regarding on-product warning labels *(i.e., Section 8)*.

With respect to the design of warnings in instructional literature, the NPR proposed highly contrasting colors and referenced ANSI Z535.6, *Product Safety Information in Product Manuals, Instructions, and Collateral Materials* (ANSI Z535.6), for optional design guidance. Like the NPR, ASTM F404-18 references ANSI Z535.6, but also includes more-detailed requirements regarding text size, alignment, and organization, and requires conformance with ANSI Z535.4 (with some exceptions for areas that are not critical for instructions). These requirements eliminate some areas of confusion commenters noted regarding the requirements proposed in the NPR.

HF staff has reviewed the instructional literature requirements in ASTM F404-18 and believes they are effective. The requirements in ASTM F404-18 are consistent with the types of formatting and content provisions proposed in the NPR and are based on the Ad Hoc TG recommendations, which staff believes are effective and resolve areas of confusion raised in the NPR comments.

4. Restaurant-Style High Chairs

The NPR discussed whether a mandatory standard should apply to restaurant-style high chairs (*i.e.*, high chairs intended for use in restaurants, also known as "food service high chairs") or whether the hazards, environment, and product features useful in a restaurant, as well as compliance costs, justified fully or partially exempting restaurant-style high chairs from the final rule or creating different requirements for them. The ASTM standard does not distinguish restaurant-style high chairs from those intended for home use, and applies to all high chairs.

CPSC has determined that restaurant-style high chairs should remain within the scope of the final rule, consistent with ASTM F404-18. NEISS data indicate that an estimated 1,600 incidents related to high chairs occurred in restaurants and were treated in U.S. EDs between 2011 and 2016. The hazard patterns in these incidents appear similar to those in homes, primarily involving children falling from high chairs due to issues with restraints, tip overs, or when a child was climbing into or out of the high chair. In addition, CPSC staff identified four firms that sell restaurant-style high chairs to both restaurants and consumers. Finally, section 104 of the CPSIA requires the Commission to adopt a mandatory standard that is substantially the same as the voluntary standard, or more stringent than the voluntary standard. Because the voluntary standard for high chairs applies to all high chairs, including those used in restaurant-style high chairs would be inconsistent with the CPSIA.

C. Incorporation by Reference

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. These regulations require the preamble to a final rule to summarize the material and discuss the ways in which the material the agency incorporates by reference is

reasonably available to interested persons, and how interested parties can obtain the material. 1 CFR 51.5(b). In accordance with the OFR regulations, this section summarizes ASTM F404-18, and describes how interested parties may obtain a copy of the standard.

ASTM F404-18 contains requirements concerning:

- threaded fasteners;
- sharp edges and points;
- small parts;
- wood parts;
- latching or locking mechanisms;
- permanency of labels;
- openings;
- lead in paint;
- forward, sideways, and rearward stability;
- exposed coil springs;
- scissoring, shearing, and pinching;
- restraint systems;
- structural integrity;
- tray latch release mechanisms;
- side containment;
- protrusions;
- protective components;
- tray or front torso support;
- static loads on the seat, step, footrest, and tray;

- bounded openings;
- warnings and labels; and
- instructional literature.

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

Interested parties may obtain a copy of ASTM F404-18 from ASTM, through its website (<u>http://www.astm.org</u>), or by mail from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428. Alternatively, interested parties may inspect a copy of the standard at CPSC's Office of the Secretary.

VI. Comments Filed in Response to the NPR

CPSC received 16 comments in response to the NPR. The comments are available in the docket for this rulemaking, CPSC-2015-0031, at: <u>www.regulations.gov</u>. A summary of the comments, grouped by topic, and CPSC staff's responses are below.

A. Effective Date

Comment: CPSC received a comment from four consumer advocate groups that supported the proposed six-month effective date. Another commenter, representing juvenile product manufacturers, requested a one-year effective date, stating that additional time would be necessary to change products to meet the new requirements, particularly for warning labels and instructional literature.

Response: The warning label and instructional literature requirements in the final rule should require less-burdensome product changes than the proposed rule, particularly because the final rule allows for two separate labels with distinct placement requirements. This reduces the need for a longer effective date. However, some firms will need to modify their products to meet the final rule. For 49 percent of small firms, CPSC staff cannot rule out the possibility that the

final rule will have a significant economic impact. In addition, staff believes that some firms may not be aware of the ASTM standard or that CPSC is issuing a rule on high chairs. A longer effective date would reduce this impact. Accordingly, the Commission is providing a longer effective date for the final rule than proposed. The rule will take effect 12 months after publication of this final rule.

B. Passive Crotch Restraint

Comment: One commenter stated that the ASTM requirement that passive crotch restraints must be permanently attached to a high chair or tray before shipment (section 6.9.1.5) should not apply to high chairs for which consumers assemble every component, with instructions.

Response: CPSC believes that this exception would be inappropriate for two reasons. First, CPSC staff believes that it is important for passive restraints to be attached permanently to a high chair or tray before shipment, because it helps ensure that users do not intentionally or inadvertently assemble or use a high chair without the passive restraint. This requirement is intended to reduce the likelihood of death from positional asphyxia. Second, section 104 of the CPSIA does not permit CPSC to create such an exception. Section 104 requires the Commission to adopt a mandatory standard for high chairs that is "substantially the same as" or "more stringent than" the voluntary standard. Because ASTM F404 requires permanent attachment of passive restraints (and has since 2015), creating an exception to this requirement would be less stringent than the voluntary standard.

C. Rearward Stability

Two commenters raised issues regarding the clarity and repeatability of the proposed rearward stability requirements.

Comment: One commenter pointed out that section 1231.2(b) of the proposed rule, which the Commission proposed to replace section 6.5 of ASTM F404-15, would have required compliance with sections 7.7.2.4 to 7.7.2.4.6 of ASTM F404, instead of all of section 7.7.

Response: Some section references were mistakenly omitted from the ASTM standard when ASTM revised the stability requirements in the standard. Correspondingly, the NPR included incomplete section references. ASTM corrected this error in later revisions to ASTM F404. Section 6.5 of ASTM F404-18, which the Commission incorporates by reference in this final rule, now properly references all of section 7.7.

Comment: One commenter stated that the phrase "verge of tipping over," used to determine the RSI, is subjective, and will cause variation in measurements of tipping distance.

Response: ASTM revised this language in ASTM F404-18 to add clarity, and the provision now states: "the point that [the high chair] becomes unstable and begins to tip over," which CPSC staff believes addresses this issue.

Comment: One commenter stated that the rearward tipping force load application "must be reached in at least 5 seconds" and suggested that the load force varies, depending on how quickly or slowly a particular tester applies this load, leading to variation in the RSI of about 4 points.

Response: ASTM F404-15, which was in effect at the time the Commission issued the NPR, stated: "Gradually apply the force over a period of 5 s." In the NPR, the Commission proposed to modify this language to state: "Gradually increase the horizontal force over a period of at least 5 seconds." ASTM F404-18 includes the language proposed in the NPR, which makes it clear that 5 seconds is a minimum, not a maximum, timeframe, and to emphasize that testers

should apply the load slowly and steadily. As in other ASTM standards that include stability requirements, the 5-second reference is not meant to be an upper time limit during which testers must hurriedly apply force. If testers apply force sufficiently slowly, negligible dynamic force should factor into the equation and maximum tip-over force readings will be consistent.

Comment: One commenter stated that the wording, diagram, and calculation formula for rearward stability in the NPR are confusing and flawed, including confusing identifiers, crossed out words, and multiple definitions of "F."

Response: ASTM revised the diagram in ASTM F404-18 to resolve these issues, removing crossed out words and defining the forces more clearly, by designating F1 and F2 as unique and clearly identified forces. Likewise, the RSI calculation in ASTM F404-18 includes the maximum F2 force, rather than the original, ambiguous force F. The new diagram is in ASTM F404-18 Figure 10, and the RSI formula is in section 7.7.2.6(4).

- D. Warning Labels
- 1. Content

CPSC received five comments that discussed issues related to warning content. One commenter supported the Commission's proposed warning content, particularly the statement: "Falls can happen quickly if child is not restrained properly." Another commenter supported the warning content in ASTM F404-15, rather than the NPR, but did not provide specific reasons for preferring the ASTM content. The remaining three comments discussed the following issues.

Comment: Two commenters were concerned about the increased length of the proposed warning, and one of the two was concerned with the proposed requirement that all warning information appear on a single label.

Response: These comments address two related issues—spreading warning content across multiple labels, and the length of warning content. With respect to the first issue, the NPR proposed to require all warnings to appear on a single label. The NPR and staff's supporting briefing package explained the reasons for that proposed requirement. As an example, in ASTM F404-15, the warning: "Never leave child unattended," did not appear on the same label that described the fall hazard and potential consequences. However, never leaving a child unattended is one behavior consumers can use to avoid the fall hazard. Consequently, staff believed that the warning would be more effective if the mitigating behavior appeared on the same label as the information about the hazard and consequences. Unlike the NPR, ASTM F404-18 spreads the required warnings across two labels. As section V of this notice discusses, HF staff believes that spreading the warnings across two labels is acceptable.

With respect to the length of warning content, the warnings the Commission proposed in the NPR were longer than the warnings in ASTM F404-15. ASTM F404-18 includes revised warning content that is consistent with the NPR. CPSC staff worked with ASTM to ensure that ASTM F404-18 includes the essentials of the warnings the NPR proposed, but also addresses comments submitted in response to the NPR, and ASTM subcommittee members' concerns. This final rule incorporates by reference ASTM F404-18, without modifications. CPSC staff maintains that the additional warning content proposed in the NPR, and the analogous content in ASTM F404-18, is appropriate, because it addresses deficiencies in the warning content in ASTM F404-15. For example, the description of injuries that could be sustained from high chair incidents in ASTM F404-15 (*i.e.*, "serious injury or death") was vague. Research suggests that more explicit descriptions improve consumer compliance with recommended hazard-avoidance behaviors. Similarly, the warning in ASTM F404-15 did not describe the speed with which

incidents can occur. This information is important because consumers have reported that they may not use restraints on high chairs because they think they can notice and stop emerging incidents in time. In addition, the warning did not state that a tray is not intended to restrain a child. This information is necessary because consumers have reported that they consider the tray, functionally, to be part of a high chair's restraint system, and some incidents suggest that consumers rely on the tray alone to restrain the child. Finally, the warning lacked a statement about properly adjusting the restraint system. There have been fall-related incidents where children were restrained, but the restraint system was loose or otherwise allowed the child to wriggle out.

Staff acknowledges that consumers are more likely to fully read short warnings than longer ones. However, brevity is only one factor to consider when designing a warning. A short warning is unlikely to be effective if it does not convey all key information about the hazards, and carefully selected additional content can enhance consumer compliance with warnings. In addition, staff does not consider the warnings in the NPR and ASTM F404-18 to be unusually long, or so long that they would dissuade consumers from reading the full content.

Comment: Two commenters stated that referring to serious injuries broadly, such as "serious injury or death," is likely to be more effective than a specific and limited reference to "skull fractures." One of these commenters stated that referring to skull fractures alone, may cause caregivers to ignore other, more frequent risks.

Response: ASTM F404-18 includes broader language (*i.e.*, "severe head injuries") than the Commission proposed in the NPR, in addition to the specific injuries (*i.e.*, "skull fractures") referenced in the NPR warning. Staff believes that including the broader language avoids the perception that skull fractures are the only type of serious injuries that occur. Staff believes that

coupling the broad and specific injuries, rather than stating only the broader injury, is important to improve consumer compliance with the recommended hazard-avoidance behavior because research shows that more explicit or detailed information in a warning increases warning effectiveness, and vividness increases the salience of the message, which triggers the reader's motivation to act.

Comment: Two commenters noted that CPSC should not require the warning statement about trays (*i.e.*, "Tray is not designed to hold child in chair") for high chairs that do not have trays.

Response: CPSC agrees with this comment. ASTM F404-18 requires the same warning regarding trays as the Commission proposed in the NPR, but only requires this warning for high chairs that are designed to be used with a tray.

2. Format

CPSC received several comments regarding the warning format requirements proposed in the NPR. A summary of the comments, and staff's responses, are below. First, however, is a general discussion of the changes to warning format requirements in the ASTM standard since the NPR. These changes are the result of the Ad Hoc TG's efforts and address comments CPSC received about warning format.

After the Commission issued the NPR, there were several developments related to warning format and design. In short, the Ad Hoc TG finalized and published recommendations for warning format, and ASTM revised the warning requirements in ASTM F404-18 to be consistent with the Ad Hoc TG recommendations.

The Ad Hoc TG was formed to develop standardized language across ASTM juvenile products standards, and was developing recommendations for warning format when the Commission issued the high chairs NPR. HF staff serves on the Ad Hoc TG, as well as the ANSI Z535 Committee on Safety Signs and Colors. In this capacity, staff collaborated with the other members of the Ad Hoc TG to develop the finalized recommendations for warning format.

With the goal of providing consistent formatting requirements for all juvenile-product standards and addressing warning format issues that impact the effectiveness of warnings, the Ad Hoc TG recommendations require warning content to be "easy to read and understand"; not contradict information elsewhere on the product; be in English (at a minimum); and meet various formatting requirements. The formatting requirements include minimum text size; text alignment; bullet, lists, outline, and paragraph forms for hazard-avoidance statements; and compliance with sections of ASNI Z535.4—specifically, sections 6.1 to 6.4 (which include requirements for safety alert symbols, signal words, and warning panel format, arrangement, and shape), 7.2 to 7.6.3 (which include color requirements), and 8.1 (which addresses letter style). The Ad Hoc TG recommendations also include recommended requirements for general labeling issues, such as labeling permanency, and content related to manufacturer contact information and date of manufacture.

The Ad Hoc TG recommendations and the resulting changes to ASTM F404-18 address many of the comments filed in response to the proposed warning format requirements in the NPR. Below are the comments CPSC received on that topic, and staff's responses.

Comment: Four commenters objected to the NPR proposal to require "key words" to appear in boldface, because the phrase is open to interpretation. One commenter also noted that because the NPR proposed to require warnings to "address" the specified warning content, rather than state it exactly as phrased in the standard, a rule could not designate specific words as "key words."

Response: The commenter is correct that the standard does not define "key words" and requires warning statements to "address" the specified warning content, rather than state it exactly as it is worded in the standard. ASTM F404-18 does not include this proposed requirement.

Comment: Three commenters stated that there is no clear definition or understanding of "non-condensed" sans serif typeface, and this provision may be misinterpreted or confusing. One commenter also stated that some compressed and narrow typefaces are easy to read, and therefore, the rule should not preclude them.

Response: There is no formal definition of "non-condensed typeface," and some condensed typefaces could be adequately legible. ASTM F404-18 does not include the proposed provision or prohibit the use of condensed type, but it does include a note that recommends avoiding typefaces with "large height-to-width ratios, which are commonly identified as 'condensed,' 'compressed,' 'narrow,' or similar."

Comment: Two commenters stated that the proposed note, referring readers to ANSI Z535.4 for "optional additional guidance," may not be clear to manufacturers or test laboratories.

Response: ASTM F404-18 does not include the proposed note; instead, the standard includes specific warning format requirements and requires conformance to the 2011 version of ANSI Z535.4.

Comment: Two commenters stated that the reference to "instructions" in section 8.4.2 of the NPR is inappropriate because section 8 of the standard addresses warnings, not instructions (which are addressed in section 9).

Response: ASTM F404-18 corrects this inconsistency, referring to "marking or labeling" rather than "labels or written instructions."

Comment: One commenter stated that the NPR proposal that warning message text must be black on a white background conflicts with the NPR proposal that warning statements be in "highly contrasting colors."

Response: ASTM F404-18 does not include the proposed requirements as they were stated in the NPR. Instead, ASTM F404-18 requires conformance with ANSI Z535.4-2011, section 7.3, which requires message panel text to be black lettering on a white background or white lettering on a black background. These color requirements apply unless special circumstances preclude the use of these colors (section 7.6.3), in which case the warning text must contrast with the background.

Comment: One commenter stated that the proposed warning requirements should apply only to the warnings that the standard requires, and not to additional warnings that are not requirements.

Response: Since the Commission issued the NPR, CPSC staff has continued to work with the Ad Hoc TG to develop final warning format recommendations, which ASTM F404-18 includes. Consistent with the Ad Hoc TG recommendations, ASTM F404-18 requires all warnings to meet the format requirements in the standard. CPSC staff believes that all warning statements should meet these format requirements because they are important to capture consumer attention, improve readability, and increase hazard perception and avoidance behavior.

Comment: Two commenters recommended that CPSC wait to issue a mandatory standard for warnings until the Ad Hoc TG completes its work on general warning format requirements.

Response: The Ad Hoc TG has completed and published its recommendations, and ASTM F404-18 includes updates to reflect those recommendations.

3. Placement

Comment: Four commenters discussed warning placement. One commenter supported the proposed placement requirements (*i.e.*, that the warning be visible while placing the child in the high chair and while the child is seated in the high chair) and the remaining three commenters did not. These three commenters raised general concerns about limited space on some high chairs, especially models with low seatbacks. The commenters stated that it would be difficult, and perhaps impossible, to meet the proposed placement requirements on those models, suggesting that manufacturers would have to redesign or discontinue the models. The commenters emphasized the need for flexibility. One commenter stated that there is no clear evidence that a label that is visible when a child is in a high chair, or a secondary label if the seatback is not high enough, will actually change caregivers' behaviors.

Response: Consistent with these comments, ASTM F404-18 includes modified warning placement requirements, which provide greater flexibility than the requirements proposed in the NPR. ASTM F404-18 requires two labels, each with respective placement requirements, which CPSC staff believes are sufficient. ASTM F404-18 requires that fall-related warnings be visible to a caregiver only when placing a child into the high chair. CPSC staff believes this is sufficient because this allows caregivers to see the warning about the hazard, its consequences, and the key actions to avoid the hazard, immediately before this information is relevant. Although the warning may not be visible once a child is in the high chair, the warning likely would be visible when the high chair is not in use, exposing consumers to the message at other times, such as when cleaning or moving the high chair.

ASTM F404-18 also requires a second warning statement (which may appear on a separate label), instructing caregivers to "stay near and watch child during use." This warning

must be "conspicuous" (*i.e.*, visible to a person standing near the high chair when a child is in the high chair, but not necessarily visible from all positions). Commenters and ASTM high chair subcommittee members have pointed out that this warning statement also applies to hazards other than falls, such as choking hazards. CPSC staff agrees and believes that this warning, in a conspicuous location, separate from the fall-related warning, will serve as a general reminder to remain with a child who is in the high chair. Because the warning statement must be visible when the child is still seated in the high chair, caregivers will be more likely to see the warning when they are about to leave the seated child than if the warning statement were included as part of the warning that must be visible while placing the child into the high chair.

4. Miscellaneous Comments About Warning Labels

Comment: Three commenters stated that there is no justification to revise the ASTM F404-15 warning requirements. Two of these commenters noted that ASTM F404-15 had only recently been adopted, so there is no evidence that the warning requirements are ineffective.

Response: In accordance with the statutory language in the CPSIA, when assessing an ASTM standard for rulemaking under section 104, CPSC staff considers whether more stringent requirements would further reduce the risk of injury associated with the product. Accordingly, for this rulemaking, staff considered whether more stringent warning requirements for high chairs would further reduce the risk of injury, were appropriate, and were supported by scientific and technical literature. Based on staff's assessment, the NPR proposed more stringent warning requirements, many of which ASTM F404-18 includes.

Comment: One commenter stated that large warning labels would be sufficient to address the hazards associated with high chairs.

Response: Staff does not believe that warnings, alone, are sufficient to address the demonstrated hazards. Literature on safety and warnings consistently identifies a hierarchy of approaches to controlling hazards. In this hierarchy, warnings are less effective at eliminating or reducing exposure to hazards than designing the hazard out of a product or guarding consumers from the hazard. Warnings are less effective than these other approaches because they do not prevent consumer exposure to the hazard. Rather, warnings rely on educating consumers about the hazard and then persuading them to alter their behavior to avoid the hazard. For warnings to be effective, consumers need to behave consistently, which may not be the case when situational factors, such as fatigue, stress, or social influences, impact precautionary behavior. As a result, warnings should supplement, rather than replace, design standards or provisions that attempt to guard consumers from a hazard, unless those alternatives are not possible.

Comment: One commenter recommended adding pictograms to the warning provisions in the standard to convey the hazard effectively and reduce language barriers.

Response: Well-designed graphics may be useful to convey the fall hazard associated with high chairs. However, designing effective graphics can be difficult. Some seemingly obvious graphics can be misinterpreted. Consequently, CPSC staff believes that it is appropriate to permit supporting graphics in high chair warnings, but not require them.

Comment: One commenter noted that the NPR included warning requirements for high chairs that have seats that are also used as seats in strollers, but does not address high chairs with seats that also function as booster seats.

Response: A product with a seat that functions as a seat for a high chair and a booster seat must meet the requirements in both the high chair and booster seat standards. CPSC staff

believes that manufacturers are capable of meeting the requirements of both standards, and therefore, staff does not believe that revisions to the requirements are necessary.

E. Instructional Literature

Comment: Three commenters expressed confusion about the proposed color requirements for instructional literature in the NPR. Two commenters stated that the requirements were contradictory, and another commenter stated that the proposed color requirements take away the flexibility to use other colors.

Response: CPSC agrees that the proposed color requirements for instructional literature may be unclear and that manufacturers should have some flexibility in choosing colors for instructional literature. After the Commission issued the NPR, the Ad Hoc TG published recommendations for the format of warnings in instructional literature. The instructional literature requirements in ASTM F404-18 are based on those recommendations, and CPSC believes that the requirements are appropriate and address commenters' concerns. ASTM F404-18, section 9.3, clarifies that instructional literature is not required to meet the same color requirements as on-product labels. Instead, section 9.4 of ASTM F404-18 provides flexibility, stating that warnings must stand out within instructional literature, by requiring "the signal word and safety alert symbol [to] contrast with the background of the signal word panel, and the warnings [to] contrast with the background of the instructional literature."

Comment: Two commenters stated that the sentence "Additional warnings similar to the statements included in this section shall also be included," which was in proposed section 1231.2(e)(1) in the NPR, was unclear.

Response: The ASTM high chairs subcommittee replaced this statement in ASTM F404-18 with a new section 9.3, which states: "The instructions shall address the following additional warnings." This modification should resolve any confusion.

Comment: Two commenters stated that the note proposed in the NPR, referring readers to ANSI Z535.6 for "optional additional guidance," may not be clear to manufacturers or test laboratories.

Response: ASTM standards regularly use "notes" to make suggestions that are not mandatory requirements. Because other ASTM standards include notes, manufacturers and test laboratories understand their meaning and know that they are not requirements. In addition, the Ad Hoc TG recommendations, which were developed in collaboration with industry members, reference ANSI Z535.6 for additional guidance on the design of warnings in instructional literature. In accordance with that recommendation, ASTM F404-18 includes the note referring to ANSI Z535.6.

F. Restaurant-Style High Chairs

Comment: CPSC received three comments about restaurant-style high chairs.

Commenters suggested that stability or warning and instructional requirements, alone, would be adequate for restaurant-style high chairs; that there should be a separate commercial high chair standard; or that no standard is necessary for these products. Commenters cited several reasons to create a different standard for restaurant-style high chairs. For example, commenters noted that restaurant settings make particular features useful in a high chair, such as large seats, trayless designs, and the ability to stack multiple high chairs. In addition, consumer behavior, such as more-attentive supervision of children, may occur in restaurant settings. Moreover, commenters stated, injury data do not indicate a need to regulate these products. One

manufacturer noted receiving complaints about a restaurant-style high chair that conformed to ASTM F404. The complaints stated that it was difficult for children to get in and out of the chair, the chair did not accommodate children wearing bulky clothing, and the chair did not accommodate children over one-year old. One commenter noted that some restaurant-style high chairs are only available through commercial portals, while another commenter noted that restaurant-style high chairs are sold to the public for home use. Commenters suggested using educational efforts, such as affixing labels or instructions to restaurant-style high chairs to inform consumers and restaurant staff about proper use, the intended setting, and hazards; or providing similar information on packaging, product websites, and at points of sale.

Response: CPSC understands that there may be differences in the useful features and level of supervision in restaurant settings and homes. It is possible that requiring restaurant-style high chairs to meet ASTM F404-18 would interfere with design features that make high chairs useful in a restaurant setting, such as large leg openings. In addition, it is possible that design features that meet ASTM F404-18 could contribute to injuries in a restaurant setting. For example, small leg openings could make it more difficult to remove children from a high chair when they are wearing bulky outerwear or shoes; or consumers may opt for potentially hazardous alternatives to a high chair if the high chair is inconvenient to use, such as placing children on an unsecured and elevated chair. However, CPSC staff does not have evidence that these possibilities will occur.

To the contrary, CPSC has several reasons to believe that the final rule should apply to all high chairs, including restaurant-style high chairs. First, after issuing the NPR, CPSC staff further examined incident data to determine the extent to which high chair-related injuries occur in restaurant settings. Staff found that between 2011 and 2016, there were an estimated 1,600

injuries treated in U.S. EDs that involved high chairs in restaurant settings. Most incidents involved children falling from high chairs, commonly when climbing into or out of the high chair, when the high chair tipped over, or when restraints were not used, failed, or were defeated. These hazard patterns are consistent with high chair incidents in homes. As a result, CPSC believes that there is no safety justification to exclude restaurant-style high chairs from the final rule.

Second, although only a small number of firms sell restaurant-style high chairs directly to consumers for use in their homes, these sales indicate that the features and settings for restaurant-style high chairs do not provide a basis for distinguishing them from home-use high chairs. CPSC staff identified four firms that supply high chairs to the U.S. market that sell their high chairs to both consumers and restaurants.

Third, CPSIA section 104 requires the Commission to adopt a mandatory standard that is substantially the same as the voluntary standard, or more stringent than the voluntary standard. Because ASTM F404 applies to all high chairs, excluding restaurant-style products from the mandatory standard would make the mandatory standard less stringent than the voluntary standard, contrary to the CPSIA requirement.

VII. Final Rule

Section 1231.2(a) of the final rule requires high chairs to comply with ASTM F404-18 and incorporates the standard by reference. Section V of this preamble describes the OFR requirements for incorporating material by reference. In accordance with those requirements, section V summarizes ASTM F404-18, explains how the standard is reasonably available to interested parties, and how interested parties may obtain a copy of the standard.

The final rule also amends 16 CFR part 1112 to add a new section 1112.15(b)(44) that lists 16 CFR part 1231, *Safety Standard for High Chairs*, as a children's product safety rule for which the CPSC has issued an NOR. Section XIII of this preamble provides additional information about certifications and NORs.

VIII. Effective Date

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

IX. Paperwork Reduction Act

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

In this rule, section 8 of ASTM F404-18 contains labeling requirements that meet the definition of "collection of information" in the PRA. 44 U.S.C. 3502(3). In addition, section 9 of ASTM F404-18 requires instructions to be provided with high chairs; however, CPSC believes this requirement can be excluded from the PRA burden estimate. OMB allows agencies to

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

The preamble to the NPR discussed the information collection burden of the proposed rule and requested comments on the accuracy of CPSC's estimates. 80 FR 69158 to 69159. CPSC did not receive any comments about the information collection burden of the proposed rule. However, the information collection burden has changed since the NPR because CPSC staff has identified 68 high chair suppliers (59 domestic firms and 9 foreign firms), rather than the 62 firms identified in the NPR, that it estimates will be subject to the information collection burden. Accordingly, the estimated burden of this collection of information is as follows:

 TABLE 1.—Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1231.2	68	2	136	1	136

The estimated reporting burden is based on CPSC staff's expectation that all 68 high chair suppliers will need to modify their labels to comply with the final rule. CPSC staff estimates that it will take about 1 hour per model to make these modifications and, based on staff's evaluation of product lines, that each supplier has an average of 2 models of high chairs. As a result, CPSC estimates that the burden associated with the labeling requirements is: 68 entities \times 1 hour per model \times 2 models per entity = 136 hours. CPSC staff estimates that the

hourly compensation for the time required to create and update labels is \$34.21 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," Sept. 2017, Table 9, total compensation for all sales and office workers in goods-producing private industries: <u>http://www.bls.gov/ncs/</u>). Therefore, the estimated annual cost associated with the labeling requirements is: \$34.21 per hour \times 136 hours = \$4,652.56. CPSC does not expect there to be operating, maintenance, or capital costs associated with this information collection.

As the PRA requires, CPSC has submitted the information collection requirements of this final rule to OMB. 44 U.S.C. 3507(d). OMB has assigned control number 3041-0173 to this information collection.

X. Regulatory Flexibility Act

A. Introduction

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

- the need for and objectives of the rule;
- significant issues raised in public comments about the initial regulatory flexibility analysis (IRFA), a response to comments from the Chief Counsel for Advocacy of the SBA, the agency's assessment of the comments, and any changes made to the rule as a result of the comments;
- the description and estimated number of small entities that will be subject to the rule;

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

5 U.S.C. 604.

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

B. Reason for Agency Action

Section 104 of the CPSIA requires the Commission to issue a mandatory standard for high chairs that is substantially the same as the voluntary standard, or more stringent than the voluntary standard. In this final rule, the Commission incorporates by reference the voluntary standard, ASTM F404-18, as the mandatory safety standard for high chairs. This rule aims to address the safety hazards associated with high chairs that are demonstrated in incident data.

C. Comments Relevant to the FRFA

CPSC did not received any comments specifically addressing the IRFA that accompanied the proposed rule or from the Chief Counsel for Advocacy of SBA. However, CPSC received comments about the effective date of the final rule and restaurant-style high chairs, which are relevant to the FRFA insofar as they impact the costs associated with the rule.

1. Effective Date

In the NPR, the Commission proposed that the rule would take effect six months after publication in the *Federal Register*. One comment, from four consumer advocate groups, expressed support for the proposed six-month effective date. Another comment, filed on behalf of juvenile product manufacturers, requested a one-year effective date, to provide time for firms to change their products to meet the new standard.

After considering these comments, and the potential economic impact of the rule on small firms, the Commission is extending the effective date for the final rule to one year. CPSC staff believes that this longer effective date will reduce the economic impact of the rule on firms, some of which may not be aware of the ASTM standard or the rulemaking, by reducing the potential for a lapse in production or imports while bringing products into compliance with the rule, and spreading the costs of compliance over a longer time period.

2. Restaurant-Style High Chairs

CPSC received three comments about restaurant-style high chairs. Section VI of this preamble detailed these comments. To summarize, commenters noted that it may be appropriate to apply only some requirements, no requirements, or to create new requirements for restaurant-style high chairs. Commenters noted that restaurant settings make certain features useful on a high chair, which may not comply with the standard, and that safety features may be less necessary in restaurants, where caregivers are likely to be near children and supervising them when they are in a high chair.

CPSC has considered this information and believes that it is appropriate to apply the final rule to all high chairs, including restaurant-style high chairs. The final rule may particularly impact firms that supply restaurant-style high chairs, because they have features intended to

accommodate restaurant settings and these features may be difficult to retain while complying with the standard, thereby requiring more extensive changes than home-use models. Nevertheless, consumer safety, home-use of these products, and statutory limitations justify applying the rule to all high chairs. The rationale for including restaurant-style high chairs in the rule is discussed elsewhere in this notice.

D. Description of Small Entities Subject to the Rule

CPSC staff identified 68 firms that supply high chairs to the U.S. market, of which 59 are domestic, and 9 are foreign. Of the 59 domestic firms, 33 manufacture high chairs, and 26 of those 33 manufacturers are small, according to SBA's standards. The remaining 26 domestic firms import high chairs, and 17 of those 26 importers are small, according to SBA's standards. Of the 59 domestic firms, 43 market their high chairs only to consumers, and 4 sell their high chairs to both consumers and restaurants. It is possible that there are additional high chair suppliers in the U.S. market that staff has not identified.

E. Description of the Final Rule

Sections V and VII of this preamble describe the requirements in the final rule, which incorporates by reference ASTM F404-18. In addition, the final rule amends the regulations regarding third party conformity assessment bodies to include the safety standard for high chairs in the list of NORs.

F. Impact on Small Businesses

For the FRFA, staff limited its analysis to the 59 domestic firms staff identified as supplying high chairs to the U.S. market because SBA guidelines and definitions apply to domestic entities. In assessing whether a rule will have a significant economic impact on small

entities, staff generally considers impacts "significant" if they exceed 1 percent of a firm's revenue.

1. Small Manufacturers

At the time staff prepared the FRFA, 13 of the 26 small manufacturers reported that their high chairs complied with the ASTM standard that was in effect for testing purposes. Staff believes that firms that report complying with the voluntary standard will continue to comply with the standard as it evolves, as part of an established business practice. Of these 13 firms, 2 manufacture compact high chairs with limited space for warning labels. In the IRFA, staff predicted that the proposed rule could have a significant impact on these two firms because the NPR required a single warning label to be visible when placing a child in the high chair and when the child was seated in the high chair. However, the final rule does not include this requirement, instead dividing the warning information over two labels, each with different placement requirements. This change reduces the burden on firms to modify their products to accommodate labeling requirements. Therefore, staff does not expect the final rule to have a significant economic impact on any of these 13 firms and third party testing costs are expected to be minimal because these firms already test their products for compliance with the voluntary standard.

The remaining 13 small manufacturers produce high chairs that do not comply with the voluntary standard. Seven of these firms manufacture high chairs for home use, and six produce restaurant-style high chairs. For the seven firms that manufacture high chairs for home use, the final rule could have a significant economic impact. The cost of redesigning their products to meet ASTM F404-18 could exceed 1 percent of each firm's respective revenue. In addition, these firms do not have extensive product lines; one of these firms produces only high chairs. For

the six firms that manufacture high chairs for restaurant settings, the final rule could also have a significant economic impact. In particular, two of these firms make plastic high chairs, which could require them to create new molds for their products to comply with the rule. Staff believes that third party testing costs could potentially have a significant economic impact on some of these firms, but these costs would be small, relative to the overall impact of the rule.

2. Small Importers

At the time staff prepared the FRFA, 9 of the 17 small importers reported that their high chairs complied with the ASTM standard that was in effect for testing purposes. In the IRFA, staff anticipated that the proposed rule could have a significant economic impact on four of these firms because they imported compact high chairs that might have needed to be redesigned to create space for a label that met the proposed label placement requirements. Because the final rule does not include this requirement, allowing greater flexibility, staff does not expect that these firms will have to redesign their products. One importer supplies a relatively new type of high chair that includes a reclining seat insert, but preliminary staff testing indicates that the product meets the requirements in the final rule. In addition, staff believes that any third party testing over their current testing regimes. Therefore, staff does not expect the final rule to have a significant economic impact on any of these nine firms.

The remaining eight small importers supply high chairs that do not comply with the voluntary standard. Staff does not have sufficient information to conclude that the rule will not have a significant economic impact on these firms. The economic impact of the rule on importers depends on the extent of the changes needed for their products to comply with the rule and the response of their suppliers. Staff generally cannot determine this information for importers that

do not already comply with the voluntary standard. Nevertheless, staff expects that the final rule will have a smaller economic impact than the proposed rule, because the final rule includes lessburdensome warning placement requirements than the NPR.

Suppliers are more likely to pass on the costs of producing or redesigning products to comply with the final rule to importers with whom they do not have direct ties. Six of the eight small importers of noncompliant high chairs do not have direct ties with their suppliers. To avoid these costs, the six importers may replace their suppliers, select alternative products, or stop supplying high chairs if they have diverse product lines. For the remaining two importers that have direct ties to their suppliers, finding an alternative supply source likely is not a viable alternative. However, these firms' foreign suppliers may absorb some of the costs to maintain a presence in the U.S. market. Alternatively, these two importers could stop supplying high chairs, although this may be unlikely because both firms have only a few products in their product lines.

In addition, staff believes that third party testing could result in significant costs for two of the firms that import noncompliant high chairs. For one of these firms, testing costs could exceed 1 percent of its gross revenue if it tests as few as two units per model. The second firm would need to test about three units per model before testing costs would exceed 1 percent of its gross revenue. For two additional small importers of noncompliant high chairs, each of which supply only one high chair model, staff could not obtain revenue data to determine the potential impact of third party testing.

3. Accreditation Requirements for Testing Laboratories

Section 14 of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089) requires all children's products that are subject to a children's product safety rule to be tested by a third party conformity assessment body (*i.e.*, testing laboratory) that has been accredited by CPSC.

Testing laboratories that want to conduct this testing must meet the NOR for third party conformity testing. The final rule amends 16 CFR part 1112 to establish an NOR for testing laboratories to test for compliance with the high chair rule.

In the IRFA for this rule, staff anticipated that the accreditation requirements would not have a significant economic impact on a substantial number of small laboratories because: (1) the rule imposed requirements only on laboratories that intended to provide third party testing services; (2) laboratories would assume the costs only if they anticipated receiving sufficient revenue from the testing to justify accepting the requirements as a business decision; and (3) most laboratories would already have accreditation to test for conformance to other juvenile product standards, thereby limiting the costs to adding the high chair standard to their scope of accreditation. CPSC has not received any information to date that contradicts this assessment. Therefore, staff believes that the NOR for the high chair standard will not have a significant economic impact on a substantial number of small entities.

G. Alternatives and Steps to Minimize Economic Impacts

In the NPR, the Commission discussed several alternatives to the proposed rule that would reduce the economic impact of the rule on small entities. In effect, the Commission has incorporated two of these alternatives into the final rule.

One option the Commission discussed in the NPR involved modifying the rule to require compliance with the ASTM standard, without the additional more stringent requirements proposed in the NPR, or at least without the more stringent label placement requirements in the NPR. This alternative would allow the Commission to meet the mandate in CPSIA section 104 to adopt a rule that is substantially the same as the voluntary standard, but reduce the economic impact of the rule by reducing the changes needed to conform to the rule.

ASTM F404-18 includes the more stringent requirements proposed in the NPR, except for the label placement requirements, which remain consistent with ASTM F404-15. Under the final rule, firms will not have to meet additional, more stringent requirements than those in the voluntary standard. Moreover, the warning label placement requirements in the final rule provide more flexibility than the NPR—allowing for two separate labels, each of which is subject to only one visibility requirement, rather than two—thereby requiring less-burdensome product changes than the proposed rule. Therefore, in effect, the Commission has adopted this alternative, by incorporating by reference ASTM F404-18 without additional, more stringent requirements, and eliminating the more stringent label placement requirements proposed in the NPR.

Another alternative CPSC considered was extending the effective date of the rule. In the NPR, the Commission proposed a six-month effective date for the final rule, consistent with other durable infant and toddler product rules. CPSC received comments about the effective date, suggesting that firms need one year to modify products to meet the standard, as some firms will need to redesign their products, test new products, and modify their production processes. Based on this information, CPSC believes that one year is a reasonable amount of time to account for needed changes, and is extending the effective date of the rule to one year. This should reduce the economic costs of the rule for small entities. Setting a later effective date reduces the likelihood of a lapse in production or imports if firms cannot comply with the standard or obtain third party testing within the time provided. In addition, a later effective date spreads the costs of compliance over a longer period, reducing annual costs and the present value of total costs.

Finally, CPSC considered partially or fully excluding restaurant-style high chairs from the final rule, or adopting more-limited requirements for these products. The requirements could be particularly costly for manufacturers and importers of restaurant-style high chairs because this

style of chair has features intended to accommodate restaurant settings that would be difficult to retain while complying with the standard.

As discussed previously in this preamble, although excluding restaurant-style high chairs from the final rule would reduce the economic impact on several small entities, CPSC believes that this alternative would not be appropriate given incident data, home use of these products, and the mandate in CPSIA section 104.

XI. Environmental Considerations

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

XII. Preemption

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

One of the functions of the CPSIA was to amend the CPSA, adding several provisions to the CPSA, including CPSIA section 104 in 15 U.S.C. 2056a. As such, consumer product safety standards that the Commission creates under CPSIA section 104 are covered by the preemption provision in the CPSA. As a result, the preemption provision in section 26 of the CPSA applies to the mandatory safety standard for high chairs.

XIII. Testing, Certification, and Notification of Requirements

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

On March 12, 2013, the Commission published a final rule in the *Federal Register*, entitled *Requirements Pertaining to Third Party Conformity Assessment Bodies*, establishing 16 CFR part 1112, which sets out the general requirements and criteria concerning testing laboratories. 78 FR 15836. Part 1112 includes procedures for CPSC to accept a testing laboratory's accreditation and lists the children's product safety rules for which CPSC has published NORs. When CPSC issues a new NOR, it must amend part 1112 to include that NOR. Accordingly, the Commission is amending part 1112 to include the high chairs standard.

Testing laboratories that apply for CPSC acceptance to test high chairs for compliance with the new high chair rule would have to meet the requirements in part 1112. When a

laboratory meets the requirements of a CPSC-accepted third party conformity assessment body, the laboratory can apply to CPSC to include 16 CFR part 1231, *Safety Standard for High Chairs*, in the laboratory's scope of accreditation of CPSC safety rules listed on the CPSC website at: <u>www.cpsc.gov/labsearch</u>.

As the RFA requires, CPSC staff conducted a FRFA for the rulemaking in which the Commission adopted part 1112. 78 FR 15836, 15855-58. To summarize, the FRFA concluded that the accreditation requirements would not have a significant economic impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories CPSC expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

By the same reasoning, adding an NOR for the high chair standard to part 1112 will not have a significant economic impact on small test laboratories. A relatively small number of laboratories in the United States have applied for accreditation to test for conformance to existing juvenile product standards. Accordingly, CPSC expects that only a few laboratories will seek accreditation to test for compliance with the high chair standard. Of those that seek accreditation, CPSC expects that most will have already been accredited to test for conformance to other juvenile product standards. The only costs to those laboratories will be the cost of adding the high chair standard to their scopes of accreditation. For these reasons, CPSC certifies that amending 16 CFR part 1112 to include an NOR for the high chairs standard will not have a significant economic impact on a substantial number of small entities.

List of Subjects in

16 CFR Part 1112

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

16 CFR Part 1231

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling,

Law enforcement, and Toys.

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

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY

ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

2. Amend § 1112.15 by adding paragraph (b)(44) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance

for a particular CPSC rule or test method?

* * * *

(b) * * *

(44) 16 CFR part 1231, Safety Standard for High Chairs.

* *

3. Add part 1231 to read as follows:

*

PART 1231-SAFETY STANDARD FOR HIGH CHAIRS

Sec.

1231.1 Scope.

1231.2 Requirements for high chairs.

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

§ 1231.1 Scope.

This part establishes a consumer product safety standard for high chairs.

§ 1231.2 Requirements for high chairs.

(a) Each high chair shall comply with all applicable provisions of ASTM F404-18,

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

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

(b) [Reserved]

Dated:

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



Staff Briefing Package

Staff's Draft Final Rule for Infant High Chairs under the Danny Keysar Child Product Safety Notification Act

May 2018

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

Table of Contents

Briefing Memoiii
TAB A: High Chair-Related Deaths, Injuries, and Potential Injuries Reported Between January 1,
2015 and September 30, 2017
TAB B: Engineering Update and Response to Comments: High Chairs Draft Final Rule Briefing Package
TAB C: Human Factors Staff Response to NPR Comments, and Revised Warning Requirements
for High Chairs (CPSIA Section 104)
TAB D: Final Regulatory Flexibility Analysis of the Draft Final Rule for High Chairs and the
Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the
High Chairs Standard
TAB E: Updated Summary of High Chair Recalls 58

Briefing Memo



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

Memorandum

This document has been electronically approved and signed.

May 30, 2018

TO:	The Commission
	Alberta E. Mills, Secretary
THROUGH:	Patricia M. Hanz, General Counsel
	Patricia H. Adkins, Executive Director
	DeWane Ray, Deputy Executive Director for Safety Operations
FROM:	George A. Borlase, Ph.D., Assistant Executive Director Office of Hazard Identification and Reduction
	Stefanie C. Marques, Ph.D., Project Manager Office of Hazard Identification and Reduction
SUBJECT:	Infant High Chairs, Section 104 of the Consumer Product Safety Improvement Act of 2008, Final Rule

I. Introduction

Section 104 of the Consumer Product Safety Improvement Act 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act. This Act requires the U.S. Consumer Product Safety Commission (CPSC) to: (1) examine and assess voluntary safety standards for certain infant or toddler products; and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. The list of products in section 104 includes high chairs.

The CPSIA also requires the CPSC to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. This consultation process has been ongoing with staff's participation in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers,

users, consumers, government, and academia.¹ In September 2013, staff began this consultation process for high chairs and became involved in high chair tasks groups.

This briefing package includes staff's responses to comments received following the high chairs notice of proposed rulemaking (NPR). This package also assesses the current voluntary standard, reviews the incident data, discusses a new high chair product, discusses the potential impact of a rule on small businesses, and provides staff's recommendations for a draft final rule to address potential hazards associated with high chairs.

II. Background

A. Product Review

The current voluntary standard, ASTM F404-18, Standard Consumer Safety Specification for High Chairs, defines a "high chair" as:

> A free standing chair for a child up to 3 years of age which has a seating surface more than 15 inches above the floor and elevates the child normally for the purposes of feeding or eating ... A high chair may be sold with or without a tray and may be height adjustable to higher or lower use positions. It may also include a recline position for infants not able to sit up unassisted.

Typical high chair construction consists of a plastic, wooden, or metal frame, often with a padded fabric seating area. Some models fold for easy storage or transport, and some include a removable snack tray or toy accessories that mount on the main tray. The voluntary standard requires that high chairs must have a passive crotch restraint and a 3-point restraint system; some products employ a full, 5-point restraint with shoulder harnesses. In addition to the required restraining systems, many chairs also have a rigid, front torso support to help contain the occupant in the seating area even when the caretaker removes the tray. Other design variations include trayless chairs for use at standard dining room tables, and youth chair systems that use different high chair seating products to accommodate children as they grow. A variety of frame constructions exist in today's marketplace, including: food-service high chairs,² four-legged "A-

¹ASTM International website: <u>www.astm.org</u>, About ASTM International. ² This type of high chair was referred to as "restaurant-style" in the NPR, but staff has since learned that the more common name for this type of product is "food-service" high chair.

frame" styles, single "leg" pedestals, as well as "Z" frames (shown in respective order in Figure 1).



Figure 1: High Chair Examples

Food-service high chairs tend to be easily stackable and more compact than high chairs designed for home use; they also may have other features, such as larger leg openings to accommodate children using the product in outerwear that may make it challenging for these products to comply with the voluntary standard. The ASTM standard does not differentiate food-service high chairs from home-use high chairs in the high chair standard. Therefore, the standard applies to all high chairs. The NPR discussed that the manufacturers of these products may be significantly impacted by a mandatory rule and specifically requested comments and feedback on food-service high chairs. Based on the comments to the NPR (discussed in section III. C in this memorandum), an analysis of incidents specifically involving food-service high chairs (discussed in section III. A of this memorandum) and consistent with the scope of the ASTM standard, staff is recommending in the federal standard that food-service high chairs should be subject to the same requirements as high chairs designed for home use.

B. Reclined Seat High Chair Products

Since the Commission issued the NPR, CPSC staff has learned of a new type of high chair product; this product is a reclined seat accessory that is placed on a high chair base and allows younger infants to be raised to dining table height. This product typically has one reclined seat position and is sold separately from the high chair base, as part of a youth chair system that can accommodate different high chair seat products (two examples of the types of products are shown in Figure 2).

CPSC staff and ASTM have discussed whether these types of products would fall under the high chair standard (when they meet the height and age criteria in the "high chairs" definition), and together we developed the following guidelines to help determine when such products would be covered by the ASTM high chair standard:

1. Products that offer a means to elevate the seat above the floor and promote, through words or visuals, the product being used for feeding or eating in at least one use mode, or shown at a dining table, would be considered a high chair, and thus, would likely come under the scope of the high chair standard.

2. Youth chairs with an installed restraint system accessory that converts the chair into a high chair for use with children younger than 3 years of age, for feeding or eating, would likely come under the scope of the high chair standard. If that same youth chair also offers a reclined infant seat accessory, the chair would also come under the scope of the high chair standard with the reclined infant seat accessory installed.



Figure 2: Reclining Seat High Chair Examples

C. Rulemaking History

In November 2015, the Commission issued an NPR for high chairs (80 FR 69144, published on November 9, 2015).³ The NPR proposed to incorporate by reference the voluntary standard, ASTM F404-15, *Standard Consumer Safety Specification for High Chairs*, with modifications. Specifically, the NPR proposed more stringent requirements for rearward stability and warnings in labels and instructional literature. The CPSC received statements from 15 commenters on the NPR.⁴ Staff's responses to these comments are discussed in section III.C of this memorandum, and in the attached memoranda.

D. ASTM Voluntary Standard Overview

ASTM first approved and published the ASTM voluntary standard for high chairs in 1975, as F404-75, *Standard Consumer Safety Specification for High Chairs*. ASTM has revised

³ On January 21, 2016, the Commission issued a correction notice, correcting an error in the NPR (81 FR 3354).

⁴ Commenters included individuals, manufacturers, industry associations and consumer advocate groups. One submission was from four consumer advocate groups.

the voluntary standard many times since this original version. ASTM F404-15 is the version the CPSC proposed to incorporate by reference, with modifications, in the NPR. Since the NPR, ASTM has revised the standard five times. The current voluntary standard for high chairs is ASTM F404-18, which includes the rearward stability requirements and warning label improvements similar to those proposed in the NPR.

III. Discussion

A. Overview of Incident Data

In the NPR briefing package, CPSC staff identified a total of 1,296 incidents related to high chairs that reportedly occurred from January 1, 2011 through December 31, 2014. Of the 1,296 high-chair related incidents, 138 (11 percent) involved a nonfatal injury. There was one report of a death associated with a broken high chair, but very little information was available about the decedent or the circumstances leading up to the incident, and the role of the high chair remains undetermined. The hazard patterns associated with high chair incidents were mostly related to specific high chair components, such as the frame, seat, restraints, armrests, toy accessories, trays, wheels and footrest; and overall product-related issues, such as the design and the stability of the high chair.

Since the NPR, CPSC staff has received a total of 546 new incident reports related to high chairs. Four hundred twenty-six (78 percent) of the 546 new incidents reportedly occurred between January 1, 2015 and September 30, 2017 (*i.e.*, after the timeframe covered in the NPR); the remaining 22 percent were newly reported incidents that occurred in the earlier timeframe of January 1, 2011 to December 31, 2014. Of the 546 reported incidents, 133 involved a nonfatal injury. One new reported fatality occurred in 2016: a parent left a 23-month-old child in the care of a 13-year-old sibling, and upon returning home, the parent found the child hanging from the high chair. CPSC field staff could not complete a follow-up investigation of the incident because the consumer did not respond. As such, the role of the high chair remains undetermined. No new hazard patterns were reported beyond what the NPR briefing package identified.

In the NPR briefing package, staff indicated that an estimated total of 31,300 high chairrelated injuries were treated in U.S. hospital emergency departments (EDs) over the 4-year period from 2011 to 2014. No deaths were reported through the National Electronic Injury Surveillance System (NEISS)⁵ for this period. Most of the incidents were due to falls when a child attempted to climb into or out of the high chair; when the chair tipped over as a child

⁵ NEISS is a statistically valid injury surveillance system. NEISS injury data are gathered from EDs of hospitals selected as a probability sample of all the U.S. hospitals with EDs

pushed back or rocked back and forth while seated in the high chair; or when some component (such as the restraint, tray, or lock) of the high chair failed.

For the NPR, CPSC staff presented NEISS estimates for January 1, 2011 to December 31, 2014. Since then, complete injury data for 2015 and 2016 have become available. In 2015, an estimated 8,300 high chair-related injuries, and in 2016, an estimated 10,200 high chair-related injuries were treated in U.S. hospital EDs. This brings the estimated injury total over the 6-year period from January 1, 2011 to December 31, 2016 to 49,900. An estimated total of 1,600 injuries treated in U.S. EDs during that period were related to the use of a high chair in a restaurant setting. Staff also evaluated hazard patterns associated with high chairs in a restaurant setting, which were found to be similar to hazard patterns identified in home settings. Most of the injuries were sustained in falls from the high chair when the restraint failed, was defeated, or was not used at all; falls when the high chair tipped over; or falls while a child attempted to climb into or out of the high chair. However, for a majority of the fall injuries, the cause of the fall was not described in the reports.

B. Improvements to High Chair Standard Since the NPR

The NPR proposed incorporating by reference the 2015 version of the ASTM high chair voluntary standard, *Standard Consumer Safety Specifications for High Chairs* (F404-15), with modifications to improve the rearward stability requirement, warning label requirements, and instructional literature section. CPSC staff worked with ASTM on the improvements to these requirements, and the rearward stability requirement proposed in the NPR was included in the ASTM F404-16 standard. In addition, the warning label requirements that were similar to proposals in the NPR were included in the ASTM F404-17 standard. CPSC staff and ASTM together made editorial changes and clarified parts of these requirements to improve the ASTM standard, based on public comments and recommendations from the Ad Hoc Language Task Group. The F404-17a high chair standard continued to improve the warning label requirements, and F404-18 included revisions to the instructional literature section, based on proposals in the NPR and the Ad Hoc Language Task Group. Given these changes, staff believes that the requirements in ASTM F404-18 address the issues with the standard that were raised in the NPR, and staff recommends that the Commission adopt ASTM F404-18, without modifications.

C. Staff Responses to NPR Comments

CPSC received comments on the NPR from 15 commenters, including comments from industry, consumer groups, trade associations, and consumers. Three commenters expressed general support for the NPR. The remaining comments focused on issues related to the passive crotch restraint requirement, rearward stability testing, warning labels, food-service high chairs, and the proposed effective date. Staff's detailed responses to technical and labeling comments

can be found in Tab B (Mechanical Engineering) and Tab C (Human Factors), respectively; a discussion of comments regarding food-service high chairs and the proposed effective date is below.

1. Food-Service High Chairs

Comment: Staff received three comments following our request for input on including food-service high chairs in the scope of the mandatory standard (the ASTM standard applies to food-service high chairs as well as residential). Food-service high chair suppliers provided two comments and a group of consumer advocates provided one comment.

The two food-service high chair suppliers reiterated many of the points discussed in the NPR and staff's initial regulatory flexibility analysis (IRFA). They discussed the different levels of supervision in the two environments and the intentional differences in design meant to make food-service high chairs more useful in the restaurant environment (*e.g.*, roomier seating; a shorter, typically trayless design; and a compact, stackable structure).

One of these firms pointed out that the ASTM F404 standard was created specifically to address high chairs used in the home environment, while the other noted that the "unique design of food-service high chairs often impedes their compliance" with the voluntary standard. One of the firms, a manufacturer of an ASTM-compliant food-service high chair, reported receiving complaints that the seating surface and smaller leg openings make the high chair unusable for children more than 1-year-old (when high chairs are intended to be used up until a child is 3 years of age). Another firm noted that some food-service "high chairs have no point of sale opportunity for consumers as they are exclusive to a restaurant chain and can only be purchased through their internal portal."

Both firms agreed that labels and point-of-purchase information warning against using food-service high chairs in the home are appropriate. One firm also suggested educational efforts in restaurants to encourage safe food-service high chair use, while another recommended developing a commercial high chair standard.

The consumer advocates commented that they were not concerned with food-service high chairs when used in restaurants, given the typical level of supervision and the "lack of injury data for these high chairs." However, they were concerned about food-service high chair use in homes and recommended that they be subject to the warning label requirements regarding restraints and the basic stability requirements, rather than the entire voluntary standard.

Response: Staff agrees that there are some differences between food-service high chairs and high chairs intended for home use. Staff further agrees that few manufacturers and importers

sell food-service high chairs directly to consumers. Staff research found only three suppliers of food-service high chairs that sell products directly to consumers. Of those three firms, only one was selling food-service high chairs that did not claim compliance with the voluntary ASTM standard. However, additional food-service high chairs are sold to the public through second and third parties. Additionally, after publication of the NPR and in contrast to comments received, staff analyzed the NEISS data and found that there were 1,600 incidents related to high chairs that occurred in restaurants and that required treatment in U.S. hospital EDs between 2011 and 2016. These incidents indicate that the hazard patterns seen in restaurants are similar to in-home incidents. Accordingly, and because section 104 of the CPSIA requires that a mandatory standard be "substantially the same as" or "more stringent" than the voluntary standard (again, the ASTM standard applies to food-service high chairs as well as residential), the draft final rule does not exclude or adopt different requirements for food-service high chairs.

Staff shares one commenter's concern that mandating food-service high chair conformance with ASTM could interfere with the design elements intended to make these high chairs more useful in a restaurant setting, such as larger leg openings. Smaller leg openings could cause injuries if they make it difficult to remove some children.⁶ It is also possible that applying this requirement to food-service high chairs could create unintended consequences by making the restaurant environment less safe for young children. For example, if patrons found the compliant food-service high chairs too inconvenient to use, this could encourage potentially less safe options, like placing infant carriers on elevated surfaces, such as tables or chairs. However, staff has no direct evidence of this possibility. Including food-service high chairs in the scope of the mandatory rule will address known restaurant incident hazards.

Staff intends to monitor the incident data for any change in restaurant hazard patterns so that any unintended consequences can be addressed in a timely manner; we ask that food-service high chair suppliers and restaurant staff assist us in this effort by supplying us with incident information as it becomes available. Staff also notes that the ASTM subcommittee declined to address food-service high chairs in any of the previous five revisions to the voluntary standard, and staff encourages food-service high chair suppliers to become involved in the ASTM high chair voluntary standard development process.

2. Proposed Effective Date

Comment: Staff received two comments on CPSC's proposed 6-month effective date for the high chairs mandatory standard. One comment, submitted by four consumer advocate

⁶ This type of injury occurs primarily with frame carriers and soft infant and toddler carriers, but there were also two incidents in the NEISS high chair incidents. A small number of incidents resulted in nursemaid's elbow injuries when the adult caregiver had difficulty removing the child from the product.

groups, supported the 6-month effective date. A second comment, submitted by a group representing juvenile product manufacturers, requested a 1-year effective date, which they stated is necessary to implement the proposed warning labels and instructional literature changes in an "orderly" manner.

Response: Based on public comments received in response to the NPR, staff has modified its recommendations for warning labels and instructional literature. The revised recommendations are expected to be less burdensome to suppliers. However, staff could not rule out a significant impact on 39 percent of small suppliers; and a longer effective date would reduce the impact. Staff believes that many of these firms may not be aware of the ASTM voluntary standard or the CPSC high chairs rulemaking. This is likely to be particularly true of food-service high chair suppliers, which staff found make up two-thirds of the 39 percent of small suppliers for which a significant impact could not be ruled out. Staff now recommends a 12-month effective date to reduce the impact on small businesses to the extent possible.

E. Impact on Small Businesses

Staff identified 59 domestic firms that supply high chairs to the U.S. market. Based on U.S. Small Business Administration guidelines, 43 of the 59 domestic firms are "small businesses," including 26 manufacturers and 17 importers. Staff identified nine additional foreign suppliers and numerous high chairs entering the U.S. market via Amazon storefronts and other online firms that act as brokers between buyers and sellers.

As described in Tab D, although it seems unlikely that the rule would impose a significant impact on manufacturers and importers of compliant high chairs, the rule could potentially have a significant economic impact on the 21 domestic suppliers of noncompliant high chairs (13 manufacturers and 8 importers). Accordingly, staff prepared a Final Regulatory Flexibility Analysis. However, in contrast to the NPR, the draft final rule is expected to reduce the overall impact of the rule on small businesses.

F. Paperwork Reduction Act

The draft final rule would require each high chair to comply with ASTM F404-18. Sections 8 and 9 of ASTM F404-18 contain requirements for labeling and instructional literature. These are disclosure requirements that fall within the definition of "collection of information" in 5 C.F.R. § 1320.3(c). Since the Commission published the NPR, staff has determined that there are 68 known firms (including 59 domestic firms) supplying high chairs to the U.S. marketplace. All firms are assumed to use labels on their products and their packaging already, but they may need to modify their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each of these firms supplies an average of two different models of high chairs; therefore, the estimated burden hours associated with labeling requirements is 1 hour \times 68 firms \times 2 models per firm = 136 annual hours. Because high chairs generally require use and assembly instructions, staff can exclude the instructional literature requirements from a burden estimate.

G. Effective Date of Final Rule

The Administrative Procedure Act generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C. § 553(d)). In the NPR, the Commission proposed a 6-month effective date. As discussed, staff received two comments on CPSC's proposed 6-month effective date. One comment supported the 6-month effective date, and the other requested a 1-year effective date.

Staff believes that a longer effective date would reduce the impact on firms, some that may not be aware of the ASTM voluntary standard or the CPSC high chairs rulemaking. Therefore, staff recommends that the Commission set an effective date of 12 months after publication of the final rule for products manufactured or imported on or after that date.

IV. Staff Recommendations

CPSC staff recommends that the Commission issue a final rule that would incorporate by reference the voluntary standard, ASTM F404-18, with no modifications. Staff recommends that the rule take effect 12 months after the final rule is published in the *Federal Register*. Staff also recommends that the Commission amend 16 C.F.R. part 1112, which would establish the notice of requirements (NOR) for testing laboratories that want to test high chairs for compliance with the high chairs final rule.

TAB A: High Chair-Related Deaths, Injuries, and Potential Injuries Reported Between January 1, 2015 and September 30, 2017





UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION 4330 East West Highway Bethesda, Maryland 20814

Memorandum

Date: Oct 17, 2017

TO :	Stefanie Marques High Chairs Project Manager Division of Pharmacology and Physiology Assessment Directorate for Health Sciences
THROUGH:	Stephen Hanway Director, Division of Hazard Analysis Directorate for Epidemiology
FROM :	Risana T. Chowdhury Division of Hazard Analysis Directorate for Epidemiology
SUBJECT :	High Chair-Related Deaths, Injuries, and Potential Injuries

SUBJECT : High Chair-Related Deaths, Injuries, and Potential Injuries Reported Between January 1, 2015, and September 30, 2017

Introduction

This memorandum updates the data in the high chairs notice of proposed rulemaking (NPR) briefing package presented to the Commission in October 2015. Those earlier data were extracted on January 21, 2015, and included all incidents that reportedly occurred from January 1, 2011 through December 31, 2014. This memorandum includes any newly reported high chair-related incidents from 2011 through 2014, as well as all new reported incidents that occurred between January 1, 2015 and September 30, 2017. In addition, the 2015 and 2016 data for CPSC's National Electronic Injury Surveillance System (NEISS) database, which contains injury reports received through emergency departments (EDs), are now complete. As such, the national injury estimates for 2015 and 2016, as well as a comparison with estimates from 2011through 2014 are also presented in this memorandum.

Incident Data⁷

Since the NPR, CPSC staff has received a total of 546 new incident reports related to high chairs. Seventy-eight percent of the new incidents reportedly occurred between January 1, 2015 and September 30, 2017 (*i.e.*, after the timeframe covered in the NPR); the remaining 22 percent were newly reported incidents that occurred in the earlier timeframe of January 1, 2011 to December 31, 2014. Information on 82 percent (450 out of 546) of the incidents was based solely on reports submitted to CPSC by manufacturers and retailers through CPSC's "Retailer Reporting Program."

Of the 546 reported incidents, one was a fatality; of the remaining 545 nonfatal incident reports, 133 reported an injury. Age of the child was reported in 376 incident reports. Table 1 provides the age breakdown as available from the 546 incident reports.

Age of Child	All Incidents		Injuries and Fatalities	
	Frequency	Percentage	Frequency	Percentage
Unreported*	170	31	35	26
One – Six Months	35	6	7	5
Seven – Twelve Months	140	26	50	37
Thirteen – Eighteen Months	105	19	26	19
Nineteen – Twenty-Three Months	36	7	10	7
Two Years	48	9	6	4
Three Years	12	2		
Total	546	100	134	100

 Table 1: Age Distribution in High Chair-Related Incidents

 Reported Between January 1, 2015 and September 30, 2017

Source: CPSC epidemiological database CPSRMS; percentages may not add to 100 due to rounding.

* Age may be "unreported" under two circumstances: age was unknown or age was not reported because the incident involved no injury.

⁷ The data discussed in this section come from CPSC's database, titled, the Consumer Product Safety Risk Management System (CPSRMS). These reported deaths and incidents do not provide a complete count of all that occurred during this period. However, they do provide a minimum number of incidents occurring during this period and illustrate the circumstances involved in the incidents related to high chairs.

CPSC staff extracted the reported incident data on October 4, 2017. Staff extracted all data coded under product code 1555 (*high chairs*). Upon careful joint review with CPSC's Directorate for Health Sciences, staff considered many cases to be out of scope for the purposes of this memorandum. For example, staff excluded from this analysis cases involving attachable high chairs or booster seats (which were coded as high chairs) or cases where the child involved was older than the manufacturer-recommended age of 3 years. Except for incidents occurring on U.S. military bases, staff excluded all incidents that occurred outside of the United States. To prevent any double-counting, when staff identified multiple reports of the same incident, they consolidated and counted them as one incident. Following the ASTM F404 user age recommendations, staff set 3 years as the upper age limit in the incident data for this analysis

Fatal Incidents

In 2016, one strangulation fatality was reported to CPSC staff. A parent left their 23-month-old child in the care of a 13-year-old sibling. Upon returning home, the parent found the younger child hanging from the high chair. CPSC field staff could not complete a follow-up investigation of the incident because the consumer did not respond. As such, the role of the high chair remains undetermined.

Nonfatal Incidents

One hundred and thirty-three of the 546 high chair-related incident reports involved a nonfatal injury. Among these injuries, hospital admission was reported for one child who suffered a skull fracture and retinal hemorrhage. Twelve other children were treated in a hospital ED. The diagnoses for these injuries included lacerations and contusions of the head, face, and limbs, as well as a compound fracture of the finger. An additional injury report mentioned both a broken wrist and an unspecified head injury, but there was no mention of the treatment the infant received. The other injuries resulted mostly in contusions, abrasions, and lacerations from falls or entrapment of limbs/extremities.

The remaining 412 incident reports specified that no injury had occurred or else provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

Hazard Pattern Identification

Like the NPR data, 27 incident reports in the new data contained complaints of multiple issues. As such, the 546 reports actually reported 576 *incidents*. CPSC staff considered the 576 incidents (rather than the 546 incident reports) for the characterization of the hazard patterns associated with the use of a high chair in this section. CPSC staff found that the hazard patterns among the new incidents were similar to those in the NPR data. As seen in the NPR data, most of the issues in the new data were determined to be product-related issues. They are grouped in descending order of frequency of incidents below:

A. Specific component related

- a. *Tray*-related issues accounted for 194 (34 percent) of the 576 reported incidents. Trays failing to lock/stay locked, releasing too easily, too tight/difficult to release, or pinching fingers, were some of the more common problems. Eighty-five injuries, including seven treated at a hospital ED, were reported in this category.
- b. Of the 576 incidents, 171 (30 percent) were attributed to the *frame*, which supports the seat. Examples of complaints included broken or cracked frames, legs, bases, height adjusters, or seat supports; failure of frame-release latches; and

frames folding inwards or collapsing outwards, among others. Seven injuries were reported in this category.

- c. *Restraint* failures were reported in 66 (11 percent) of the 576 reported incidents. Problems included buckles/prongs breaking, jamming, releasing too easily, or separating from straps; straps tearing or fraying, pinching, or coming undone; and inadequacy or ineffectiveness of restraints. Seventeen reported injuries, including one hospital admission and three treated at a hospital ED, were associated with restraint problems.
- d. High chair *seat*-related issues constituted 59 (10 percent) of the 576 reported incidents. Examples of incidents included seat pads tearing, cracking, and/or peeling; failures of the lock/latch that controls the seat-recline function; seat backs detaching altogether; and loose screw(s). This category includes 11 of the reported injuries.
- e. Problems with high chair *armrests* cracking or breaking accounted for 49 (9 percent) of the 576 reported incidents. No injuries were reported in this category.
- f. *Toy accessory*-related issues were reported in 7 (1 percent) of the 576 reported incidents. One incident involving a finger entrapment resulted in an injury.
- g. The paint peeling off of the *footrest* was reported in 1 (less than 0.5 percent) of the 576 incidents. No injury was associated with this problem.
- B. General product related
 - a. A potential entrapment hazard due to the *design* of the high chair was reported in 7 (1 percent) of the 576 reported incidents. Most descriptions were of limbs, fingers, and toes entrapped in spaces/openings in a high chair (between armrest and backrest, for example). One reported a child getting partially suspended by the neck between the seat (which slid back) and the tray table of a high chair; another reported a child getting into a potentially dangerous position with her chin on a rear leg brace of a high chair. In both cases, the presence of the caregiver nearby prevented any serious injury. Three injuries were reported in this category.
 - b. *Stability*-related issues were reported in 7 (1 percent) of the 576 reported incidents. Most of these incidents reported the high chair actually or nearly tipping over. Six injuries were reported in this category.

c. *Miscellaneous other* product-related issues, such as the overall poor quality of construction or material, or breakage of unspecified high chair part(s), were reported in 6 (1 percent) of the 576 reported incidents. No injuries were reported in this category.

C. Other

- a. *Undetermined* issues were reported in 7 (1 percent) of the 576 reported incidents. Insufficient information was available for CPSC staff to determine how the incidents occurred. One of these incidents was a fatality, which, as described above, involved strangulation. Of the three nonfatal injuries, two were ED-treated injuries.
- b. *Consumer's comment/observation* about unauthorized sale of used high chairs or a perceived safety hazard about a high chair accounted for 2 (less than 0.5 percent) of the complaints. It was unclear whether any incident had actually occurred.

National Injury Estimates⁸

For the NPR, CPSC staff presented NEISS estimates for January 1, 2011 to December 31, 2014. Since then, complete injury data for 2015 and 2016 have become available. In 2015, an estimated 8,300 high chair-related injuries (sample size = 323, coefficient of variation = 0.17), and in 2016, an estimated 10,200 high chair-related injuries (sample size=393, coefficient of variation=0.16) were treated in U.S. hospital EDs. This brings the estimated injury total over the 6-year period from January 1, 2011 to December 31, 2016 to 49,900. The injury estimates for individual years are shown in Table 2. There was no statistically significant increase or decrease in the estimated injuries from one year to the next; nor was there any statistically significant trend over the 2011 through 2016 period.

⁸ The source of the injury estimates is NEISS, a statistically valid injury surveillance system. NEISS injury data are gathered from EDs of hospitals selected as a probability sample of *all* the U.S. hospitals with EDs. The surveillance data gathered from the sample hospitals enable CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

Staff extracted all data coded under product code 1555 (*high chairs*) for patients ages 3 years and under. Staff considered certain records to be out of scope for the purposes of this memorandum. One such example was an infant who sustained scald burns from spillage of hot tea, which a parent had placed on the high chair tray. Another example was of an older sibling stepping onto the back of the high chair and causing the chair to tip over with the infant in it. Staff excluded these records before deriving the statistical injury estimates.

Calendar Year	Estimated Injuries	Sample Size	Coefficient of Variation
2011	7,400	281	0.15
2012	8,800	260	0.14
2013	6,700	246	0.18
2014	8,400	291	0.19
2015	8,300	323	0.17
2016	10,200	393	0.16
2011-2016 Combined	49,900	1,794	0.14

Table 2: High Chair-Related Injuries Treated in U.S. Hospital EDsJanuary 1, 2011–December 31, 2016

Source: NEISS, CPSC. Injury estimates rounded to nearest 100; individual estimates do not add to total due to rounding.

As in the 2011 through 2014 period, no deaths were reported through the NEISS in 2015 through 2016. Of the estimated 2-year total of 18,500 injuries in 2015 through 2016, about 74 percent were sustained by 7- to 23-month- old infants. In addition, the following characteristics occurred most frequently:

- Hazard falls (with no cause specified) out of the high chair to a lower level (75 percent); a substantial number (23 percent) of additional injuries, mostly falls, were sustained when one of the following occurred: a child attempted to climb into/out of the high chair; when the chair tipped over as a child pushed back or rocked back and forth while seated in the high chair; or some component (such as the restraint, tray, or lock) of the high chair failed or was disengaged.
- Injured body part head (65 percent) and face (17 percent).
- Injury type internal organ injury (51 percent), contusions/abrasions (16 percent), and lacerations (16 percent).
- Disposition treated and released (nearly 95 percent).

National Estimate of Injuries in a Restaurant Setting

To determine the extent to which high chair-related injuries may occur in restaurant settings, CPSC staff reviewed NEISS data where the incident narratives mentioned a restaurant specifically by name or in general. Between 2011 and 2016, CPSC staff estimated that a total of 1,600 injuries (sample size=51), related to the use of a high chair in a restaurant setting were treated in U.S. EDs. The sample size for individual years was insufficient to derive reportable national estimates.⁹ Most of the injuries were sustained in a fall from the high chair; these

⁹According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

included falls when the restraint failed, was defeated, or was not used at all; falls when the high chair tipped over; or falls while a child attempted to climb into or out of the high chair. However, for a majority of the fall injuries, the cause of the fall was not described in the reports.

TAB B: Engineering Update and Response to Comments: High Chairs Draft Final Rule Briefing Package





UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION 4330 East West Highway Bethesda, Maryland 20814

Memorandum

February 27, 2018

TO:	Stefanie Marques, High Chairs Project Manager Division of Pharmacology and Physiology Assessment, Directorate for Health Sciences
THROUGH:	Joel Recht, Ph.D. Associate Executive Director for Engineering Sciences
	Mark Kumagai, P.E., Director Division of Mechanical and Combustion Engineering Directorate for Engineering Sciences
FROM:	John Murphy, Mechanical Engineer Division of Mechanical and Combustion Engineering Directorate for Engineering Sciences

SUBJECT: Engineering Update and Response to Comments: High Chairs Final Rule

I. Introduction

In November 2015, the Commission published a notice of proposed rulemaking (NPR) for high chairs (*80 Fed. Reg. 69144* (Nov. 9, 2015)). The NPR proposed to incorporate by reference the voluntary standard, ASTM F404-15, *Standard Consumer Safety Specification for High Chairs*, with modifications to have more stringent requirements for rearward stability and instructional literature/labels to strengthen the ASTM standard.

This memorandum discusses the current edition of ASTM F404-18 (excluding instructional literature and labeling requirements), which was approved on January 31, 2018, and published in March 2018. In addition, the memorandum provides responses to technical comments CPSC received following the NPR.

II. ASTM Standard Update

In the NPR, CPSC staff proposed adopting ASTM F404-15 with an additional rearward stability test that was developed in conjunction with an ASTM F404 subcommittee task group. The test requires that all high chairs have a rearward stability index of at least 50. The rearward stability

index is based on a review of various stability requirements, the incident data, and testing of various models of high chairs, including high chairs reportedly involved in rearward tip-over incidents and high chairs not reported in rearward stability incidents. The rearward stability index rates high chairs based on two characteristics associated with a rearward tip over: the force (F2) required to tip the chair over in the rearward direction, and the distance (D) that a reference point on the back of the high chair travels as the chair tilts from the manufacturer's recommended use position to the point of instability just before tipping over. This index is meant to measure the elements associated with an occupant pushing backward off of a table in front of them: force and distance. A chair design will have a higher stability index as the push-off force, and/or the distance to reach its tipping point increases. Through testing completed by the Division of Mechanical and Combustion Engineering (ESMC) staff and several manufacturers, the tip force was determined to be the dominant factor in identifying unstable chairs; so it is weighted twice as heavily in the stability index calculation: rearward stability index $= 2 \times (F2) + D$.

Staff has continued to work with the ASTM task group to ensure that the rearward stability test in ASTM F404-18 provides the same level of safety or exceeds the level of safety of the stability test proposed in the NPR.

The NPR was published in November 2015, and referenced ASTM F404-15. Since the NPR, ASTM F404-15 has been revised five times (ASTM F404-16, ASTM F404-16a, ASTM F404-17, ASTMF404-17a and ASTM F404-18). In March 2018, ASTM published the current standard, ASTM F404-18.

Since the NPR, ASTM has revised F404-15 to address proposals in the NPR and to clarify the test procedure. The current ASTM F404-18 standard includes stability requirements that are essentially the same as the requirements proposed in the NPR, with some clarifications of the requirements, certain editorial changes, and other corrections. These clarifications, editorial changes, and corrections are described below:

- The NPR proposed adopting ASTM F404-15 and increasing the Rearward Stability Index to 50 to address rearward tip over incidents. ASTM F404-18 standard now requires all high chairs to have a "Rearward Stability Index" of 50 or more.
- ASTM F404-16 was published without the requirement for "Stability with Child Climbing into Chair." ASTM corrected this error in ASTM F404-16a that was published in August 2016, and the requirement is retained in ASTM F404-18.
- Since the NPR, ASTM has revised F404 section 7.7.2.1 to address the setup for tests involving "Stability with Child in Chair." The current ASTM F404-18 text indicates that "For high chairs with a seat back that can be reclined, adjust the seat back into the most upright position," and "For high chairs with a seat back that is adjustable in the front to

back direction on the high chair, adjust the seat back into the rearmost adjustment position."

- Since the NPR, ASTM has revised F404-15 to clarify the test procedure. The current ASTM F404-18 provides greater specificity for the correct placement of the test weight that simulates the weight of the child in the high chair for the stability test.
- The current ASTM F404-18 has a revised forward stability test to account for the possibility of a front torso support if a tray is not provided.
- Note 12 was revised to indicate that any cord used to apply the force to the high chair in the rearward stability test, shall be a low stretch cord, such as a 7-strand military rope or parachute cord with a tensile strength of 550 lb. This was done to provide a better description of the equipment that should be used in the test.
- In ASTM F404-16, the phrase "verge of tipping" was changed to "begins to tip over." The new text was added to clarify that the rear pull should continue until the high chair reaches the point that it becomes unstable and begins to tip over. "Begins to tip over" replaces the original text that indicated that the chair becomes unstable and is on the "verge of tipping" over. This edit eliminates confusion about what "tipping over" actually means.
- ASTM F404-16 was revised with an updated Figure 10 to illustrate how the rearward stability test should be performed and to add a visual description of the test to provide a thorough understanding of the test.

When preparing the NPR, staff also proposed requiring that a passive crotch restraint be installed on the high chair before shipment to consumers, ensuring that it is in place when the high chair is used. The ASTM high chair subcommittee placed that language into the F404-15 version of the standard, which was issued before the NPR. ASTM F404-18 retains that language.

III. Responses to Technical Comments

Applicability of Pre-Attached Passive Crotch Restraint Requirement

Comment: One commenter proposed that ASTM 404-15 requirement 6.9.1.5 (which requires passive crotch restraints to be permanently attached prior to shipment) should not apply to high chairs where consumers assemble every component of the high chair with instructions.

Response: Staff disagrees with this suggestion. Staff believes that the passive restraint should be permanently attached to the high chair or tray before shipment to ensure that the high chair cannot be installed (intentionally or inadvertently) without the passive restraint. This requirement is intended to reduce the likelihood of death from positional asphyxia. This

requirement has been in the ASTM standard since 2015. Section 104 requires the Commission to issue standards that are substantially the same as, or more stringent than, the voluntary standard. Thus, the Commission cannot issue a standard that is less protective than the voluntary standard.

Rearward Stability Testing

Comment: Two commenters raised several issues or questions regarding the clarity and repeatability of the proposed rearward stability index requirement. The specific issues raised in the comments, and staff's responses, follow:

<u>Sequencing of Test References</u> – The commenter points out that requirement 6.5 calls for following 7.7.2.4-7.7.2.4.6 instead of ALL of 7.7

Response: The commenter is calling attention to an error of omission in the ASTM F404-16 version of the standard. That error was corrected in ASTM F404-16a.

<u>"Verge of Tipping Over" Is Unclear and Can Cause Variation</u> – The commenter believes the phrase "verge of tipping over" is subjective and will cause variation in the tipping distance as measured by different testers.

Response: In ASTM F404-18, this language was revised to specify more clearly the point at which the chair "begins to tip over." This revision addresses the comment.

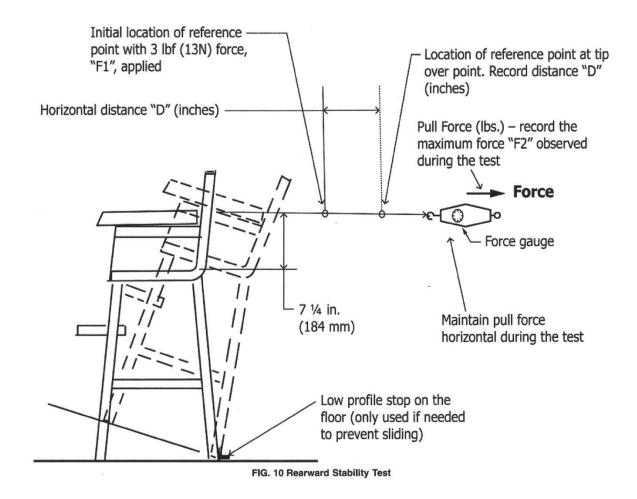
<u>Speed of Tipping Force Application Can Cause Variation</u>– The commenter points out that the rearward tipping force load application "must be reached in at least 5 seconds" and suggests that the load force varies depending on how quickly or slowly a particular tester applies this load, thus leading to a Stability Index variation of about 4 points.

Response: The ASTM F404-15 standard in effect at the time that the NPR was published indicated "Gradually apply the force over a period of 5 s." CPSC staff indicated in the NPR that they believed the language should reflect what is currently written in ASTM F404-18. In ASTM F404-18, the requirement instructs testers to "Gradually increase the horizontal force over a period of <u>at least 5</u> seconds and continue to pull the high chair rearward until the high chair reaches the point that it becomes unstable and begins to tip over." As in other ASTM tip-over standard requirements, the 5-second reference is not meant to be an upper time limit during which the force must be hurriedly applied, but instead, should be viewed as a suggestion of how slowly and steadily the load should be applied. If the force is applied sufficiently slowly, negligible dynamic force should factor into the equation, and maximum tip-over force readings

will be very consistent from test to test. The text of the standard has been changed to emphasize that the pull should be slow and steady.

<u>Confusing Rearward Tip-Over Test Set-Up Diagram</u> – The commenter indicates the wording, diagram, and calculation formula for rearward stability are confusing and flawed (confusing identifiers, crossed out words, multiple definitions of F).

Response: ASTM revised this diagram in the current standard to specify more clearly the various forces (F1 and F2 are now unique and clearly identified forces). Furthermore, the "Rearward Stability Index" calculation was also edited to clearly include the maximum F2 force (rather than the original, ambiguous force F). The new diagram and equation were included in ASTM F404-18 as Figure 10.



IV. Conclusion

ASTM F404-18 includes stability requirements that are essentially the same as the requirements proposed in the NPR, with some clarifications of the requirements, editorial

changes, and corrections. Staff agrees with all of these clarifications, changes, and corrections. The ASTM standard now requires that all high chairs have a Rearward Stability Index of at least 50. The Rearward Stability Index is based on a review of various stability requirements, the incident data, and testing of various models of high chairs, including high chairs reportedly involved in rearward tip over-incidents, and those not reported in rearward stability incidents. Staff believes that the Rearward Stability Index is adequate to address rearward stability issues. The stability requirements of ASTM F404-18 provide the same level of safety or exceed the level of safety provided by the stability test in the NPR.

The Commission also proposed in the NPR that a passive crotch restraint shall be installed on the high chair before shipment to consumers, ensuring that it is in place when the high chair is used. The ASTM high chair subcommittee placed that language into the F404-15 version of the standard. ASTM F404-18 retains that language.

TAB C: Human Factors Staff Response to NPR Comments, and Revised Warning Requirements for High Chairs (CPSIA Section 104)





UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION ROCKVILLE, MD 20850

MEMORANDUM

DATE: February 27, 2018

To:	Stefanie C. Marques, Ph.D., Project Manager, High Chairs Rulemaking, Division of Pharmacology and Physiology Assessment, Directorate for Health Sciences
THROUGH:	Joel R. Recht, Ph.D., Associate Executive Director, Directorate for Engineering Sciences
	Rana Balci-Sinha, Ph.D., Director, Division of Human Factors, Directorate for Engineering Sciences
FROM:	Timothy P. Smith, Senior Human Factors Engineer, Division of Human Factors, Directorate for Engineering Sciences
SUBJECT:	Human Factors Staff Response to NPR Comments, and Revised Warning Requirements for High Chairs (CPSIA Section 104)

BACKGROUND

The ASTM International (ASTM) voluntary standard ASTM F404, *Standard Consumer Safety Specification for High Chairs*, establishes requirements for high chairs in the United States and is intended to minimize the hazards associated with the reasonably foreseeable use and misuse, or abuse, of these products. ASTM developed this voluntary standard in response to incident data supplied by staff of the U.S. Consumer Product Safety Commission (CPSC).

On October 7, 2015, CPSC staff delivered to the Commission a draft notice of proposed rulemaking (NPR) for publication in the *Federal Register*, and a briefing package that assessed the effectiveness of the ASTM voluntary standard and presented staff's draft proposed rule for high chairs. In the package, staff recommended that the Commission publish an NPR that incorporates by reference ASTM F404 – 15, with revisions to improve requirements for rearward stability testing, warnings, and instructions. The NPR appeared in the *Federal Register* on November 9, 2015 (80 FR 69144).

The public comment period for the NPR closed on January 25, 2016, and CPSC received 18 comments. Nine comments addressed the product warning and instructional-literature requirements. Since publication of the NPR, ASTM has approved a new revision to the voluntary standard, ASTM F404 – 18. Some revisions to the voluntary standard were to the warnings and instructional literature requirements, and many of these address the changes proposed in the NPR as well as issues raised in the public comments. This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors

(ESHF), responds to the public comments on the NPR and discusses staff's recommendations for the draft final rule based on ASTM F404 - 18.

DISCUSSION

PUBLIC COMMENTS

The nine public comments related to the NPR warning and instructional-literature requirements address the following general topics: warning content, warning format, warning placement, instructional literature, and other miscellaneous issues. The comments and ESHF staff's responses to the comments are grouped below by these topics.

Warning Content

Five comments (CPSC-2015-0031-0009, -0015, -0016, -0017, and -0018) discuss issues related to warning content. One comment (-0016) expresses general support for warning content staff recommended in the NPR briefing package, particularly the statement: "Falls can happen quickly if child is not restrained properly." Another comment (-0017) expresses support for the warning content in ASTM F404 – 15, rather than the NPR, but does not provide specific arguments for why the ASTM content was superior. The remaining three comments discuss the following specific issues.

Comment: Two comments (-0009 and -0015) express concern over the increased length of the proposed warning, and one of these two (-0015) express concern about all warning information having to be on a single label.

Response: ESHF staff acknowledges that the warning proposed in the NPR is lengthier than the version that appeared in ASTM F404 – 15. However, staff's decision to group all warning statements together, and to add descriptive text to the warning, was not arbitrary. The reasons for staff's recommendations in the NPR briefing package were discussed in detail. In summary, staff noted the following content-related deficiencies in the warning requirements of ASTM F404 – 15 (see Smith, 2015, for more details):

- "Never leave child unattended," is one behavior in which consumers can engage to avoid the fall hazard, but ASTM F404 15 did not require this statement on the label that describes the fall hazard and its consequences.
- The description of the types of injuries that might be sustained from exposure to the hazard was vague. Research suggests that a more explicit description would improve consumer compliance with the recommended hazard-avoidance behavior.
- The warning did not describe or emphasize the speed with which incidents can occur. This information is important because consumers have reported that they might not need to use restraints on high chairs because they think they can notice and stop emerging incidents in time.

- The warning lacked a statement about the tray not being intended to restrain the child. This information is necessary because consumers have reported that they consider the tray, functionally, to be part of a high chair's restraint system, and some incidents suggest that consumers rely on the tray alone to restrain the child.
- The warning lacked a statement about properly adjusting the restraint system. Staff is aware of fall-related incidents involving children who were restrained, but the restraint system was loose, or otherwise allowed the child to wriggle out.

Staff acknowledges that consumers are more likely to read short warnings than lengthy ones entirely. However, brevity is only one factor that a warning designer must consider. A short warning is unlikely to be effective if it does not convey all key information pertaining to the hazards. Carefully selected additional content can enhance warning compliance. In addition, staff does not consider the warning that was proposed in the NPR to be unusually long or one that would dissuade consumers from reading the full content.

The current version of the voluntary standard, ASTM F404 – 18, continues to have requirements for two separate warnings, but includes revised warning content that is more consistent with the NPR's proposed requirements. For example, the secondary "conspicuous" warning statement originally read: "Never leave child unattended." This warning statement has been revised in ASTM F404 – 18 to read: "Stay near and watch child during use." Staff supports this change, because the statement, "never leave child unattended," is essentially a double-negative that requires consumers to infer what qualifies as "unattended" (see Smith, 2015). A more detailed explanation of the two required warnings and their content is discussed later in this memorandum, in the discussion of ASTM subcommittee activities and ASTM F404 – 18.

Comment: Two comments (-0009 and -0015) claim that referring to serious injuries more broadly, such as referring to "serious injury or death," is likely to be more effective than a specific and limited reference to "skull fractures." One of these comments (-0015) claims that the reference to skull fractures alone, may cause caregivers to ignore other, more frequent risks.

Response: The assertion that a warning that solely refers to "serious injury or death" is likely to be more effective than one that specifically references "skull fractures" is unsupported by warnings research. As staff discussed in the NPR briefing package, research has found that providing more explicit or detailed information in a warning increases warning effectiveness, and vividness increases message salience, which triggers one's motivation to act (see Smith, 2015). Thus, research indicates that a more explicit description of the injuries that have occurred will improve consumer compliance with the recommended hazard-avoidance behavior.

Although a vague reference to "serious injuries," alone, is unlikely to be very effective, staff is amenable to broadening the language to avoid the perception that skull fractures are the only types of serious injuries that might occur. The revised warning language that appears in ASTM F404 – 18 has taken this approach, and staff discusses this and the other relevant voluntary standard revisions later in this memorandum.

Comment: Two comments (-0015 and -0018) note that some high chairs do not have trays, so the warning statement about trays should not be applied to those products.

Response: ESHF staff agrees that the warning statement about trays (*i.e.*, "Tray is not designed to hold child in chair") should be used only on products that can use a tray. The warning specified in ASTM F404 – 18 now includes the tray-related warning statement in the product warning, as staff had recommended for the NPR, but only for high chairs that are designed to be used with a tray. Staff supports this change to the voluntary standard warning requirements.

Warning Format

Four comments (-0002, -0010, -0014,¹⁰ and -0015) discuss issues related to warning format and design. A summary of these issues appears below.

Comment: Four comments (-0002, -0010, -0014,¹⁰ and -0015) object to the requirement for "key words" to be in boldface because the phrase is undefined and open to interpretation. One comment (-0002) also points out that the warning content specified in the standard only need be addressed, not exactly as stated, so the standard could not identify specific key words to be in boldface. Three comments (-0010, -0014,¹⁰ and -0015) claim that "non-condensed" sans serif typeface is not clearly defined or understood, and may be misinterpreted or confusing. One comment (-0015) also states that some compressed and narrow typefaces are easy to read and should not be precluded. Two comments (-0010 and -0014¹⁰⁾ assert that how manufacturers or test laboratories will interpret the "note" that refers the reader to ANSI Z535.4 is unclear. These commenters also state that a reference to "instructions" in section 8.4.2 of the NPR requirements is incorrect because this section of the standard addresses warnings, not instructions. One comment (-0015) states that requiring the warning message to use black text on a white background conflicts with another requirement that the warning statements be in highly contrasting colors. The comment also states that the proposed formatting requirements are written so they apply to warning statements beyond those that are required by the standard. Two comments (-0010 and -0015) recommend that staff wait until the Ad Hoc Language Task Group ("Ad Hoc TG") completes its work related to general warning format requirements.

Response: Since the close of the public comment period, there have been several developments related to warning format and design. In short, the Ad Hoc TG, referenced in some of the public comments, finalized and published its recommendations for warning format, and these revisions address the public comments related to this issue. In addition, the warning requirements in the ASTM F404 voluntary standard were revised to be consistent with the Ad Hoc TG recommendations.

The Ad Hoc TG was formed to develop standardized language across ASTM juvenile products standards, and was developing recommendations for warning format when the High Chairs NPR was published. The author of this memorandum is a member of the Ad Hoc TG and also serves as the CPSC staff representative on the ANSI Z535 Committee on Safety Signs and Colors. ESHF staff collaborated with the other members of the Ad Hoc TG to develop recommendations for warning format that are based largely on the requirements of ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, while also accounting for the wide range and unique nature of durable nursery products, the concerns raised by industry representatives,

¹⁰ Comment -0014 addresses these issues indirectly, by expressing support for comment -0010.

and ESHF staff recommendations associated with durable nursery product rulemaking projects over the past several years.

The Ad Hoc TG recommendations should result in permanent, conspicuous, and consistently formatted on-product warning labels across juvenile-product standards, and the recommendations also address numerous warning-format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior among consumers. The recommendations include requirements for:

- content that is "easy to read and understand," not contradicted elsewhere on the product, and in English, at a minimum;
- conformance to the following sections of ANSI Z535.4 2011, American National Standard: Product Safety Signs and Labels:
 - ANSI Z535.4, sections 6.1–6.4, which include requirements related to safety alert symbol use, signal word selection, and warning panel format, arrangement, and shape;
 - ANSI Z535.4, sections 7.2–7.6.3, which include color requirements for each panel; and
 - ANSI Z535.4, section 8.1, which addresses letter style;
- minimum text size and text alignment; and
- the use of bullets, lists, outline, and paragraph form for hazard-avoidance statements.

The Ad Hoc TG recommendations also include recommended text for general labeling issues, such as labeling permanency, and content related to manufacturer contact information and date of manufacture. The latest version of the "Recommended Language Approved by Ad Hoc Task Group, Revision C" document is dated November 10, 2017, and is published in the "Committee Documents" section of the Committee F15 ASTM website.¹¹ As staff noted earlier, the ASTM F404 voluntary standard has adopted these recommendations, which can be seen in the Appendix at the end of this memorandum. ESHF staff supports these revisions to the voluntary standard. Regarding the specific issues identified in the public comments:

- *The requirement for "key words" to be in boldface.* ESHF staff agrees that the phrase "key words" is undefined, and that the allowance for warning content to be "addressed"¹² rather than exactly as stated means that specific key words could not be required to be in boldface unless those key words and phrases are explicitly required in the standard. Thus, ESHF staff agrees that the requirement to put key words in boldface is not appropriate.
- *Concerns surrounding "non-condensed" sans serif type*. Staff agrees that "noncondensed" type is not formally defined and that some typefaces that could be considered condensed may be adequately legible. The new ASTM F404 warning requirements do

¹¹ See <u>https://myastm.astm.org/KEY_DOCUMENTS/PDF_FILES/f150000adhoc5.pdf</u>. This link is accessible to Committee F15 members only.

¹² The warning requirements state that "address" means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

not prohibit the use of condensed type, but do include a note that recommends against the use of typefaces with large height-to-width ratios, which are commonly identified as "condensed," "compressed," "narrow," or similar. ESHF staff supports this revision.

- Confusion about how to interpret a "note" that references ANSI Z535.4. ASTM standards regularly use "notes" to offer informative suggestions that are not mandatory requirements for standards (see ASTM International, 2015, Section A27). Notes are used elsewhere, in other ASTM standards, so manufacturers and test laboratories should have no difficulty understanding their meaning or that they are not required for conformance to the standard. To staff's knowledge, manufacturers and test laboratories understand how notes are to be interpreted. Regardless, the warning format requirements in ASTM F404 18 no longer include a note that references ANSI Z535.4, because the warning format requirements and references to ANSI Z535.4 are now included within ASTM F404 18 itself.
- *The reference to "instructions" in section 8.4.2 of the NPR warning requirements.* Staff recognizes the commenter's concern, and the warning requirements in the new voluntary standard now refer to "marking and labeling." ESHF staff supports this revision.
- The potential conflict between the requirement for the warning message to use black text on a white background, given the requirement for warning statements to be in highly contrasting colors. The warning requirements in the voluntary standard have been revised to specify that the warning signal word panel must be black text on an orange background and that the message panel must be black text on a white background, or vice versa. These color requirements apply unless special circumstances preclude the use of these colors. In such circumstances, the warning text must contrast with the background.
- Concerns that the format requirements apply to warning statements beyond the statements required by the standard. Staff worked with the Ad Hoc TG to develop the final warning format recommendations, and the final agreed-upon recommendations do require that all warnings on the product must meet the format requirements specified in the standard. ESHF staff believes that these format requirements are important to capture consumer attention, improve readability, and increase hazard perception and avoidance behavior, and that any "warning" statement should meet these format requirements, at a minimum.

Warning Placement

Four comments (-0009, -0014, -0015, and -0016) discuss issues related to warning placement or location. One comment (-0016) supports the proposed placement requirements (*i.e.*, that the warning be visible while placing the child in the high chair and while the child is seated in the high chair). The remaining three comments do not support the proposed requirements and discuss the issues below.

Comment: The three comments that do not support the proposed warning placement requirements (-0009, -0014, and -0015) raised general concerns about limited available space

on some high chairs, especially models with low seatbacks. The comments argue that it would be difficult, and perhaps impossible, to meet the proposed placement requirements on these models, suggesting that they would have to be redesigned or discontinued. The comments emphasize the need for flexibility. One comment (-0014) argues that there is no clear evidence that a label that is visible when a child is in the high chair, or a secondary label if the seatback is not high enough, will actually change behavior.

Response: ESHF staff discussed in the NPR briefing package, and earlier in this memorandum, the rationale for combining the fall-related warning statements into a single warning. As staff discussed in the NPR briefing package, the ideal placement of this warning, which instructs consumers to always use and properly adjust the restraint system and to stay near and watch the child during use, would be in a location that allows the warning to be visible: (1) just before, or immediately after, the child is seated in the high chair; and (2) just before the caregiver would leave the seated child unattended in the high chair.

Public commenters and members of the ASTM High Chairs subcommittee have provided staff with examples of a variety of high chair models on the market that would have difficulty meeting the NPR's warning-placement requirement¹³; staff concludes that the commenters' concerns are valid. Staff agrees that the ideal placement of the NPR warning, in a location that is visible while placing the child in the high chair and after the child is seated in the high chair, may be challenging—perhaps impossible—for some high chair designs to meet, due to space limitations. Moreover, a requirement for the warning to be visible from the front of the high chair while the child is seated¹⁴ would demand some form of test to assess objectively whether a particular location would conform to the requirement. The range of potential occupants, which includes infants as well as children up to 3 years old, would make it challenging to develop such a test.

Given these issues, ESHF staff agrees that the placement requirements for the fall-related warning should state that the warning needs to be visible to the consumer only while placing the child into the high chair, as required in ASTM F404 – 18. This requirement will allow consumers to see the warning, and thus, provide consumers with information about the hazard, its consequences, and the key actions that must be taken or avoided to avert the hazard, immediately before this information is needed. Although the warning would not necessarily be visible once the child is seated in the high chair, a warning that is visible while placing a child into the high chair (*e.g.*, on the front of the seatback) would likely be visible to the consumer when the high chair is not in use, as well, meaning that consumers most likely would be exposed to the message at various times beyond the specific instances in which the child is being placed into the high chair (*e.g.*, when cleaning or moving the high chair).

¹³ For example, during a meeting of the Ad Hoc TG on January 27, 2016, members of the Ad Hoc TG, some of whom are members of the ASTM High Chair subcommittee, provided staff with numerous examples of products that would have difficulty meeting certain format requirements that were under consideration. Staff's meeting log can be found at <u>https://www.cpsc.gov/s3fs-</u>

<u>public/pdfs/foia_012716MeetingoftheASTMAdHocWordingTaskGroup.pdf</u>. In addition, during a meeting of the ASTM High Chairs warning task group on August 1, 2016, task group members presented and discussed examples of high chair designs that might pose difficulties because of limited space.

¹⁴ Staff refers to the front of the high chair because, for a warning to be visible while the caregiver is placing the child in the high chair and while the child is seated in the high chair, the warning most likely would have to be visible to a caregiver facing the front of the high chair.

Like ASTM F404 – 15, the current version of the voluntary standard, ASTM F404 – 18, also requires a "conspicuous" secondary warning statement. As staff previously noted earlier, the voluntary standard was revised to change the language of the warning statement from "Never leave child unattended," to "Stay near and watch child during use." Staff supports this change to the warning statement for the reasons described earlier. In addition, NPR commenters and ASTM High Chair subcommittee members have pointed out that this warning statement applies to other hazards besides falls, such as choking hazards. Staff agrees and believes that this statement alone, placed in a conspicuous location, will serve as a general reminder to remain with a child who is in the high chair. Because the warning statement must be "conspicuous," it must be visible to the consumer while the child is still seated in the high chair. Thus, such a warning statement may be more likely to be seen by a consumer who is about to leave the seated child than if the statement were included as part of the warning that must be visible while placing the child into the high chair. More discussion on this issue appears later in this memorandum, when discussing ASTM subcommittee activities and ASTM F404 – 18.

Instructional Literature

Three comments (-0010, -0014,¹⁰ and -0015) discuss issues related to the NPR instructionalliterature requirements. These comments discuss the issues below.

Comment: All three comments (-0010, -0014,¹⁰ and -0015) express confusion over the NPR's proposed color requirements for instructional literature. Two comments (-0010 and -0014¹⁰) state that the requirements appear to be contradictory, initially requiring the warning statements to be in contrasting colors, but also stating that the colors must meet the same requirements as product warnings (i.e., red, orange, or yellow). The remaining comment (-0015) points out that manuals are often printed in two colors and that the proposed color requirements take away the flexibility to use other colors. The comment also seems to interpret the requirements to mean that if any color other than white is used, it must be red, orange, or yellow.

Response: Staff understands the commenters' confusion about the NPR's proposed color requirements for instructional literature, and agrees that the language might be unclear or open to interpretation. Staff also agrees that manufacturers should be provided with some flexibility regarding the colors used for instructional literature.

Since publication of the NPR, the Ad Hoc TG has developed, balloted, and published new, recommended requirements for formatting warnings in instructional literature. These requirements can be found in the latest revision to the "Ad Hoc Approved Language" document, referenced earlier¹¹; ASTM F404 – 18 includes instructional literature requirements that are based on these recommendations. ESHF staff continues to be involved in Ad Hoc TG activities and believes that the requirements that have been adopted by the current ASTM voluntary standard for high chairs are more appropriate than the analogous requirements in the high chairs NPR. These revised requirements, which can be seen in the Appendix at the end of this memorandum, also fully address the concerns raised by public commenters. For example, section 9.3 of ASTM F404 – 18 requires warnings in instructional literature to meet the format requirements specified for product warnings, "except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 need not be applied." Section 6.4 of ANSI Z535.4 specifically relates to the distinctiveness of the warning on the product itself, and therefore, this section is not relevant to

instructional literature. Sections 7.2 through 7.6.3 are purely color requirements, meaning that the warnings in instructional literature do not have to meet the same color requirements as product labels. However, section 9.3 of ASTM F404 – 18 also specifies: "the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the warnings shall contrast with the background of the instructional literature." Thus, the warnings must stand out within the instructional literature.

Comment: Two comments (-0010 and -0014¹⁰) claim that the sentence, "Additional warnings similar to the statements included in this section shall also be included," in the NPR requirements, is unclear and confusing.

Response: The sentence called out by the comment and attributed to the NPR was not revised by staff, but rather, was reproduced verbatim from section 9.2 of ASTM F404 – 15. However, as part of the subcommittee's efforts to revise the instructional literature section to be consistent with the recommendations of the Ad Hoc TG, this statement was deleted from the F404 – 18 version of the standard and replaced with a new section (9.3) that states: "The instructions shall address the following additional warnings." ESHF staff believes that this language is clearer, and therefore, staff supports this revision.

Comment: Two comments (-0010 and -0014¹⁰) argue that is it unclear how the note that references ANSI Z535.6 would be interpreted by manufacturers and test laboratories.

Response: As staff previously noted, regarding the on-product warning format, ASTM standards regularly use "notes" to offer informative suggestions that are not mandatory requirements for standards, and notes are used in other ASTM standards. Thus, manufacturers and test laboratories should have no difficulty understanding the meaning of notes, or understanding that what is stated in a note is not required for conformance to the standard. Furthermore, the voluntary standard's new requirements for the formatting of warnings in instructional literature were developed by the Ad Hoc TG, which includes representatives from various ASTM subcommittees, including many subcommittee chairpersons. The Ad Hoc TG agreed to include in these requirements the note that refers the reader to ANSI Z535.6, *American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials*, "[f]or additional guidance on the design of warnings for instructional literature."

Miscellaneous

Six comments (-0005, -0010, -0014,¹⁰ -0015, -0016, and -0017) discuss miscellaneous issues related to staff's proposed warning and instructional-literature requirements. These are detailed below.

Comment: Three comments (-0010, -0014,¹⁰ and -0017) claim that there is no justification to revise the ASTM F404 – 15 warning requirements. Two of these comments (-0010 and -0014¹⁰) note that the requirements were just adopted, so there is no evidence that they are ineffective.

Response: The question considered by CPSC staff when examining and assessing an ASTM voluntary standard subject to rulemaking under section 104 of the CPSIA is not whether the

current requirements are merely adequate, but rather, whether more stringent performance requirements and warning label requirements would further reduce the risk of injury.¹⁵ Although the warning requirements in ASTM F404 – 15 had been adopted only recently when the NPR briefing package was published, staff considers additional or more stringent requirements, if staff believes that these requirements are appropriate, are supported by scientific and technical literature, and would further reduce the risk of injury. Staff refers the commenters to the ESHF staff memorandum in the NPR briefing package (Smith, 2015). The memorandum explains, in detail, the rationale behind staff's recommended changes. Many of these requirements have been adopted, at least in part, in the new, approved version of the standard, ASTM F404 – 18.

Comment: One comment (-0005) claims that "a few of the big warning labels" should be enough to address the hazards associated with high chairs.

Response: Safety and warnings literature consistently identify a classic hierarchy of approaches that one should follow to control hazards. Warning about hazards is viewed universally as less effective at eliminating or reducing exposure to hazards than designing the hazard out of a product, or guarding the consumer from the hazard; therefore, the use of warnings is lower in the hazard-control hierarchy than the other two approaches (Laughery & Wogalter, 2011; Vredenburgh & Zackowitz, 2005; Wogalter, 2006; Wogalter & Laughery, 2005). Warnings are less effective because they do not prevent consumer exposure to the hazard. Rather, warnings rely on educating consumers about the hazard. In addition, to be effective, warnings rely on consumers behaving consistently, regardless of situational or contextual factors that influence precautionary behavior, such as fatigue, stress, or social influences. Thus, one should view warnings as a "last resort" measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher level hazard-control efforts are not feasible.

Comment: One comment (-0016) recommends the addition of pictograms to convey the hazard more effectively and to avoid language barriers that might affect comprehension.

Response: ESHF staff acknowledges that well-designed graphics might be useful to convey the fall hazard associated with high chairs. However, the design of effective graphics can be difficult. Some seemingly obvious graphics are poorly understood and can even give rise to interpretations that are opposite the intended meaning (cf. Johnson, 2006; Wogalter, Silver, Leonard, & Zaikina, 2006). Thus, at this time, staff recommends permitting, but not mandating, supporting graphics for high chair warnings. Staff may recommend action in the future if we conclude that graphical symbols are needed to further reduce the risk of injury associated with these products.

Comment: One comment (-0015) notes that the proposed warning requirements address high chairs that have seats that are also used as a seat in a stroller, but there are similar issues with high chairs whose seats also function as a booster seat.

¹⁵ Section 104(b) of the CPSIA requires the Commission to promulgate consumer product safety standards for durable infant or toddler products that are substantially the same as applicable voluntary standards, or more stringent than such voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

Response: The manufacturer of a product whose seat can function as a seat for a high chair and a booster seat would be required to make sure the product meets both standards, and staff believes that manufacturers are capable of meeting the requirements of both standards. Thus, staff does not believe that revisions to the proposed requirements are needed at this time.

ASTM SUBCOMMITTEE ACTIVITIES AND ASTM F404 – 18

Since publication of the NPR, the ASTM Subcommittee on High Chairs balloted and approved revised requirements for high chairs. The current, approved version of the voluntary standard, ASTM F404 – 18, includes revised requirements for product warnings and instructional literature.

Marking and Labeling

ASTM F404 – 18 continues to include requirements for two on-product warnings: one that must be visible to the caregiver when placing the child into the high chair, and one that must be "conspicuous," as defined by the standard; that is, visible from any one position around the high chair, but not necessarily all positions, while the child is seated in the high chair. The contents of these warnings, however, have been revised to reflect much of what was proposed in the NPR.

The following table shows the required content for the NPR warning and for the fall-related warning specified in ASTM F404 – 18 that must be visible to the caregiver when placing the child into the high chair: 16

NPR	ASTM F404 – 18
Children have suffered skull fractures after	FALL HAZARD: Children have suffered severe
falling from high chairs. Falls can happen	head injuries including skull fractures when
quickly if child is not restrained properly.	falling from high chairs. Falls can happen
	suddenly if child is not restrained properly.
 Always use restraints, and adjust to fit 	
snugly. Tray is not designed to hold child	 Always use restraint system and adjust to
in chair.	fit snugly.
• Stay near and watch your child during use.	• Tray is not designed to hold child in chair.

As is evident from the table, the ASTM F404 - 18 version of the warning is very similar to the NPR warning. Most differences are intentional changes made by the subcommittee to address concerns raised in the public comments. The most significant differences relative to the NPR are:

- the addition of the phrase "FALL HAZARD" at the beginning of the warning;
- the reference to severe head injuries, with skull fractures cited as one type of severe head injury; and
- the absence of the statement: "Stay near and watch your child during use."

 $^{^{16}}$ Per ASTM F404 – 18, high chairs that are not designed to be used with a tray do not require the final, tray-related statement.

Although ESHF staff does not believe that the phrase "FALL HAZARD" is necessary, staff does not object to its presence in ASTM F404 – 18. Furthermore, as discussed earlier in this memorandum, in response to the public comments, staff is amenable to broadening the language related to the consequences of hazard exposure to avoid the perception that skull fractures are the only types of serious injuries that might be sustained. Thus, staff does not object to the revised language that appears in ASTM F404 – 18, which states: "Children have suffered severe head injuries including skull fractures when falling from high chairs."

The question of whether the fall-related warning should include the statement, "Stay near and watch your child during use," is less clear. ESHF staff previously pointed out that the fall-related warning should be comprehensive and that this statement describes a key step that consumers can take to avoid the fall hazard (see Smith, 2015). However, for various reasons, discussed below, staff concludes that the addition of this statement to the fall-related warning might not reduce the risk of injury.

As staff previously noted, ASTM F404 – 18 requires a secondary "conspicuous" warning. This warning not only warns about unattended use, but the language of the warning was revised from "Never leave child unattended" (ASTM F404 – 15), to "Stay near and watch child during use." This statement is nearly identical to the language proposed in the NPR,¹⁷ and is the same statement that is missing from the fall-related warning. Thus, ASTM F404 – 18 *does* require this warning statement to appear on the product, just not necessarily in the same location as the fall-related warning. Instead, the fall-related warning focuses on the importance of using and properly adjusting the restraint system, which often goes unused by consumers.

The "Stay near and watch child during use" warning statement is required to be "conspicuous," which the standard defines as having to be visible, when the child is seated in the high chair, from any one position around the high chair, but not necessarily from all positions around the high chair. Staff recognizes that the "conspicuous" definition could permit the warning to be located on the back of the high chair, which might not be as visible during use. However, the definition also requires the warning to be visible even while the child is seated in the high chair. The fall-related warning, by contrast, is not required to be visible while the child is seated, so it would likely not be available to consumers when they are about to leave the child. In addition, as staff noted earlier in its response to public comments, the recommendation to stay near and watch the child during use applies to various hazards, not only falls. Thus, this warning statement alone, in a conspicuous location, can function as a general reminder to remain with a child who is in the high chair.

As is evident from the discussion above, there are several competing factors that influence the effectiveness of the overall warning system. Taken as a whole, staff finds it difficult to conclude that the addition of the "Stay near and watch child during use" statement to the fall-related warning would reduce the risk of injury associated with high chairs. Thus, staff recommends that the Commission adopt the warning content requirements of ASTM F404 – 18, without modifications. Staff can continue to monitor high chair-related incidents and consider

¹⁷ The warning statement is missing the word "your" before "child." The ASTM subcommittee argued that the occupant of the high chair would not necessarily be the reader's child, so "your" was not appropriate.

recommending future revisions, such as the addition of the "Stay near and watch child during use" statement to the fall-related warning or a revision to the "conspicuous" definition, if the data suggest that such changes are warranted.

Regarding warning format, as staff noted earlier in this memorandum, ASTM F404 – 18 includes revised warning format requirements that are consistent with the recommendations of the Ad Hoc TG. Staff supports these revisions. Numerous public comments relate to warning format, so staff refers the reader to the earlier discussion of this issue in staff's responses to the public comments.

Instructional Literature

ASTM F404 – 18 includes revisions to the format requirements for warnings in instructional literature that are consistent with the most current recommendations of the Ad Hoc TG. As discussed earlier in this memorandum, in response to public comments on the NPR, staff has concluded that these requirements are more appropriate than the analogous requirements that appeared in the NPR for high chairs and address the NPR public comments.

CONCLUSIONS

ESHF staff has reviewed and considered the public comments received on the NPR for high chairs, provided responses to these comments, and recommends that the Commission adopt the warning and instructional literature requirements in the current voluntary standard for high chairs, ASTM F404 – 18, without changes. The Appendix at the end of this memorandum shows the differences between the warning and instructional requirements specified in the NPR and those in ASTM F404 – 18.

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APPENDIX: COMPARISON OF NPR AND ASTM F404 – 18 REQUIREMENTS

Section 8: Marking and Labeling Requirements:

NPR Requirements	ASTM F404 – 18	Rationale
 8.4 Warning Statements—Each Product Shall Have Warning Statements: 8.4.1 The warnings shall be easy to read and understand and be in the English language at a minimum. 8.4.2 Any labels or written instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer. 8.4.3 The warning statements shall be conspicuous, in highly contrasting color(s) (e.g., black text on a white background), permanent, and in non-condensed sans serif style type. 	 8.4 Warning Design for Product: 8.4.1 The warnings shall be easy to read and understand and be in the English language at a minimum. 8.4.2 Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer. 8.4.3 The warning statements shall be permanent. 	The version in ASTM F404 – 18 is consistent with the latest Ad Hoc TG recommendations. In addition, these requirements are substantially the same as those in the NPR, except for some of the NPR requirements in 8.4.3, which are addressed later in ASTM F404 – 18.

NPR Requirements

Rationale

8.4.4 Each warning statement or group of warning statements shall be preceded by the Safety Alert Symbol "**A**" and the signal word "WARNING" in bold uppercase letters. If warnings are placed directly under or adjacent to one another, then the safety alert symbol and the signal word WARNING, need to be displayed only once. The Safety Alert Symbol "**A**" and the signal word "WARNING" shall not be less than 0.2 in. (5 mm) high and the remainder of the text shall be in characters whose uppercase shall not be less than 0.1 in. (2.5 mm) high. The height of the safety alert symbol shall equal or exceed the signal word height.

8.4.5 The safety alert symbol "A" and the signal word "WARNING" shall be in contrasting color to the background and delineated with solid black line borders. The background color behind the safety alert symbol "**A**" and the signal word "WARNING" shall be orange, red, or yellow, whichever provides best contrast against the product background. The signal word "WARNING" and the solid triangle portion of the safety alert symbol "A" shall be black. The exclamation mark of the safety alert symbol "**A**" shall be the same color as the background. The remainder of the text shall be black, with key words highlighted using boldface, on a white background surrounded by a solid black line border. This text also shall be left-justified, in upper- and lowercase letters (i.e., sentence capitalization), and in list or outline format, with precautionary statements indented from hazard statements and preceded with bullet points. An example label in the format described in this section is shown in Fig. X.

NOTE: For additional guidance on the design of warnings, please refer to ANSI Z535.4, American National Standard for Product Safety Signs and Labels.

8.4.4 The warnings shall conform to ANSI Z535.4–2011, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.

8.4.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace "should" with "shall."

8.4.4.2 In section 7.6.3, replace "should (when feasible)" with "shall."

8.4.4.3 Strike the word "safety" when used immediately before a color (for example, replace "safety white" with "white").

8.4.5 The Safety Alert Symbol **A** and the signal word "WARNING" shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose uppercase shall be at least 0.1 in. (2.5 mm) high.

NOTE 14—For improved warning readability, typefaces with large height-to-width ratios, which are commonly identified as "condensed," "compressed," "narrow," or similar should be avoided.

8.4.6 Message Panel Text Layout:

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

NOTE 15—Left aligned means that the text is aligned along the left margin, and, in the case of multiple columns of text, along the left side of each individual column. Please see Fig. X1.1 in Appendix X1 for examples of left aligned text.

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

8.4.7 An example in the format described in this section is shown in Fig. 17.

The version in ASTM F404 – 18 is consistent with the latest Ad Hoc TG recommendations, which are substantially the same as the NPR requirements, overall, with some changes to address public comments and to clarify and detail the requirements, or to be consistent with ASTM-standard formatting practices (*e.g.*, the full name of the ANSI standard is not included in the requirements, but is included in Section 2, *Referenced Documents*). See staff's discussion of these requirements in the memorandum.

NPR Requirements	ASTM F404 – 18	Rationale	
8.4.6 The warning statements shall be in a location that is visible by the caregiver while placing the occupant into the highchair in each of the manufacturer's recommended use positions.	 8.5 Warning Statements—High chairs shall have warning statements to address the following, at a minimum. 8.5.1 The warning statement in this section shall be in a location that is visible by the caregiver while placing the occupant into the high chair in each of the manufacturer's recommended use positions but not necessarily visible when the occupant is in the high chair. NOTE 16—Address means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented. 	The version in ASTM F404 – 18 is consistent with revisions considered by ESHF staff to address public comments on warning placement.	
 8.4.7 High chairs that do not have a seating component that is also used as a seating component of a stroller, shall address the following warning statements: Children have suffered skull fractures after falling from high chairs. Falls can happen quickly if child is not restrained properly. Always use restraints, and adjust to fit snugly. Tray is not designed to hold child in chair. Stay near and watch your child during use. 	 8.5.1.1 High chairs that do not have a seating component that is also used as a seating component of a stroller shall address the following warning statement: "FALL HAZARD: Children have suffered severe head injuries including skull fractures when falling from high chairs. Falls can happen suddenly if child is not restrained properly. Always use restraints, and adjust to fit snugly." 	The version in ASTM F404 – 18 is largely consistent the NPR requirements, with minor changes, except for the missing warning statement about staying near the child during use. However, this statement appears elsewhere on the product, as a separate warning. See staff's discussion of this issue in the memorandum.	
8.4.8 High chairs that have a seating component that is also used as a seating component of a stroller shall use the warning statements as specified in Consumer Safety Performance Specification F833, subsections 8.2.2.1 and 8.2.2.2, in place of the warning statements in 8.4.7.	 8.5.1.2 High chairs that have a seating component that is also used as a seating component of a stroller shall use the warning statements as specified in 8.2.2.1 and 8.2.2.2 of the version of the standard that is incorporated by reference in 16 CFR Part 1227 Safety Standard for Carriages and Strollers, in place of the warning statements in 8.5.1.1. 8.5.2 For high chairs that are designed to be used with a tray, include the additional warning in this section: Tray is not designed to hold child in chair. 8.5.3 High chairs shall address the warning in this section and this warning shall be conspicuous: 8.5.3.1 • Stay near and watch child during use. 	The version in ASTM F404 – 18 is consistent with revisions considered by ESHF staff to address public comments on warning placement.	

NPR Requirements

ASTM F404 – 18

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Rationale
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Children have suffered skull fractures after falling from high chairs. Falls can happen quickly if child is not restrained properly. • Always use restraints, and adjust to fit snugly. Tray is not designed to hold child in chair. • Stay near and watch your child during use.	A WARNING FALL HAZARD: Children have suffered severe head injuries including skull fractures when falling from high chairs. Falls can happen suddenly if child is not restrained properly. • Always use restraints, and adjust to fit snugly. • Tray is not designed to hold child in chair.	The version in ASTM F404 – 18 reflects the appropriate example warning based on the new requirements, discussed earlier. Note that the example warnings are not shown in actual size.
Fig. X. Label Format Example	FIG. 17 Example – Warning Statement Text Layout	
(No requirement)	<section-header><section-header><section-header><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></section-header></section-header></section-header>	The voluntary standard's addition of a figure showing examples of left-aligned text is beyond what was required in the NPR. Note that this figure is not shown in actual size.
	<section-header><section-header><section-header><section-header><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></section-header></section-header></section-header></section-header>	
	FIG. X1.1 Examples of Left Aligned Text	

NPR Requirements	ASTM F404 – 18	Rationale
 9.2 The instructions shall contain the warnings as specified in 8.4. Additional warnings similar to the statements included in this section shall also be included. These required warning statements shall meet the requirements described in 8.4, except for the color requirements (e.g., the background of the signal word panel need not be orange, red, or yellow). However, the warning statements still must be in highly contrasting color(s) (e.g., black text on a white background), and if color is used, those colors must meet the color requirements specified in 8.4. NOTE: For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials. 	 9.2 The instructions shall contain the applicable warnings for the high chair design specified in 8.5.1.1 or 8.5.1.2. The instructions shall also include the warnings specified in 8.5.2 and 8.5.3.1. 9.3 The instructions shall address the following additional warnings. 9.4 The warnings in the instructions shall meet the requirements specified in 8.4.4, 8.4.5 and 8.4.6, except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the warnings shall contrast with the background of the instructional literature. NOTE 17—For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination. 9.5 Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer. NOTE 18—For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6. 	The version in ASTM F404 – 18 is consistent with the latest Ad Hoc TG recommendations, which are substantially the same as the NPR requirements, overall, with some changes to address public comments and to clarify and detail the requirements, or to be consistent with ASTM-standard formatting practices (<i>e.g.</i> , the full name of the ANSI standard is not included in the requirements, but is included in Section 2, <i>Referenced Documents</i>). See staff's discussion of these requirements in the memorandum. Note that subsections 9.3.1 and 9.3.2 of ASTM F404 – 18 list the additional warnings referenced in 9.3. Aside from renumbering, these subsections are identical to subsections 9.2.1 and 9.2.2 in ASTM F404 – 15, to which the NPR referenced. They are not included here for simplicity and to avoid confusion, because the NPR did not include changes to those requirements.

TAB D: Final Regulatory Flexibility Analysis of the Draft Final Rule for High Chairs and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the High Chairs Standard





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

Memorandum

Date: February 27, 2018

- TO : Stefanie C. Marques, Ph.D. Project Manager, High Chairs Division of Pharmacology and Physiology Assessment Directorate for Health Sciences
- THROUGH: Gregory B. Rodgers, Ph.D. Associate Executive Director Directorate for Economic Analysis

Robert L. Franklin Senior Staff Coordinator Directorate for Economic Analysis

- FROM : Jill L. Jenkins, Ph.D. Economist Directorate for Economic Analysis
- SUBJECT : Final Regulatory Flexibility Analysis of the Draft Final Rule for High Chairs and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the High Chairs Standard

I. Introduction

On November 9, 2015, the Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking (NPR) in the *Federal Register* (FR) (80 FR 69144).¹⁸ The proposed rule incorporated by reference the then current voluntary ASTM International (ASTM) standard for high chairs (F404-15), with modifications to the rearward stability test procedure and the requirements for warning labels and instructional literature. Since the NPR, ASTM has published an updated version of the standard, F404-18, which includes the rearward stability test modifications and the majority of the warning label and instructional literature changes proposed by the Commission.¹⁹ Staff now recommends incorporating by reference ASTM F404-18 without modifications.

¹⁸ A correction to the rearward stability requirement was published on January 21, 2016 (81 FR 3354).

¹⁹ For more, see memoranda from John Murphy, Division of Mechanical and Combustion Engineering, Directorate for Engineering Sciences, dated February 8, 2018, Subject: Engineering Update and Response to Comments: High Chairs Draft Final Rule Briefing Package and Timothy P. Smith, Division of Human Factors, Directorate for

This memorandum evaluates the potential economic impact of adopting ASTM F404-18 as a mandatory rule on small entities, including small businesses, as required by the Regulatory Flexibility Act (RFA).²⁰ Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis (FRFA) when the Commission promulgates a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained below, staff cannot rule out a significant economic impact for 21 of the 43 (49 percent) known small suppliers of high chairs to the U.S. market. Accordingly, we have prepared a FRFA.

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

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

II. The Product

A high chair is defined in ASTM F404-18, *Standard Consumer Safety Specification for High Chairs*, as "a free standing chair for a child up to 3 years of age which has a seating surface more than 15 in. above the floor and elevates the child normally for the purposes of feeding or eating." It "may be sold with or without a tray and may be height adjustable to higher or lower use positions. It may also include a recline position for infants not able to sit up unassisted." High

Engineering Sciences, dated February 12, 2018, Subject: Human Factors Staff Response to NPR Comments, and Revised Warning Requirements for High Chairs (CPSIA Section 104). ²⁰ 5 U.S.C. §§ 601-612.

chairs vary widely in price; they can be purchased for as little as \$35, but can also cost as much as \$1,500.

The standard does not cover booster seats, which are subject to a voluntary ASTM standard (F2640-17^{ϵ 1}).²¹ The high chair standard also does not cover portable hook-on chairs, for which the Commission has published a mandatory standard.²²

Some high chairs fall into more than one product category. For example, a few firms produce high chairs that can recline to a flat or nearly flat position meant to enable napping. These products may also be considered bassinets or inclined sleepers, respectively. Recently, CPSC staff has become aware of a few high chair models that include a separate reclining seat that can be inserted onto the high chair base to create a reclining high chair that have entered the U.S. market. Also, some high chairs have seats that can be removed to act as a booster seat, and one firm makes a stroller where the seat can be used as a high chair when attached to a separate stand accessory. These products would be required to meet the draft final rule when placed in a high chair configuration.

As discussed in the initial regulatory flexibility analysis (IRFA), some suppliers produce high chairs intended for use predominately in restaurants. These food-service high chairs are also available to consumers for purchase; although as mentioned by one commenter (and substantiated by additional staff research) most often this is through second- or third-parties rather than the original manufacturer or importer. So, some food-service high chairs may be found in homes. Further, consumers use food-service high chairs in establishments open to the public, making them a consumer product under the Consumer Product Safety Act (CPSA).²³ As part of the IRFA, staff requested public comments about including food-service high chairs in the mandatory high chairs rule. After reviewing these comments, staff continues to recommend that food-service high chairs be included in the mandatory rule. A discussion of the consideration staff gave to excluding food-service high chairs from the rule as a way to reduce the impact on small entities, as well as the reasons why this alternative was not selected, is included in Section VIII. Staff's response to these public comments can be found in the briefing memo.²⁴

III. Objectives of the Draft Final Rule

The objective of the draft final rule is to comply with the CPSIA and address the risk of injury associated with high chairs. Section 104 of the CPSIA requires the CPSC to promulgate a mandatory standard for high chairs that is substantially the same as the voluntary standard or more stringent than the voluntary standard if the Commission determines that more stringent

²¹ CPSC has also published an NPR for booster seats in the *Federal Register* (82 FR 22925). The public comment period closed on August 2, 2017.

²² 16 C.F.R. part 1233.

²³ 15 U.S.C. §§ 2051-2089.

²⁴ Memorandum from George A. Borlase and Stephanie C. Marques, Ph.D., Office of Hazard Identification and Reduction, dated February 8, 2018, Subject: Infant High Chairs, Section 104 of the Consumer Product Safety Improvement Act of 2008, Final Rule.

requirements would further reduce the risk of injury associated with the product.²⁵ Based on National Electronic Injury Surveillance System (NEISS) injury estimates²⁶ and data on the number of high chairs in use from CPSC's Durable Nursery Product Exposure Survey (DNPES),²⁷ staff found that the risk associated with high chair use in homes is approximately 11.73 emergency department-treated injuries per 10,000 high chairs in use annually [(8,317 injuries \div 7.09 million high chairs in use in U.S. households) x 10,000]. CPSC staff worked closely with ASTM to ensure that the requirements, test procedures, warning labels, and instructional literature in ASTM F404-18 address the hazard patterns identified in the incident data presented in the Directorate for Epidemiology memo.²⁸

IV. Issues Raised by Public Comments

The IRFA requested public feedback on three major questions.

1. What actions might firms take to bring their high chairs into compliance with the proposed rule? What costs might be associated with those actions?

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

2. <u>Should food-service high chairs be included in the mandatory standard and, if so, to what extent?</u>

Staff received three comments on the inclusion of food-service high chairs: two from suppliers and one from consumer advocates. The food-service high chair suppliers reiterated several points discussed in the IRFA, including the level of supervision in restaurants versus homes and the design differences between homeuse and food-service high chairs. They pointed out that the voluntary standard was created to specifically address high chair use in the home environment and that some food-service "high chairs have no point of sale opportunity for consumers," although as noted by the consumer advocates (and in the IRFA), food service high chairs are available to the public. One of the firms that manufactures an ASTM-compliant food-service high chair said that it has received numerous complaints regarding that high chair. Both firms agreed that labels and information at purchase points warning against using food-service high chairs in the home are appropriate. One also suggested educational efforts in restaurants to encourage safe food-service high chair use, while the other recommended that a commercial high chair standard be developed. The consumer advocates said that

²⁵ High chairs were specifically mentioned as a durable infant or toddler product in section 104(f)(2).

²⁶ Memorandum from Risana Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated October 17, 2017, Subject: High Chair-Related Deaths, Injuries, and Potential Injuries Reported Between January 1, 2015 and September 30, 2017.

²⁷ Melia, K.L. and J.L. Jenkins (November 2014). Durable Nursery Products Exposure Survey (DNPES): Final Summary Report. U.S. Consumer Product Safety Commission, prepared by Westat.

²⁸ Chowdhury, 2017.

warning labels and some select requirements would be appropriate, given the limited evidence of restaurant incidents.

Staff agrees that there are some differences between food-service high chairs and high chairs intended for home-use and that few food-service high chairs are sold directly to consumers by their manufacturer or importer. However, food-service high chairs are sold to the public through second and third parties. Additionally, consumers are exposed to similar risks with high chairs when they are used in restaurants. Since the NPR was published, staff analyzed NEISS data related to high chair use in restaurant settings and now estimates that there were 1,600 injuries over a six year period, with hazard patterns similar to those found in home-use settings.

For these reasons, and because section 104 of the CPSIA requires that a mandatory standard be "substantially the same as" or "more stringent" than the voluntary standard (which applies to food-service high chairs), the draft final rule does not exclude or adopt different requirements for food-service high chairs as a result of these comments.²⁹

3. What is the appropriate effective date for the proposed rule?

Staff received two comments on CPSC's proposed 6-month effective date. One comment, submitted by three consumer advocate groups, supported the 6-month effective date. A second comment, submitted by a group representing juvenile product manufacturers, requested a one-year effective date which they feel is necessary to implement the proposed warning labels and instructional literature changes in an "orderly" manner.

Staff believes that a longer effective date would reduce the impact on firms, some of whom may not be aware of the ASTM voluntary standard or the CPSC high chairs rulemaking. Therefore, staff is recommending a 12-month effective date. Again, the full comment summary and response is part of the briefing memo³⁰ and additional discussion of this alternative is part of Section VII.

V. **Requirements of the Draft Final Rule**

The draft final rule would incorporate by reference the voluntary standard for high chairs (F404-18) with no modifications. If approved, it would become a mandatory product safety rule under the CPSIA. If it becomes a mandatory standard, firms whose high chairs do not comply will need to evaluate their products, determine what changes would be required to meet the standard, and decide how to proceed. Noncompliant products would need to be removed from the U.S. market or modified to meet the mandatory standard.

²⁹ The complete comment and response is included in the briefing memorandum from Borlase and Marques, 2018. ³⁰ Borlase and Marques, 2018.

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

A. ASTM F404-18

The draft final high chair rule incorporates by reference ASTM F404-18 without modifications. The requirements of ASTM F404-15 (upon which the proposed rule was based) were outlined in the IRFA.³¹ Several versions of the voluntary standard have been passed between F404-15 and F404-18. The fundamental requirements remain similar for each, however. For this reason, the requirements of the voluntary standard are not outlined again here. However, ASTM F404-18 now includes several changes that could, in conjunction with other requirements, result in significant redesign costs for small firms with noncompliant high chairs. ASTM F404-18 includes the rearward stability test changes proposed by the Commission in the NPR and a new stability test to address children climbing into a high chair.

Also worth noting are the modified requirements for product warnings and instructional literature, addressing, in part, public comments submitted in response to the high chairs NPR. In particular, ASTM F404-18 requires that the warning label be visible when the child is put into the high chair (but not also when the child is in the high chair, which the NPR proposed).³² This reduces the impact on suppliers of very compact high chairs, including food-service high chairs, relative to the NPR.

B. Third Party Testing

Under section 14 of the CPSA, once the new high chair requirements become effective, all suppliers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR part 1107) (1107 rule), which requires that manufacturers and importers certify that their products comply with the applicable children's product safety standards, based on third party testing, and subject their products to third party testing periodically. Third party testing costs are in addition to the costs of modifying the high chairs to meet the standard. For high chairs, the third party testing costs are expected to be \$600 to \$900 per sample tested.³³ As allowed by the component part testing rule (16 C.F.R. 1109), importers may rely upon third party tests obtained by their suppliers, which could reduce the impact on importers. The incremental costs would be lower for suppliers of compliant high chairs, if they are already obtaining third party tests to assure conformance with the voluntary standard.

³¹ See memorandum from Jill L. Jenkins, Ph.D., Directorate for Economic Analysis, dated September 30, 2015, Subject: Initial Regulatory Flexibility Analysis of the Staff-Recommended Proposed Standard for High Chairs and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the High Chairs Standard for a complete list of the requirements.

³² The changes to the warning labels and instructional literature are discussed in Smith, 2018.

³³ These cost estimates are for testing compliance with the physical or mechanical requirements in the standard only. Manufacturers and importers of high chairs are already subject to third party testing requirements with respect to lead content.

VI. The Market for High Chairs and the Impact on Small Businesses

Table 1 describes the domestic firms in the high chair market. Staff identified 59 domestic firms supplying high chairs to the U.S. market. Of this 59, 43 market their high chairs exclusively to consumers, 12 sell exclusively to restaurant or restaurant supply stores (usually through regional distributors or an internal portal), and four sell food-service high chairs to both restaurants and consumers. Thirty-three of the 59 known domestic firms are manufacturers (26 small and 7 large) and 26 are importers (17 small and 9 large).³⁴

CATEGORY	NUMBER OF FIRMS SUPPLYING HIGH CHAIRS (ALL TYPES)	NUMBER OF FIRMS SUPPLYING FOOD-SERVICE HIGH CHAIRS	
Total Domestic Firms	59	16	
Small	43	14	
Manufacturers	26	8	
Compliant with ASTM Voluntary Standard	13	2	
Not Compliant with ASTM Voluntary Standard	13	6	
Importers	17	6	
Compliant with ASTM Voluntary Standard	9	2	
Not Compliant with ASTM Voluntary Standard	8	4	
Large	16	2	
Manufacturers	7	1	
Importers	9	1	
Highlighted categories are the focus of this analysis.			

Table 1. Domestic Firms in the U.S. High Chairs Market

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of high chairs is considered small if it has 500 or fewer employees; and importers are considered small if they have 100 or fewer employees. Staff limited our analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, about 43 of the 59 domestic firms are small—26 domestic manufacturers and 17 domestic importers (Table 1). There may be additional small domestic high chair suppliers operating in the U.S. market that we have not identified.

³⁴ Staff made these determinations using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

In addition to domestic firms, staff identified nine foreign firms (eight manufacturers and one importer), as well as numerous foreign high chairs entering the U.S. market via Amazon storefronts and other on-line firms acting as brokers between buyers and sellers. In many cases, it is impossible to determine whether the seller is located domestically or overseas, making it difficult to categorize these companies for analysis. However, foreign suppliers are not considered in the regulatory flexibility analysis and none of the suppliers specialize in high chairs. Each sells a wide variety of products beyond those for children. Therefore, the impact of a high chairs mandatory standard on these firms would be small.

A. Small Manufacturers

1. Small Manufacturers with Compliant High Chairs

Currently, 13 of the 26 small manufacturers produce high chairs that comply with the ASTM voluntary standard now in effect for testing purposes (ASTM F404-17).³⁵ Staff assumes that compliant firms will remain compliant with the voluntary standard as it evolves, because compliance is part of an established business practice. Two of these firms produce compact high chairs with limited space for warning labels. Initially, in the NPR, staff believed that the proposed rule could have a significant impact on these two firms due to the requirement for a warning label on the front of the high chair back where it would be visible both when placing the child in the high chair and when the child is seated in the high chair. However, this requirement is not included in the draft final rule. Therefore, the draft final rule is not expected to have a significant impact on any of the 13 firms with compliant high chairs. These firms are expected to be in compliance with ASTM F404-18 before the final high chair rule becomes effective.

2. Small Manufacturers with Noncompliant High Chairs

Thirteen small manufacturers produce high chairs that do not comply with the voluntary standard, six of which produce food-service high chairs and seven produce high chairs for home use. As with the proposed rule, the draft final rule could have a significant impact on all seven of the firms producing noncompliant high chairs for home use. Generally, staff considers impacts that exceed one percent of a firm's revenue to be potentially significant. For all seven firms producing noncompliant high chairs for home use, the cost of redesigning the products to meet the ASTM standard could exceed this threshold. Additionally, none of the seven firms has an extensive product line, with a high chair being one firm's only product.

The draft final rule could have a significant impact on the 6 small manufacturers of noncompliant food-service high chairs as well. The impact is particularly likely to be significant for two of these firms. The two firms make plastic high chairs that could require new molds as part of the product redesign.

³⁵ There is typically a six month delay between the publication of a new ASTM voluntary standard and it adoption for compliance testing. Published in March of 2017, ASTM F404-17 went into effect for testing purposes in September 2017. ASTM F404-17a was published in November 2017 and will not be effective for testing purposes until May 2018. ASTM F404-18 was published in March 2018 and will not be effective for testing purposes until September 2018.

B. Small Importers

1. Small Importers with Compliant High Chairs

Staff identified nine high chair importers currently in compliance with the voluntary standard. The IRFA found that the economic impact of the proposed rule could be significant for four firms importing compact high chairs, due in large part to the label placement requirement, which would necessitate redesigning the high chairs to create additional space on the seat back. ASTM F404-18 allows greater flexibility for locating warnings, which eliminates the need for these firms to redesign their products.³⁶ One of these importers supplies a relatively new type of high chair that includes a reclining seat insert. However, preliminary staff testing of the high chair with this insert indicates that they will meet the draft final rule without modification. As with small manufacturers of compliant high chairs, these firms are expected to be in compliance with ASTM F404-18 before the final high chair rule becomes effective. Therefore, under the draft final rule, the economic impact is unlikely to be significant for any of the nine small importers with compliant high chairs. Any third party testing costs for importers of compliant high chairs would be limited to the incremental costs associated with third party testing over their current testing regime.

2. Small Importers with Noncompliant High Chairs

There is insufficient information to rule out a significant impact for any of the eight importers with noncompliant high chairs under the draft final rule. The economic impact on importers depends upon the extent of the changes required to come into compliance and the response of their supplying firms, which cannot generally be determined for noncompliant importers. However, because the draft final rule does not include the requirement for a warning label on the front of the high chair back that would be visible both when the child was being placed in the high chair and when the child was seated in the high chair, staff believes that the impact of the draft final rule will be less than the impact of the proposed rule would have been.

The increase in production or redesign costs as a result of changes made to meet the mandatory standard is more likely to be fully passed on to importers without direct ties to their suppliers (6 of the 8 small importers of noncompliant high chairs). These firms may opt to switch to alternative suppliers (or, in some cases, alternative products) rather than bear the cost of complying with the standard. Alternatively, firms with diverse product lines (and more than one supplier) may be able to drop high chairs from their product lines.

Finding an alternative supply source would not be a viable alternative for importers with direct ties to their suppliers (2 of the 8 small importers of noncompliant high chairs). However, the foreign suppliers to these firms may have an incentive to work with their U.S. subsidiaries/distributors to maintain an American market presence, potentially absorbing some of

³⁶ There are also two food-service high chair importers within this group (one of which sells their high chairs directly to consumers, while the other sells to restaurants and restaurant supply stores). Because the high chairs of both firms already meet the ASTM voluntary standard, they would be unaffected by staff's other final rule recommendations.

the costs associated with compliance. If they are unable to come to a practical agreement with their supplier, importers with direct ties to their supplier may be able to discontinue the sale of high chairs altogether, although this seems unlikely in the case of the two small importers of noncompliant high chairs with direct ties to their suppliers, because high chairs represent one of only a few products in each firm's product line.

Third party certification of the draft final rule could result in significant costs for two firms with noncompliant high chairs. For one of these firms, testing costs could exceed one percent of gross revenue with as few as two units per model tested. A second firm would need to test about three units per model before testing costs would exceed one percent of gross revenue. There were no revenue data available for two small importers of noncompliant high chairs. However, each supplies only one high chair model.

C. Summary of Impacts

CPSC staff is aware of 43 small firms, consisting of 26 domestic manufacturers and 17 domestic importers, currently marketing high chairs in the United States. It appears unlikely that there would be a significant economic impact on the 13 small manufacturers or 9 small importers of compliant high chairs. However, staff could not rule out a significant economic impact for any of the 21 suppliers of noncompliant high chairs (13 manufacturers and eight importers). Regardless, the impact of the draft final rule relative to the proposed rule has been reduced for 14 firms.³⁷

VII. Efforts to Minimize the Impact on Small Entities

The proposed rule included a requirement for a single warning label that would be visible both when placing the child in the high chair and when the child was seated in the high chair. For many smaller or compact high chair designs, this requirement might have necessitated some design changes to accommodate the single label, which could have been burdensome. The draft final rule would allow the warning that a child not be left unattended to be on a separate label and placed in any conspicuous location on the high chair. This change would provide more flexibility in the placement of warning labels and reduce the impact on firms compared to what the impact would have been under the proposed rule.

In the NPR, the Commission requested public comments on excluding food-service high chairs from the scope of the rule as a potential method for reducing the impact of the standard on small businesses. After reviewing the public comments, staff considered either eliminating food-service high chairs entirely from the scope of the mandatory standard or limiting the requirements to which they would be subject. Although limiting or excluding food-service high chairs from the draft final rule would reduce or eliminate the economic impact on 14 small suppliers, staff does not recommend this alternative because it would potentially be inconsistent

³⁷ The IRFA for the NPR concluded that we could not rule out a significant impact for 20 of the 38 firms identified (53 percent).

with the objective of section 104 of the CPSIA. Section 104 requires that the mandatory standard be "substantially the same as" or "more stringent" than the voluntary standard. Moreover, based on an analysis of NEISS data, staff now estimates that there were 1,600 injuries over a six year period related to high chair use in restaurant settings. The hazard patterns were similar to those found in home-use settings, with falls being the most common risk.³⁸

CPSC proposed a 6-month effective date in the NPR and requested public comments on the most appropriate effective date. A later effective date would reduce the economic impact on firms in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third party test within the required timeframe. Also, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. Staff received one comment from a group representing juvenile product manufacturers requesting a one-year effective date, as well as a comment from three consumer advocate groups supporting CPSC's proposed 6-month effective date. Given the potential for a significant impact on some small firms, as well as the possibility that many of these firms may not be aware of the ASTM voluntary standard or the CPSC high chairs rulemaking, staff believes that a longer effective date is an appropriate way to reduce the impact on affected firms. Therefore, staff now recommends a 12-month effective date.

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

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

The Commission certified in the notice of proposed rulemaking that the proposed NOR would not have a significant impact on a substantial number of small laboratories because:

- No requirements were imposed on laboratories that did not intend to provide third party testing services;
- Only firms that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements would provide testing services; and

³⁸ Chowdhury, 2017.

• Most of these laboratories will already be accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the children's high chairs standard to their scope of accreditation.

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

TAB E: Updated Summary of High Chair Recalls

T A B E



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

Memorandum

DATE:

February 27, 2018

TO:	Stefanie Marques High Chair Project Manager Division of Health Sciences
THROUGH:	Robert Kaye, Director, EXC Office of Compliance and Field Operations
	Carol Cave, Deputy Director, EXC Office of Compliance and Field Operations
	Mary F. Toro, Director, Regulatory Enforcement Division, CRE Office of Compliance and Field Operations
FROM:	Keysha L. Walker, Team Leader, Regulatory Enforcement Division, CRE Office of Compliance and Field Operations
SUBJECT:	Summary of High Chair Recalls Update

PURPOSE

This memo provides an update on high chair recalls conducted since August 31, 2015. This information is being provided to support drafting of the final rule for a mandatory high chair standard for the U.S. Consumer Product Safety Commission's consideration.

RECALL INFORMATION

On August 31, 2015, Compliance staff prepared a summary of the product safety recalls conducted under section 15 of the Consumer Product Safety Act. Since that date, there have been an additional three recalls involving high chairs, one of which occurred prior to the publishing of the NPR. The recalls involved three firms. (See Table I below). The number of incidents reported in the recall notices totaled 131, of which 17 resulted in an injury. The recalls involved fall hazards to young children.

<u>Table I.</u>

Summary of High Chair Recalls

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents (Injuries) Reported	Press Release Number
10/08/2015	Safety 1 st	Fall Hazard	35,000	68 (11) reports of injuries	16-006 ³⁹
02/11/2016	Nuna Baby Essentials, Inc.	Fall Hazard	5,600	50 (4) reports of injuries	16-100 ⁴⁰
01/09/2018	Skip Hop, Inc.	Fall Hazard	7,900	13 (2) reports of injuries	18-078 ⁴¹
Total	3		48,500	131/17	

³⁹ <u>https://www.cpsc.gov/Recalls/2018/Skip-Hop-Recalls-Convertible-High-Chairs-Due-to-Fall-Hazard</u>

⁴⁰ <u>https://www.cpsc.gov/Recalls/2016/Nuna-Baby-Essentials-Recalls-High-Chairs</u>

⁴¹ <u>https://www.cpsc.gov/Recalls/2016/Safety-1st-Recalls-Decor-Wood-Highchair</u>