



## MEETING LOG

**SUBJECT:** ASTM F15.19 November 2023 Subcommittee Meeting on Wearable Infant Blankets

**FY 24 OP PLAN ENTRY:** Wearable Infant Blankets

**DATE OF MEETING:** 11/30/2023

**LOCATION OF MEETING:** Hybrid, In Person at ASTM Headquarters, West Conshohocken, PA

**CPSC STAFF FILING MEETING LOG:** Khalisa Phillips, Ph.D., ESHF

**FILING DATE:** 01/03/2024

**CPSC ATTENDEE(S):** In person: Jacqueline Campbell, EXHR; Khalisa Phillips, Ph.D., Timothy Smith, & Celestine Kish, ESHF; Virtual: Rana Balci-Sinha, Ph.D., ESHF; Stefanie Marques, Ph.D., & Suad Wanna-Nakamura, Ph.D., & Ashley Johnson, Ph.D., HSPP; Paige Witzen (LSE); & Daniel Taxier, ESMC

**NON-CPSC ATTENDEE(S):** Contact ASTM for the full attendee list

### Summary of Meeting:

The Subcommittee met to review F15.19 (23-03) ballot results for Item 001 WK81176 - *Standard Consumer Safety Specification for Wearable Blankets & Swaddles Intended for Use by Infants and Toddlers*. The draft standard received more than 20 negative votes and statements. Much of the meeting was spent reviewing the most prevalent questions and concerns from members' negative statements.

The meeting began by questioning whether to simplify the title by removing the term 'toddler' from the balloted standard. The group decided not to remove the term and instead added 24 months as an upper age limit to the scope. Other members expressed concerns that the upper age limit needs to be expressed as a maximum value due to age requirements being different across products. One title change was made to the title and involved replacing the phrase 'wearable blankets' with 'wearable sleep products' to be more inclusive of swaddles without wearable blanket features (e.g., sleepsuit). There appears to be some confusion about what is meant by the term 'swaddle' and how adding 'wearable' could be used to distinguish swaddles with fasteners from loose blankets used for swaddling. A member also suggested adding an exclusion for foot muffs. Another member questioned whether to make any changes to the standards referenced in the balloted standard. One member recommended adding a reference to the AATCC 150 test method for laundering. A broader suggestion was to go through the list of referenced standards and only keep within the body of the standard those that form the basis for performance requirements. Standards that are nice to know for manufacturers should be listed in the appendix.

Next, a CPSC staff member presented results of a recent market scan of infant and toddler sleep products, some marketed as containing added fill material 'weighted.' On November 16, 2023<sup>1</sup> staff sent F15.19

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<sup>1</sup> [CPSC Staff Comments on Wearable Infant Blankets Swaddles Ballot ASTM F15.19 \(23-03\)](#)



subcommittee for Wearable Infant Blankets a letter outlining rationale for their negative vote and describing the results of the market scan. At a high level, the market scan collected total conditioned weights for all products, and for a subset of products concentrated weights for a 10.6inch<sup>2</sup> area potentially representing an infant's chest. Staff walked members through each of the tables and scatterplots in the letter which focused on comparisons between weighted and non-weighted products. While differentiation was noted between weighted versus non-weighted product values, staff clarified the market scan was not a safety study and further research was still needed. Members responded by asking CPSC staff if there are any implications of the market scan. Staff responded by encouraging the subcommittee to establish weight concentration limits for applicable infant and toddler age groups using all available scientific research, results of staff's market scan, and NIH and CDC concerns about weighted blankets not being safe for infants.

One member stated we don't have any incidents and that the absence of data should be taken as an indicator of safety, especially when some weighted infant products have been on the market for more than a decade in a litigious country like the US. Another member and loss-parent advocate vehemently disputed this claim, highlighting a recent fatality associated with an infant weighted wearable blanket (and a secondary non-weighted wearable swaddle), and claimed that fatalities and injuries are likely under-reported. Others raised concerns about the paucity of safety research on weighted blankets for infants in an unsupervised setting for a period of longer than 30 minutes, and that the amount of weight placed on an infant's chest can inhibit breathing and needs to record infant oxygenation levels. An additional request was made for CPSC Health Sciences staff to provide more input on potential safety concerns with weighted infant products taking the above into consideration along with the relative weight of an infant's head compared to their body, given that it is a higher percentage than an adult.

Two major manufacturers of weighted wearable infant blankets have started or are about to start fully monitored overnight studies with infants. Some preliminary data may be available as soon as March 2024. One industry partner disputed the claim that safety research is only conducted after deaths occur, stating that her company conducted preliminary safety research prior to selling their weighted infant products starting in 2012, and that there were no adverse effects on respiration or blood saturation when 30 grams of weight were added to their product. However, this industry partner fully acknowledged that more research is needed and is planning a more extensive study. One member who is also a manufacturer of a non-weighted product responded by stating that we need to heed the recommendations from health professionals who have already expressed their concerns with adding fill weight to infant wearable blankets and wearable swaddles. One loss-parent member proposed a motion to assist in analyzing incident data and the subcommittee approved her motion, which added her as a co-lead for the Data task group. Lastly, to address the range of negative votes, the subcommittee agreed to reopen all task groups.

### **Next Steps:**

Several task group meetings have been set for January 2024. There also will be a hybrid subcommittee meeting on January 31<sup>st</sup> at the CPSC NPTEC facility in Rockville, MD. The subcommittee members are working diligently to address negatives and issue a second draft of the standard for ballot as quickly as possible.