United States
Consumer Product Safety Commission

TRANSMITTED VIA EMAIL November 16, 2023

Michelle Barry & Tara Williams
Subcommittee Co-Chairs for ASTM F15.19
100 Barr Harbor Dr.
West Conshohocken, PA 19428-2959

Dear Ms. Barry & Ms. Williams:

U.S. Consumer Product Safety Commission (CPSC) staff[1] is casting a negative vote and submits the following statement on ballot F15.19(23-03) Item 1.

For the May 2023 subcommittee meeting, staff provided ASTM with reported incident data (87 CPSRMS, 6 NEISS)[2] for the period 1/1/2011 to 2/14/2023. For the October 2023 subcommittee meeting, staff provided six redacted in-depth investigations (IDIs). Staff reviewed available incident data to assess whether performance requirements in the balloted standard adequately address the hazard patterns in the incidents.

Staff noted incidents of material bunched at the neck, chin, or covering an infant's mouth and/or nose (suffocation / strangulation hazard). Some reports noted precursor events such as (1) "submarining[3]" into oversized neck openings, (2) swaddle bands[4] migrating upwards when an infant brings their hands to their mouth, or (3) zippers sliding down or separating, resulting in loose blankets. Other incidents / complaints include choking (some with detached zippers), cuts and scratches due to zippers, arm dislocation and fracture, appendage entrapment, tooth entrapment, rash or bruising, and concerns about hip dislocation.

In general, staff agrees that the balloted standard improves the safety of the products within its scope by addressing the hazards summarized above because the proposed requirements do not allow hoods, require neck openings to be accurately sized to the age range for which product is labeled, require fasteners to remain secure, and require that swaddle bands migrate as little as possible.

However, staff has concerns that dictate a negative vote for the balloted standard. Most notable, weighted wearable infant blankets and swaddles are included in the scope of the standard without an accompanying specification of maximum weight limits by age. Staff is concerned that were the draft safety specification to pass as currently written, a manufacturer

[1] The views expressed in this letter are those of CPSC staff. They have not been reviewed or approved by, and may not reflect the views of, the Commission.
[2] CPSRMS: Consumer Product safety Risk Management System, NEISS: National Electronic Injury Surveillance System
[3] Slipping below the neck hole into the wearable blanket.
[4] A strip of fabric which is attached to a wearable blanket and is designed to wrap around a swaddled infant to secure/restrict limbs.

could sell a wearable blanket or swaddle with an extremely heavy weight in it and still meet the standard.

Our prior letter dated October 2nd, 2023, recommended removing Table 2 that specified certain weight limits by age because the limits did not provide rationale to indicate they were safe. But in that previous letter, staff encouraged members to review all available scientific research on weighted products, and to continue to conduct and share research, testing, and evaluation on weighted products moving forward. However, staff recommends setting a standard as soon as possible to ensure unsafe products are precluded from the market. This can be updated later, once recently started studies are completed, but should not wait the 1-2 years staff understands them to need.

To contribute to the evaluation of the products and noting a lack of publicly available research relating to the issue at hand, staff has collected and measured a variety of wearable blankets and swaddles marketed as weighted ("weighted") and a variety of those products without any such marketing ("non-weighted") currently sold on the market. The range of products were all marketed as sleep products for infants and toddlers. Our goal was to conduct a market scan of non-weighted wearable blankets and swaddles as well as a range of products marketed as "weighted" and make comparisons between the two groups. The observations found in this market scan are included in the attached appendix.

One product characteristic is the weight on the chest when worn by the infant, identified with a 10.6 inch^2 area, possibly representing the chest region of an infant.[5] The tables below show the measured concentrated weight on an area of 10.6 inch^2 representing chest region.[6]

[5] The original weight table in the draft standard included this figure for surface area.
[6] Conditioned all samples in chamber to ASTM D1776 (21 ± 1 °C (70 ± 2 °F) and 65 ± 2 % RH)

Non-Weighted Sample#	Total Weight Concentration (lb/10.6inch^2)
1	0.0035
2	0.0039
3	0.0042
4	0.0048
5	0.0059
6	0.0067
7	0.0068
8	0.0072
9	0.0076
10	0.0082
11	0.0083
12	0.0085
13	0.0157
14	0.0213
15	0.0245

Weighted Sample#	Total Weight Concentration (lb/10.6inch^2)
1	0.0288
2	0.0399
3	0.0422
4	0.0433
5	0.0500
6	0.0579
7	0.0596
8	0.0633
9	0.0635
10	0.0706
11	0.0846

Of the products we characterized, we observed a distinct separation between the non-weighted and the weighted products in terms of concentrated weight on the chest area. The range of concentrated weights for non-weighted products was between 0.0035 and 0.0245 lb/10.6inch^2 whereas the range was between 0.0288 and 0.0846 lb/10.6inch^2 for the weighted samples.

While we recognize that this scan is limited, we encourage the subcommittee to consider these observations and expand on the comparison between the two groups of products to establish a maximum weight limit that is proven to be safe for all products within the scope of the standard. CPSC staff recommends the Subcommittee consider establishing weight concentration limits given existing scientific research, the differentiation CPSC staff observed, and NIH[7] and CDC[8] concerns about weighted blankets not being safe for infants.

[7] https://safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment
[8] https://www.cdc.gov/reproductivehealth/features/baby-safe-sleep/index.html#:~:text=Weighted%20products%20such%20as%20weighted,with%20no%20soft%20bedding%20use.

Staff appreciates the work of the subcommittee towards improving the safety of infant and juvenile products, and to better understand the hazards associated with such products.

Feel free to contact me with any questions.

Sincerely,

Khalisa Phillips, Ph.D., Psychologist,
Division of Human Factors (301) 987-2592, or kphillips@cpsc.gov

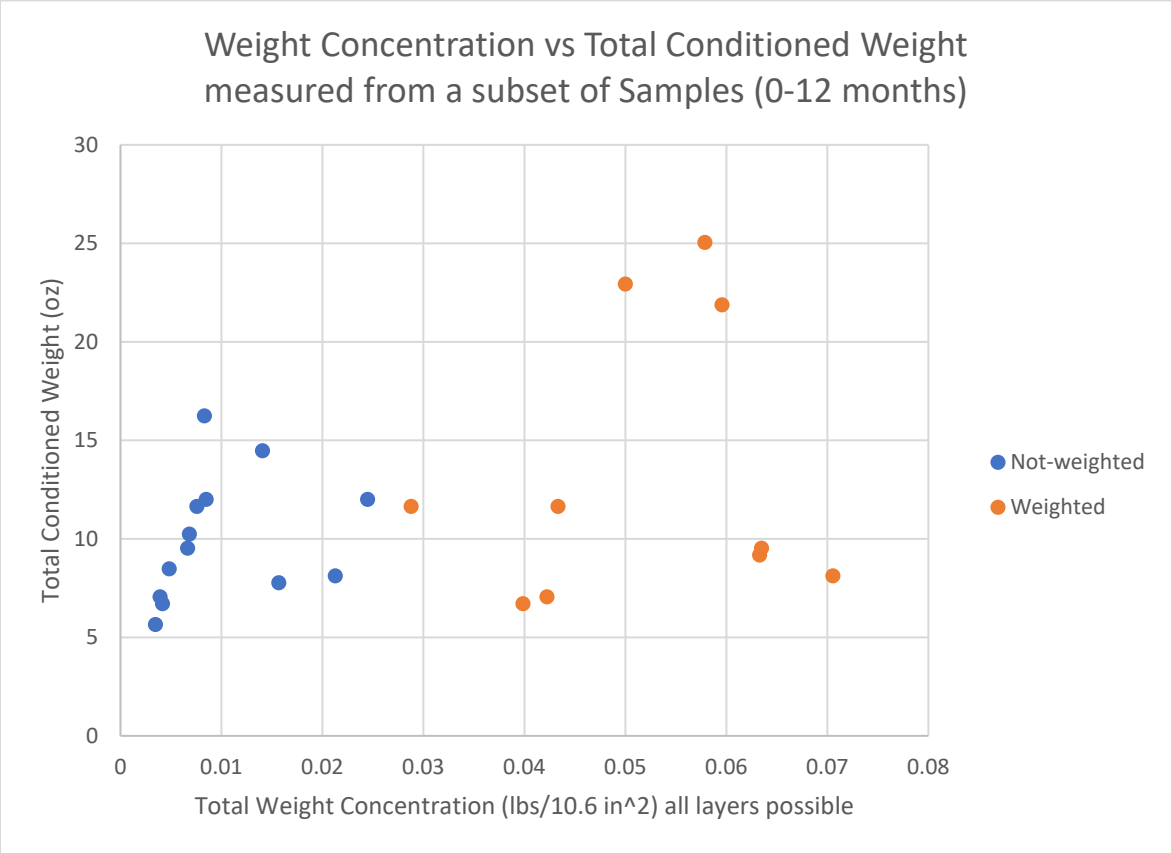
CC: Molly Lynyak, ASTM F15 Staff Manager
Jailynn McGhee, JPMA Government Affairs Standards and Certification Associate
Jacqueline Campbell, CPSC Voluntary Standards Coordinator

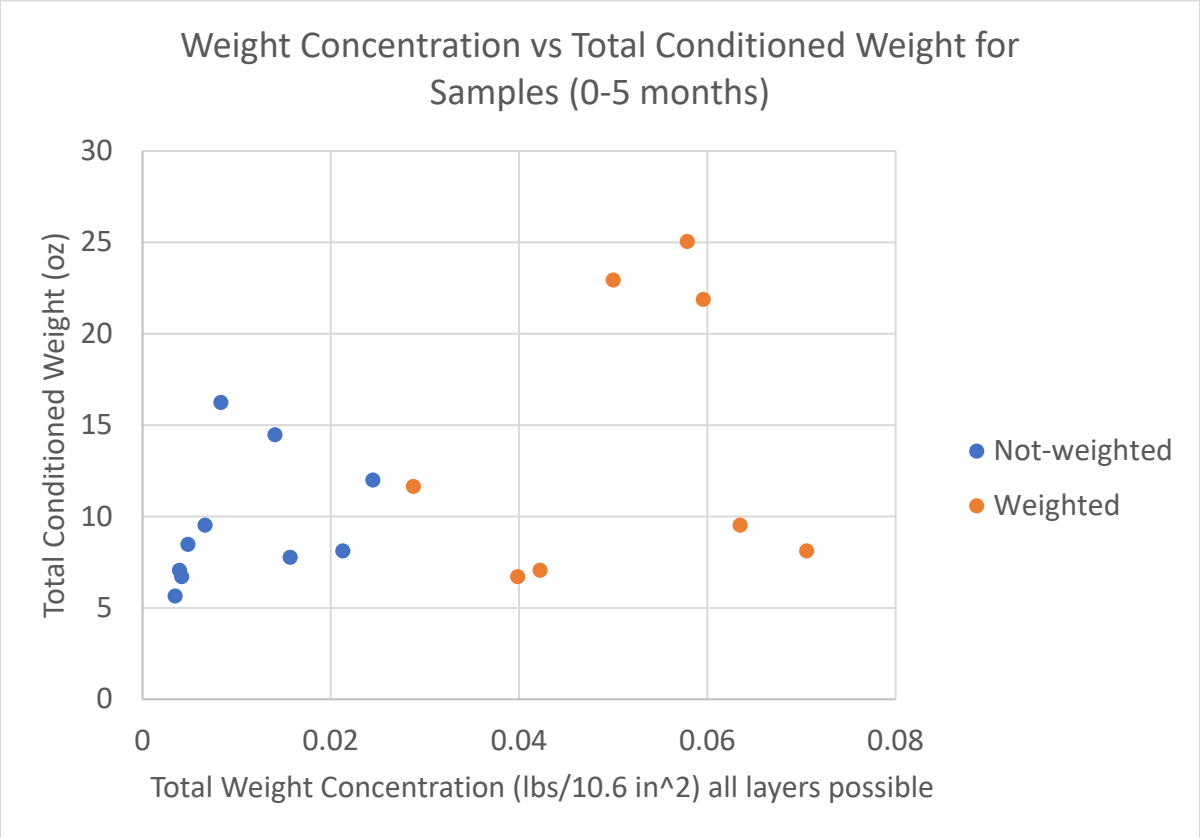
APPENDIX

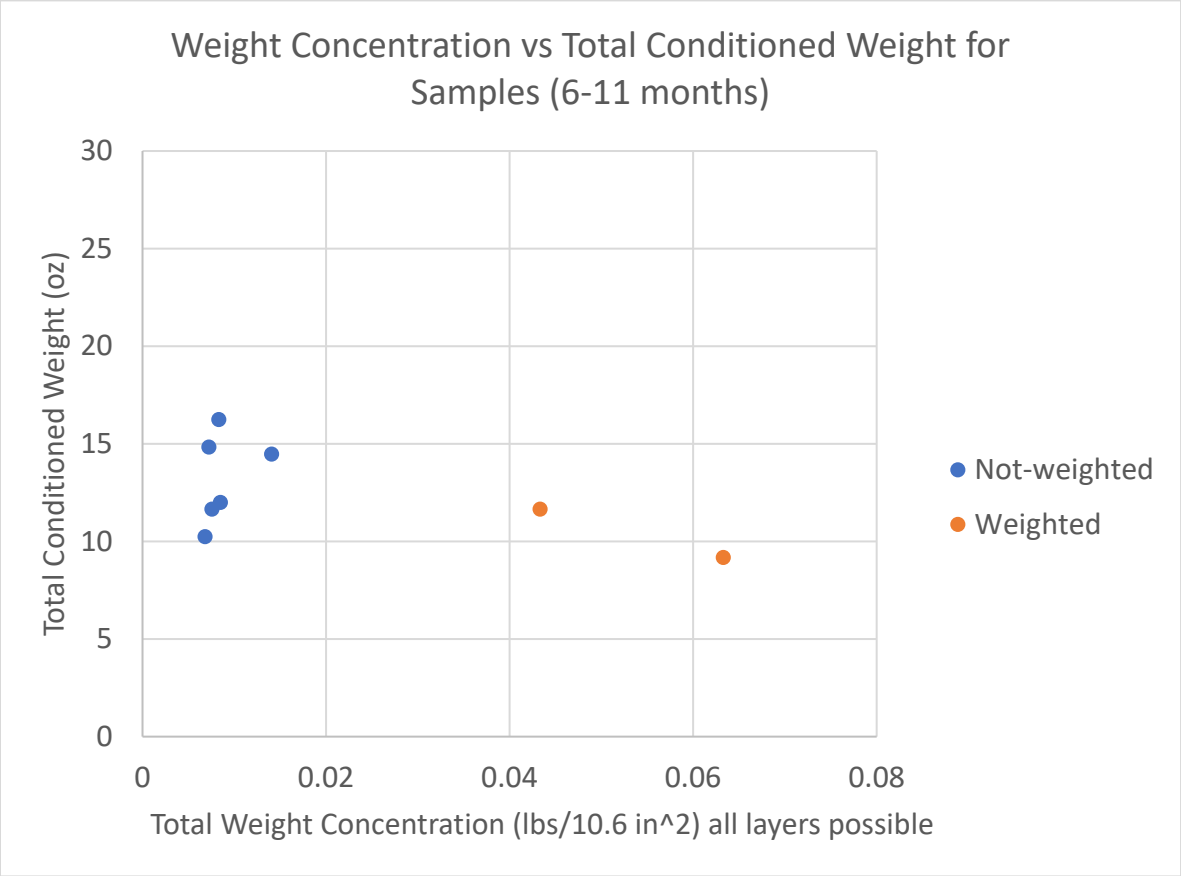
MARKET SCAN OF WEIGHTED AND NON-WEIGHTED BLANKETS

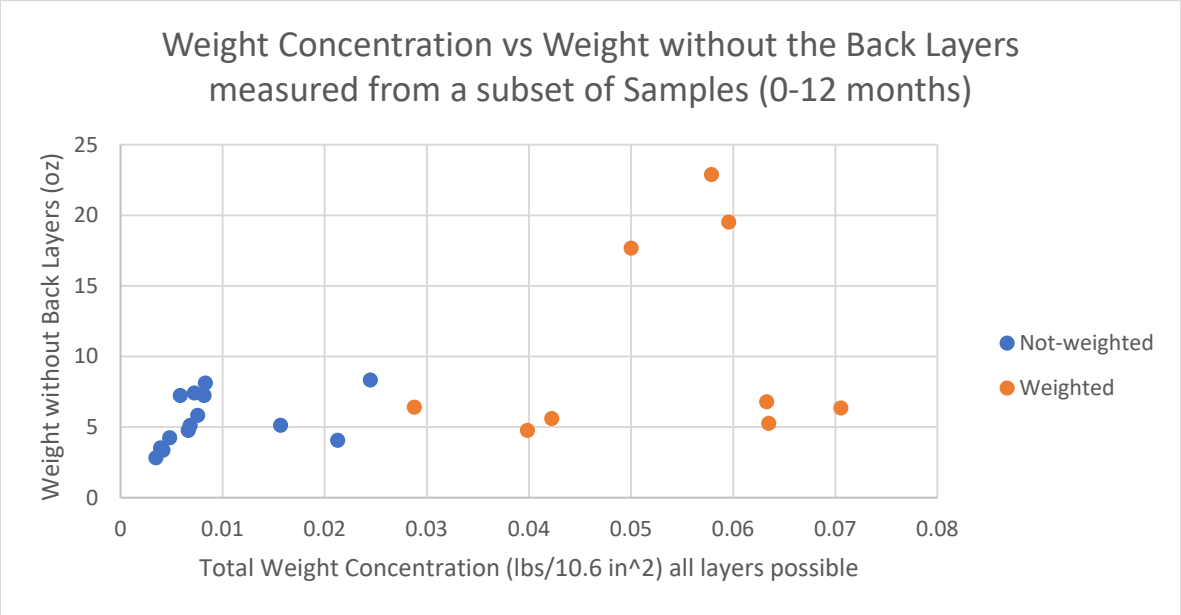
Total Conditioned Weight of all Samples (0-12 months): 93 non-weighted and 15 weighted samples were measured, some products weighed the same.

Non-weighted samples: Total Conditioned Weight (oz)	Weighted Samples: Total Conditioned Weight (oz)
2.82	6.70
3.17	7.05
3.53	8.11
3.88	9.17
4.23	9.52
4.59	11.64
4.94	20.11
5.29	21.87
5.64	22.93
6.00	25.04
6.35	32.10
6.70	11.64
7.05	
7.41	
7.76	
8.11	
8.47	
8.82	
9.17	
9.52	
9.88	
10.23	
10.58	
10.93	
11.29	
11.64	
11.99	
13.05	
14.46	
14.82	
16.23	


Weight Concentration vs Total Conditioned Weight measured from a subset of Samples (0-12 months)
Total Conditioned Weight (oz)
30
25
20
15
10
5
0
0
0.01
0.02
0.03
0.04
0.05
0.06
0.07
0.08
Total Weight Concentration (lbs/10.6 in^2) all layers possible
Not-weighted
Weighted


Weight Concentration vs Total Conditioned Weight for Samples (0-5 months)
Total Conditioned Weight (oz)
30
25
20
15
10
5
0
0
0.02
0.04
0.06
0.08
Total Weight Concentration (lbs/10.6 in^2) all layers possible
Not-weighted
Weighted


Weight Concentration vs Total Conditioned Weight for Samples (6-11 months)
Total Conditioned Weight (oz)
30
25
20
15
10
5
0
0
0.02
0.04
0.06
0.08
Total Weight Concentration (lbs/10.6 in^2) all layers possible
Not-weighted
Weighted


Weight Concentration vs Weight without the Back Layers measured from a subset of Samples (0-12 months)
Weight without Back Layers (oz)
25
20
15
10
5
0
0
0.01
0.02
0.03
0.04
0.05
0.06
0.07
0.08
Total Weight Concentration (lbs/10.6 in^2) all layers possible
Not-weighted
Weighted

Weight without back layers (oz):

Non-weighted (oz)	Weighted (oz)
2.82	4.76
3.35	5.26
3.53	5.60
4.05	6.35
4.24	6.40
4.76	6.79
5.11	17.67
5.12	19.52
5.82	22.88
7.23	
7.23	
7.41	
8.12	
8.33	

Total Weight Concentration of a subset of Samples (0-12 months): Total weight concentration was measured for only a subset of samples as listed below.

Non- Weighted Sample#	Total Weight Concentration (lb/10.6inch^2)
1	0.0035
2	0.0039
3	0.0042
4	0.0048
5	0.0059
6	0.0067
7	0.0068
8	0.0072
9	0.0076
10	0.0082
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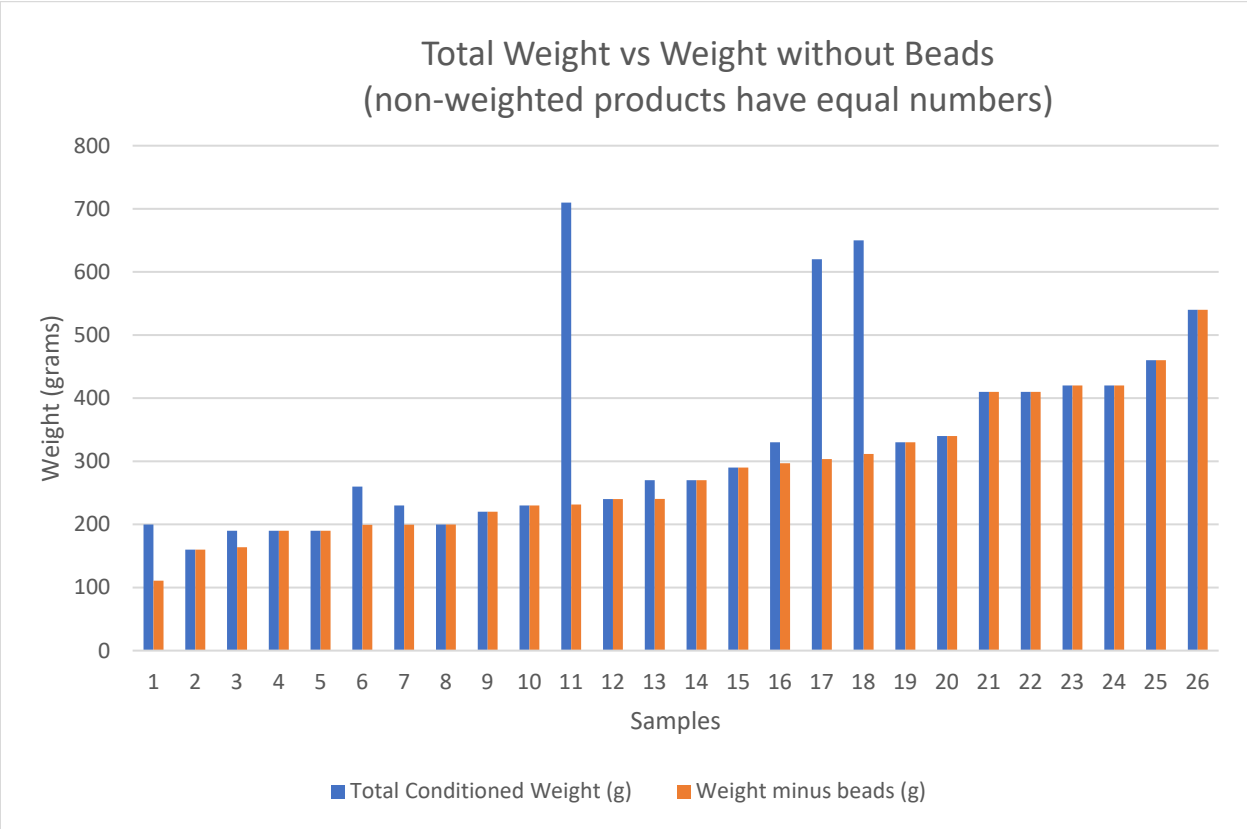
Total Weight vs Weight without Beads
(non-weighted products have equal numbers)
Weight (grams)
800
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26
Samples
Total Conditioned Weight (g)
Weight minus beads (g)