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

This document has been electronically approved and signed.

Date: September 4, 2013

To: The Commission
Todd A. Stevenson, Secretary

Through: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director
Safety Operations

From: Stephen Hanway, Division Director
Division of Hazard Analysis

Subject: Bassinet Mattress Bright-Line Criterion versus the Threshold-Plus-Averaging Criterion

I. Introduction

Staff from CPSC's Directorate for Epidemiology was asked to evaluate statistically and characterize: (1) sources of variability and (2) compliance (pass/fail) conclusions for alternative criteria for evaluating the flatness of segmented mattresses for bassinets and cradles. In addition, Commissioner Nord submitted the following question for the record: *"In light of the amendment circulated to Commission offices and CPSC staff, what is CPSC staff's confidence in the accuracy of a pass or fail result under the BLC as compared to the TAC?"*

The data evaluated were inclinometer measurements from a May 2012, repeatability and reproducibility study of five different segmented bassinet mattresses (products) by three testers (operators), who each took two trials of seam and side of the mattress. The gauge used by all operators was the ASTM cylinder.

For a segmented mattress to pass the Bright-Line Criterion (BLC) flatness test, all 2n measurements (right and left seam side measurements for all seams where n is the number of seams) must be less than or equal to 10 degrees. The Commission proposed the BLC flatness test in the supplemental notice of proposed rulemaking (SNPR) published October 18, 2012. 77 Fed. Reg. 64055. Some stakeholders have suggested an alternative criterion, the Threshold-Plus-Averaging Criterion (TAC), where if an initial measurement for a product's seam and side pair exceeds 10 degrees, then two more measurements are taken, and the average is assessed against the pass/fail criterion. Additionally, staff simulated several other multiple measurement tests using these data to evaluate how they would perform.

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II. Methodology

The data obtained included inclinometer measurements of five products. Four of the five mattresses had three seams, while the fifth had four seams. Three operators took two measurements of each product, on the left and right of each seam. (For example, if a mattress had three seams, then a total of 36 measurements were taken: 3 operators times 2 measurements of the mattress times 3 seams times 2 sides per seam.) Each operator used a different inclinometer. The ASTM cylinder was reset between measurements (although both a right and left measurement were taken at a time), so that each trial allowed for the angles to change as they might under real-world conditions. This provided a data set that included 192 measurements across the five products, or six measurements for each product, seam, and side (see Appendix).

An Analysis of Variance (ANOVA) was conducted of the data to determine how much of the observed variability in angle measurements was attributable to the combination of operator and inclinometer, how much to the product, how much between different seams of a given product, and how much of it was attributable to being on one side or another of a given seam. Additionally, bootstrap resampling techniques were employed to help compute the mean and confidence interval that would be expected under different testing rules (the BLC, the TAC, 5, 10, and 30 measurements per seam/side, and a testing rule where an initial passing or failing test near the mean [*e.g.*, between 9 and 12] triggered additional measurements).

III. Results

The ANOVA found very little variability that could be attributed to the combination of operator and inclinometer. Still, ***the ANOVA confirmed that it is possible to measure angles with a high degree of precision for testing purposes.*** Nearly all of the variability observed was found between products and between the seam and side combinations within a product, likely emulating real-world conditions.

Two of the five tested products passed because each of the seam and side measurements for the six attempts was less than 10 degrees. The confidence intervals for the mean of these measurements, based on a bootstrapping resampling technique, show that the probability of each seam and side combination for these products failing is effectively zero. ***This confirms that it is possible to produce a product that complies with the standard and will not fail these tests any meaningful percentage of the time.***

One product failed because two of its seam and side combinations produced measurements over 10 degrees all six out of six times. The confidence intervals for the mean of these measurements,

based on a bootstrapping resampling technique, show that the probability of all seam and side combinations for this product passing is effectively zero. ***This confirms that the BLC testing can identify products that will not (and should not) pass these tests any meaningful percentage of the time.***

This left two products that had seams that passed every time, along with seams with measurements that would both have passed and failed the BLC across six measurements, but no consistent failures (*i.e.,* all six measurements above 10 degrees for a single seam and side combination). When all six measurements are considered for every seam and side combination for these two products, it is clear that these products should fail these tests (*i.e.,* be determined to be noncompliant with a 10-degree standard for every seam and side combination). Whether we apply the BLC or TAC criteria, there is a low likelihood that these products would be deemed compliant. Where a single seam on a product could be found in which the TAC might result in a passing test that failed the BLC test, another seam on that same product would still trigger a failure in either case. Thus, ***we could find no example of a compliant product that would fail the BLC but pass the TAC.*** Simulations of more robust testing rules with 5, 10, or 30 measurements per seam and side, and 9- to 12-degree additional measurement triggers also produced substantively similar results.

IV. Discussion

The scope of this analysis was limited to the data collected. These data suggest that the joint operator and inclinometer variability would be low, that compliant products can be produced and consistently measured, that noncompliant products can be identified, and that the data did not provide an example where the TAC would identify a compliant product where the BLC did not.

If instead, we are asked to imagine circumstances where a compliant product from a batch of uniformly compliant products would fail a BLC when they would have passed a TAC, we consider the likelihood to be low based on these data.

The risk of a failed test due to measurement error can be taken into account for product design and production quality control. No similar TAC proposal was offered by industry to protect the consumer from a similar risk of purchasing a noncompliant product. That is, no procedure for taking additional measurements when a product passes by a narrow margin was offered (where additional measurements would identify the product as noncompliant). Therefore, it's questionable why a single test should be considered acceptable for consumers but not manufacturers since similar risks of compliance or noncompliance are present for each party.

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It is worth noting that while only a single product is submitted for testing, there are two measures per seam (one for each side) and multiple seams per product (at least in the tested products). So a single product is measured 6 to 8 times. In this study, the products with a seam and side combination that narrowly passed or narrowly failed in each case were accompanied by a seam and side combination that more surely failed. ***This 2n measurement provides an additional margin of consumer safety over a measurement of only a single side of a single seam per product.*** These multiple measures increase the likelihood that a noncompliant product will be identified as such.

V. Appendix

08/28/2013 – Assessment of proposed test of the criterion: if $9 \leq X_1 \leq 12$ then $\sum X_i/3 \leq 10$ and $(\prod I(X_i<12)=1)$ where i=1,2,3.

The table below includes the 192 measurements over 96 trials of mattress flatness.

Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	Conclusions
1	1	1	1	1	2.7	1.7	
2	1	1	1	2	2.8	1.6	
3	1	1	2	1	2.5	1.3	
4	1	1	2	2	3.1	1.1	
5	1	1	3	1	5.4	0.4	
6	1	1	3	2	5.1	1.2	Both right and left sides of seam 1 pass.
7	1	2	1	1	3.2	1.2	
8	1	2	1	2	3.5	0.6	
9	1	2	2	1	3.6	0.5	
10	1	2	2	2	3.9	0.2	
11	1	2	3	1	3.8	0.8	
12	1	2	3	2	3.8	0.7	Both right and left sides of seam 2 pass.
13	1	3	1	1	7.4	0.7	
14	1	3	1	2	6.8	1.6	
15	1	3	2	1	8.6	1.3	**All 6 seam*side measurements ≤10. Product 1 passes all BLC, TAC unnecessary.**
16	1	3	2	2	8.1	1.4	**All 6 seam*side measurements pass the proposed criterion. Product 1 passes.**
17	1	3	3	1	5.9	0.1	
18	1	3	3	2	7.1	1	Both right and left sides of seam 3 pass.

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Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	Conclusions
19	2	1	1	1	3.2	**10.7**	
20	2	1	1	2	4.2	**11.5**	
21	2	1	2	1	2.5	7.5	
22	2	1	2	2	1.7	9.1	
23	2	1	3	1	3.7	**10.4**	Right side of seam 1 passes.
24	2	1	3	2	3	8.9	Left side of seam 1 neither consistently passes nor consistently fails with BLC or TAC. **The left side of seam 1 passes the proposed criterion 55% of the time given a first measure between 9 and 12.**
25	2	2	1	1	6.5	2.4	
26	2	2	1	2	6.3	2.1	
27	2	2	2	1	3.8	2.4	**Product 2 fails because of the right side of seam 3 highly likely to fail BLC and fails TLC.** **Product 2 fails the proposed criterion because of the right side of seam 3.**
28	2	2	2	2	5.7	2.7	
29	2	2	3	1	7.2	2	
30	2	2	3	2	7.2	2.8	Both right and left sides of seam 2 pass.
31	2	3	1	1	**11.8**	1.8	
32	2	3	1	2	**13.5**	2.5	
33	2	3	2	1	**10.3**	2	
34	2	3	2	2	10	0.6	
35	2	3	3	1	**11.9**	2.2	Left side of seam 3 passes
36	2	3	3	2	**12.5**	2.1	Right side of seam 3 highly likely to fail BLC. Mean of simulated distribution exceeds 11. Fails TAC. **Right side of seam 3 fails the proposed criterion 100% of the time.**
37	3	1	1	1	0.4	1.5	
38	3	1	1	2	0.3	1.9	
39	3	1	2	1	0.2	1.9	
40	3	1	2	2	0	2	
41	3	1	3	1	0.9	1.8	
42	3	1	3	2	0.3	1.7	Both right and left sides of seam 1 pass.
43	3	2	1	1	1.6	1.3	
44	3	2	1	2	1.1	1.7	
45	3	2	2	1	1.3	1.8	**All 6 seam*side measurements ≤10. Product 3 passes BLC, TAC unnecessary.**
46	3	2	2	2	1.3	1	**Product 3 passes the proposed criterion.**
47	3	2	3	1	1.3	1.4	
48	3	2	3	2	1.8	1.3	Both right and left sides of seam 2 pass.
49	3	3	1	1	2.1	0.6	
50	3	3	1	2	2	0.2	
51	3	3	2	1	1.8	0.5	
52	3	3	2	2	1.2	0.3	
53	3	3	3	1	1.4	0.3	
54	3	3	3	2	1.5	0.5	Both right and left sides of seam 3 pass.

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Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	Conclusions
55	4	1	1	1	6.6	**13.7**	
56	4	1	1	2	4.1	**12**	
57	4	1	2	1	2.2	**11.1**	
58	4	1	2	2	2.1	**10.2**	
59	4	1	3	1	9.1	**12**	Right side of seam 1 passes.
60	4	1	3	2	8.1	**12.3**	Left side of seam 1 fails BLC and TAC. Observed mean is 11.88. No confidence intervals about the mean contain 10 or less. **Left side of seam 1 fails the proposed criterion 100% of the time. Three observations >12.**
61	4	2	1	1	**10.7**	**11.1**	
62	4	2	1	2	7.8	**12**	Right side of seam 2 likely to pass BLC. Observed mean is 8.53. TAC mean is 9.25. **Right side of seam 2 passes the proposed criterion. All observations <12.**
63	4	2	2	1	8.7	**12.5**	
64	4	2	2	2	7.4	**12.6**	Left side of seam 2 likely to fail BLC. Observed mean is 10.83. TAC mean is 11.43 and likely to fail. **Left side of seam 2 fails the proposed criterion 89% of the time. Two observations are >12.**
65	4	2	3	1	8.4	8.3	
66	4	2	3	2	8.2	8.5	
67	4	3	1	1	**12.6**	1.2	
68	4	3	1	2	**14.2**	0.4	**Product 4 fails because of the left side of seam 1 and the right side of seam 3.** **Product 4 fails the proposed criterion because of failures at the left side of seam 1, the left side of seam 2 and the right side of seam 3.**
69	4	3	2	1	**11.7**	1.4	
70	4	3	2	2	**13**	0.4	
71	4	3	3	1	**13.5**	3.1	Right side of seam 3 fails both BLC and TAC. TAC unnecessary. Observed mean is 13.17. No confidence intervals about the mean contain 10 or less. **Right side of seam 3 fails the proposed criterion 100% of the time. Five observations are >12.**
72	4	3	3	2	**14**	2.5	Left side of seam 3 passes.

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Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	Conclusions
73	5	1	1	1	**10.4**	**12.5**	
74	5	1	1	2	8.7	9.9	
75	5	1	2	1	**11.7**	**10.2**	
76	5	1	2	2	**11.7**	**14**	
77	5	1	3	1	9.8	**10.9**	Right side of seam 1 likely to fail BLC and TAC. Observed mean is 10.48. TAC mean is 10.62. **Right side of seam 1 fails the proposed criterion 86% of the time.**
78	5	1	3	2	**10.6**	**10.8**	Left side of seam 1 likely to fail BLC and TAC. Observed mean is 11.38. TAC is 11.19. **The left side of seam 1 fails the proposed criterion 97% of the time. One observation is >12.**
79	5	2	1	1	0.7	9.6	
80	5	2	1	2	0.1	5	
81	5	2	2	1	2.5	**12.5**	
82	5	2	2	2	0.4	**10.1**	Right side of seam 2 passes.
83	5	2	3	1	1.7	**10.3**	Left side of seam 2 neither consistently passes nor consistently fails with BLC or TAC. TAC mean is 10.54. **Left side of seam 2 fails the proposed criterion 44% of the time. The mean is 10.54 and one observation>12.**
84	5	2	3	2	0.6	9.9	
85	5	3	1	1	4.2	1.7	
86	5	3	1	2	3	2.5	**Product 5 fails because both sides of seam 1 are likely to fail BLC and TAC, the left side of seam 2 produces inconsistent failures for BLC and TAC and the right side of seam 4 produces frequent failures for BLC and TAC.**
87	5	3	2	1	3.5	3.6	**Product 5 fails the proposed criterion because of failures on both sides of seam 1, the left side of seam 2 and the right side of seam 4.**
88	5	3	2	2	1.7	2.1	
89	5	3	3	1	5.7	5.3	
90	5	3	3	2	8.2	3.8	Both right and left sides of seam 3 pass.
91	5	4	1	1	**12.2**	5.8	
92	5	4	1	2	**13.1**	6.8	
93	5	4	2	1	**14.9**	7.5	
94	5	4	2	2	7	8.9	
95	5	4	3	1	**14.5**	7.8	Right side of seam 4 highly likely to fail BLC. Observed mean is 12.93. TAC mean is 13.92. **Right side of seam 4 fails the proposed criterion 97% of the time. Five observations are >12.**
96	5	4	3	2	**15.9**	8.6	Left side of seam 4 passes.