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

Memorandum

July 19, 2013

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: George A. Borlase, Ph.D., P.E., Associate Executive Director
Directorate for Engineering Sciences

Patricia L. Edwards, Project Manager
Division of Mechanical Engineering, Directorate for Engineering Sciences

SUBJECT: Staff's Response to Questions for the Record, Final Rule for Bassinets and Cradles under Consumer Product Safety Improvement Act § 104(b)

On July 11, 2013, staff received Questions for the Record from Commissioner Nord. Below are the questions, followed by staff's answers.

Segmented mattress flatness test

1. *For all segmented-mattress–flatness tests that CPSC staff is aware of, please provide test results and indicate whether the test subject mattress passed or failed under the Bright-Line Criterion, and the Threshold-plus-Averaging Criterion.*[1]

CPSC staff initiated segmented-mattress flatness tests before the 2010 NPR. We completed testing in summer 2012. Most testing performed by staff consisted of test method development evaluations to determine the best method of conducting the test to minimize variability in test results. CPSC staff did not conduct testing to compare the pass-fail rates of bassinets using the Bright-Line Criterion (BLC) with the pass-fail rates of the Threshold-Plus-Averaging Criterion (TAC). Because the test methods for both criteria are similar, existing test results can be used to demonstrate that bassinets consistently can pass the BLC. Additionally, it should be noted that staff cannot reconstruct testing to the TAC with current test data because additional test measurements ─where three trials were taken and averaged for each measurement ─were not taken by staff. Although the existing testing data associated with the segmented mattress flatness test doesn't specifically answer the question posed, it does provide useful information.

[1] *For ease of reference, I refer to the 10° criterion as the Bright-Line Criterion. The other I refer to as the Threshold-plus-Averaging Criterion.*

Appendix A contains results from staff's March 2012 developmental tests, where the results of two different proposed testing cylinders were evaluated. The results presented are for the infant cylinder only, which is the same cylinder used in the current test methodology. Although very similar, the test procedure used in Appendix A is not exactly the same as the one used in the current test methodology. Thus, while the test results can give an indication of whether a bassinet might comply with the actual ASTM test, the results in Appendix A cannot be used as a definitive, qualitative answer.

Appendix A contains data on 16 different bassinets, but the details needed to compare the BLC and the TAC are not part of this raw data. Regardless, some valuable information can be gleaned from the data. For instance, the data indicate that CPSC staff measured mattress angles of less than 10 degrees for all seams on 12 of the 16 bassinets , and only three of those 12 bassinets have any measurement (across all seams of the mattress) recorded greater than eight degrees. It should be noted that the manufacturing dates of the 12 bassinets with angles that measured less than 10 degrees range from November 2009 to January 2012; thus, many of these products were designed and made before the BLC was defined.

Appendices B and C contain another set of results taken from developmental tests. These appendices contain the test data from a repeatability and reproducibility (R&R) study conducted in May 2012, in conjunction with the ASTM task group on segmented mattress flatness. Repeatability is the variation in measurements taken by a single person or instrument on the same item and under the same conditions; and reproducibility is the variation induced when different operators, instruments, or laboratories measure the same or replicate specimen. This study was performed by Graco Children's Products staff, with the participation of CPSC staff. The study was the basis for the bassinet task group meeting held on May 30 and 31, 2012. That study compared three different gages (instruments), including the cylinder that was eventually adopted by ASTM; five different bassinets (specimens); and three testers (operators), who each took two trials of every measurement. Appendix B is the raw unedited data of the R&R study, and Appendix C is an edited version that focuses on the testing associated with one of the gages, the ASTM cylinder.

While Appendix C contains the results for the ASTM cylinder and evaluates whether the bassinet passes the BLC, the pass/fail results from these tests cannot be extrapolated to evaluate the ease by which the entire population of bassinets will pass or fail the BLC. The purpose of the testing was not to determine the ease by which the bassinet population would pass or fail any criteria, but rather to determine the repeatability and reproducibility of the results. To perform the R&R study, some of the bassinets were selected because they likely had angles near 10 degrees, based on their design.

2. *In its July 8th letter, JPMA wrote that "extensive testing done in conjunction with CPSC staff that showed variation in repeatability of the testing results within the same mattress seam (passed and then failed or failed and then passed)." Please identify any such tests (identifying which tests they correspond to among those listed in in response to Question 1), and explain whether the variation is relevant, and why the variation occurred.*

As can be seen in Appendix C, there were 89 out of 96 instances of a consistent segmented mattress angle measurement resulting in either a pass or fail when measured to the BLC. When comparing all 48 pairs of test results for the same bassinet, seam, and operator to evaluate repeatability, the first and second angle measurement varied less than two degrees more than 90 percent of the time. Additionally, when comparing all 32 pairs of test results for the same bassinet, seam, and measurement number to evaluate reproducibility, the angle measured by each of the three operators varied less than three degrees more than 90 percent of the time.

There were seven out of 96 instances in which there was a pass and a fail measured for the same product, seam, and operator: Trial #23 and 24 Cylinder Left, Trial #33 and 34 Cylinder Right, Trial #73 and #74 Cylinder Left and Right, Trial #83 and Trial #84 Cylinder Left, Trial #77 and #78 Cylinder Right, and Trial #93 and #94 Cylinder Right. CPSC staff recognized this variability when proposing a maximum allowable angle of no more than 10 degrees and believes it is not significant for the following reasons:

1. Thirteen of the 14 angles measured in the seven pairs of Trials were within three degrees of the BLC, which indicates that the bassinets mattress angles were all close to 10 degrees.
2. The average discrepancy in the measurement between all seven pairs of Trials is 2.1 degrees, and the difference in the measurement for five of the seven pairs of Trials is no more than 1.7 degrees.
3. For all seven of the Trial pairs, the same product and seam was measured to fail the BLC by at least one other operator.

Thus, not only is the magnitude of the variations described above small, but the incidence of a pass and fail result for the same seam was rare, and to be expected, because most of these incidences had measurements close to 10 degrees. Moreover, the R&R test data show that manufacturers are capable of designing and manufacturing products with all measurement trials close to zero degrees, so that the design tolerances are well below 10 degrees (bassinet #3). The test data in Appendix A demonstrates the same capability for many other bassinets. For these reasons, staff does not believe the variation is problematic.

3. *Please explain the extent to which, and reasons why, staff agrees or disagrees with the following statement: "The results of CPSC and outside tests show that, in general and in the real world, test subjects that would pass or fail under one criterion—the Bright-Line Criterion or the Threshold-plus-Averaging Criterion—would receive the same pass-or-fail result under the other criterion."*

Even though staff does not have knowledge of all outside test data, nor do we know of any real world examples where these criteria have been compared, we generally agree with the statement, while also noting there are potential exceptions because the TAC allows for multiple measurements under certain conditions. The TAC allowance occurs if there is an initial angle measurement that is greater than 10 degrees but equal or less than 14 degrees. When this occurs, then two additional measurements are taken, for averaging purposes. Under these conditions, it is possible to pass the flatness test using the TAC and fail it using the BLC.

To explain in more detail, presented first are the conditions where the statement in question #3 is true:

- When every angle across the mattress is measured to be at 10 degrees or less (these bassinets will pass both the BLC and the TAC).
- When at least one mattress angle is measured to be greater than 14 degrees (these bassinets will fail both the BLC and the TAC).
- When the averaging method is used (*i.e*., an initial measurement was more than 10 degrees but equal to or less than 14 degrees); and the average of the three measurements is greater than 10 degrees (these bassinets will fail both the BLC and the TAC).

The condition when this statement is not true is as follows:

- When the averaging method is used (*i.e*., the initial measurement was more than 10 degrees but equal to or less than 14 degrees), and the average of the three measurements is 10 degrees or less (these bassinets would fail the BLC and pass the TAC).

4. *During the July 9th briefing, CPSC staff indicated that the 10° criterion was both supported and unsupported by various data sources, including medical literature, incident data, and anthropometric data. Specifically, CPSC staff indicated that it could not confidently identify a lower bound for an appropriate angle, but could identify an upper bound. Please identify and describe the data, and explain the basis for identifying an upper bound.*

To clarify, staff can identify confidently the lower bound for an appropriate sleep surface slope: zero degrees. The lower bound angle for a sleeping surface should be level and flat. The upper bound of a surface that still constitutes “flat” without being perfectly flat is the debatable parameter. This parameter amounts to a measurement tolerance. Staff recommends that 10 degrees is the maximum allowable tolerance from zero degrees, which is the desirable flatness. The challenge for the bassinet rule is to select a tolerance for flatness that allows the manufacture of sleep surfaces with seams that can fold for storage without creating a hazardous valley when in use.

In the SNPR briefing package, Dr. Jonathan Midgett cited a medical article that was pertinent to the issue of mattress flatness. The research findings reported by Beal, et al. (1995) and the requirements in the Australian/New Zealand standard for infant’s rocking cradles (AS/NZS 4385:1996) suggest that a maximum 5-degree rest angle for rocking cradles could minimize the risk of an infant rolling and getting trapped in a corner or other asphyxiation scenario.
The main problem with this study was that it examined suffocation risks in the valley formed at the edge of a tilted cradle with rigid sides. It was not a study of the folding mattresses found in play yard bassinet accessories. The ASTM subcommittee for bassinets expressed concerns that using data from rocking cradles was too strict and would make the manufacture of folding mattresses impossible.

Alternatively, the ASTM task group turned to anthropometric data that CPSC staff supplied. The derivation of the angles formed by a probe constructed using facial anthropometry from Farkas (1994) is described in the SNPR package (page 74). The ASTM subcommittee approved of the use of a maximum tolerance of 14 degrees based on average facial dimensions rather than 10 degrees, which is one degree less than the same minimal facial dimensions. Staff contends that applying average dimensions to this hazard pattern is ill-advised because the average facial dimensions fail to minimize the risk sufficiently.

Additional validation of the anthropometric strategy was warranted because the facial features of infants are variable enough to shed some doubt on whether a single degree subtracted from the extrapolated triangle formed by the chosen facial features is protective enough. Specifically, Incident 090213HCC1421 provided photographs from which some estimates of the angles of the sleep surface could be made. Staff is not confident that the available photographs are reliably measurable. However, if one makes some assumptions of the angles from which the photos were taken and the size of the mesh commonly used in play yards, the angles of the surfaces adjacent to the victim's face can be estimated. Depending on such assumptions and which photograph is used, CPSC staff arrived at angles ranging from eight to 17 degrees for this incident. The exact angle cannot be determined with a high degree of confidence.

These different approaches to finding a suitable tolerance from flat that might still be manufactured are challenging. The medical literature suggests that five degrees from horizontal seems safe. An extrapolation of facial anthropometry suggests that 10 degrees seems safe. An extrapolation of angles from photos of incident samples suggests that an angle between eight and 17 degrees has been fatal. Staff, however, does not believe that a maximum allowable angle for any measurement of 14 degrees provides sufficient population-wide protection from the risk of suffocation.

5. *Under a scenario where a segmented bassinet mattress is tested under the Bright-Line Criterion and is measured at 10.1 °, how can a manufacturer determine whether the result is due to manufacture error or lab error?*

The <u>lab error</u> or test method repeatability depends on the accuracy of the measuring device and variance of the angle measurement due to the test method. ASTM specifies that the test shall be conducted using a digital inclinometer with an accuracy of 0.5 degrees. So a measurement of 10.1 degrees indicates that the true angle is between 9.6 and 10.6 or +/- 0.5 of the measured angle.

The variance of the angle measurement based on the test method for one sample bassinet is due to the assembly and installation of the mattress pad onto the shell and placement of the cylinder and inclinometer in the seam. This angle will vary from test to test; however, the measured angle is the true angle +/- 0.5 degrees and is the angle that the occupant could be exposed to. The data included in the Appendices show that manufacturers are capable of producing products with mattress pad angles that are consistently less than 10 degrees.

The <u>manufacturer error</u> or the dimensional variance of the products due to manufacturing will affect the angle measurement at the seam. Manufacturing variance is in the fabrication of the frame and soft goods and assembly and installation of the mattress pad into the play yard/bassinet shell. The manufacturer designs their product with allowable dimensional tolerances for each individual part. Once the play yard/bassinet is assembled, the tolerances of each individual part can add up to create an overall variance from the nominal dimension. This is known as a tolerance stack up. This overall variance will be different from one sample to another but should be within the design tolerance. The <u>manufacturer error</u> will affect the angle measurements from one sample to another.

The manufacturer cannot separate the effects of lab error or manufacturing error because these two are related. For example, if two measurements are made by different testers or at different times, one tester may place the cylinder in a location that allows the mattress to sag more than a second tester who places the cylinder in a slightly different location. The differences between the two measurements are due to the product (manufacturer error) and the placement of the cylinder (lab error). Both measurements are true measures of the angle within the accuracy of the inclinometer. Therefore both measures are angles to which the occupant could be exposed. The manufacturer should know the maximum adverse effects of the tolerance stack up to determine the worst case angle that is possible for his product. Using this information, the manufacturer should be able to confirm that properly manufactured and assembled products will have mattress flatness within a specified tolerance when measured per the ASTM test method. As stated earlier, the data included in the Appendices show that many manufacturers have already done this.

6. *Given that the Bright-Line Criterion was initially proposed in the SNPR:*
    a. *When and to what extent did CPSC staff communicate its concerns about the Threshold-plus-Averaging Criterion to members of the relevant task group or subcommittee, or any other ASTM participant?*

During the April 2011 subcommittee meeting, CPSC staff first expressed concern and informed the subcommittee that CPSC staff was assessing the then-balloted mattress flatness test procedure, which had a different test procedure and different pass/fail criterion than what is in the current published ASTM standard. Based on ASTM and CPSC staff's notes taken at follow-up subcommittee or task group meetings, staff's concerns regarding the development of the TAC were raised again during the following meeting dates: June 14, 2011, October 3, 2011, December 6, 2011, January 23, 2012, and May 30, 2012. The SNPR briefing package, dated August 31, 2012, also documented staff's concerns with the TAC.

    b. *Please describe any process or discussion within the ASTM process that did center on the Bright-Line Criterion.*

At the June 2011 meeting, an extensive discussion occurred where Dr. Jonathan Midgett addressed the 10-degree maximum, and why staff believes this maximum addresses the known fatal hazard better than any criteria that allowed up to a 14 degree measurement. The medical literature sited above, as well as the IDI photograph angle measurement approximations were also discussed. During various subcommittee and task group meetings, opinions were raised by several manufacturing representatives with regard to the two criteria; some of the manufacturing representatives had no issues with the use of the BLC.

c. *What is your understanding of why the criterion was never balloted by the F2194 subcommittee?*

Staff does not know why the segmented mattress flatness pass/fail criterion, as published in the SNPR, was never balloted by the F2194 subcommittee. The Commission's decision to propose the BLC was made public with the publication of the SNPR, thus it was available at that time for all stakeholders, including members of the ASTM subcommittee, to see. A revision to use the BLC could have been balloted by ASTM after the SNPR was published; but a motion has not yet been raised to do so. It should also be noted that this particular subcommittee has been very productive in the past two years, publishing multiple updates to the F2194 standard.

7. *Has CPSC staff considered a test procedure that would require multiple measurements of the same seam and using the average angle measurement as the pass-fail criterion? (Unlike F2194's test, multiple measurements would be taken regardless of the first result.) why would not such a procedure be preferable in the case of a mattress that passes the test that should actually fail?*

Yes, in the 2010 NPR, the Commission proposed a five measurement test to evaluate mattress flatness. The test procedure was totally different than what is proposed in the SNPR (only one seam tested, and a CAMI dummy was used rather than a cylinder). In the 2010 NPR, the criterion was five degrees and all five measurements had to be below that threshold. Staff also considered using a three-measurement trial with the BLC, where all measurements had to be below 10 degrees. But, the segmented mattress flatness test is a time-consuming test. Thus, in the interest of reducing the time required to conduct the test, staff eliminated several variations of the test procedure, including the idea of running multiple trials for each measurement. Based on the testing results provided, staff is confident that one measurement of each seam, as proposed in the 2012 SNPR and staff's recommendation to the Final Rule, provides a balance of safety and minimal testing burden.

Regulatory impact analyses

In performing regulatory impact analyses (including the analysis for this rule), it appears that CPSC staff generally evaluates only the costs formally added by Commission actions. Under the statutory framework of CPSIA § 104, however, there have been several occasions when voluntary standards development groups have adopted CPSC staff suggestions before the standards are formally considered by the Commission. In these instances, the Commission (and the public) does not get any analysis of the regulatory impact even though the regulatory action was triggered by agency actions. The Administrative Conference of the United States has recommended that agencies consider the costs of their actions more broadly, however, and not be limited solely to formally added costs or benefits.[2]

Had ASTM adopted all the provisions in the draft final rule, would we have considered this rule to be cost-free?

---

[2] *See, for example*, Administrative Conference of the United States, Recommendation 2013-2, *Benefit-Cost Analysis at Independent Regulatory Agencies*, 7 (June 13, 2013), http://www.acus.gov/sites/default/files/documents/Recommendation%202013-2%20%28Benefit-Cost%20Analysis%29.pdf (item 6).

How could staff provide information more consistent with ACUS's recommendations?

First, to clarify, for rules under section 104 of the CPSIA, the staff conducts a regulatory flexibility analysis in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 601-605. This analysis assesses the potential economic impact of a regulation on small entities. It is not a benefit-cost or regulatory impact analysis, but it is a more limited analysis, focusing on the potential impact a rule would have on small entities to which the rule would apply. When developing RFA analyses, staff follows the guidance set forth by the U.S. Small Business Administration (SBA) in the SBA's "Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act."

In general, for section 104 rules, we have treated the most recent voluntary standard in place before the mandatory standard's effective date (and the expected level of compliance with that standard) as the baseline against which impacts are assessed. Thus, if a voluntary standard is in place before the mandatory rule's effective date, we assume that the standard was developed by the industry voluntarily. Of course, it is possible that staff influenced the development of the existing voluntary standard (and this influence is possible in all voluntary standards processes in which staff participates). However, because of the collaborative process, and the give and take that the process requires, it would be difficult to determine the extent of the CPSC's influence over the development of the voluntary standard with any certainty. In addition, we typically assume that the firms in compliance with the voluntary standard have chosen to comply voluntarily because they believe it is in their interest and that they will continue to comply with the standard moving forward.

In answer to your first question, if ASTM had adopted *all* the provisions in the final draft rule, and if the voluntary standard had become effective prior to the effective date of the mandatory standard, we likely would have assumed that the nursery product manufacturers that historically have chosen to conform to a voluntary standard would continue to choose to comply. Consequently, in assessing the impact on small entities that historically have conformed, we would expect the impact on these entities to be small or minimal because the manufacturers would likely choose to absorb the costs of the voluntary standard in the absence of a mandatory standard. However, for manufacturers that have not demonstrated a propensity historically to comply with voluntary standards, we would assume that they would conform only when "forced" to conform by a mandatory standard. Thus, we would assume that these small entities would experience the full costs of the voluntary standard once it becomes a mandatory standard.

In this framework, at a minimum, for us to judge a rule to be "cost-free" for small businesses, the following conditions would need to be met: (1) ASTM would have had to adopt all provisions in the draft final rule; (2) the ASTM standard would have had to be effective prior to the mandatory standard; and (3) historically, there would have had to have been 100 percent compliance with the ASTM standard in the industry. Even then, we would probably view the impact on small entities as "small" or "minimal," rather than "zero." Moreover, we would still need to consider any indirect costs on small businesses triggered by mandating the voluntary standard and account for those in the analysis because these could be significant, even in the absence of any measurable direct costs.

In answer to your second question, as noted above, for this rulemaking and other 104 nursery product rules, staff has conducted regulatory flexibility analyses following the SBA guidelines. The ACUS's document and recommendations refer primarily to benefit- cost analyses, which staff has not been directed to conduct for the section 104 rules. If the Commission determines that that the Commission wants staff to conduct benefit-cost analyses for these rules (as we do for product safety rules under the requirements of the CPSA, FHSA, and the FFA), we will do so. Moreover, as is our current practice, to the extent possible, we would follow the Office of Management and Budget's (OMB) guidelines for conducting these analyses, which are consistent with ACUS's recommendations. However, given the CPSIA's explicit direction to develop two nursery product rules every six months, conducting benefit-cost analyses in addition to the regulatory flexibility analyses would necessarily require additional resources.

Additional Response from the Office of the General Counsel

The question conflates and confuses two different types of economic analyses, and – perhaps because of this – mischaracterizes the referenced ACUS report from the Administrative Conference of the United States (ACUS). *See* Administrative Conference of the United States, Recommendation 2013-2, *Benefit-Cost Analysis at Independent Regulatory Agencies*, (June 13, 2013). For both the bassinet and play yard rules, the staff conducted the economic analysis that the CPSC is required to conduct, namely an assessment of the potential impact on small entities as required by the Regulatory Flexibility Act (RFA) in accordance with the Small Business Administration's (SBA) guidelines for complying with the RFA. As explained below, the CPSC is not required to conduct a cost-benefit analysis for these rules. The ACUS report's recommendations address only cost-benefit analyses and are more limited than the above question suggests.

E.O. 12866 and cost-benefit analysis. The ACUS report focuses on cost-benefit (or regulatory impact) analysis. As the ACUS report indicates, Executive Order (E.O.) 12,866 "requires Cabinet departments and other covered executive agencies to 'assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.'" ACUS Report at 2. As the ACUS report notes, independent regulatory agencies are not subject to this provision of E.O. 12866,[3] but are subject to "crosscutting statutes that may require some type of regulatory analysis, such as the Regulatory Flexibility Act." *Id*. at 3.

Analysis under the RFA. As the staff's response to this question indicates, staff prepared the economic analysis for the bassinet rule pursuant to the RFA to assess the economic impact the rule could have on small entities. *See* 5 U.S.C. §§ 601-12. The ACUS report's statement that independent regulatory agencies must comply with requirements of the RFA, is the only mention in the ACUS report of the RFA. The report is silent on the analysis that an agency should include to meet the RFA.

[3] *See* E.O. 12866, section 3(b) (defining "Agency" as: "unless otherwise indicated, means any authority of the United States that is an 'agency' under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10)").

CPSC's statutes. The ACUS report further notes that some independent agencies are required by their own statutes "to prepare a formal regulatory analysis statement that describes expected costs and benefits prior to issuing certain rules." ACUS Report at 3. The report cites the CPSC as an example of such an agency and refers to section 9(f) of the CPSA. That section of the CPSA provides that, when the Commission issues a rule under section 9 of the CPSA, the agency must prepare a final regulatory analysis of the rule that must contain, among other things, a description of the potential benefits and costs of the rule. *See* 15 U.S.C. § 2058(f). The rules the Commission is currently considering for bassinets and play yards would not be issued under the authority of section 9 of the CPSA. Rather, the authority for these rules is section 104 of the CPSIA. Nothing in that section requires the Commission to perform an analysis of costs and benefits when the Commission issues a rule under section 104.

Volunteering to conduct cost-benefit analysis. To the extent that the question suggests that the staff should perform cost-benefit analyses for rules issued under section 104 of the CPSIA, we note that there is no prohibition against conducting such an analysis. We also note, however, that section 104 of the CPSIA requires the Commission to issue mandatory standards for the nursery products identified in the CPSIA. The rules must be "substantially the same as" existing voluntary standards or more stringent than those voluntary standards. The statute does not give the Commission discretion to decline to issue a mandatory standard for these products on the basis of the cost impact of the standard. Thus, the Commission must issue a bassinet standard regardless of the balance of costs and benefits.

Limited nature of ACUS's recommendations. The ACUS report recommends that independent regulatory agencies expand their use of cost-benefit analysis. However, ACUS's recommendations are more limited than the question suggests. The report states: "the recommendation proposes that, to the extent Congress decides to impose or endorse new regulatory analysis requirements on independent regulatory agencies, Congress should consider giving those agencies the discretion to scale the analyses to the significance of the rules, and should consider the agency resources needed to satisfy such requirements." ACUS report at 5. Moreover, ACUS's recommendations are limited to "major rules." *Id.* at 7. "Major rules" are generally, but not limited to, rules that are likely to result in annual effect on the economy of $100 million or more. *See* 5 U.S.C. § 804(2).

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

Memorandum

Appendix A

Manufacturers Code	Man date	Total Incline Range		Infant Weighted Cylinder Test Results (Left / Right)				Result	Total Incline Range	Incline Range for all Failed Readings
				Seam 1	Seam 2	Seam 3	Seam 4			
A	8/1/2010	<1-6.0		P/P	P/P	P/P	Na	Pass	<1-6.0	
B1	1/30/2012	<1-4.0		P/P	P/P	P/P	Na	Pass	<1-4.0	
B2	1/30/2012	1.0-6.6		P/P	P/P	P/P	Na	Pass	1.0-6.6	
C	2/15/2011	<1-9.5		P/P	P/P	P/P	P/P	Pass	<1-9.5	
D	10/21/2011	**1.0-13.0**		**F/P**	P/P	P/P	Na	**Fail**	**1.0-13.0**	13
E	8/25/2011	5.0-8.8		P/P	Na	Na	Na	Pass	5.0-8.8	
F	May-11	**3.6-16.4**		**F/P**	P/P	P/P	**P/F**	**Fail**	**3.6-16.4**	12.7-16.4
G	11/5/2009	<1-2.4		P/P	P/P	P/P	Na	Pass	<1-2.4	
H1	5/12/2011	<1-4.9		P/P	P/P	P/P	Na	Pass	<1-4.9	
H2	11/21/2011	<1-1.7		P/P	P/P	P/P	Na	Pass	<1-1.7	
I	11/1/2011	<1-5.0		P/P	P/P	P/P	Na	Pass	<1-5.0	
J1	May-08	**<1-13.3**		**F/P**	**F/F**	P/P	Na	**Fail**	**<1-13.3**	10.4-13.3
J2	May-11	**2.5-15.7**		**F/P**	P/P	**P/F**	Na	**Fail**	**2.5-15.7**	11.5-15.7
K	10/25/2011	1.4-8.2		P/P	P/P	P/P	P/P	Pass	1.4-8.2	
L	11/4/2011	<1-6.1		P/P	P/P	P/P	Na	Pass	<1-6.1	
M	9/20/2011	<1-7.7		P/P	P/P	P/P	P/P	Pass	<1-7.7	

SUMMARY NOTES: 10 degrees or less considered a pass.

13 Different Manufacturers: 10 pass and 3 fail

16 Different Bassinets: 12 pass and 4 fail (two from the same manufacturer)

Of the 12 passing bassinets, only 3 had readings above 8 degrees.

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

Memorandum

Appendix B

Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	Wedge Right	Wedge Left	Hinged Right	Hinged Left	
1	1	1	1	2.7	1.7	34.9	35.7	-4.6	-6.6	cylinder at end
1	1	1	2	2.8	1.6	34.1	34.8	-4.1	-6	
1	2	1	1	3.2	1.2	34.5	38.8	-3.3	-6.9	
1	2	1	2	3.5	0.6	33.8	37.4	-4.1	-7.3	
1	3	1	1	7.4	0.7	28.5	39.4	-1	-8.9	
1	3	1	2	6.8	1.6	27.8	38.2	-0.1	-6.9	
2	1	1	1	3.2	10.7	36.4	25.9	4.5	1.7	
2	1	1	2	4.2	11.5	36.2	24.6	6.1	0.6	
2	2	1	1	6.5	2.4	35.1	38.9	-2.5	-5.3	
2	2	1	2	6.3	2.1	36	38.7	-4.9	-7.2	re-zero'd
2	3	1	1	11.8	1.8	24.6	38.9	2.5	-4.9	
2	3	1	2	13.5	2.5	23.1	38.7	-1.9	-6.1	
3	1	1	1	0.4	1.5	41.9	39	-7.7	-6.7	
3	1	1	2	0.3	1.9	41.2	38.8	-8.5	-6.5	
3	2	1	1	1.6	1.3	41.2	40.5	-6.6	-7.9	
3	2	1	2	1.1	1.7	39.9	40.3	-7.4	-7.7	
3	3	1	1	2.1	0.6	39.6	42	-6.6	-9.4	
3	3	1	2	2	0.2	37.3	40.9	-7	-8.6	
4	1	1	1	6.6	13.7	33.5	23.7	-1.1	3.5	
4	1	1	2	4.1	12	33	25.2	-2.7	3.6	
4	2	1	1	10.7	11.1	30.6	29.4	1.4	3	
4	2	1	2	7.8	12	30.2	29.7	0.7	3.5	
4	3	1	1	12.6	1.2	23.3	40.2	-7.2	5.6	
4	3	1	2	14.2	0.4	20	41	-6.3	6.5	

5	1	1	1	10.4	12.5	36.6	34.1	-0.9	-1.2	Measured left side First
5	1	1	2	8.7	9.9	35.5	35.9	-1.1	-2	
5	2	1	1	0.7	9.6	45.9	35.7	-9.7	-3.3	
5	2	1	2	0.1	5	44.8	24.4	-10.3	-6.3	
5	3	1	1	4.2	1.7	37.4	39.4	-7.1	-5.5	
5	3	1	2	3	2.5	31.6	40.4	-8.9	-6.6	
5	4	1	1	12.2	5.8	34.8	38	-2.6	-4	
5	4	1	2	13.1	6.8	23.7	39	-5	-4.9	
1	1	2	1	2.5	1.3	36.2	35.3	-8.4	-9.2	
1	1	2	2	3.1	1.1	35.8	36.3	6.2	-6.9	Position of the Cycliner
1	2	2	1	3.6	0.5	34.7	38.1	-6.6	-9.8	
1	2	2	2	3.9	0.2	35	38.2	-9.8	-8.7	
1	3	2	1	8.6	1.3	29.1	37.9	2.8	-9.5	
1	3	2	2	8.1	1.4	28.8	38.1	-2	-9.5	
2	1	2	1	2.5	7.5	38.4	28	-5.7	1	
2	1	2	2	1.7	9.1	37.8	26.1	-6.2	0	
2	2	2	1	3.8	2.4	36.8	40.1	-4.5	-6.1	
2	2	2	2	5.7	2.7	36.8	39.6	-3.5	-6.3	
2	3	2	1	10.3	2	25.7	38	-3.3	-6.5	
2	3	2	2	10	0.6	25.7	38.6	-2.6	-8	
3	1	2	1	0.2	1.9	41.6	38.4	-9.2	-7.3	Turned off again
3	1	2	2	0	2	42.3	38.2	-8.5	-5.9	Gage turned off automatically. Turned back on no re-zeroing
3	2	2	1	1.3	1.8	41	40.5	-7.6	-8.5	
3	2	2	2	1.3	1	41.1	40.4	-7.7	-8.8	
3	3	2	1	1.8	0.5	39.4	40.9	7.1	-8.9	
3	3	2	2	1.2	0.3	39.8	41.3	-7	-9.4	
4	1	2	1	2.2	11.1	39.3	30.5	2.8	3	
4	1	2	2	2.1	10.2	38.7	30.4	3.7	2.6	
4	2	2	1	8.7	12.5	29.3	27.2	0.6	2	

4	2	2	2	7.4	12.6	30.1	28.3	1.5	2.3	
4	3	2	1	11.7	1.4	24.1	27.2	6.8	-6.9	
4	3	2	2	13	0.4	22.6	40.3	8.1	-7.5	
5	1	2	1	11.7	10.2	33.7	38.8	1.2	-2.9	
5	1	2	2	11.7	14	35.5	38	-4.1	-2.5	
5	2	2	1	2.5	12.5	45	35.7	-9.9	-10.4	
5	2	2	2	0.4	10.1	44.8	34.3	-6.1	-10.2	
5	3	2	1	3.5	3.6	42.6	40.6	-6.2	-8.8	Seam 2 cylinder needed a stop for right side measurement
5	3	2	2	1.7	2.1	44	40.9	-6.8	-9.1	
5	4	2	1	14.9	7.5	35.8	38.6	-3.3	-3.8	
5	4	2	2	7	8.9	35	37	-4.9	-0.6	
1	1	3	1	5.4	0.4	35.3	37.4	-6.7	-7.7	
1	1	3	2	5.1	1.2	31.1	40.7	-5.7	-7.3	Arranged seam 2 no stop
1	2	3	1	3.8	0.8	33.7	37.9	-5.3	-9.3	Left on the outside (Cylinder is off center due to width)
1	2	3	2	3.8	0.7	29.6	41.8	-3.8	-7.9	
1	3	3	1	5.9	0.1	28.5	38.5	-2.1	-10.1	
1	3	3	2	7.1	1	23.3	43	-1.2	-9.4	
2	1	3	1	3.7	10.4	37	27.2	-7.9	-7.1	
2	1	3	2	3	8.9	33.4	33.7	-5.6	-0.5	
2	2	3	1	7.2	2	36.9	39	-7.2	-6.2	Left on the outside
2	2	3	2	7.2	2.8	32.7	42.9	-4.2	-7	
2	3	3	1	11.9	2.2	25.4	39.1	0.2	-6.7	
2	3	3	2	12.5	2.1	22.8	42.7	2.1	-7.7	
3	1	3	1	0.9	1.8	41.5	39.2	-8.2	-5.1	
3	1	3	2	0.3	1.7	37.4	42.8	-9.2	-6.3	
3	2	3	1	1.3	1.4	40.5	40.5	-8.5	-9.6	Left is on the outside
3	2	3	2	1.8	1.3	36.2	44.4	-7.5	-8	
3	3	3	1	1.4	0.3	39.2	41.1	-7.6	-9.8	

3	3	3	2	1.5	0.5	35.6	45.8	-7.5	-8.6	
4	1	3	1	9.1	12	33.5	25.9	-9.5	3.1	
4	1	3	2	8.1	12.3	30.5	30.5	-2.4	2.7	
4	2	3	1	8.4	8.3	30.9	28.8	0.2	2.8	
4	2	3	2	8.2	8.5	25.4	33.9	1.9	1.4	Left is the outside
4	3	3	1	13.5	3.1	22.1	39.9	6	-6.7	
4	3	3	2	14	2.5	16.4	43.9	7.1	-7.1	
5	1	3	1	9.8	10.9	34	34.6	-2.7	-1.7	
5	1	3	2	10.6	10.8	35.3	34.1	-2.2	1	
5	2	3	1	1.7	10.3	46.1	30.7	-6.8	-10.6	seam 3 left side needed a stop
5	2	3	2	0.6	9.9	44.8	31.9	-5.8	-10.6	right is the outside
5	3	3	1	5.7	5.3	42.2	40	-7	-11.2	
5	3	3	2	8.2	3.8	42.2	40	-6.2	-8.4	
5	4	3	1	14.5	7.8	38.9	37	-3.7	-4	
5	4	3	2	15.9	8.6	34.1	37.7	-4.3	-4.9	

Memorandum

Appendix C

Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	BLC Pass /Fail
1	1	1	1	1	2.7	1.7	PASS
2	1	1	1	2	2.8	1.6	PASS
3	1	1	2	1	2.5	1.3	PASS
4	1	1	2	2	3.1	1.1	PASS
5	1	1	3	1	5.4	0.4	PASS
6	1	1	3	2	5.1	1.2	PASS
7	1	2	1	1	3.2	1.2	PASS
8	1	2	1	2	3.5	0.6	PASS
9	1	2	2	1	3.6	0.5	PASS
10	1	2	2	2	3.9	0.2	PASS
11	1	2	3	1	3.8	0.8	PASS
12	1	2	3	2	3.8	0.7	PASS
13	1	3	1	1	7.4	0.7	PASS
14	1	3	1	2	6.8	1.6	PASS
15	1	3	2	1	8.6	1.3	PASS
16	1	3	2	2	8.1	1.4	PASS
17	1	3	3	1	5.9	0.1	PASS
18	1	3	3	2	7.1	1	PASS
19	2	1	1	1	3.2	**10.7**	**FAIL**
20	2	1	1	2	4.2	**11.5**	**FAIL**
21	2	1	2	1	2.5	7.5	PASS
22	2	1	2	2	1.7	9.1	PASS
23	2	1	3	1	3.7	**10.4**	**FAIL**
24	2	1	3	2	3	8.9	PASS

Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	BLC Pass/Fail
25	2	2	1	1	6.5	2.4	PASS
26	2	2	1	2	6.3	2.1	PASS
27	2	2	2	1	3.8	2.4	PASS
28	2	2	2	2	5.7	2.7	PASS
29	2	2	3	1	7.2	2	PASS
30	2	2	3	2	7.2	2.8	PASS
31	2	3	1	1	**11.8**	1.8	**FAIL**
32	2	3	1	2	**13.5**	2.5	**FAIL**
33	2	3	2	1	**10.3**	2	**FAIL**
34	2	3	2	2	10	0.6	PASS
35	2	3	3	1	**11.9**	2.2	**FAIL**
36	2	3	3	2	**12.5**	2.1	**FAIL**
37	3	1	1	1	0.4	1.5	PASS
38	3	1	1	2	0.3	1.9	PASS
39	3	1	2	1	0.2	1.9	PASS
40	3	1	2	2	0	2	PASS
41	3	1	3	1	0.9	1.8	PASS
42	3	1	3	2	0.3	1.7	PASS
43	3	2	1	1	1.6	1.3	PASS
44	3	2	1	2	1.1	1.7	PASS
45	3	2	2	1	1.3	1.8	PASS
46	3	2	2	2	1.3	1	PASS
47	3	2	3	1	1.3	1.4	PASS
48	3	2	3	2	1.8	1.3	PASS
49	3	3	1	1	2.1	0.6	PASS
50	3	3	1	2	2	0.2	PASS
51	3	3	2	1	1.8	0.5	PASS
52	3	3	2	2	1.2	0.3	PASS
53	3	3	3	1	1.4	0.3	PASS
54	3	3	3	2	1.5	0.5	PASS
55	4	1	1	1	6.6	**13.7**	**FAIL**

Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	BLC Pass/Fail
56	4	1	1	2	4.1	**12**	**FAIL**
57	4	1	2	1	2.2	**11.1**	**FAIL**
58	4	1	2	2	2.1	**10.2**	**FAIL**
59	4	1	3	1	9.1	**12**	**FAIL**
60	4	1	3	2	8.1	**12.3**	**FAIL**
61	4	2	1	1	**10.7**	**11.1**	**FAIL**
62	4	2	1	2	7.8	**12**	**FAIL**
63	4	2	2	1	8.7	**12.5**	**FAIL**
64	4	2	2	2	7.4	**12.6**	**FAIL**
65	4	2	3	1	8.4	8.3	PASS
66	4	2	3	2	8.2	8.5	PASS
67	4	3	1	1	**12.6**	1.2	**FAIL**
68	4	3	1	2	**14.2**	0.4	**FAIL**
69	4	3	2	1	**11.7**	1.4	**FAIL**
70	4	3	2	2	**13**	0.4	**FAIL**
71	4	3	3	1	**13.5**	3.1	**FAIL**
72	4	3	3	2	**14**	2.5	**FAIL**
73	5	1	1	1	**10.4**	**12.5**	**FAIL**
74	5	1	1	2	8.7	9.9	PASS
75	5	1	2	1	**11.7**	**10.2**	**FAIL**
76	5	1	2	2	**11.7**	**14**	**FAIL**
77	5	1	3	1	9.8	**10.9**	**FAIL**
78	5	1	3	2	**10.6**	**10.8**	**FAIL**
79	5	2	1	1	0.7	9.6	PASS
80	5	2	1	2	0.1	5	PASS
81	5	2	2	1	2.5	**12.5**	**FAIL**
82	5	2	2	2	0.4	**10.1**	**FAIL**
83	5	2	3	1	1.7	**10.3**	**FAIL**
84	5	2	3	2	0.6	9.9	PASS
85	5	3	1	1	4.2	1.7	PASS
86	5	3	1	2	3	2.5	PASS

Trial	Product	Seam	Operator	Rep	Cylinder Right	Cylinder Left	BLC Pass/Fail
87	5	3	2	1	3.5	3.6	PASS
88	5	3	2	2	1.7	2.1	PASS
89	5	3	3	1	5.7	5.3	PASS
90	5	3	3	2	8.2	3.8	PASS
91	5	4	1	1	**12.2**	5.8	**FAIL**
92	5	4	1	2	**13.1**	6.8	**FAIL**
93	5	4	2	1	**14.9**	7.5	**FAIL**
94	5	4	2	2	7	8.9	PASS
95	5	4	3	1	**14.5**	7.8	**FAIL**
96	5	4	3	2	**15.9**	8.6	**FAIL**