

ESTTA Tracking number: **ESTTA642965**

Filing date: **12/05/2014**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91205483
Party	Plaintiff Baba Slings Pty Ltd
Correspondence Address	MARK BORGHESE BORGHESE LEGAL LTD 10161 PARK RUN DRIVE, SUITE 150 LAS VEGAS, NV 89145 UNITED STATES mark@borgheselegal.com
Submission	Plaintiff's Notice of Reliance
Filer's Name	Mark Borghese
Filer's e-mail	mark@borgheselegal.com,docket@borgheselegal.com
Signature	/MB/
Date	12/05/2014
Attachments	2014-12-05-Notice of Reliance.pdf(20050 bytes ) Exhibit A.pdf(882050 bytes ) Exhibit B.pdf(1577978 bytes ) Exhibit C.pdf(2129263 bytes ) Exhibit D.pdf(933787 bytes )



- The file wrapper for Trademark App. Serial No.: 79/103197 for theBabaSling
- The file wrapper for Trademark App. Serial No.: 85/633700 for Baba Slings

This evidence is relevant to the standing of Opposer, the priority of Opposer's mark, the similarity of the parties' respective marks, the similarity and relatedness of the goods at issue, the similarity of the marketing channels, and the registrability of Applicant's mark.

2. Opposer will rely on and introduce into evidence Applicant's responses to Interrogatories 1 and 6 and Applicant's Responses to Requests for Production of Documents 1-8, attached hereto as **Exhibit B**. This evidence is relevant to the standing of Opposer, the priority of Opposer's mark, and the registrability of Applicant's mark.

3. Opposer will rely on printouts of Internet websites and printed publications attached as **Exhibit C** this evidence is relevant to the priority of Opposer's mark, the similarity of the parties' respective marks, the similarity and relatedness of the goods at issue, the similarity of the marketing channels.

- The following pages of Exhibit C related to the priority of Opposer's mark: BABA 0021, BABA 024 - 033, BABA 0043, BABA 0435, BABA 0440, BABA 0442, BABA 0445 – 0457, BABA 0493, BABA 0496 – 0499, and BABA 0501.

- The following pages of Exhibit C relate to the similarities of the parties' respective marks: all pages.

- The following pages of Exhibit C relate to the similarity and relatedness of the goods at issue and the similarity of the marketing channels: BABA 0021, BABA 024 - 033, BABA 0043, BABA 0435, BABA 0440, BABA 0442, BABA 0445 – 0457, BABA 0493, BABA 0496 – 0499, and BABA 0501.

4. Opposer will rely on and introduce into evidence the following printed publications and official records from the Federal Register attached hereto as **Exhibit D**:

- Vol. 76, No. 143, Tuesday, July 26, 2011, pp. 44463 – 44464
- Vol. 76, No. 154, Wednesday, August 10, 2011, pp. 49286 – 49291
- Vol. 76, No. 216, Tuesday, November 8, 2011, pp. 69482 – 69544
- Vol. 78, No. 66, Friday, April 5, 2013, pp. 20511 – 20522
- Vol. 79, No. 60, Friday, March 28, 2014, pp. 17422 – 17433
- Vol. 79, No. 141, Wednesday, July 23, 2014, pp. 4274 – 42734

This evidence is relevant to the priority of Opposer’s mark.

True and correct copies of the forgoing are submitted herewith.

Respectfully submitted,

Dated: December 5, 2014

By:   
Mark Borghese, Esq.  
Borghese Legal, Ltd.  
10161 Park Run Drive, Suite 150  
Las Vegas, Nevada 89145  
Tel: (702) 382-0200  
Fax: (702) 382-0212  
Email: [mark@borgheselegal.com](mailto:mark@borgheselegal.com)  
*Attorney for Opposer Baba Slings Pty Ltd*

**CERTIFICATE OF SERVICE**

I hereby certify that a true and complete copy of the foregoing **OPPOSER'S NOTICE OF RELIANCE** has been served on the attorney of record for the Applicant, by mailing said copy on December 5, 2014, via First Class Mail, postage prepaid, and sending a courtesy copy via email to the attorney's correspondence address of record:

Brian A. Coleman  
**Drinker Biddle & Reath LLP**  
1500 K Street, N.W.  
Washington, DC 20005-1209  
Brian.Coleman@dbr.com

  
\_\_\_\_\_  
Mark Borghese

# **EXHIBIT A**

# **EXHIBIT A**

**THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

**In the Matter of Trademark Application No.: 79/103197**

**Mark: theBabaSling**

**Filed on: September 6, 2011**

Baba Slings Pty Ltd,	)	
	)	
Opposer,	)	Opposition No:
	)	
vs.	)	
	)	
BabaSlings Limited,	)	
	)	
Applicant.	)	
_____	)	

**NOTICE OF OPPOSITION**

Opposer, Baba Slings Pty Ltd, an Australian proprietary limited company (“Opposer”) will be damaged by registration of the design mark theBabaSling set forth in Application Serial No. 79/103197 (the “Application”), owned by Applicant BabaSlings Limited, a United Kingdom private limited company (“Applicant”). Opposer timely filed an extension of time to oppose and now states the following grounds for its opposition to the Application:

1. Opposer is the company behind the popular sling baby carriers sold under the mark BABA SLINGS and variations thereof. Opposer’s products are sold in numerous countries around the world including the United States.

2. Opposer is the owner of international trademark registrations and applications in twenty six (26) countries for the mark BABA SLINGS and variations thereof (“BABA SLINGS Marks”), including an application for the word mark BABA SLINGS pending before the United States Trademark Office, Application No. 85/633700 for goods in Class 018, namely, “Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags;

Sling bags for carrying infants; Slings for carrying infants.”

3. Applicant is a rouge licensee of Opposer which previously had authority to sell Opposer’s baby carrier products in Europe under the derivative design mark theBabaSling appearing in the Application.

4. To the extent Applicant still claims a license from Opposer, such license has never included the right to sell any products in the United States under the BABA SLINGS mark or under the derivative design mark theBabaSling.

5. Moreover, Applicant has no rights in the BABA SLINGS mark itself and is at best a geographically limited licensee of the derivative design mark theBabaSling appearing in the Application.

6. Upon information and belief, Applicant has never sold any products in the United States under the design mark theBabaSling.

7. In contrast, Opposer has nearly ten (10) years of strong common law rights in the United States with product sales using the BABA SLINGS Marks beginning at least as early as October 2002 in United States commerce.

8. By virtue of Opposer’s continuous and extensive use and advertising in connection with Opposer’s goods, the BABA SLINGS Marks are widely and favorable known by the relevant public in the United States and are symbols of the substantial goodwill and recognition established by Opposer for its BABA SLINGS Marks.

9. On September 6, 2011, Applicant filed an application to register theBabaSlings mark for goods in Class 018 including, “baby carrying bags, and bags for carrying babies' accessories; carriers for babies and children worn on the body; slings for carrying babies and children; sling bags for carrying babies and children” (“Applicant’s Mark”).

10. Applicant’s Mark is highly similar in sight, sound, appearance, and commercial

impression to Opposer's BABA SLINGS Marks.

11. Applicant had actual knowledge of Opposer's BABA SLINGS Marks prior to filing the Application.

12. Opposer will be damaged by registration of Applicant's Mark, because the mark so resembles Opposer's BABA SLINGS Marks as to be likely to cause confusion, mistake, and/or deception, particularly because the parties' goods are identical or nearly identical.

13. Persons familiar with Opposer's BABA SLINGS Marks and the goods offered by Opposer under its BABA SLINGS Marks would be likely to believe erroneously that Applicant's goods are the goods of Opposer or are authorized, endorsed, sponsored, or licensed by Opposer for sale in the United States.

14. Thus, registration of Applicant's Mark on the Principal Register would be inconsistent with Opposer's prior rights in its BABA SLINGS Marks and in violation of Section 2(a) and Section 2(d) of the Lanham Act, 15 U.S.C. § 1052(a) and 15 U.S.C. § 1052(d).

FOR THESE REASONS, Opposer requests that the Board sustain this proceeding in Opposer's favor by refusing registration of theBabaSlings mark underlying Application Serial No. 79/103197. Please direct all notices, pleadings, and correspondence in this matter to the undersigned counsel for Opposer Baba Slings Pty Ltd.

Respectfully submitted,

Dated: June 5, 2012

By:   
Mark Borghese, Esq.  
Borghese Legal, Ltd.  
10161 Park Run Drive, Suite 150  
Las Vegas, Nevada 89145  
Tel: (702) 382-0200  
Fax: (702) 382-0212  
Email: [mark@borgheselegal.com](mailto:mark@borgheselegal.com)  
*Attorney for Opposer Baba Slings Pty Ltd*

**CERTIFICATE OF SERVICE**

I hereby certify that a true and complete copy of the foregoing **NOTICE OF OPPOSITION** has been served on Michael M. Ballard, the attorney of record for the Applicant, by mailing said copy on June 5, 2012, via First Class Mail, postage prepaid, to the attorney's correspondence address of record:

Michael M. Ballard  
**Workman Nydegger**  
1000 Eagle Gate Tower  
60 East South Temple  
Salt Lake City UT 84111

  
\_\_\_\_\_  
Mark Borghese



**Electronic System for Trademark Trials and Appeals**

**Receipt**

Your submission has been received by the USPTO.  
 The content of your submission is listed below.  
 You may print a copy of this receipt for your records.

ESTTA Tracking number: **ESTTA476217**

Filing date: **06/05/2012**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
 BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

**Notice of Opposition**

Notice is hereby given that the following party opposes registration of the indicated application.

**Opposer Information**

<b>Name</b>	Baba Slings Pty Ltd
<b>Granted to Date of previous extension</b>	06/09/2012
<b>Address</b>	486 Hunchy Rd Hunchy, 4555 AUSTRALIA

<b>Attorney information</b>	Mark Borghese Borghese Legal, Ltd. 10161 Park Run Drive, Suite 150 Las Vegas, NV 89145 UNITED STATES mark@borgheselegal.com Phone:(702) 382-0200
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**Applicant Information**

<b>Application No</b>	79103197	<b>Publication date</b>	04/10/2012
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<b>Opposition Filing Date</b>	06/05/2012	<b>Opposition Period Ends</b>	06/09/2012
<b>International Registration No.</b>	1088031	<b>International Registration Date</b>	07/07/2011
<b>Applicant</b>	BabaSlings Limited 1 Amber House, 22b St John's Road Hove, BN3 2EZ UNITED KINGDOM		

### Goods/Services Affected by Opposition

<p>Class 018.</p> <p>All goods and services in the class are opposed, namely: Bags, namely, all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and traveling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods</p>
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### Grounds for Opposition

Deceptiveness	Trademark Act section 2(a)
False suggestion of a connection	Trademark Act section 2(a)
Priority and likelihood of confusion	Trademark Act section 2(d)

### Mark Cited by Opposer as Basis for Opposition

<b>U.S. Application No.</b>	85633700	<b>Application Date</b>	05/23/2012
<b>Registration Date</b>	NONE	<b>Foreign Priority Date</b>	NONE
<b>Word Mark</b>	BABA SLINGS		
<b>Design Mark</b>	85633700#TMSN.jpeg		
<b>Description of Mark</b>	NONE		

<b>Goods/Services</b>	Class 018. First use: First Use: 1999/00/00 First Use In Commerce: 2002/10/00 (Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants(Based on 44(e)) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants
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<b>Attachments</b>	85633700#TMSN.jpeg ( 1 page )( bytes ) 2012-06-05-Opposition.pdf ( 4 pages )(153340 bytes )
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### Certificate of Service

The undersigned hereby certifies that a copy of this paper has been served upon all parties, at their address record by First Class Mail on this date.

<b>Signature</b>	/MB/
<b>Name</b>	Mark Borghese
<b>Date</b>	06/05/2012

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ESTTA Tracking number: **ESTTA485307**

Filing date: **07/24/2012**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91205483
Party	Defendant Baba Slings Limited
Correspondence Address	ROBYN L PHILLIPS WORKMAN NYDEGGER 1000 EAGLE GATE TOWER , 60 EAST SOUTH TEMPLE SALT LAKE CITY, UT 84111 UNITED STATES mballard@wnlaw.com, docketing@wnlaw.com, rphillips@wnlaw.com
Submission	Answer
Filer's Name	Robyn L. Phillips
Filer's e-mail	rphillips@wnlaw.com, docketing@wnlaw.com
Signature	/Robyn L. Phillips/
Date	07/24/2012
Attachments	15584_53_1 Answer.pdf ( 6 pages )(224384 bytes )

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Trademark Serial No. 79/103,197  
Filing Date: September 6, 2011  
For the Mark: **theBabaSling**

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BABA SLINGS PTY LTD,	)	
	)	
Opposer,	)	Opposition No. 91205483
	)	
v.	)	<b>APPLICANT’S ANSWER TO NOTICE</b>
	)	<b>OF OPPOSITION</b>
BABASLINGS LIMITED,	)	
	)	
Applicant.	)	

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In response to the Notice of Opposition, dated June 5, 2012, Applicant Babaslings Limited (“Applicant”) hereby responds and answers the Notice of Opposition filed by Opposer Baba Slings Pty Ltd. (“Opposer”) follows:

**ANSWER TO NOTICE OF OPPOSITION**

Applicant admits that it is a United Kingdom company. Applicant lacks knowledge or information sufficient to form a basis to admit or deny that Opposer is an Australian proprietary limited company. Applicant admits that the records of the Trademark Trial and Appeal Board (“TTAB”) appear to show that Opposer filed an extension of time to oppose Applicant’s mark before the deadline. Applicant denies any and all remaining allegations of the opening paragraph of the Notice of Opposition.

Applicant hereby answers Opposer’s grounds for opposition as follows:

1. Applicant denies that “Opposer is the company behind the popular sling baby carriers” sold under the name or mark BABA SLINGS and variations thereof. Applicant lacks

knowledge or information sufficient to form a basis to admit or deny any and all remaining allegations set forth in paragraph 1 of the Notice of Opposition, and, therefore, denies such allegations.

2. Applicant admits that a review of the Trademark Electronic Search System (“TESS”) database of the United States Patent and Trademark Office (“PTO”) reveals that Opposer is listed as the owner of United States Trademark Application Serial No. 85/633,700 (“the ‘700 Application’”) for goods in International Class 18 identified as “Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies’ accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants” as identified in paragraph 2 of the Notice of Opposition. Applicant lacks knowledge or information sufficient to form a basis to admit or deny whether Opposer is currently the owner of this application, and therefore, denies the same. Applicant denies any and all remaining allegations set forth in paragraph 2 of the Notice of Opposition.

3. Denied.

4. Denied.

5. Denied.

6. Denied.

7. Applicant lacks knowledge or information sufficient to form a basis to admit or deny any and all allegations set forth in paragraph 7 of the Notice of Opposition, and, therefore, denies such allegations.

8. Applicant lacks knowledge or information sufficient to form a basis to admit or deny any and all allegations set forth in paragraph 8 of the Notice of Opposition, and, therefore, denies such allegations.

9. Applicant admits that on September 6, 2011, Applicant filed a trademark application with the PTO, United States Trademark Application Serial No. 79/103,197 (“the ‘197 Application’”) for the mark “theBabaSling with design” for use on goods in International Class 18 identified as “Bags, namely, all purpose carrying bags, baby carrying bags, and bags for

carrying babies' accessories; trunks and traveling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods." Applicant denies any and all remaining allegations set forth in paragraph 9 of the Notice of Opposition.

10. Applicant lacks knowledge or information sufficient to form a basis to admit or deny any and all allegations set forth in paragraph 10 of the Notice of Opposition, and, therefore, denies such allegations.

11. Applicant lacks knowledge or information sufficient to form a basis to admit or deny any and all allegations set forth in paragraph 11 of the Notice of Opposition, and, therefore, denies such allegations.

12. Applicant lacks knowledge or information sufficient to form a basis to admit or deny any and all allegations set forth in paragraph 12 of the Notice of Opposition, and, therefore, denies such allegations.

13. Applicant lacks knowledge or information sufficient to form a basis to admit or deny any and all allegations set forth in paragraph 13 of the Notice of Opposition, and, therefore, denies such allegations.

14. Denied.

Applicant denies any and all remaining allegations set forth in the Notice of Opposition.

#### **AFFIRMATIVE DEFENSES**

By way of defense to the allegations set forth in the Notice of Opposition, Applicant asserts the following:

#### **FIRST AFFIRMATIVE DEFENSE**

Opposer's Notice of Opposition fails to state a claim upon which relief can be granted.

## **SECOND AFFIRMATIVE DEFENSE**

Opposer's claims are barred by the doctrine of laches, estoppel, acquiescence, and/or waiver.

## **THIRD AFFIRMATIVE DEFENSE**

Opposer is not likely to be damaged by registration of the '197 Application, and therefore, lacks standing to oppose the same.

## **FOURTH AFFIRMATIVE DEFENSE**

Any rights Opposer may have in its asserted mark are limited and narrow in scope of protection and, therefore, no likelihood of confusion exists between Opposer's mark in the '700 Application as applied to Opposer's services and goods and Applicant's mark covered by the '197 Application as applied to Applicant's goods.

## **FIFTH AFFIRMATIVE DEFENSE**

Applicant has priority over any rights Opposer may have in its mark covered by the '700 Application, and as a result any rights that Opposer does have in the mark covered by the '700 Application are inferior to Applicant's rights.

## **RELIEF REQUESTED**

In view of the foregoing, Applicant respectfully requests that the relief requested by Opposer be denied, that the Notice of Opposition be dismissed with prejudice, and that the registration of Applicant's '197 Application be granted.

All correspondence and telephonic communications should be directed to:

Robyn L. Phillips, Reg. No. 39,330  
WORKMAN NYDEGGER  
60 East South Temple Street, Ste. 1000  
Salt Lake City, Utah 84111  
Telephone: (801) 533-9800  
rphillips@wnlaw.com

DATED this 24th day of July, 2012.

Respectfully submitted,

/Robyn L. Phillips/  
Robyn L. Phillips, Reg. No. 39,330

**WORKMAN | NYDEGGER**  
60 East South Temple,  
Suite 1000  
Salt Lake City, Utah 84111  
Telephone: (801) 533-9800  
Facsimile: (801) 328-1707

Attorneys for Applicant  
**BABASLINGS LIMITED**

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the foregoing APPLICANT'S ANSWER TO THE NOTICE OF OPPOSITION was served on Opposer by mailing a true copy thereof to its attorney of record by First Class Mail, postage prepaid this 24th day of July, 2012, in an envelope addressed as follows:

Mark Borghese, Esq.  
Borghese Legal, Ltd.  
10161 Park Run Drive, Suite 150  
Las Vegas, NV 89145

/Robyn L. Phillips/

Generated on: This page was generated by TSDR on 2013-05-15 13:47:58 EDT

Mark: THEBABASLING



US Serial Number: 79103197

Application Filing Date: Sep. 06, 2011

Register: Principal

Mark Type: Trademark

Status: An opposition after publication is pending at the Trademark Trial and Appeal Board. For further information, see TTABVue on the Trademark Trial and Appeal Board web page.

Status Date: Jun. 07, 2012

Publication Date: Apr. 10, 2012

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## Mark Information

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Mark Literal Elements: THEBABASLING

Standard Character Claim: No

Mark Drawing Type: 3 - AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/ LETTER(S)/NUMBER(S)

Description of Mark: The mark consists of the wording "THEBABASLING" below a design of a crescent moon holding a baby.

Color(s) Claimed: Color is not claimed as a feature of the mark.

Design Search Code(s): 01.11.02 - Moons, crescent; Partial moons, including half moons and crescent moons (not a moon with craters); Moons, half  
02.05.01 - Children, heads, portraiture, busts; Heads of children; Busts of children  
02.05.02 - Children depicted in silhouettes or profiles of children; Silhouettes of children  
02.05.06 - Baby; Children, baby or babies

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## Related Properties Information

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International Registration Number: 1088031

International Registration Date: Jul. 07, 2011

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## Goods and Services

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Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis (()) identify any goods/services not claimed in a Section 15 affidavit of
- Asterisks \*.\* identify additional (new) wording in the goods/services.

**For:** Bags, namely, all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and traveling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods

International Class(es): 018 - Primary Class

U.S Class(es): 001, 002, 003, 022, 041

Class Status: ACTIVE

Basis: 66(a)

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## Basis Information (Case Level)

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Filed Use: No

Currently Use: No

Amended Use: No

Filed ITU: No

Currently ITU: No

Amended ITU: No

Filed 44D: No

Currently 44D: No

Amended 44D: No

Filed 44E: No

Currently 44E: No

Amended 44E: No

Filed 66A: Yes

Currently 66A: Yes

Filed No Basis: No

Currently No Basis: No

## Current Owner(s) Information

**Owner Name:** BabaSlings Limited

**Owner Address:** 1 Amber House, 22b St John's Road  
Hove BN3 2EZ  
UNITED KINGDOM

**Legal Entity Type:** Private Limited Company

**State or Country Where Organized:** UNITED KINGDOM

## Attorney/Correspondence Information

### Attorney of Record

**Attorney Name:** Michael M. Ballard

**Docket Number:** 15584.53

**Attorney Primary Email Address:** [mballard@wnlaw.com](mailto:mballard@wnlaw.com)

**Attorney Email Authorized:** Yes

### Correspondent

**Correspondent Name/Address:** ROBERT L STOLL  
DRINKER BIDDLE & REATH LLP  
1500 K STREET NW  
SUITE 1100  
WASHINGTON, DISTRICT OF COLUMBIA 20005-1209  
UNITED STATES

**Phone:** 801 533-9800

**Fax:** 801 328-1707

**Correspondent e-mail:** [mballard@wnlaw.com](mailto:mballard@wnlaw.com) [docketing@wnlaw.com](mailto:docketing@wnlaw.com)

**Correspondent e-mail Authorized:** Yes

### Domestic Representative - Not Found

## Prosecution History

Date	Description	Proceeding Number
Dec. 02, 2012	NOTIFICATION PROCESSED BY IB	
Jul. 28, 2012	REFUSAL PROCESSED BY IB	
Jun. 07, 2012	OPPOSITION INSTITUTED NO. 999999	205483
Jun. 06, 2012	OPPOSITION NOTICE (IB REFUSAL) SENT TO IB	
Jun. 06, 2012	OPPOSITION NOTICE (IB REFUSAL) CREATED	
Apr. 27, 2012	EXTENSION OF TIME TO OPPOSE RECEIVED	
Apr. 10, 2012	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Apr. 10, 2012	PUBLISHED FOR OPPOSITION	
Apr. 04, 2012	NOTIFICATION OF POSSIBLE OPPOSITION SENT TO IB	
Apr. 04, 2012	NOTICE OF START OF OPPOSITION PERIOD CREATED, TO BE SENT TO IB	
Mar. 21, 2012	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Mar. 05, 2012	LAW OFFICE PUBLICATION REVIEW COMPLETED	73787
Mar. 01, 2012	ASSIGNED TO LIE	73787
Feb. 14, 2012	APPROVED FOR PUB - PRINCIPAL REGISTER	
Feb. 03, 2012	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Feb. 02, 2012	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Feb. 02, 2012	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jan. 19, 2012	REFUSAL PROCESSED BY IB	
Dec. 29, 2011	NON-FINAL ACTION MAILED - REFUSAL SENT TO IB	
Dec. 29, 2011	REFUSAL PROCESSED BY MPU	67442
Dec. 28, 2011	NON-FINAL ACTION (IB REFUSAL) PREPARED FOR REVIEW	
Dec. 27, 2011	NON-FINAL ACTION WRITTEN	82103
Dec. 22, 2011	ASSIGNED TO EXAMINER	82103
Oct. 21, 2011	APPLICATION FILING RECEIPT MAILED	
Oct. 17, 2011	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Oct. 14, 2011	SN ASSIGNED FOR SECT 66A SUBSEQ DESIG FROM IB	

## International Registration Information (Section 66a)

<b>International Registration Number:</b> 1088031  <b>Intl. Registration Status:</b> REQUEST FOR EXTENSION OF PROTECTION PROCESSED  <b>Notification of Designation Date:</b> Oct. 13, 2011  <b>International Registration Renewal Date:</b> Jul. 07, 2021  <b>First Refusal Flag:</b> Yes	<b>International Registration Date:</b> Jul. 07, 2011  <b>Date of International Registration Status:</b> Oct. 14, 2011  <b>Date of Automatic Protection:</b> Apr. 13, 2013
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### TM Staff and Location Information

#### TM Staff Information

**TM Attorney:** HALMEN, KATHERINE E      **Law Office Assigned:** LAW OFFICE 109

#### File Location

**Current Location:** PUBLICATION AND ISSUE SECTION      **Date in Location:** Mar. 05, 2012

### Proceedings

#### Summary

**Number of Proceedings:** 2

#### Type of Proceeding: Opposition

<b>Proceeding Number:</b> <a href="#">91205483</a>	<b>Filing Date:</b> Jun 05, 2012
<b>Status:</b> Pending	<b>Status Date:</b> Jun 05, 2012
<b>Interlocutory Attorney:</b> JENNIFER KRISP	

#### Defendant

**Name:** Baba Slings Limited

**Correspondent Address:** ROBERT L STOLL  
DRINKER BIDDLE & REATH LLP  
1500 K STREET NW, SUITE 1100  
WASHINGTON DC , 20005-1209  
UNITED STATES

**Correspondent e-mail:** [dctrademarks@dbr.com](mailto:dctrademarks@dbr.com) , [brian.coleman@dbr.com](mailto:brian.coleman@dbr.com) , [anthony.palumbo@dbr.com](mailto:anthony.palumbo@dbr.com)

#### Associated marks

Mark	Application Status	Serial Number	Registration Number
THEBABASLING	Opposition Pending	<a href="#">79103197</a>	

#### Plaintiff(s)

**Name:** Baba Slings Pty Ltd

**Correspondent Address:** MARK BORGHESE  
BORGHESE LEGAL LTD  
10161 PARK RUM DRIVE , SUITE 150  
LAS VEGAS NV , 89145  
UNITED STATES

**Correspondent e-mail:** [mark@borghesellegal.com](mailto:mark@borghesellegal.com)

#### Associated marks

Mark	Application Status	Serial Number	Registration Number
BABA SLINGS	Suspension Letter - Mailed	<a href="#">85633700</a>	

#### Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Jun 05, 2012	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Jun 07, 2012	Jul 17, 2012
3	PENDING, INSTITUTED	Jun 07, 2012	
4	D'S MOT FOR EXTEN. OF TIME W/ CONSENT	Jul 17, 2012	
5	EXTENSION OF TIME GRANTED	Jul 19, 2012	
6	ANSWER	Jul 24, 2012	
7	D'S APPEARANCE OF COUNSEL/POWER OF ATTORNEY	Sep 24, 2012	

8 STIP TO SUSPEND PEND SETTLEMENT NEGOTNS Jan 30, 2013  
9 SUSPENDED Jan 30, 2013

**Type of Proceeding: Extension of Time**

**Proceeding Number:** [79103197](#) **Filing Date:** Apr 27, 2012  
**Status:** Terminated **Status Date:** Jun 09, 2012

**Interlocutory Attorney:**

**Defendant**

**Name:** BabaSlings Limited

**Correspondent Address:** Michael M. Ballard  
Workman Nydegger  
1000 Eagle Gate Tower 60 East South Temple  
Salt Lake City UT , 84111

**Associated marks**

Mark	Application Status	Serial Number	Registration Number
THEBABASLING	Opposition Pending	<a href="#">79103197</a>	
<b>Potential Opposer(s)</b>			

**Name:** Baba Slings Pty Ltd

**Correspondent Address:** Mark Borghese  
Borghese Legal, Ltd.  
10161 Park Run Drive, Suite 150  
Las Vegas NV , 89145  
UNITED STATES

**Correspondent e-mail:** [mark@borgheselegal.com](mailto:mark@borgheselegal.com)

**Associated marks**

Mark	Application Status	Serial Number	Registration Number
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**Prosecution History**

Entry Number	History Text	Date	Due Date
1	INCOMING - EXT TIME TO OPPOSE FILED	Apr 27, 2012	
2	EXTENSION OF TIME GRANTED	Apr 27, 2012	

**NOTICE THAT TRANSACTION HAS BEEN PROCESSED BY IB**

**SERIAL NUMBER: 79103197**

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**The table below presents the data as entered.**

<b>Input Field</b>	<b>Entered</b>
INTERNATIONAL REGISTRATION NUMBER	1088031
EFFECTIVE DATE OF MODIFICATION	04/04/2012
IB DOCUMENT ID	662254101
OFFICE REFERENCE	79103197
TRANSACTION TYPE	GPN - Grant of Protection

**NOTICE THAT TRANSACTION HAS BEEN PROCESSED BY IB**

**SERIAL NUMBER: 79103197**

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**The table below presents the data as entered.**

<b>Input Field</b>	<b>Entered</b>
INTERNATIONAL REGISTRATION NUMBER	1088031
EFFECTIVE DATE OF MODIFICATION	06/06/2012
IB DOCUMENT ID	673279801
OFFICE REFERENCE	79103197
TRANSACTION TYPE	RFNP - Partial Refusal

## OPPOSITION FILED

The table below presents the data as entered.

Input Field	Entered
<b>IDENTIFICATION SECTION</b>	
INTERNATIONAL REGISTRATION NUMBER	1088031
OFFICE REFERENCE	79103197
ORIGINAL LANGUAGE CODE	ENGLISH
<b>GOODS AND SERVICES SECTION</b>	
NICE CLASS NUMBER	18
LIMITED LIST	List limited to
GOODS AND SERVICE TERMS IN ORIGINAL LANGUAGE	Bags, namely, all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and traveling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods
<b>INSTRUCTIONS SECTION</b>	
FREE TEXT PROCESSING INSTRUCTIONS	U. S. designated on 20110906; Opposition filed
MAIL DATE	06/06/2012

---

**From:** TMOfficialNotices@USPTO.GOV  
**Sent:** Tuesday, April 10, 2012 00:28 AM  
**To:** mballard@wnlaw.com  
**Cc:** docketing@wnlaw.com  
**Subject:** 15584.53 Official USPTO Notification: OG Publication Confirmation for Serial Number 79103197

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## OFFICIAL GAZETTE PUBLICATION CONFIRMATION

**Serial Number:** 79-103,197  
**Mark:** THEBABASLING(STYLIZED/DESIGN)  
**International Class(es):** 018  
**Applicant:** BabaSlings Limited  
**Docket/Reference Number:** 15584.53

The mark identified above has been published in the *Trademark Official Gazette* (OG) on Apr 10, 2012. Any party who believes it will be damaged by the registration of the mark may file a notice of opposition (or extension of time therefor) with the Trademark Trial and Appeal Board. If no party files an opposition or extension request within thirty (30) days after the publication date, then within twelve (12) weeks of the publication date a certificate of registration should issue.

On the publication date or shortly thereafter, the applicant should carefully review the information that appears in the OG for accuracy (see steps, *below*). If any information is incorrect, the applicant should immediately email the requested correction to **TMPPostPubQuery@uspto.gov**. For general information about this notice, please contact the Trademark Assistance Center at 1-800-786-9199.

1. Click on the following link or paste the URL into an internet browser:  
[http://www.uspto.gov/web/trademarks/tmog/20120410\\_OG.pdf#page=1](http://www.uspto.gov/web/trademarks/tmog/20120410_OG.pdf#page=1)
2. Wait for the total OG to download completely (as indicated on bottom of OG page).
3. At the top/side of the displayed page, click wherever the "binoculars" icon appears.
4. Enter in the "search" box the name of the applicant (for individual: last name, first name) or the serial number in this exact format (with hyphen and comma): 79-103,197, e.g.
5. View the retrieved result(s). If multiple results appear in the "results" box, click directly on each "search term" shown in the box to access all separate appearances in the OG.

To view this notice and other documents for this application on-line, go to <http://tdr.uspto.gov/search.action?sn=79103197>.

NOTE: This notice will only be available on-line the next business day after receipt of this e-mail.

# NOTICE OF POSSIBLE OPPOSITION SENT TO INTERNATIONAL BUREAU

The table below presents the data as entered.

Input Field	Entered
<b>IDENTIFICATION SECTION</b>	
INTERNATIONAL REGISTRATION NUMBER	1088031
OFFICE REFERENCE NUMBER	79103197
ORIGINAL LANGUAGE CODE	ENGLISH
<b>NAME AND ADDRESS SECTION</b>	
NAME AND ADDRESS TYPE	Applicant/Holder
NAME	BabaSlings Limited
ADDRESS	1 Amber House, 22b St John's Road Hove BN3 2EZ
<b>OPPOSITION PERIOD SECTION</b>	
OPPOSITION PERIOD START DATE	04/10/2012
<b>INSTRUCTIONS SECTION</b>	
FREE TEXT PROCESSING INSTRUCTIONS	U. S. designated on 20110906, Opposition period is starting 20120410 Type 4





Commissioner for Trademarks  
P.O. Box 1451  
Alexandria, VA 22313-1451  
[www.uspto.gov](http://www.uspto.gov)

### Notification of Opposition Possible

Statement sent to the International Bureau of the World Intellectual Property Organization (WIPO) in accordance with **Rule 18bis(1)(b)** of the Common Regulations under the Madrid Agreement and Protocol.

**International Registration No.:** 1088031  
**Holder:** BabaSlings Limited

By this notification, the United States Patent and Trademark Office (USPTO) hereby informs the International Bureau (IB) that the *ex officio* examination has been completed and the USPTO no longer has grounds for refusal. However, the protection of the mark is still subject to opposition or observations by third parties. The opposition or observations period is scheduled to begin on April 10, 2012, the date of publication by the USPTO.

An opposition must be filed within thirty (30) days after publication. Upon request, the opposition period is extendable, but shall not exceed 180 days after publication. 37 C.F.R. §§2.101(c), 2.102.

Sincerely,

Madrid Processing Unit  
United States Patent & Trademark Office  
(571) 272-8910

**\*\* STATUS AND INFORMATION CHECK \*\***

For questions about this notification or the referenced international registration, email the USPTO Madrid Processing Unit at [MPU@uspto.gov](mailto:MPU@uspto.gov) or visit their website at <http://www.uspto.gov/web/trademarks/madrid/madridindex.htm>.

To check the status of the application, use the USPTO Trademark Applications and Registrations Retrieval (TARR) online system at <http://tarr.uspto.gov>. To view and download documents in pending

applications and registrations, please access the Trademark Document Retrieval (TDR) website at <http://tdr.uspto.gov/>.

To view any notice of publication for opposition published in the Official Gazette, visit the USPTO website at <http://www.uspto.gov/web/trademarks/tmog/>.



UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Trademarks  
P.O. Box 1451  
Alexandria, VA 22313-1451  
www.uspto.gov

Mar 21, 2012

**NOTICE OF PUBLICATION**

- |                                      |   |
|--------------------------------------|---|
| 1. Serial No.:<br>79-103,197         | 2. Mark:<br>THEBABASLING<br>(STYLIZED/DESIGN) |
| 3. International Class(es):<br>18    |   |
| 4. Publication Date:<br>Apr 10, 2012 | 5. Applicant:<br>BabaSlings Limited           |

The mark of the application identified appears to be entitled to registration. The mark will, in accordance with Section 12(a) of the Trademark Act of 1946, as amended, be published in the *Official Gazette* on the date indicated above for the purpose of opposition by any person who believes he will be damaged by the registration of the mark. If no opposition is filed within the time specified by Section 13(a) of the Statute or by rules 2.101 or 2.102 of the Trademark Rules, the Commissioner of Patents and Trademarks may issue a certificate of registration.

Copies of the trademark portion of the *Official Gazette* containing the publication of the mark may be obtained from:

The Superintendent of Documents  
U.S. Government Printing Office  
PO Box 371954  
Pittsburgh, PA 15250-7954  
Phone: 202-512-1800

By direction of the Commissioner.

---

**Email Address(es):**

mballard@wnlaw.com  
docketing@wnlaw.com

BABA 0353

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**From:** TMOfficialNotices@USPTO.GOV  
**Sent:** Wednesday, March 21, 2012 03:26 AM  
**To:** mballard@wnlaw.com  
**Cc:** docketing@wnlaw.com  
**Subject:** 15584.53 Official USPTO Notification: Issuance of Notice of Publication for Serial Number 79103197

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### NOTIFICATION OF "NOTICE OF PUBLICATION"

Your trademark application (Serial No. 79103197) is scheduled to publish in the *Official Gazette* on Apr 10, 2012. To preview the Notice of Publication, go to <http://tdr.uspto.gov/search.action?sn=79103197>. If you have difficulty accessing the Notice of Publication, contact [TDR@uspto.gov](mailto:TDR@uspto.gov).

**PLEASE NOTE:**

1. The Notice of Publication may not be immediately available but will be viewable within 24 hours of this e-mail notification.
2. You will receive a second e-mail on the actual "Publication Date," which will include a link to the issue of the *Official Gazette* in which the mark has published.

Do NOT hit "Reply" to this e-mail notification. If you have any questions about the content of the Notice of Publication, contact [TMPPostPubQuery@uspto.gov](mailto:TMPPostPubQuery@uspto.gov).

**Trademark Snap Shot Publication & Issue Review Stylesheet**  
(Table presents the data on Publication & Issue Review Complete)

**OVERVIEW**

SERIAL NUMBER	79103197	FILING DATE	09/06/2011
REG NUMBER	0000000	REG DATE	N/A
REGISTER	PRINCIPAL	MARK TYPE	TRADEMARK
INTL REG #	1088031	INTL REG DATE	07/07/2011
TM ATTORNEY	HALMEN, KATHERINE E	L.O. ASSIGNED	109

**PUB INFORMATION**

RUN DATE	03/06/2012		
PUB DATE	04/10/2012		
STATUS	681-PUBLICATION/ISSUE REVIEW COMPLETE		
STATUS DATE	03/05/2012		
LITERAL MARK ELEMENT	THEBABASLING		
DATE ABANDONED	N/A	DATE CANCELLED	N/A
SECTION 2F	NO	SECTION 2F IN PART	NO
SECTION 8	NO	SECTION 8 IN PART	NO
SECTION 15	NO	REPUB 12C	N/A
RENEWAL FILED	NO	RENEWAL DATE	N/A
DATE AMEND REG	N/A		

**FILING BASIS**

FILED BASIS		CURRENT BASIS		AMENDED BASIS	
1 (a)	NO	1 (a)	NO	1 (a)	NO
1 (b)	NO	1 (b)	NO	1 (b)	NO
44D	NO	44D	NO	44D	NO
44E	NO	44E	NO	44E	NO
66A	YES	66A	YES		
NO BASIS	NO	NO BASIS	NO		

**MARK DATA**

STANDARD CHARACTER MARK	NO
LITERAL MARK ELEMENT	THEBABASLING

MARK DRAWING CODE	3-AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/LETTER(S)/NUMBER(S)
COLOR DRAWING FLAG	NO

### CURRENT OWNER INFORMATION

PARTY TYPE	10-ORIGINAL APPLICANT
NAME	BabaSlings Limited
ADDRESS	1 Amber House, 22b St John's Road Hove, BN3 2EZ
ENTITY	99-Private Limited Company
CITIZENSHIP	United Kingdom

### GOODS AND SERVICES

INTERNATIONAL CLASS	018
DESCRIPTION TEXT	Bags, namely, all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and traveling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods

### GOODS AND SERVICES CLASSIFICATION

INTERNATIONAL CLASS	018	FIRST USE DATE	NONE	FIRST USE IN COMMERCE DATE	NONE	CLASS STATUS	6-ACTIVE
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### MISCELLANEOUS INFORMATION/STATEMENTS

CHANGE IN REGISTRATION	NO
COLORS CLAIMED STATEMENT	Color is not claimed as a feature of the mark.
DESCRIPTION OF MARK	The mark consists of the wording "THEBABASLING" below a design of a crescent moon holding a baby.
PSEUDO MARK	THE BABA SLING

### SECTION 66A INTERNATIONAL REGISTRATION DATA

INTL REG #	1088031
INTL REG DATE	07/07/2011
PRIORITY CLMD	NO

PRIOR CLMD DATE	N/A
INTL STATUS	001-REQUEST FOR EXTENSION OF PROTECTION PROCESSED
INTL STATUS DATE	10/14/2011
AUTO PROTECTION DATE	04/13/2013
INTL RENEWAL DATE	07/07/2021
INTL REG DEATH DATE	N/A
FIRST REFUSAL	YES

### PROSECUTION HISTORY

DATE	ENT CD	ENT TYPE	DESCRIPTION	ENT NUM
03/05/2012	PREV	O	LAW OFFICE PUBLICATION REVIEW COMPLETED	015
03/01/2012	ALIE	A	ASSIGNED TO LIE	014
02/14/2012	CNSA	O	APPROVED FOR PUB - PRINCIPAL REGISTER	013
02/03/2012	TEME	I	TEAS/EMAIL CORRESPONDENCE ENTERED	012
02/02/2012	CRFA	I	CORRESPONDENCE RECEIVED IN LAW OFFICE	011
02/02/2012	TROA	I	TEAS RESPONSE TO OFFICE ACTION RECEIVED	010
01/19/2012	RFNT	P	REFUSAL PROCESSED BY IB	009
12/29/2011	RFCS	P	NON-FINAL ACTION MAILED - REFUSAL SENT TO IB	008
12/29/2011	RFRR	P	REFUSAL PROCESSED BY MPU	007
12/28/2011	RFGR	E	NON-FINAL ACTION (IB REFUSAL) PREPARED FOR REVIEW	006
12/27/2011	CNRT	R	NON-FINAL ACTION WRITTEN	005
12/22/2011	DOCK	D	ASSIGNED TO EXAMINER	004
10/21/2011	MAFR	O	APPLICATION FILING RECEIPT MAILED	003
10/17/2011	NWOS	I	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	002
10/14/2011	SDRC	M	SN ASSIGNED FOR SECT 66A SUBSEQ DESIG FROM IB	001

### CURRENT CORRESPONDENCE INFORMATION

ATTORNEY	Michael M. Ballard
CORRESPONDENCE ADDRESS	Michael M. Ballard Workman Nydegger 1000 Eagle Gate Tower 60 East South Temple Salt Lake City UT 84111
DOMESTIC REPRESENTATIVE	NONE



theBabaSling

**Trademark Snap Shot Publication Stylesheet**  
(Table presents the data on Publication Approval)

**OVERVIEW**

SERIAL NUMBER	79103197	FILING DATE	09/06/2011
REG NUMBER	0000000	REG DATE	N/A
REGISTER	PRINCIPAL	MARK TYPE	TRADEMARK
INTL REG #	1088031	INTL REG DATE	07/07/2011
TM ATTORNEY	HALMEN, KATHERINE E	L.O. ASSIGNED	109

**PUB INFORMATION**

RUN DATE	02/15/2012		
PUB DATE	N/A		
STATUS	680-APPROVED FOR PUBLICATON		
STATUS DATE	02/14/2012		
LITERAL MARK ELEMENT	THEBABASLING		
DATE ABANDONED	N/A	DATE CANCELLED	N/A
SECTION 2F	NO	SECTION 2F IN PART	NO
SECTION 8	NO	SECTION 8 IN PART	NO
SECTION 15	NO	REPUB 12C	N/A
RENEWAL FILED	NO	RENEWAL DATE	N/A
DATE AMEND REG	N/A		

**FILING BASIS**

FILED BASIS		CURRENT BASIS		AMENDED BASIS	
1 (a)	NO	1 (a)	NO	1 (a)	NO
1 (b)	NO	1 (b)	NO	1 (b)	NO
44D	NO	44D	NO	44D	NO
44E	NO	44E	NO	44E	NO
66A	YES	66A	YES		
NO BASIS	NO	NO BASIS	NO		

**MARK DATA**

STANDARD CHARACTER MARK	NO
LITERAL MARK ELEMENT	THEBABASLING

MARK DRAWING CODE	3-AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/LETTER(S)/NUMBER(S)
COLOR DRAWING FLAG	NO

### CURRENT OWNER INFORMATION

PARTY TYPE	10-ORIGINAL APPLICANT
NAME	BabaSlings Limited
ADDRESS	1 Amber House, 22b St John's Road Hove BN3 2EZ
ENTITY	99-Private Limited Company
CITIZENSHIP	United Kingdom

### GOODS AND SERVICES

INTERNATIONAL CLASS	018
DESCRIPTION TEXT	Bags, namely all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and travelling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods

### GOODS AND SERVICES CLASSIFICATION

INTERNATIONAL CLASS	018	FIRST USE DATE	NONE	FIRST USE IN COMMERCE DATE	NONE	CLASS STATUS	6-ACTIVE
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### MISCELLANEOUS INFORMATION/STATEMENTS

CHANGE IN REGISTRATION	NO
COLORS CLAIMED STATEMENT	Color is not claimed as a feature of the mark.
DESCRIPTION OF MARK	The mark consists of the wording "THEBABASLING" below a design of a crescent moon holding a baby.
PSEUDO MARK	THE BABA SLING

### SECTION 66A INTERNATIONAL REGISTRATION DATA

INTL REG #	1088031
INTL REG DATE	07/07/2011
PRIORITY CLMD	NO

PRIOR CLMD DATE	N/A
INTL STATUS	001-REQUEST FOR EXTENSION OF PROTECTION PROCESSED
INTL STATUS DATE	10/14/2011
AUTO PROTECTION DATE	04/13/2013
INTL RENEWAL DATE	07/07/2021
INTL REG DEATH DATE	N/A
FIRST REFUSAL	YES

### PROSECUTION HISTORY

DATE	ENT CD	ENT TYPE	DESCRIPTION	ENT NUM
02/14/2012	CNSA	O	APPROVED FOR PUB - PRINCIPAL REGISTER	013
02/03/2012	TEME	I	TEAS/EMAIL CORRESPONDENCE ENTERED	012
02/02/2012	CRFA	I	CORRESPONDENCE RECEIVED IN LAW OFFICE	011
02/02/2012	TROA	I	TEAS RESPONSE TO OFFICE ACTION RECEIVED	010
01/19/2012	RFNT	P	REFUSAL PROCESSED BY IB	009
12/29/2011	RFCS	P	NON-FINAL ACTION MAILED - REFUSAL SENT TO IB	008
12/29/2011	RFRR	P	REFUSAL PROCESSED BY MPU	007
12/28/2011	RFCR	E	NON-FINAL ACTION (IB REFUSAL) PREPARED FOR REVIEW	006
12/27/2011	CNRT	R	NON-FINAL ACTION WRITTEN	005
12/22/2011	DOCK	D	ASSIGNED TO EXAMINER	004
10/21/2011	MAFR	O	APPLICATION FILING RECEIPT MAILED	003
10/17/2011	NWOS	I	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	002
10/14/2011	SDRC	M	SN ASSIGNED FOR SECT 66A SUBSEQ DESIG FROM IB	001

### CURRENT CORRESPONDENCE INFORMATION

ATTORNEY	Michael M. Ballard
CORRESPONDENCE ADDRESS	Michael M. Ballard Workman Nydegger 1000 Eagle Gate Tower 60 East South Temple Salt Lake City UT 84111
DOMESTIC REPRESENTATIVE	NONE



theBabaSling

**Trademark Snap Shot Amendment & Mail Processing Stylesheet**  
(Table presents the data on Amendment & Mail Processing Complete)

**OVERVIEW**

SERIAL NUMBER	79103197	FILING DATE	09/06/2011
REG NUMBER	0000000	REG DATE	N/A
REGISTER	PRINCIPAL	MARK TYPE	TRADEMARK
INTL REG #	1088031	INTL REG DATE	07/07/2011
TM ATTORNEY	HALMEN, KATHERINE E	L.O. ASSIGNED	109

**PUB INFORMATION**

RUN DATE	02/04/2012		
PUB DATE	N/A		
STATUS	661-RESPONSE AFTER NON-FINAL-ACTION-ENTERED		
STATUS DATE	02/03/2012		
LITERAL MARK ELEMENT	THEBABASLING		
DATE ABANDONED	N/A	DATE CANCELLED	N/A
SECTION 2F	NO	SECTION 2F IN PART	NO
SECTION 8	NO	SECTION 8 IN PART	NO
SECTION 15	NO	REPUB 12C	N/A
RENEWAL FILED	NO	RENEWAL DATE	N/A
DATE AMEND REG	N/A		

**FILING BASIS**

FILED BASIS		CURRENT BASIS		AMENDED BASIS	
1 (a)	NO	1 (a)	NO	1 (a)	NO
1 (b)	NO	1 (b)	NO	1 (b)	NO
44D	NO	44D	NO	44D	NO
44E	NO	44E	NO	44E	NO
66A	YES	66A	YES		
NO BASIS	NO	NO BASIS	NO		

**MARK DATA**

STANDARD CHARACTER MARK	NO
LITERAL MARK ELEMENT	THEBABASLING

MARK DRAWING CODE	3-AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/LETTER(S)/NUMBER(S)
COLOR DRAWING FLAG	NO

### CURRENT OWNER INFORMATION

PARTY TYPE	10-ORIGINAL APPLICANT
NAME	BabaSlings Limited
ADDRESS	1 Amber House, 22b St John's Road Hove BN3 2EZ
ENTITY	99-Private Limited Company
CITIZENSHIP	United Kingdom

### GOODS AND SERVICES

INTERNATIONAL CLASS	018
DESCRIPTION TEXT	Bags, namely all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and travelling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods

### GOODS AND SERVICES CLASSIFICATION

INTERNATIONAL CLASS	018	FIRST USE DATE	NONE	FIRST USE IN COMMERCE DATE	NONE	CLASS STATUS	6-ACTIVE
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### MISCELLANEOUS INFORMATION/STATEMENTS

CHANGE IN REGISTRATION	NO
COLORS CLAIMED STATEMENT	Color is not claimed as a feature of the mark.
DESCRIPTION OF MARK	The mark consists of the wording "THEBABASLING" below a design of a crescent moon holding a baby.
PSEUDO MARK	THE BABA SLING

### SECTION 66A INTERNATIONAL REGISTRATION DATA

INTL REG #	1088031
INTL REG DATE	07/07/2011
PRIORITY CLMD	NO

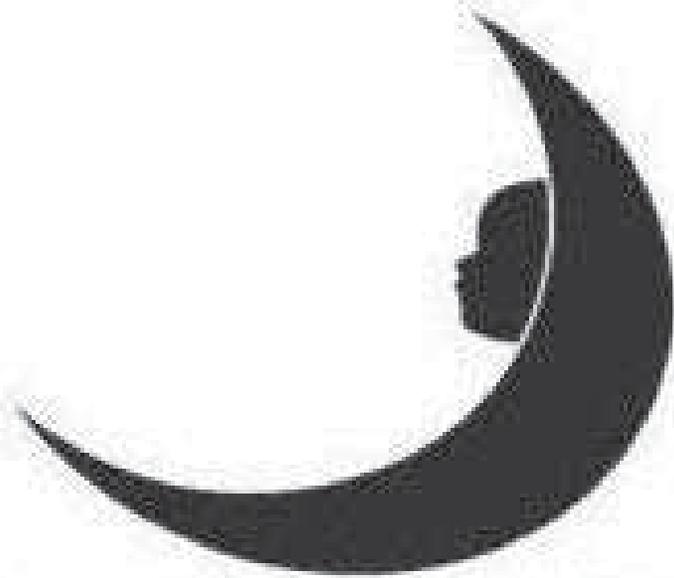
PRIOR CLMD DATE	N/A
INTL STATUS	001-REQUEST FOR EXTENSION OF PROTECTION PROCESSED
INTL STATUS DATE	10/14/2011
AUTO PROTECTION DATE	04/13/2013
INTL RENEWAL DATE	07/07/2021
INTL REG DEATH DATE	N/A
FIRST REFUSAL	YES

### PROSECUTION HISTORY

DATE	ENT CD	ENT TYPE	DESCRIPTION	ENT NUM
02/03/2012	TEME	I	TEAS/EMAIL CORRESPONDENCE ENTERED	012
02/02/2012	CRFA	I	CORRESPONDENCE RECEIVED IN LAW OFFICE	011
02/02/2012	TROA	I	TEAS RESPONSE TO OFFICE ACTION RECEIVED	010
01/19/2012	RFNT	P	REFUSAL PROCESSED BY IB	009
12/29/2011	RFCS	P	NON-FINAL ACTION MAILED - REFUSAL SENT TO IB	008
12/29/2011	RFRR	P	REFUSAL PROCESSED BY MPU	007
12/28/2011	RFCR	E	NON-FINAL ACTION (IB REFUSAL) PREPARED FOR REVIEW	006
12/27/2011	CNRT	R	NON-FINAL ACTION WRITTEN	005
12/22/2011	DOCK	D	ASSIGNED TO EXAMINER	004
10/21/2011	MAFR	O	APPLICATION FILING RECEIPT MAILED	003
10/17/2011	NWOS	I	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	002
10/14/2011	SDRC	M	SN ASSIGNED FOR SECT 66A SUBSEQ DESIG FROM IB	001

### CURRENT CORRESPONDENCE INFORMATION

ATTORNEY	Michael M. Ballard
CORRESPONDENCE ADDRESS	Michael M. Ballard Workman Nydegger 1000 Eagle Gate Tower 60 East South Temple Salt Lake City UT 84111
DOMESTIC REPRESENTATIVE	NONE



theBabaSling

## Response to Office Action

**The table below presents the data as entered.**

Input Field	Entered
<b>SERIAL NUMBER</b>	79103197
<b>LAW OFFICE ASSIGNED</b>	LAW OFFICE 109
<b>MARK SECTION (no change)</b>	
<b>GOODS AND/OR SERVICES SECTION (current)</b>	
<b>INTERNATIONAL CLASS</b>	018
<b>DESCRIPTION</b>	
<p>Bags; trunks and travelling bags; carriers for babies and children; harnesses for babies and children; slings for babies and children; sling bags for carrying babies and children; frames for carrying babies and children; backpacks for carrying babies and children; baby changing bags; nappy bags; baby care bags (empty); travel bags; backpacks; suitcases; shopping bags; shopping bags in frames on wheels; umbrellas; parasols; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods</p>	
<b>GOODS AND/OR SERVICES SECTION (proposed)</b>	
<b>INTERNATIONAL CLASS</b>	018
<b>TRACKED TEXT DESCRIPTION</b>	
<p><u>Bags</u>; <u>Bags, namely all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories</u>; trunks and travelling bags; <del>carriers for babies and children</del>; <u>carriers for babies and children worn on the body</u>; <del>harnesses for babies and children</del>; <u>slings for carrying babies and children</u>; <del>slings for babies and children</del>; <u>back frames for carrying babies and children</u>; sling bags for carrying babies and children; <del>frames for carrying babies and children</del>; <u>baby changing bags in the nature of bags for carrying babies' accessories</u>; <del>backpacks for carrying babies and children</del>; <u>nappy bags in the nature of diaper bags</u>; <del>baby changing bags</del>; <u>baby care bags in the nature of bags for carrying babies' accessories sold empty</u>; <del>nappy bags</del>; travel bags; <del>baby care bags (empty)</del>; backpacks; suitcases; <u>reusable shopping bags</u>; <u>reusable shopping bags in frames on wheels</u>; <del>shopping bags</del>; umbrellas; <del>shopping bags in frames on wheels</del>; parasols; <u>structural parts and fittings for all the aforementioned goods</u>; <del>parasols for strollers and for buggies</del>; <del>parts and fittings for all the aforementioned goods</del></p>	
<b>FINAL DESCRIPTION</b>	
<p>Bags, namely all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and travelling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of</p>	

diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods

#### ADDITIONAL STATEMENTS SECTION

<b>DESCRIPTION OF THE MARK (and Color Location, if applicable)</b>	The mark consists of the wording "THEBABASLING" below a design of a crescent moon holding a baby.
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#### NEW ATTORNEY SECTION

<b>NAME</b>	Michael M. Ballard
<b>FIRM NAME</b>	Workman Nydegger
<b>INDIVIDUAL ATTORNEY DOCKET/REFERENCE NUMBER</b>	15584.53
<b>INTERNAL ADDRESS</b>	1000 Eagle Gate Tower
<b>STREET</b>	60 East South Temple
<b>CITY</b>	Salt Lake City
<b>STATE</b>	Utah
<b>ZIP/POSTAL CODE</b>	84111
<b>COUNTRY</b>	United States
<b>PHONE</b>	801 533-9800
<b>FAX</b>	801 328-1707
<b>EMAIL</b>	mballard@wnlaw.com
<b>AUTHORIZED EMAIL COMMUNICATION</b>	Yes

#### CORRESPONDENCE SECTION

<b>ORIGINAL ADDRESS</b>	MURGITROYD & COMPANY SCOTLAND HOUSE, 165-169 SCOTLAND STREET GLASGOW G5 8PL GB
-------------------------	--

#### NEW CORRESPONDENCE SECTION

<b>NAME</b>	Michael M. Ballard
<b>FIRM NAME</b>	Workman Nydegger
<b>INDIVIDUAL ATTORNEY DOCKET/REFERENCE NUMBER</b>	15584.53
<b>INTERNAL ADDRESS</b>	1000 Eagle Gate Tower
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<b>CITY</b>	

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<b>ZIP/POSTAL CODE</b>	84111
<b>COUNTRY</b>	United States
<b>PHONE</b>	801 533-9800
<b>FAX</b>	801 328-1707
<b>EMAIL</b>	mballard@wnlaw.com;docketing@wnlaw.com
<b>AUTHORIZED EMAIL COMMUNICATION</b>	Yes
<b>SIGNATURE SECTION</b>	
<b>RESPONSE SIGNATURE</b>	/Michael M. Ballard/
<b>SIGNATORY'S NAME</b>	Michael M. Ballard
<b>SIGNATORY'S POSITION</b>	Attorney, Utah bar member
<b>SIGNATORY'S PHONE NUMBER</b>	801 533-9800
<b>DATE SIGNED</b>	02/02/2012
<b>AUTHORIZED SIGNATORY</b>	YES
<b>FILING INFORMATION SECTION</b>	
<b>SUBMIT DATE</b>	Thu Feb 02 22:25:53 EST 2012
<b>TEAS STAMP</b>	USPTO/ROA-209.180.88.130- 20120202222553287375-7910 3197-4909231bee83ddfcab79 9b28bd38b7efc2-N/A-N/A-20 120202221739507949

PTO Form 1957 (Rev 9/2005)  
OMB No. 0651-0050 (Exp. 05/31/2014)

**Response to Office Action  
To the Commissioner for Trademarks:**

Application serial no. **79103197** has been amended as follows:

**CLASSIFICATION AND LISTING OF GOODS/SERVICES**

**Applicant proposes to amend the following class of goods/services in the application:**

**Current:** Class 018 for Bags; trunks and travelling bags; carriers for babies and children; harnesses for babies and children; slings for babies and children; sling bags for carrying babies and children; frames for

carrying babies and children; backpacks for carrying babies and children; baby changing bags; nappy bags; baby care bags (empty); travel bags; backpacks; suitcases; shopping bags; shopping bags in frames on wheels; umbrellas; parasols; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods

Original Filing Basis:

**Filing Basis Section 66(a)**, Request for Extension of Protection to the United States. Section 66(a) of the Trademark Act, 15 U.S.C. §1141f.

**Proposed:**

**Tracked Text Description:** ~~Bags; carriers for babies and children; carriers for babies and children worn on the body; harnesses for babies and children; slings for carrying babies and children; slings for babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; frames for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; backpacks for carrying babies and children; nappy bags in the nature of diaper bags; baby changing bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; nappy bags; travel bags; baby care bags (empty); backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; shopping bags; umbrellas; shopping bags in frames on wheels; parasols; structural parts and fittings for all the aforementioned goods; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods~~ Bags; Bags, namely all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and travelling bags; carriers for babies and children worn on the body; harnesses for babies and children; slings for carrying babies and children; slings for babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; frames for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; backpacks for carrying babies and children; nappy bags in the nature of diaper bags; baby changing bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; nappy bags; travel bags; baby care bags (empty); backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; shopping bags; umbrellas; shopping bags in frames on wheels; parasols; structural parts and fittings for all the aforementioned goods; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods

Class 018 for Bags, namely all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and travelling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods

**Filing Basis Section 66(a)**, Request for Extension of Protection to the United States. Section 66(a) of the Trademark Act, 15 U.S.C. §1141f.

#### **ATTORNEY ADDRESS**

Applicant proposes to amend the following:

**Proposed:**

Michael M. Ballard of Workman Nydegger, having an address of  
1000 Eagle Gate Tower 60 East South Temple Salt Lake City, Utah 84111

United States

mballard@wnlaw.com

801 533-9800

801 328-1707

The attorney docket/reference number is 15584.53.

#### **CORRESPONDENCE ADDRESS CHANGE**

Applicant proposes to amend the following:

**Current:**

MURGITROYD & COMPANY

SCOTLAND HOUSE,

165-169 SCOTLAND STREET  
GLASGOW G5 8PL  
GB

**Proposed:**

Michael M. Ballard of Workman Nydegger, having an address of  
1000 Eagle Gate Tower 60 East South Temple Salt Lake City, Utah 84111  
United States  
mballard@wnlaw.com;docketing@wnlaw.com  
801 533-9800  
801 328-1707  
The attorney docket/reference number is 15584.53.

**ADDITIONAL STATEMENTS**

**Description of mark**

The mark consists of the wording "THEBABASLING" below a design of a crescent moon holding a baby.

**SIGNATURE(S)**

**Response Signature**

Signature: /Michael M. Ballard/ Date: 02/02/2012  
Signatory's Name: Michael M. Ballard  
Signatory's Position: Attorney, Utah bar member

Signatory's Phone Number: 801 533-9800

The signatory has confirmed that he/she is an attorney who is a member in good standing of the bar of the highest court of a U.S. state, which includes the District of Columbia, Puerto Rico, and other federal territories and possessions; and he/she is currently the applicant's attorney or an associate thereof; and to the best of his/her knowledge, if prior to his/her appointment another U.S. attorney or a Canadian attorney/agent not currently associated with his/her company/firm previously represented the applicant in this matter: (1) the applicant has filed or is concurrently filing a signed revocation of or substitute power of attorney with the USPTO; (2) the USPTO has granted the request of the prior representative to withdraw; (3) the applicant has filed a power of attorney appointing him/her in this matter; or (4) the applicant's appointed U.S. attorney or Canadian attorney/agent has filed a power of attorney appointing him/her as an associate attorney in this matter.

Mailing Address: Michael M. Ballard  
Workman Nydegger  
1000 Eagle Gate Tower  
60 East South Temple  
Salt Lake City, Utah 84111

Serial Number: 79103197

Internet Transmission Date: Thu Feb 02 22:25:53 EST 2012  
TEAS Stamp: USPTO/ROA-209.180.88.130-201202022225532  
87375-79103197-4909231bee83ddfcab799b28b  
d38b7efc2-N/A-N/A-20120202221739507949

**NOTICE THAT TRANSACTION HAS BEEN PROCESSED BY IB**

**SERIAL NUMBER: 79103197**

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**The table below presents the data as entered.**

<b>Input Field</b>	<b>Entered</b>
INTERNATIONAL REGISTRATION NUMBER	1088031
EFFECTIVE DATE OF MODIFICATION	12/29/2011
IB DOCUMENT ID	644093001
OFFICE REFERENCE	79103197
TRANSACTION TYPE	RFNT - Total Refusal

## PROVISIONAL REFUSAL OF PROTECTION

The table below presents the data as entered.

Input Field	Entered
<b>IDENTIFICATION SECTION</b>	
INTERNATIONAL REGISTRATION NUMBER	1088031
OFFICE REFERENCE	79103197
ORIGINAL LANGUAGE CODE	ENGLISH
<b>FILE SECTION</b>	
FILE SPECIFICATION OF THE DOCUMENT	<a href="#">\\TICRS\EXPORT11\IMAGEOUT11\791\031\79103197\xml5\MOC0002.xml</a>
<b>GOODS AND SERVICES SECTION</b>	
ALL GOODS AND SERVICES INDICATOR	Protection has been refused for all the goods and services.
<b>INSTRUCTIONS SECTION</b>	
FREE TEXT PROCESSING INSTRUCTIONS	U. S. designated on 20110906; Non-final examiner action
MAIL DATE	12/29/2011

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)  
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION

APPLICATION SERIAL NO. 79103197

MARK: THEBABASLING

**\*79103197\***

**CORRESPONDENT ADDRESS:**

MURGITROYD & COMPANY  
Scotland House,  
165-169 Scotland Street  
Glasgow G5 8PL  
UNITED KINGDOM

**CLICK HERE TO RESPOND TO THIS LETTER:**

[http://www.uspto.gov/trademarks/teas/response\\_forms.jsp](http://www.uspto.gov/trademarks/teas/response_forms.jsp)

APPLICANT: BabaSlings Limited

**CORRESPONDENT'S REFERENCE/DOCKET**

**NO:**

N/A

**CORRESPONDENT E-MAIL ADDRESS:**

**OFFICE ACTION**

**STRICT DEADLINE TO RESPOND TO THIS LETTER**

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

**ISSUE/MAILING DATE:**

**INTERNATIONAL REGISTRATION NO. 1088031**

This is a **PROVISIONAL FULL REFUSAL** of the trademark and/or service mark in the above-referenced U.S. application. *See* 15 U.S.C. §1141h(c).

**WHO IS PERMITTED TO RESPOND TO THIS PROVISIONAL FULL REFUSAL:**

Applicant may respond directly to this provisional refusal Office action if applicant is not represented by an authorized attorney. *See* 37 C.F.R. §2.193(e)(2)(ii). Otherwise, applicant's authorized attorney must respond on applicant's behalf. *See* 37 C.F.R. §2.193(e)(2)(i). However, **the only attorneys who are authorized to sign responses and practice before the USPTO** in trademark matters are as follows:

- (1) **Attorneys in good standing with a bar of the highest court of any U.S. state**, the District of Columbia, Puerto Rico, and other federal territories and possessions of the United States; and
- (2) **Canadian agents/attorneys** who represent applicants located in Canada and (a) are registered with the USPTO and in good standing as patent agents or (b) have been granted reciprocal recognition by the USPTO.

See 37 C.F.R. §§2.17(e), 2.62(b), 11.1, 11.5(b)(2), 11.14(a), (c); TMEP §§602, 712.03.

Foreign attorneys, other than authorized Canadian attorneys, are not permitted to represent applicants before the USPTO. See 37 C.F.R. §§2.17(e), 11.14(c), (e); TMEP §602.03-.03(b). That is, foreign attorneys may not file written communications, authorize an amendment to an application, or submit legal arguments in response to a requirement or refusal, among other things. See 37 C.F.R. §11.5(b)(2); TMEP §§602.03(c), 608.01. If applicant is represented by such a foreign attorney, applicant must respond directly to this provisional refusal Office action. See 37 C.F.R. §2.193(e)(2)(ii).

#### **DESIGNATION OF DOMESTIC REPRESENTATIVE:**

The USPTO encourages applicants who do not reside in the U.S. to designate a domestic representative upon whom notices or process may be served. 15 U.S.C. §§1051(e), 1141h(d); 37 C.F.R. §2.24(a)(1)-(2); see TMEP §610. Such designations may be filed online at <http://www.uspto.gov/teas/index.html>.

#### **THE APPLICATION HAS BEEN PROVISIONALLY REFUSED AS FOLLOWS:**

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

#### **SEARCH OF OFFICE'S DATABASE OF MARKS**

The trademark examining attorney has searched the Office's database of registered and pending marks and has found no conflicting marks that would bar registration under Trademark Act Section 2(d). TMEP §704.02; see 15 U.S.C. §1052(d).

#### **IDENTIFICATION OF GOODS**

The goods/services are:

Class 18: Bags; trunks and travelling bags; carriers for babies and children; harnesses for babies and children; slings for babies and children; sling bags for carrying babies and children; frames for carrying babies and children; backpacks for carrying babies and children; baby changing bags; nappy bags; baby care bags (empty); travel bags; backpacks; suitcases; shopping bags; shopping bags in frames on wheels; umbrellas; parasols; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods

The identification of goods and/or services is indefinite and must be clarified. In particular, the applicant must specify the common commercial names and/or clarify the exact nature of the specific goods intended. See TMEP §1402.01. Applicant may adopt the following identification, if accurate:

Class 18: Bags, NAMELY, {*specify common commercial names of specific Class 18 goods intended, e.g., athletic bags, barrel bags, belt bags*}; trunks and travelling bags; carriers for babies and children WORN ON THE BODY; {"*harnesses for babies and children*" is indefinite and appears to be

*improperly classified. Applicant must either delete this wording or replace it with acceptable Class 18 wording that is within the scope of the original identification.*}; slings for CARRYING babies and children; sling bags for carrying babies and children; BACK frames for carrying babies and children; backpacks for carrying babies and children; baby changing bags IN THE NATURE OF DIAPER BAGS; nappy bags IN THE NATURE OF DIAPER BAGS; baby care bags IN THE NATURE OF DIAPER BAGS SOLD EMPTY; travel bags; backpacks; suitcases; REUSABLE shopping bags; REUSABLE shopping bags in frames on wheels; umbrellas; parasols; {"*parasols for strollers and for buggies*" is indefinite and appears to be improperly classified. Applicant must either delete this wording or amend the wording such that it clearly falls in Class 18 and is within the scope of the original identification.}; STRUCTURAL parts and fittings for all the aforementioned goods

For assistance with identifying and classifying goods and/or services in trademark applications, please see the online searchable *Manual of Acceptable Identifications of Goods and Services* at <http://tess2.uspto.gov/netahtml/tidm.html>. See TMEP §1402.04.

In an application filed under Trademark Act Section 66(a), an applicant may not change the classification of goods and/or services from that assigned by the International Bureau in the corresponding international registration. 37 C.F.R. §2.85(d); TMEP §§1401.03(d), 1904.02(b). Further, in a multiple-class Section 66(a) application, an applicant may not transfer goods and/or services from one existing international class to another. 37 C.F.R. §2.85(d); see TMEP §§1402.07(a), 1904.02(c).

An applicant may amend an identification of goods only to clarify or limit the goods; adding to or broadening the scope of the goods is not permitted. 37 C.F.R. §2.71(a); see TMEP §§1402.06 *et seq.*, 1402.07 *et seq.*

## **DESCRIPTION OF MARK REQUIRED**

Applicant must submit an accurate and concise description of the literal and design elements in the mark. 37 C.F.R. §2.37; see TMEP §§808.01, 808.02. The following is suggested, if accurate:

**The mark consists of the wording “THEBABASLING” appearing below the design of a crescent moon holding a baby.**

If applicant has questions regarding this Office action, please telephone or e-mail the assigned trademark examining attorney. All relevant e-mail communications will be placed in the official application record; however, an e-mail communication will not be accepted as a response to this Office action and will not extend the deadline for filing a proper response. See 37 C.F.R. §2.191; TMEP §§304.01-.02, 709.04-.05. Further, although the trademark examining attorney may provide additional explanation pertaining to the refusal(s) and/or requirement(s) in this Office action, the trademark examining attorney may not provide legal advice or statements about applicant’s rights. See TMEP §§705.02, 709.06.

/Katy Halmen/  
Trademark Examining Attorney  
Law Office 109  
Phone: (571) 272-8911

Email: [katy.halmen@uspto.gov](mailto:katy.halmen@uspto.gov)

**TO RESPOND TO THIS LETTER:** Go to [http://www.uspto.gov/trademarks/teas/response\\_forms.jsp](http://www.uspto.gov/trademarks/teas/response_forms.jsp). Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail [TEAS@uspto.gov](mailto:TEAS@uspto.gov). For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

**All informal e-mail communications relevant to this application will be placed in the official application record.**

**WHO MUST SIGN THE RESPONSE:** It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

**PERIODICALLY CHECK THE STATUS OF THE APPLICATION:** To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at <http://tarr.uspto.gov/>. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

**TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS:** Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)  
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION

APPLICATION SERIAL NO. 79103197

MARK: THEBABASLING

**\*79103197\***

**CORRESPONDENT ADDRESS:**

MURGITROYD & COMPANY  
Scotland House,  
165-169 Scotland Street  
Glasgow G5 8PL  
UNITED KINGDOM

**CLICK HERE TO RESPOND TO THIS LETTER:**

[http://www.uspto.gov/trademarks/teas/response\\_forms.jsp](http://www.uspto.gov/trademarks/teas/response_forms.jsp)

APPLICANT: BabaSlings Limited

**CORRESPONDENT'S REFERENCE/DOCKET**

**NO:**

N/A

**CORRESPONDENT E-MAIL ADDRESS:**

**OFFICE ACTION**

**STRICT DEADLINE TO RESPOND TO THIS LETTER**

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

**ISSUE/MAILING DATE:**

**INTERNATIONAL REGISTRATION NO. 1088031**

This is a **PROVISIONAL FULL REFUSAL** of the trademark and/or service mark in the above-referenced U.S. application. *See* 15 U.S.C. §1141h(c).

**WHO IS PERMITTED TO RESPOND TO THIS PROVISIONAL FULL REFUSAL:**

Applicant may respond directly to this provisional refusal Office action if applicant is not represented by an authorized attorney. *See* 37 C.F.R. §2.193(e)(2)(ii). Otherwise, applicant's authorized attorney must respond on applicant's behalf. *See* 37 C.F.R. §2.193(e)(2)(i). However, **the only attorneys who are authorized to sign responses and practice before the USPTO** in trademark matters are as follows:

- (1) **Attorneys in good standing with a bar of the highest court of any U.S. state**, the District of Columbia, Puerto Rico, and other federal territories and possessions of the United States; and
- (2) **Canadian agents/attorneys** who represent applicants located in Canada and (a) are registered with the USPTO and in good standing as patent agents or (b) have been granted reciprocal recognition by the USPTO.

See 37 C.F.R. §§2.17(e), 2.62(b), 11.1, 11.5(b)(2), 11.14(a), (c); TMEP §§602, 712.03.

Foreign attorneys, other than authorized Canadian attorneys, are not permitted to represent applicants before the USPTO. See 37 C.F.R. §§2.17(e), 11.14(c), (e); TMEP §602.03-.03(b). That is, foreign attorneys may not file written communications, authorize an amendment to an application, or submit legal arguments in response to a requirement or refusal, among other things. See 37 C.F.R. §11.5(b)(2); TMEP §§602.03(c), 608.01. If applicant is represented by such a foreign attorney, applicant must respond directly to this provisional refusal Office action. See 37 C.F.R. §2.193(e)(2)(ii).

#### **DESIGNATION OF DOMESTIC REPRESENTATIVE:**

The USPTO encourages applicants who do not reside in the U.S. to designate a domestic representative upon whom notices or process may be served. 15 U.S.C. §§1051(e), 1141h(d); 37 C.F.R. §2.24(a)(1)-(2); see TMEP §610. Such designations may be filed online at <http://www.uspto.gov/teas/index.html>.

#### **THE APPLICATION HAS BEEN PROVISIONALLY REFUSED AS FOLLOWS:**

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

#### **SEARCH OF OFFICE'S DATABASE OF MARKS**

The trademark examining attorney has searched the Office's database of registered and pending marks and has found no conflicting marks that would bar registration under Trademark Act Section 2(d). TMEP §704.02; see 15 U.S.C. §1052(d).

#### **IDENTIFICATION OF GOODS**

The goods/services are:

Class 18: Bags; trunks and travelling bags; carriers for babies and children; harnesses for babies and children; slings for babies and children; sling bags for carrying babies and children; frames for carrying babies and children; backpacks for carrying babies and children; baby changing bags; nappy bags; baby care bags (empty); travel bags; backpacks; suitcases; shopping bags; shopping bags in frames on wheels; umbrellas; parasols; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods

The identification of goods and/or services is indefinite and must be clarified. In particular, the applicant must specify the common commercial names and/or clarify the exact nature of the specific goods intended. See TMEP §1402.01. Applicant may adopt the following identification, if accurate:

Class 18: Bags, NAMELY, {*specify common commercial names of specific Class 18 goods intended, e.g., athletic bags, barrel bags, belt bags*}; trunks and travelling bags; carriers for babies and children WORN ON THE BODY; {"*harnesses for babies and children*" is indefinite and appears to be

*improperly classified. Applicant must either delete this wording or replace it with acceptable Class 18 wording that is within the scope of the original identification.*}; slings for CARRYING babies and children; sling bags for carrying babies and children; BACK frames for carrying babies and children; backpacks for carrying babies and children; baby changing bags IN THE NATURE OF DIAPER BAGS; nappy bags IN THE NATURE OF DIAPER BAGS; baby care bags IN THE NATURE OF DIAPER BAGS SOLD EMPTY; travel bags; backpacks; suitcases; REUSABLE shopping bags; REUSABLE shopping bags in frames on wheels; umbrellas; parasols; {“*parasols for strollers and for buggies*” is indefinite and appears to be improperly classified. Applicant must either delete this wording or amend the wording such that it clearly falls in Class 18 and is within the scope of the original identification.}; STRUCTURAL parts and fittings for all the aforementioned goods

For assistance with identifying and classifying goods and/or services in trademark applications, please see the online searchable *Manual of Acceptable Identifications of Goods and Services* at <http://tess2.uspto.gov/netahtml/tidm.html>. See TMEP §1402.04.

In an application filed under Trademark Act Section 66(a), an applicant may not change the classification of goods and/or services from that assigned by the International Bureau in the corresponding international registration. 37 C.F.R. §2.85(d); TMEP §§1401.03(d), 1904.02(b). Further, in a multiple-class Section 66(a) application, an applicant may not transfer goods and/or services from one existing international class to another. 37 C.F.R. §2.85(d); see TMEP §§1402.07(a), 1904.02(c).

An applicant may amend an identification of goods only to clarify or limit the goods; adding to or broadening the scope of the goods is not permitted. 37 C.F.R. §2.71(a); see TMEP §§1402.06 *et seq.*, 1402.07 *et seq.*

## **DESCRIPTION OF MARK REQUIRED**

Applicant must submit an accurate and concise description of the literal and design elements in the mark. 37 C.F.R. §2.37; see TMEP §§808.01, 808.02. The following is suggested, if accurate:

**The mark consists of the wording “THEBABASLING” appearing below the design of a crescent moon holding a baby.**

If applicant has questions regarding this Office action, please telephone or e-mail the assigned trademark examining attorney. All relevant e-mail communications will be placed in the official application record; however, an e-mail communication will not be accepted as a response to this Office action and will not extend the deadline for filing a proper response. See 37 C.F.R. §2.191; TMEP §§304.01-.02, 709.04-.05. Further, although the trademark examining attorney may provide additional explanation pertaining to the refusal(s) and/or requirement(s) in this Office action, the trademark examining attorney may not provide legal advice or statements about applicant’s rights. See TMEP §§705.02, 709.06.

/Katy Halmen/  
Trademark Examining Attorney  
Law Office 109  
Phone: (571) 272-8911

Email: [katy.halmen@uspto.gov](mailto:katy.halmen@uspto.gov)

**TO RESPOND TO THIS LETTER:** Go to [http://www.uspto.gov/trademarks/teas/response\\_forms.jsp](http://www.uspto.gov/trademarks/teas/response_forms.jsp). Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail [TEAS@uspto.gov](mailto:TEAS@uspto.gov). For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

**All informal e-mail communications relevant to this application will be placed in the official application record.**

**WHO MUST SIGN THE RESPONSE:** It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

**PERIODICALLY CHECK THE STATUS OF THE APPLICATION:** To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at <http://tarr.uspto.gov/>. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

**TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS:** Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.

\*\*\* User:khalmen \*\*\*

#	Total Marks	Dead Marks	Live Viewed Docs	Live Viewed Images	Status/ Search Duration	Search
01	1	0	1	1	0:01	BABASLINGS[ON]
02	139	0	139	120	0:03	*baba*[bi,ti] not dead[ld]
03	1183	N/A	0	0	0:03	*{"scz"}l{v}ng*[bi,ti] not dead[ld]
04	1	0	1	1	0:01	2 and 3
05	4	0	4	3	0:02	2 and "018"[ic]
06	5683	N/A	0	0	0:03	*b{v}b{v}*[bi,ti] not dead[ld]
07	8	0	8	7	0:01	3 and 6
08	2009	N/A	0	0	0:03	011102[dc] not dead[ld]
09	1178	N/A	0	0	0:03	020501[dc] not dead[ld]
10	1669	N/A	0	0	0:04	020502[dc] not dead[ld]
11	900	N/A	0	0	0:03	020506[dc] not dead[ld]
12	40	0	3	40	0:01	8 and (9 10 11)

Session started 12/27/2011 6:27:02 PM

Session finished 12/27/2011 6:33:36 PM

Total search duration 0 minutes 28 seconds

Session duration 6 minutes 34 seconds

Default NEAR limit=1ADJ limit=1

Sent to TICRS as Serial Number: 79103197

# FILING RECEIPT FOR TRADEMARK APPLICATION

Oct 21, 2011

This acknowledges receipt on the FILING DATE of the application for registration for the mark identified below. The FILING DATE is contingent upon all minimum filing date requirements being met. Your application will be considered in the order in which it was received. Please review the status of your application every six months from the filing date of your application. You can check the status of your application on-line at <http://tarr.uspto.gov/> or by contacting the Trademark Assistance Center at 1-800-786-9199. Also, documents in the electronic file for pending applications can be viewed and downloaded at <http://www.uspto.gov/>.

MURGITROYD & COMPANY  
Scotland House,  
165-169 Scotland Street  
Glasgow G5 8PL  
UNITED KINGDOM

**ATTORNEY  
REFERENCE NUMBER**

## PLEASE REVIEW THE ACCURACY OF THE FILING RECEIPT DATA.

A request for correction to the filing receipt should be submitted within 30 days. Such requests may be submitted by mail to: COMMISSIONER FOR TRADEMARKS, P.O. BOX 1451, ALEXANDRIA, VIRGINIA 22313-1451; by fax to 571-273-9913; or by e-mail to [tmfiling\\_receipt@uspto.gov](mailto:tmfiling_receipt@uspto.gov). The USPTO will review the request and make corrections when appropriate.

SERIAL NUMBER: 79/103197  
FILING DATE: Sep 6, 2011  
REGISTER: Principal  
MARK: THEBABASLING  
MARK TYPE(S): Trademark  
DRAWING TYPE: Words, letters, or numbers and design  
FILING BASIS: Sect. 66(a)(Madrid Protocol)

OWNER: BabaSlings Limited (UNITED KINGDOM, Private Limited Company  
1 Amber House, 22b St John's Road  
Hove BN3 2EZ  
, UNITED KINGDOM

FOR: Bags; trunks and travelling bags; carriers for babies and children; harnesses for babies and children; slings for babies and children; sling bags for carrying babies and children; frames for carrying babies and children; backpacks for carrying babies and children; baby changing bags; nappy bags; baby care bags (empty); travel bags; backpacks; suitcases; shopping bags; shopping bags in frames on wheels; umbrellas; parasols; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods  
INT. CLASS: 018  
FIRST USE: NONE      USE IN COMMERCE: NONE

ALL OF THE GOODS/SERVICES IN EACH CLASS ARE LISTED

## OTHER DATA

COLOR(S) CLAIMED: Color is not claimed as a feature of the mark.

Pseudo Mark: THE BABA SLING

Design Search Codes:

01.11.02 - Moons, crescent; Moons, half; Partial moons, including half moons and crescent moons (not a moon with craters)

BABA 0383

02.05.01 - Busts of children; Children, heads, portraiture, busts; Heads of children

02.05.02 - Children depicted in silhouettes or profiles of children; Silhouettes of children

02.05.06 - Baby; Children, baby or babies

Warning: You may receive unsolicited communications from companies requesting fees for trademark related services, such as monitoring and document filing. Although solicitations from these companies frequently display customer-specific information, including USPTO serial number or registration number and owner name, companies who offer these services are not affiliated or associated with the USPTO or any other federal agency. The USPTO does not provide trademark monitoring or any similar services.

For document filing, such companies typically charge a service fee in addition to applicable USPTO fees. You can electronically file directly with the USPTO using forms available through the Trademark Electronic Application System (TEAS), accessible via the USPTO website at [www.uspto.gov](http://www.uspto.gov) <<http://www.uspto.gov/>>. Only applicable fees required by law, and no service fees, are charged. Status can be monitored directly at no cost through Trademark Application Registration Retrieval (TARR). For general information on filing and maintenance requirements for U.S. trademark applications and registrations, including required fees, please consult the USPTO website.

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INTERNATIONAL OR FOREIGN REGISTRATION DATA

INTERNATIONAL REG. NUMBER: 1088031

Note on representation: An attorney who is a member in good standing of the bar of the highest court of any U.S. state may practice before the USPTO in trademark matters. See [http://tess2.uspto.gov/tmdb/tmep/0600.htm#\\_T60206](http://tess2.uspto.gov/tmdb/tmep/0600.htm#_T60206) for more information on foreign attorneys and persons who may practice before the Office.

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ADDITIONAL INFORMATION MAY BE PRESENT IN THE USPTO RECORDS

# REQUEST FOR EXTENSION OF PROTECTION

SERIAL NUMBER: 79103197

FILING DATE: 09/06/2011

The table below presents the data as entered.

Input Field	Entered
<b>MARK SECTION</b>	
IMAGE	<a href="#">\\TICRS\EXPORT11\IMAGEOUT11\791\031\79103197\xml1\APP0002.JPG</a>
COLLECTIVE, CERTIFICATE OR GUARANTEE MARK	NO
MARK IN STANDARD CHARACTERS	NO
MARK IN COLOR	NO
THREE DIMENSIONAL MARK	NO
SOUND MARK	NO
TM IMAGE: COLOR	Grey Scale
IMAGE FILE NAME	\\TICRS\EXPORT11\IMAGEOUT11\791\031\79103197\xml1\APP0002.JPG
TYPE (IMAGE TYPE)	JPG
TEXTUAL ELEMENTS OF MARK	theBabaSling
<b>HOLDER DETAILS</b>	
CLIENT IDENTIFIER	781170
NOTIFICATION LANGUAGE	ENGLISH
NAME	BabaSlings Limited
ADDRESS	1 Amber House, 22b St John's Road Hove BN3 2EZ
COUNTRY	United Kingdom
ENTITLEMENT NATIONALITY OF APPLICANT/	United Kingdom

TRANSFEREE/  
HOLDER

LEGAL NATURE Private Limited Company

LEGAL NATURE:  
PLACE United Kingdom  
INCORPORATED

CORRESPONDENCE  
INDICATOR YES

## BASIC GOODS AND SERVICES

VERSION OF NICE  
CLASSIFICATION USED 9

NICE  
CLASSIFICATION 18

GOODS AND  
SERVICES

Bags; trunks and travelling bags; carriers for babies and children; harnesses for babies and children; slings for babies and children; sling bags for carrying babies and children; frames for carrying babies and children; backpacks for carrying babies and children; baby changing bags; nappy bags; baby care bags (empty); travel bags; backpacks; suitcases; shopping bags; shopping bags in frames on wheels; umbrellas; parasols; parasols for strollers and for buggies; parts and fittings for all the aforementioned goods.

## BASE REGISTRATION DETAILS

BASE REGISTRATION  
NUMBER 008109563

BASE REGISTRATION  
DATE 11/11/2009

BASE APPLICATION  
NUMBER 008109563

BASE APPLICATION  
DATE 02/17/2009

## REPRESENTATIVE DETAILS

CLIENT IDENTIFIER 559392

NAME MURGITROYD & COMPANY

ADDRESS Scotland House,  
165-169 Scotland Street  
Glasgow G5 8PL

COUNTRY United Kingdom

## INTENT TO USE GROUP

CONTRACTING PARTY CODE United States of America

## DESIGNATIONS

DESIGNATIONS UNDER THE PROTOCOL United States of America

## INTERNATIONAL REGISTRATION DETAILS

INTERNATIONAL REGISTRATION NUMBER 1088031

INTERNATIONAL REGISTRATION DATE OF MARK 07/07/2011

INTERNATIONAL REGISTRATION EXPIRY DATE 07/07/2021

EFFECTIVE DATE OF MODIFICATION 09/06/2011

NOTIFICATION DATE 10/13/2011

DATE OF RECORDAL IN INTERNATIONAL REGISTER 09/26/2011

IB DOCUMENT ID 626940201

OFFICE OF ORIGIN CODE Office for Harmonization in the Internal Market ( Trade Marks and Designs) (OHIM)

OFFICE REFERENCE 79103197

TRANSACTION TYPE VALUES Subsequent Designation

ORIGINAL LANGUAGE ENGLISH

INSTRUMENT UNDER WHICH CONTRACTING PARTY IS DESIGNATED Protocol

DURATION OF MARK (YEARS) 10

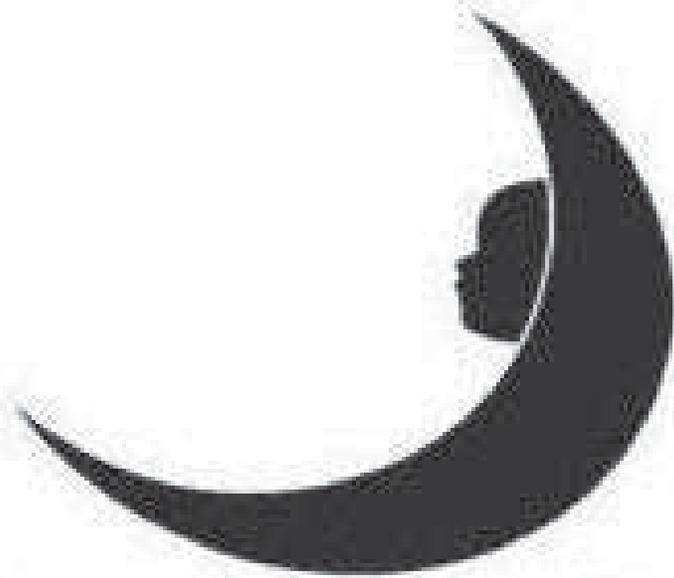
VIENNA CLASSIFICATION VERSION USED 6

VIENNA CLASS	0107
VIENNA CLASS	0205
VIENNA CLASS	2705

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theBabaSling



theBabaSling

Generated on: This page was generated by TSDR on 2013-05-15 13:47:32 EDT

Mark: BABA SLINGS

# Baba Slings

US Serial Number: 85633700

Application Filing Date: May 23, 2012

Filed as TEAS Plus: Yes

Currently TEAS Plus: Yes

Register: Principal

Mark Type: Trademark

Status: An Office action suspending further action on the application has been sent (issued) to the applicant. To view all documents in this file, click on the Trademark Document Retrieval link at the top of this page.

Status Date: Jan. 14, 2013

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## Mark Information

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Mark Literal Elements: BABA SLINGS

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Disclaimer: "SLINGS"

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## Foreign Information

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Foreign Registration Number: 1021631

Foreign Registration Date: May 23, 2005

Foreign Application/Registration Country: AUSTRALIA

Foreign Expiration Date: Sep. 22, 2014

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## Goods and Services

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Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis (...) identify any goods/services not claimed in a Section 15 affidavit of
- Asterisks "\*" identify additional (new) wording in the goods/services.

For: (Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants (Based on 44(e)) Sling bags for carrying infants; Slings for carrying infants

International Class(es): 018 - Primary Class

U.S Class(es): 001, 002, 003, 022, 041

Class Status: ACTIVE

Basis: 1(a) 44(e)

First Use: 1999

Use in Commerce: Oct. 2002

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## Basis Information (Case Level)

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Filed Use: Yes

Currently Use: Yes

Amended Use: No

Filed ITU: No

Currently ITU: No

Amended ITU: No

Filed 44D: No

Currently 44D: No

Amended 44D: No

Filed 44E: Yes

Currently 44E: Yes

Amended 44E: No

Filed 66A: No

Currently 66A: No

Filed No Basis: No

Currently No Basis: No

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## Current Owner(s) Information

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Owner Name: Baba Slings Pty Ltd

Owner Address: 486 Hunchy Rd  
Hunchy, Qld 4555  
AUSTRALIA

Legal Entity Type: proprietary limited company (p/l or pty. ltd.)

State or Country Where Organized: AUSTRALIA

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## Attorney/Correspondence Information

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BABA 0391

**Attorney of Record**

**Attorney Name:** Mark Borghese **Docket Number:** BABAS.0002T  
**Attorney Primary Email Address:** [mark@borgheselegal.com](mailto:mark@borgheselegal.com) **Attorney Email Authorized:** Yes

**Correspondent**

**Correspondent Name/Address:** MARK BORGHESE  
 BORGHESE LEGAL, LTD.  
 10161 PARK RUN DR STE 150  
 LAS VEGAS, NEVADA 89145-8872  
 UNITED STATES  
**Phone:** (702) 382-0200 **Fax:** (702) 382-0212  
**Correspondent e-mail:** [mark@borgheselegal.com](mailto:mark@borgheselegal.com) [docket@borgheselegal.com](mailto:docket@borgheselegal.com) **Correspondent e-mail Authorized:** Yes

**Domestic Representative - Not Found****Prosecution History**

Date	Description	Proceeding Number
Jan. 14, 2013	NOTIFICATION OF LETTER OF SUSPENSION E-MAILED	6332
Jan. 14, 2013	LETTER OF SUSPENSION E-MAILED	6332
Jan. 14, 2013	SUSPENSION LETTER WRITTEN	88579
Jan. 12, 2013	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Jan. 11, 2013	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Jan. 11, 2013	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Sep. 19, 2012	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Sep. 19, 2012	NON-FINAL ACTION E-MAILED	6325
Sep. 19, 2012	NON-FINAL ACTION WRITTEN	88579
Sep. 12, 2012	ASSIGNED TO EXAMINER	88579
May 31, 2012	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
May 26, 2012	NEW APPLICATION ENTERED IN TRAM	

**TM Staff and Location Information****TM Staff Information**

**TM Attorney:** CANTONE, KERI H **Law Office Assigned:** LAW OFFICE 104

**File Location**

**Current Location:** TMEG LAW OFFICE 104 - EXAMINING ATTORNEY ASSIGNED **Date in Location:** Jan. 14, 2013

**Proceedings****Summary**

**Number of Proceedings:** 1

**Type of Proceeding: Opposition**

**Proceeding Number:** [91205483](#) **Filing Date:** Jun 05, 2012  
**Status:** Pending **Status Date:** Jun 05, 2012  
**Interlocutory Attorney:** JENNIFER KRISP

**Defendant**

**Name:** Baba Slings Limited  
**Correspondent Address:** ROBERT L STOLL  
 DRINKER BIDDLE & REATH LLP  
 1500 K STREET NW, SUITE 1100  
 WASHINGTON DC , 20005-1209  
 UNITED STATES  
**Correspondent e-mail:** [dctrademarks@dbr.com](mailto:dctrademarks@dbr.com) , [brian.coleman@dbr.com](mailto:brian.coleman@dbr.com) , [anthony.palumbo@dbr.com](mailto:anthony.palumbo@dbr.com)

**Associated marks**

Mark	Application Status	Serial Number	Registration Number
THEBABASLING	Opposition Pending	<a href="#">79103197</a>	

**Plaintiff(s)**

**Name:** Baba Slings Pty Ltd

**Correspondent Address:** MARK BORGHESE  
BORGHESE LEGAL LTD  
10161 PARK RUM DRIVE , SUITE 150  
LAS VEGAS NV , 89145  
UNITED STATES

**Correspondent e-mail:** [mark@borghesellegal.com](mailto:mark@borghesellegal.com)

**Associated marks**

Mark	Application Status	Serial Number	Registration Number
BABA SLINGS	Suspension Letter - Mailed	<a href="#">85633700</a>	

**Prosecution History**

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Jun 05, 2012	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Jun 07, 2012	Jul 17, 2012
3	PENDING, INSTITUTED	Jun 07, 2012	
4	D'S MOT FOR EXTEN. OF TIME W/ CONSENT	Jul 17, 2012	
5	EXTENSION OF TIME GRANTED	Jul 19, 2012	
6	ANSWER	Jul 24, 2012	
7	D'S APPEARANCE OF COUNSEL/POWER OF ATTORNEY	Sep 24, 2012	
8	STIP TO SUSPEND PEND SETTLEMENT NEGOTNS	Jan 30, 2013	
9	SUSPENDED	Jan 30, 2013	

**Trademark Snap Shot Amendment & Mail Processing Stylesheet**  
(Table presents the data on Amendment & Mail Processing Complete)

**OVERVIEW**

SERIAL NUMBER	85633700	FILING DATE	05/23/2012
REG NUMBER	0000000	REG DATE	N/A
REGISTER	PRINCIPAL	MARK TYPE	TRADEMARK
INTL REG #	N/A	INTL REG DATE	N/A
TM ATTORNEY	CANTONE, KERI H	L.O. ASSIGNED	104

**PUB INFORMATION**

RUN DATE	01/15/2013		
PUB DATE	N/A		
STATUS	653-SUSPENSION LETTER - MAILED		
STATUS DATE	01/14/2013		
LITERAL MARK ELEMENT	BABA SLINGS		
DATE ABANDONED	N/A	DATE CANCELLED	N/A
SECTION 2F	NO	SECTION 2F IN PART	NO
SECTION 8	NO	SECTION 8 IN PART	NO
SECTION 15	NO	REPUB 12C	N/A
RENEWAL FILED	NO	RENEWAL DATE	N/A
DATE AMEND REG	N/A		

**FILING BASIS**

FILED BASIS		CURRENT BASIS		AMENDED BASIS	
1 (a)	YES	1 (a)	YES	1 (a)	NO
1 (b)	NO	1 (b)	NO	1 (b)	NO
44D	NO	44D	NO	44D	NO
44E	YES	44E	YES	44E	NO
66A	NO	66A	NO		
NO BASIS	NO	NO BASIS	NO		

**MARK DATA**

STANDARD CHARACTER MARK	YES
LITERAL MARK ELEMENT	BABA SLINGS

MARK DRAWING CODE	4-STANDARD CHARACTER MARK
COLOR DRAWING FLAG	NO

### CURRENT OWNER INFORMATION

PARTY TYPE	10-ORIGINAL APPLICANT
NAME	Baba Slings Pty Ltd
ADDRESS	486 Hunchy Rd Hunchy, Qld, 4555
ENTITY	99-proprietary limited company (p/l or Pty. Ltd.)
CITIZENSHIP	Australia

### GOODS AND SERVICES

INTERNATIONAL CLASS	018
DESCRIPTION TEXT	(Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants (Based on 44(e)) Sling bags for carrying infants; Slings for carrying infants

### GOODS AND SERVICES CLASSIFICATION

INTERNATIONAL CLASS	018	FIRST USE DATE	00/00/1999	FIRST USE IN COMMERCE DATE	10/00/2002	CLASS STATUS	6-ACTIVE
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### MISCELLANEOUS INFORMATION/STATEMENTS

CHANGE IN REGISTRATION	NO
DISCLAIMER W/PREDETER TXT	"SLINGS"

### FOREIGN INFORMATION

PRIORITY CLAIMED	N/A
APPLICATION NO.	N/A
APPLICATION FILING DATE	N/A
FOREIGN REG NO.	1021631
FOREIGN REG DATE	05/23/2005
FOREIGN RNWL NUM	N/A
DATE OF FOREIGN RNWL	N/A
FOREIGN EXPIRATION	09/22/2014
FOREIGN RNWL EXPIRATION	N/A

### PROSECUTION HISTORY

DATE	ENT CD	ENT TYPE	DESCRIPTION	ENT NUM
01/14/2013	GNS3	O	NOTIFICATION OF LETTER OF SUSPENSION E-MAILED	012
01/14/2013	GNSL	S	LETTER OF SUSPENSION E-MAILED	011
01/14/2013	CNSL	R	SUSPENSION LETTER WRITTEN	010
01/12/2013	TEME	I	TEAS/EMAIL CORRESPONDENCE ENTERED	009
01/11/2013	CRFA	I	CORRESPONDENCE RECEIVED IN LAW OFFICE	008
01/11/2013	TROA	I	TEAS RESPONSE TO OFFICE ACTION RECEIVED	007
09/19/2012	GNRN	O	NOTIFICATION OF NON-FINAL ACTION E-MAILED	006
09/19/2012	GNRT	F	NON-FINAL ACTION E-MAILED	005
09/19/2012	CNRT	R	NON-FINAL ACTION WRITTEN	004
09/12/2012	DOCK	D	ASSIGNED TO EXAMINER	003
05/31/2012	NWOS	I	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	002
05/26/2012	NWAP	I	NEW APPLICATION ENTERED IN TRAM	001

### CURRENT CORRESPONDENCE INFORMATION

ATTORNEY	Mark Borghese
CORRESPONDENCE ADDRESS	MARK BORGHESE BORGHESE LEGAL, LTD. 10161 PARK RUN DR STE 150 LAS VEGAS, NV 89145-8872
DOMESTIC REPRESENTATIVE	NONE

# Baba Slings

**To:** Baba Slings Pty Ltd ([mark@borgheselegal.com](mailto:mark@borgheselegal.com))  
**Subject:** U.S. TRADEMARK APPLICATION NO. 85633700 - BABA SLINGS - BABAS.0002T  
**Sent:** 1/14/2013 12:22:20 PM  
**Sent As:** ECOM104@USPTO.GOV  
**Attachments:**

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)  
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

**U.S. APPLICATION SERIAL NO.** 85633700

**MARK:** BABA SLINGS

**\*85633700\***

**CORRESPONDENT ADDRESS:**  
MARK BORGHESE  
BORGHESE LEGAL, LTD.  
10161 PARK RUN DR STE 150  
LAS VEGAS, NV 89145-8872

**GENERAL TRADEMARK IN**  
<http://www.uspto.gov/trademark>

**APPLICANT:** Baba Slings Pty Ltd

**CORRESPONDENT'S REFERENCE/DOCKET NO :**  
BABAS.0002T  
**CORRESPONDENT E-MAIL ADDRESS:**  
[mark@borgheselegal.com](mailto:mark@borgheselegal.com)

**SUSPENSION NOTICE: NO RESPONSE NEEDED**

**ISSUE/MAILING DATE:** 1/14/2013

Applicant's communication of January 11, 2013 is acknowledged. The amendment to the identification of goods is acceptable and the requirement has been satisfied. TMEP §§713.02, 714.04.

The trademark examining attorney is suspending action on the application for the reason(s) stated below. See 37 C.F.R. §2.67; TMEP §§716 *et seq.*

The effective filing date of the pending application(s) identified below precedes the filing date of applicant's application. If the mark in the referenced application(s) registers, applicant's mark may be refused registration under Section 2(d) because of a likelihood of confusion with that registered mark(s). See 15 U.S.C. §1052(d); 37 C.F.R. §2.83; TMEP §§1208 *et seq.* Therefore, action on this application is suspended until the earlier-filed referenced application(s) is either registered or abandoned. 37 C.F.R. §2.83(c). A copy of information relevant to this referenced application(s) was sent previously.

- Application Serial No(s). 79103197

**PENDING CIVIL PROCEEDING(S):** The pending civil proceeding(s) below pertains to (1) a registered mark that conflicts with applicant's mark under Trademark Act Section 2(d), (2) a mark in a pending application(s) that could conflict with applicant's mark under Section 2(d) if it registers, and/or (3) the registrability of applicant's mark. *See* 15 U.S.C. §1052; 37 C.F.R. §2.83; TMEP §§716.02(a), (c)-(d), 1208 *et seq.* Because the civil proceeding(s) pertains to an issue that could directly affect whether applicant's mark can be registered, action on this application is suspended pending termination of the civil proceeding(s). *See* 37 C.F.R. §2.67; TMEP §§716.02(a), (c)-(d).

- Opposition No(s). 91205483

The USPTO will periodically conduct a status check of the application to determine whether suspension remains appropriate, and the trademark examining attorney will issue as needed an inquiry letter to applicant regarding the status of the matter on which suspension is based. TMEP §§716.04, 716.05. Applicant will be notified when suspension is no longer appropriate. *See* TMEP §716.04.

No response to this notice is necessary; however, if applicant wants to respond, applicant should use the "Response to Suspension Inquiry or Letter of Suspension" form online at <http://teasroa.uspto.gov/rsi/rsi>.

/Keri-Marie Cantone/  
Examining Attorney - Law Office 104  
(571) 272-6069  
Keri.Cantone@uspto.gov

**PERIODICALLY CHECK THE STATUS OF THE APPLICATION:** To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using the Trademark Status and Document Retrieval (TSDR) system at <http://tsdr.uspto.gov/>. Please keep a copy of the TSDR status screen. If the status shows no change for more than six months, contact the Trademark Assistance Center by e-mail at [TrademarkAssistanceCenter@uspto.gov](mailto:TrademarkAssistanceCenter@uspto.gov) or call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

**TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS:** Use the Trademark Electronic Application System (TEAS) form at <http://www.uspto.gov/trademarks/teas/correspondence.jsp>.

**To:** Baba Slings Pty Ltd ([mark@borgheselegal.com](mailto:mark@borgheselegal.com))  
**Subject:** U.S. TRADEMARK APPLICATION NO. 85633700 - BABA SLINGS - BABAS.0002T  
**Sent:** 1/14/2013 12:22:21 PM  
**Sent As:** ECOM104@USPTO.GOV  
**Attachments:**

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)**

**IMPORTANT NOTICE REGARDING YOUR  
U.S. TRADEMARK APPLICATION**

USPTO OFFICE ACTION (OFFICIAL LETTER) HAS ISSUED  
ON **1/14/2013** FOR U.S. APPLICATION SERIAL NO.85633700

Please follow the instructions below:

**(1) TO READ THE LETTER:** Click on this [link](#) or go to <http://tsdr.uspto.gov/>, enter the U.S. application serial number, and click on “Documents.”

The Office action may not be immediately viewable, to allow for necessary system updates of the application, but will be available within 24 hours of this e-mail notification.

**(2) QUESTIONS:** For questions about the contents of the Office action itself, please contact the assigned trademark examining attorney. For *technical* assistance in accessing or viewing the Office action in the Trademark Status and Document Retrieval (TSDR) system, please e-mail [TSDR@uspto.gov](mailto:TSDR@uspto.gov).

**WARNING**

**PRIVATE COMPANY SOLICITATIONS REGARDING YOUR APPLICATION:** Private companies **not** associated with the USPTO are using information provided in trademark applications to mail or e-mail trademark-related solicitations. These companies often use names that closely resemble the USPTO and their solicitations may look like an official government document. Many solicitations require that you pay “fees.”

Please carefully review all correspondence you receive regarding this application to make sure that you are responding to an official document from the USPTO rather than a private company solicitation. All official USPTO correspondence will be mailed only from the “United States Patent and Trademark Office” in Alexandria, VA; or sent by e-mail from the domain “@uspto.gov.” For more information on how to handle private company solicitations, see

[http://www.uspto.gov/trademarks/solicitation\\_warnings.jsp](http://www.uspto.gov/trademarks/solicitation_warnings.jsp).

## Response to Office Action

**The table below presents the data as entered.**

Input Field	Entered
<b>SERIAL NUMBER</b>	85633700
<b>LAW OFFICE ASSIGNED</b>	LAW OFFICE 104
<b>MARK SECTION (no change)</b>	
<b>ARGUMENT(S)</b>	
<p>The prior filed application (Application Serial No. 79103197) cited by Examining Attorney is currently the subject of an opposition proceeding filed by the Applicant (Opposition No. 91205483). It is requested that this application be suspended pending the resolution of that opposition proceeding.</p> <p>In response to the Examining Attorney's inquiry regarding the identification of goods based on the foreign registration, Applicant has elected to limit the Trademark Act Section 44 basis to the scope of goods in the foreign application.</p>	
<b>GOODS AND/OR SERVICES SECTION (current)</b>	
<b>INTERNATIONAL CLASS</b>	018
<b>DESCRIPTION</b>	
(Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants(Based on 44(e)) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants	
<b>FILING BASIS</b>	Section 1(a)
<b>FIRST USE ANYWHERE DATE</b>	At least as early as 00/00/1999
<b>FIRST USE IN COMMERCE DATE</b>	At least as early as 10/00/2002
<b>FILING BASIS</b>	Section 44(e)
<b>FOREIGN REGISTRATION NUMBER</b>	1021631
<b>FOREIGN REGISTRATION COUNTRY</b>	Australia
<b>FOREIGN REGISTRATION DATE</b>	05/23/2005
<b>FOREIGN EXPIRATION DATE</b>	09/22/2014
<b>GOODS AND/OR SERVICES SECTION (proposed)</b>	

<b>INTERNATIONAL CLASS</b>	018
<b>TRACKED TEXT DESCRIPTION</b>	
(Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; <del>Slings for carrying infants</del> (Based on 44(e)) <del>Baby carriers worn on the body</del> ; <u>Slings for carrying infants (Based on 44(e))</u> <u>Sling bags for carrying infants</u> ; <del>Baby carrying bags</del> ; Slings for carrying infants; <del>Bags for carrying babies' accessories</del> ; <del>Sling bags</del> ; <del>Sling bags for carrying infants</del>	
<b>FINAL DESCRIPTION</b>	
(Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants (Based on 44(e)) Sling bags for carrying infants; Slings for carrying infants	
<b>FILING BASIS</b>	Section 1(a)
<b>FIRST USE ANYWHERE DATE</b>	At least as early as 00/00/1999
<b>FIRST USE IN COMMERCE DATE</b>	At least as early as 10/00/2002
<b>FILING BASIS</b>	Section 44(e)
<b>FOREIGN REGISTRATION NUMBER</b>	1021631
<b>FOREIGN REGISTRATION COUNTRY</b>	Australia
<b>FOREIGN REGISTRATION DATE</b>	05/23/2005
<b>FOREIGN EXPIRATION DATE</b>	09/22/2014
<b>STANDARD CHARACTERS OR EQUIVALENT</b>	YES
<b>SIGNATURE SECTION</b>	
<b>RESPONSE SIGNATURE</b>	/MB/
<b>SIGNATORY'S NAME</b>	Mark Borghese
<b>SIGNATORY'S POSITION</b>	Attorney of record, Nevada bar member
<b>SIGNATORY'S PHONE NUMBER</b>	(702) 382-0200
<b>DATE SIGNED</b>	01/11/2013
<b>AUTHORIZED SIGNATORY</b>	YES
<b>FILING INFORMATION SECTION</b>	
<b>SUBMIT DATE</b>	Fri Jan 11 19:21:29 EST 2013
<b>TEAS STAMP</b>	USPTO/ROA-68.108.59.126-2 0130111192129379494-85633 700-490f528352d436cf08aac 1d26ec653cb16b-N/A-N/A-20

## Response to Office Action To the Commissioner for Trademarks:

Application serial no. **85633700** has been amended as follows:

### ARGUMENT(S)

**In response to the substantive refusal(s), please note the following:**

The prior filed application (Application Serial No. 79103197) cited by Examining Attorney is currently the subject of an opposition proceeding filed by the Applicant (Opposition No. 91205483). It is requested that this application be suspended pending the resolution of that opposition proceeding.

In response to the Examining Attorney's inquiry regarding the identification of goods based on the foreign registration, Applicant has elected to limit the Trademark Act Section 44 basis to the scope of goods in the foreign application.

### CLASSIFICATION AND LISTING OF GOODS/SERVICES

**Applicant proposes to amend the following class of goods/services in the application:**

**Current:** Class 018 for (Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants (Based on 44(e)) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants

Original Filing Basis:

**Filing Basis: Section 1(a), Use in Commerce:** The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 00/00/1999 and first used in commerce at least as early as 10/00/2002, and is now in use in such commerce.

**Filing Basis: Section 44(e), Based on Foreign Registration:** Applicant has a bona fide intention to use the mark in commerce on or in connection with the identified goods and /or services, and submits a copy of [ Australia registration number 1021631 registered 05/23/2005 with a renewal date of \_\_\_\_\_ and an expiration date of 09/22/2014 ], and translation thereof, if appropriate. 15 U.S.C. Section 1126(e), as amended.

### Proposed:

**Tracked Text Description:** (Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; ~~Slings for carrying infants~~ (Based on 44(e)) ~~Baby carriers worn on the body~~; Slings for carrying infants (Based on 44(e)) Sling

bags for carrying infants; ~~Baby carrying bags~~; Slings for carrying infants; ~~Bags for carrying babies' accessories~~; ~~Sling bags~~; ~~Sling bags for carrying infants~~

Class 018 for (Based on Use in Commerce) Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants (Based on 44(e)) Sling bags for carrying infants; Slings for carrying infants

**Filing Basis: Section 1(a), Use in Commerce:** The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 00/00/1999 and first used in commerce at least as early as 10/00/2002, and is now in use in such commerce.

**Filing Basis: Section 44(e), Based on Foreign Registration:** Applicant has a bona fide intention to use the mark in commerce on or in connection with the identified goods and /or services, and will submit a copy of [ Australia registration number 1021631 registered 05/23/2005 with a renewal date of \_\_\_\_\_ and an expiration date of 09/22/2014 ], and translation thereof, if appropriate, before the application may proceed to registration. 15 U.S.C. Section 1126(e), as amended.

The foreign registration that is the basis of the U.S. application under §44(e) of the Trademark Act (15 U.S.C. §1126(e)) includes a claim of standard characters or the country of origin's standard character equivalent.

#### **SIGNATURE(S)**

##### **Response Signature**

Signature: /MB/ Date: 01/11/2013

Signatory's Name: Mark Borghese

Signatory's Position: Attorney of record, Nevada bar member

Signatory's Phone Number: (702) 382-0200

The signatory has confirmed that he/she is an attorney who is a member in good standing of the bar of the highest court of a U.S. state, which includes the District of Columbia, Puerto Rico, and other federal territories and possessions; and he/she is currently the applicant's attorney or an associate thereof; and to the best of his/her knowledge, if prior to his/her appointment another U.S. attorney or a Canadian attorney/agent not currently associated with his/her company/firm previously represented the applicant in this matter: (1) the applicant has filed or is concurrently filing a signed revocation of or substitute power of attorney with the USPTO; (2) the USPTO has granted the request of the prior representative to withdraw; (3) the applicant has filed a power of attorney appointing him/her in this matter; or (4) the applicant's appointed U.S. attorney or Canadian attorney/agent has filed a power of attorney appointing him/her as an associate attorney in this matter.

Serial Number: 85633700

Internet Transmission Date: Fri Jan 11 19:21:29 EST 2013

TEAS Stamp: USPTO/ROA-68.108.59.126-2013011119212937

9494-85633700-490f528352d436cf08aac1d26e

c653cb16b-N/A-N/A-20130111190719679685

**To:** Baba Slings Pty Ltd ([mark@borgheselegal.com](mailto:mark@borgheselegal.com))  
**Subject:** U.S. TRADEMARK APPLICATION NO. 85633700 - BABA SLINGS - BABAS.0002T  
**Sent:** 9/19/2012 7:22:25 AM  
**Sent As:** ECOM104@USPTO.GOV  
**Attachments:** [Attachment - 1](#)  
[Attachment - 2](#)  
[Attachment - 3](#)

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)  
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

**APPLICATION SERIAL NO.** 85633700

**MARK:** BABA SLINGS

**\*85633700\***

**CORRESPONDENT ADDRESS:**

MARK BORGHESE  
BORGHESE LEGAL, LTD.  
10161 PARK RUN DR STE 150  
LAS VEGAS, NV 89145-8872

**CLICK HERE TO RESPOND**  
<http://www.uspto.gov/trademarks/te>

**APPLICANT:** Baba Slings Pty Ltd

**CORRESPONDENT'S REFERENCE/DOCKET NO :**

BABAS.0002T

**CORRESPONDENT E-MAIL ADDRESS:**

[mark@borgheselegal.com](mailto:mark@borgheselegal.com)

**OFFICE ACTION**

**STRICT DEADLINE TO RESPOND TO THIS LETTER**

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

**ISSUE/MAILING DATE: 9/19/2012**

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

**SUMMARY OF ISSUES THAT APPLICANT MUST ADDRESS:**

- Prior-Filed Application
- Identification of Goods Exceeds Scope of Foreign Registration

## **PRIOR-FILED APPLICATION**

The trademark examining attorney has searched the Office's database of registered and pending marks and has found no similar registered mark that would bar registration under Trademark Act Section 2(d). TMEP §704.02; *see* 15 U.S.C. §1052(d). However, a mark in a prior-filed pending application may present a bar to registration of applicant's mark.

The filing date of pending U.S. Application Serial No. 79103197 precedes applicant's filing date. See attached referenced application. If the mark in the referenced application registers, applicant's mark may be refused registration under Trademark Act Section 2(d) because of a likelihood of confusion between the two marks. *See* 15 U.S.C. §1052(d); 37 C.F.R. §2.83; TMEP §§1208 *et seq.* Therefore, upon receipt of applicant's response to this Office action, action on this application may be suspended pending final disposition of the earlier-filed referenced application.

In response to this Office action, applicant may present arguments in support of registration by addressing the issue of the potential conflict between applicant's mark and the mark in the referenced application. Applicant's election not to submit arguments at this time in no way limits applicant's right to address this issue later if a refusal under Section 2(d) issues.

## **IDENTIFICATION OF GOODS EXCEEDS SCOPE OF FOREIGN REGISTRATION**

The following wording in the identification of goods in the U.S. application is unacceptable because it exceeds the scope of the goods in the foreign application or registration: "baby carriers worn on the body; baby carrying bags; bags for carrying babies' accessories." *See* 37 C.F.R. §2.32(a)(6); TMEP §1012.

Therefore, applicant must satisfy one of the following:

- (1) Amend the identification of goods in the U.S. application to correspond to the goods identified in the foreign application or registration, ensuring that all goods beyond the scope of the foreign application or registration are deleted from the U.S. application; or
- (2) Delete the Trademark Act Section 44 basis for the goods beyond the scope of the foreign application or registration and rely solely on the Section 1 basis for those goods.

*See* 15 U.S.C. §§1051, 1126(d)-(e); 37 C.F.R. §§2.32(a)(6), 2.34(b); *Marmark Ltd. v. Nutrexp S.A.*, 12 USPQ2d 1843, 1845 (TTAB 1989); TMEP §§806.02, 806.04, 1012, 1402.01(b).

Please note, the following identified goods are within the scope of the foreign application, "sling bags; sling bags for carrying infants; slings for carrying infants."

An applicant may amend an identification of goods only to clarify or limit the goods; adding to or broadening the scope of the goods is not permitted. 37 C.F.R. §2.71(a); *see* TMEP §§1402.06 *et seq.*, 1402.07 *et seq.*

For assistance with identifying and classifying goods and/or services in trademark applications, please see the USPTO's online searchable *U.S. Acceptable Identification of Goods and Services Manual* at <http://tess2.uspto.gov/netahtml/tidm.html>. *See* TMEP §1402.04.

## RESPONSE GUIDELINES

For this application to proceed toward registration, applicant must explicitly address each refusal and/or requirement raised in this Office action. If the action includes a refusal, applicant may provide arguments and/or evidence as to why the refusal should be withdrawn and the mark should register. Applicant may also have other options for responding to a refusal and should consider such options carefully. To respond to requirements and certain refusal response options, applicant should set forth in writing the required changes or statements.

If applicant does not respond to this Office action within six months of the issue/ mailing date, or responds by expressly abandoning the application, the application process will end, the trademark will fail to register, and the application fee will not be refunded. *See* 15 U.S.C. §1062(b); 37 C.F.R. §§2.65(a), 2.68(a), 2.209(a); TMEP §§405.04, 718.01, 718.02. Where the application has been abandoned for failure to respond to an Office action, applicant's only option would be to file a timely petition to revive the application, which, if granted, would allow the application to return to live status. *See* 37 C.F.R. §2.66; TMEP §1714. There is a \$100 fee for such petitions. *See* 37 C.F.R. §§2.6, 2.66(b)(1).

## ASSISTANCE

If applicant has questions regarding this Office action, please telephone or e-mail the assigned trademark examining attorney. All relevant e-mail communications will be placed in the official application record; however, an e-mail communication will not be accepted as a response to this Office action and will not extend the deadline for filing a proper response. *See* 37 C.F.R. §2.191; TMEP §§304.01-.02, 709.04-.05. Further, although the trademark examining attorney may provide additional explanation pertaining to the refusal(s) and/or requirement(s) in this Office action, the trademark examining attorney may not provide legal advice or statements about applicant's rights. *See* TMEP §§705.02, 709.06.

**TEAS PLUS APPLICANTS MUST SUBMIT DOCUMENTS ELECTRONICALLY OR SUBMIT FEE:** Applicants who filed their application online using the reduced-fee TEAS Plus application must continue to submit certain documents online using TEAS, including responses to Office actions. *See* 37 C.F.R. §2.23(a)(1). For a complete list of these documents, see TMEP §819.02(b). In addition, such applicants must accept correspondence from the Office via e-mail throughout the examination process and must maintain a valid e-mail address. 37 C.F.R. §2.23(a)(2); TMEP §§819, 819.02(a). TEAS Plus applicants who do not meet these requirements must submit an additional fee of \$50 per international class of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. In appropriate situations and where all issues can be resolved by amendment, responding by telephone to authorize an examiner's amendment will not incur this additional fee.

/Keri-Marie Cantone/  
Examining Attorney - Law Office 104  
(571) 272-6069  
Keri.Cantone@uspto.gov

**TO RESPOND TO THIS LETTER:** Go to [http://www.uspto.gov/trademarks/teas/response\\_forms.jsp](http://www.uspto.gov/trademarks/teas/response_forms.jsp). Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail [TEAS@uspto.gov](mailto:TEAS@uspto.gov). For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail**

**communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

**All informal e-mail communications relevant to this application will be placed in the official application record.**

**WHO MUST SIGN THE RESPONSE:** It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

**PERIODICALLY CHECK THE STATUS OF THE APPLICATION:** To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at <http://tarr.uspto.gov/>. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

**TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS:** Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.

**DESIGN MARK**

**Serial Number**

79103197

**Status**

OPPOSITION PENDING

**Word Mark**

THEBABASLING

**Standard Character Mark**

No

**Type of Mark**

TRADEMARK

**Register**

PRINCIPAL

**Mark Drawing Code**

(3) DESIGN PLUS WORDS, LETTERS AND/OR NUMBERS

**Owner**

BabaSlings Limited Private Limited Company UNITED KINGDOM 1 Amber House, 22b St John's Road Hove UNITED KINGDOM BN3 2EZ

**Goods/Services**

Class Status -- ACTIVE. IC 018. US 001 002 003 022 041. G & S: Bags, namely, all purpose carrying bags, baby carrying bags, and bags for carrying babies' accessories; trunks and traveling bags; carriers for babies and children worn on the body; slings for carrying babies and children; back frames for carrying babies and children; sling bags for carrying babies and children; baby changing bags in the nature of bags for carrying babies' accessories; nappy bags in the nature of diaper bags; baby care bags in the nature of bags for carrying babies' accessories sold empty; travel bags; backpacks; suitcases; reusable shopping bags; reusable shopping bags in frames on wheels; umbrellas; parasols; structural parts and fittings for all the aforementioned goods.

**Description of Mark**

The mark consists of the wording "THEBABASLING" below a design of a crescent moon holding a baby.

**Colors Claimed**

Color is not claimed as a feature of the mark.

**Filing Date**

2011/09/06

**Print: Sep 12, 2012**

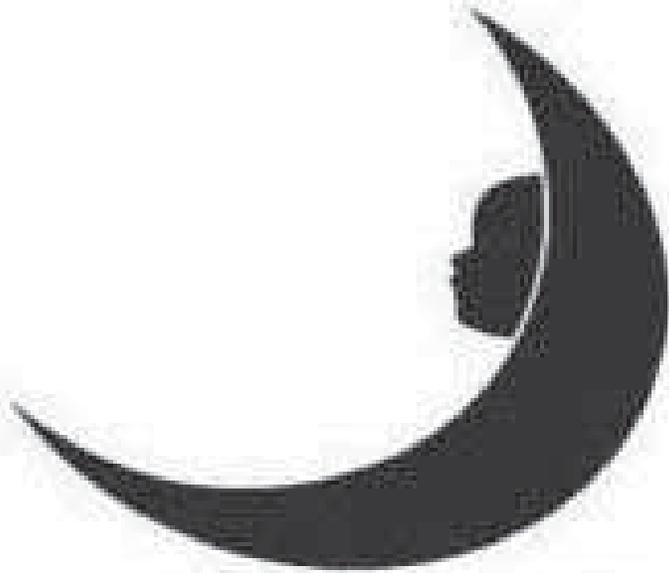
**79103197**

**Examining Attorney**

HALMEN, KATHERINE E.

**Attorney of Record**

Michael M. Ballard



theBabaSling

**To:** Baba Slings Pty Ltd ([mark@borgheselegal.com](mailto:mark@borgheselegal.com))  
**Subject:** U.S. TRADEMARK APPLICATION NO. 85633700 - BABA SLINGS - BABAS.0002T  
**Sent:** 9/19/2012 7:22:26 AM  
**Sent As:** ECOM104@USPTO.GOV  
**Attachments:**

IMPORTANT NOTICE REGARDING YOUR  
U.S. TRADEMARK APPLICATION

**USPTO OFFICE ACTION HAS ISSUED ON 9/19/2012 FOR  
SERIAL NO. 85633700**

Please follow the instructions below to continue the prosecution of your application:

**TO READ OFFICE ACTION:** Click on this [link](#) or go to <http://portal.uspto.gov/external/portal/tow> and enter the application serial number to [access](#) the Office action.

**PLEASE NOTE:** The Office action may not be immediately available but will be viewable within 24 hours of this e-mail notification.

**RESPONSE IS REQUIRED:** You should carefully review the Office action to determine (1) how to respond; and (2) the applicable [response time period](#). Your response deadline will be calculated from **9/19/2012** (or sooner if specified in the office action).

**Do NOT hit "Reply" to this e-mail notification, or otherwise attempt to e-mail your response, as the USPTO does NOT accept e-mailed responses. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System [Response Form](#).**

**HELP:** For *technical* assistance in accessing the Office action, please e-mail [TDR@uspto.gov](mailto:TDR@uspto.gov). Please contact the assigned examining attorney with questions about the Office action.

**WARNING**

**Failure to file the required response by the applicable deadline will result in the [ABANDONMENT](#) of your application.**

\*\*\* User:kcantone \*\*\*

#	Total Marks	Dead Marks	Live Viewed Docs	Live Viewed Images	Status/ Search Duration	Search
01	703	N/A	0	0	0:02	*b{"eah":2}b{"eah":2}*[bi,ti] not dead[lid]
02	1177	N/A	0	0	0:03	*{"scz"}1{"iy"}ng*[bi,ti] not dead[lid]
03	2	0	2	2	0:01	1 and 2
04	315	0	315	301	0:03	1 and "018"[cc]
05	0	0	0	0	0:01	*sling&[bi,ti] not dead[lid]
06	438	N/A	0	0	0:03	*sling*[bi,ti] not dead[lid]
07	107	0	107	99	0:03	6 and "018"[cc]

Session started 9/12/2012 2:44:11 PM

Session finished 9/12/2012 3:04:29 PM

Total search duration 0 minutes 16 seconds

Session duration 20 minutes 18 seconds

Default NEAR limit=1ADJ limit=1

Sent to TICRS as Serial Number: 85633700

# Baba Slings



# Trademark/Service Mark Application, Principal Register

## TEAS Plus Application

Serial Number: 85633700

Filing Date: 05/23/2012

*NOTE: Data fields with the \* are mandatory under TEAS Plus. The wording "(if applicable)" appears where the field is only mandatory under the facts of the particular application.*

The table below presents the data as entered.

Input Field	Entered
<b>TEAS Plus</b>	<b>YES</b>
<b>MARK INFORMATION</b>	
*MARK	<a href="#">Baba Slings</a>
*STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	Baba Slings
*MARK STATEMENT	The mark consists of standard characters, without claim to any particular font, style, size, or color.
<b>REGISTER</b>	Principal
<b>APPLICANT INFORMATION</b>	
*OWNER OF MARK	Baba Slings Pty Ltd
*STREET	486 Hunchy Rd
*CITY	Hunchy, Qld
*COUNTRY	Australia
*ZIP/POSTAL CODE (Required for U.S. applicants only)	4555
<b>LEGAL ENTITY INFORMATION</b>	
*TYPE	proprietary limited company (p/l or Pty. Ltd.)
*STATE/COUNTRY WHERE LEGALLY ORGANIZED	Australia

<b>GOODS AND/OR SERVICES AND BASIS INFORMATION</b>	
<b>*INTERNATIONAL CLASS</b>	018
<b>*IDENTIFICATION</b>	Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants
<b>*FILING BASIS</b>	SECTION 1(a)
<b>FIRST USE ANYWHERE DATE</b>	At least as early as 00/00/1999
<b>FIRST USE IN COMMERCE DATE</b>	At least as early as 10/00/2002
<b>SPECIMEN FILE NAME(S)</b>	<a href="#">\\TICRS\EXPORT16\IMAGEOUT\16\856\337\85633700\xml1\ FTK0004.JPG</a>
<b>SPECIMEN DESCRIPTION</b>	Photograph of Applicant's product.
<b>*FILING BASIS</b>	SECTION 44(e)
<b>*FOREIGN REGISTRATION COUNTRY</b>	Australia
<b>*FOREIGN REGISTRATION NUMBER</b>	1021631
<b>*FOREIGN REGISTRATION DATE</b>	05/23/2005
<b>FOREIGN REGISTRATION EXPIRATION DATE</b>	09/22/2014
<b>FOREIGN REGISTRATION FILE NAME(S)</b>	<a href="#">\\TICRS\EXPORT16\IMAGEOUT\16\856\337\85633700\xml1\ FTK0003.JPG</a>
<b>STANDARD CHARACTERS OR EQUIVALENT</b>	YES
<b>ADDITIONAL STATEMENTS SECTION</b>	
<b>*TRANSLATION (if applicable)</b>	
<b>*TRANSLITERATION (if applicable)</b>	
<b>*CLAIMED PRIOR REGISTRATION (if applicable)</b>	
<b>*CONSENT (NAME/LIKENESS) (if applicable)</b>	
<b>*CONCURRENT USE CLAIM (if applicable)</b>	
<b>DISCLAIMER</b>	No claim is made to the exclusive right to use slings apart from the mark as shown.

<b>ATTORNEY INFORMATION</b>	
<b>NAME</b>	Mark Borghese
<b>ATTORNEY DOCKET NUMBER</b>	BABAS.0002T
<b>FIRM NAME</b>	Borghese Legal, Ltd.
<b>STREET</b>	10161 Park Run Drive, Suite 150
<b>CITY</b>	Las Vegas
<b>STATE</b>	Nevada
<b>COUNTRY</b>	United States
<b>ZIP/POSTAL CODE</b>	89145
<b>PHONE</b>	(702) 382-0200
<b>FAX</b>	(702) 382-0212
<b>EMAIL ADDRESS</b>	mark@borgheselegal.com
<b>AUTHORIZED TO COMMUNICATE VIA EMAIL</b>	Yes
<b>CORRESPONDENCE INFORMATION</b>	
<b>*NAME</b>	Mark Borghese
<b>FIRM NAME</b>	Borghese Legal, Ltd.
<b>*STREET</b>	10161 Park Run Drive, Suite 150
<b>*CITY</b>	Las Vegas
<b>*STATE (Required for U.S. applicants)</b>	Nevada
<b>*COUNTRY</b>	United States
<b>*ZIP/POSTAL CODE</b>	89145
<b>PHONE</b>	(702) 382-0200
<b>FAX</b>	(702) 382-0212
<b>*EMAIL ADDRESS</b>	mark@borgheselegal.com;docket@borgheselegal.com
<b>*AUTHORIZED TO COMMUNICATE VIA EMAIL</b>	Yes
<b>FEE INFORMATION</b>	
<b>NUMBER OF CLASSES</b>	1
<b>FEE PER CLASS</b>	275
<b>*TOTAL FEE PAID</b>	275

<b>SIGNATURE INFORMATION</b>	
<b>* SIGNATURE</b>	/MB/
<b>* SIGNATORY'S NAME</b>	Mark Borghese
<b>* SIGNATORY'S POSITION</b>	Attorney of record, Nevada bar member
<b>SIGNATORY'S PHONE NUMBER</b>	(702) 382-0200
<b>* DATE SIGNED</b>	05/23/2012

---

## Trademark/Service Mark Application, Principal Register

### TEAS Plus Application

**Serial Number: 85633700**

**Filing Date: 05/23/2012**

#### To the Commissioner for Trademarks:

**MARK:** Baba Slings (Standard Characters, see [mark](#))

The literal element of the mark consists of Baba Slings.

The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, Baba Slings Pty Ltd, a proprietary limited company (p/l or pty. ltd.) legally organized under the laws of Australia, having an address of

486 Hunchy Rd  
Hunchy, Qld 4555  
Australia

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

**For specific filing basis information for each item, you must view the display within the Input Table.**

International Class 018: Baby carriers worn on the body; Baby carrying bags; Bags for carrying babies' accessories; Sling bags; Sling bags for carrying infants; Slings for carrying infants

In International Class 018, the mark was first used by the applicant or the applicant's related company or licensee predecessor in interest at least as early as 00/00/1999, and first used in commerce at least as early as 10/00/2002, and is now in use in such commerce. The applicant is submitting one(or more) specimen(s) showing the mark as used in commerce on or in connection with any item in the class of listed goods and/or services, consisting of a(n) Photograph of Applicant's product..

[Specimen File 1](#)

Based on Foreign Registration: Applicant has a bona fide intention to use the mark in commerce on or in connection with the identified goods and/or services, and submits a copy of Australia registration number 1021631, registered 05/23/2005 with a renewal date of \_\_\_\_\_ and an expiration date of 09/22/2014, and translation thereof, if appropriate. 15 U. S.C. Section 1126(e), as amended.

[Foreign Registration-1](#)

The foreign registration that is the basis of the U.S. application under Section 44(e) of the Trademark Act (15 U.S.C. Section 1126(e)) includes a claim of standard characters or the country of origin's standard character equivalent.

No claim is made to the exclusive right to use slings apart from the mark as shown.

The applicant's current Attorney Information:

Mark Borghese of Borghese Legal, Ltd.  
10161 Park Run Drive, Suite 150  
Las Vegas, Nevada 89145  
United States

The attorney docket/reference number is BABAS.0002T.

The applicant's current Correspondence Information:

Mark Borghese  
Borghese Legal, Ltd.  
10161 Park Run Drive, Suite 150  
Las Vegas, Nevada 89145  
(702) 382-0200(phone)  
(702) 382-0212(fax)  
mark@borgheselegal.com;docket@borgheselegal.com (authorized)

A fee payment in the amount of \$275 has been submitted with the application, representing payment for 1 class(es).

### **Declaration**

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Signature: /MB/ Date Signed: 05/23/2012

Signatory's Name: Mark Borghese

Signatory's Position: Attorney of record, Nevada bar member

RAM Sale Number: 8405

RAM Accounting Date: 05/24/2012

Serial Number: 85633700

Internet Transmission Date: Wed May 23 20:41:24 EDT 2012

TEAS Stamp: USPTO/FTK-68.108.71.149-2012052320412487

9403-85633700-490712a25682e6763a228a333b

fb33bcbcd-CC-8405-20120523201726506912

# Baba Slings

Commonwealth  
of Australia

# Certificate of registration of trade mark

No. 1021631

Trade Marks Act 1995

I, RUTH NAOMI MACKAY, Registrar of Trade Marks, hereby certify -

that the trade mark represented on this certificate has been registered as a Trade Mark, No. 1021631 in the Register of Trade Marks for a period of ten years commencing 22 September 2004 and that **Baba Slings** of 599 Hunchy Road HUNCHY QLD 4555 AUSTRALIA has been entered in the Register of Trade Marks as the owner of the trade mark.

The trade mark is registered for the following goods and/or services:

**A hammocking style baby sling being goods in class 18**

THE SCHEDULE

**Baba Slings**



Given under my hand and the seal of the  
Trade Marks Office on 23 May 2005

*Ruth Naomi Mackay*

**RUTH NAOMI MACKAY  
REGISTRAR OF TRADE MARKS**



# **EXHIBIT B**

# **EXHIBIT B**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

BABA SLINGS PTY LTD.,	:	
	:	
Opposer,	:	
	:	
v.	:	Opp. No. 91-205,483
	:	Serial No. 79/103,197
	:	
BABASLINGS LIMITED,	:	
	:	
Applicant.	:	

**APPLICANT'S OBJECTIONS AND ANSWERS TO  
OPPOSER'S FIRST SET OF INTERROGATORIES**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and Trademark Rules 2.116 and 2.120, Applicant Babaslings Limited ("Applicant") provides the following objections and answers to Opposer's First Set of Interrogatories ("Opposer's Interrogatories").

These objections and answers are based upon the best relevant information presently available to Applicant and are made without prejudice to its right to provide additional or modified objections and answers should better or further information or belief subsequently become available to Applicant. These answers also are provided without prejudice to any right of Applicant to offer evidence on its behalf or to object to the relevance, competence or admissibility of any ground of any evidence or witness offered by Applicant; and these answers do not constitute an admission of competence, or admissibility of evidence, or a waiver of objection on any grounds.

**GENERAL OBJECTIONS**

Applicant objects to the Definitions and Instructions forming a part of Opposer's Interrogatories as overly broad, harassing, burdensome and as imposing greater obligations than those required by the Federal Rules of Civil Procedure and the Trademark Rules of Practice.

**OBJECTIONS AND ANSWERS TO INTERROGATORIES**

**Interrogatory No. 1**

Identify and describe all of your sales to customers located in the United States from 2002 to the present.

**Answer:**

Applicant objects to this Interrogatory as overly broad and unduly burdensome. To the extent not otherwise objected to, Applicant will provide only that information in its possession which is sufficient to meet the needs of the Interrogatory.

Applicant further objects to this Interrogatory as it is unclear by its use of the phrase "your sales," as Applicant was formed by Shanti McIvor, Daniel G. Lucas and Heath O'Connor in 2005. Further, Applicant objects to Opposer's use of the phrase "all of your sales" and the request to "describe" same as vague and ambiguous, and susceptible of a reading that is overly broad and unduly burdensome.

Subject to, and without waiver of the foregoing objections, and to the extent that this Interrogatory is understood, Applicant respectfully refers, pursuant to Rule 33(d), to the documents produced in connection with its answers to Opposer's request for production of documents.

**Interrogatory No. 2**

Describe in detail your basis for your denial of the allegation that "Opposer is the company behind the popular sling baby carriers sold under the mark BABA SLINGS and variations thereof," in Paragraph 1 of your Answer, including all facts which allegedly support this denial and identifying all documents and witnesses allegedly supporting this denial.

**Answer:**

Applicant objects to this Interrogatory as overly broad and unduly burdensome, particularly to the extent it seeks the identification of "all facts" and "all documents and witnesses." To the extent not otherwise objected to, Applicant will provide only that information in its possession which is sufficient to meet the needs of the Interrogatory.

Applicant further objects to this Interrogatory to the extent that it calls for the production of attorney-client communications and/or materials subject to attorney work product immunity. Such items will not be produced. Applicant further objects to this Interrogatory as calling for information outside of Applicant's custody, possession or control.

Subject to, and without waiver of the foregoing objections, Applicant respectfully refers, pursuant to Rule 33(d), to the documents produced in connection with its answers to

**Interrogatory No. 6**

Describe in detail your basis for your denial of the allegation that “Applicant has never sold any products in the United States under the design mark “theBabaSling” in Paragraph 6 of your Answer, including all facts which allegedly support this denial and identifying all documents and witnesses allegedly supporting this denial.

**Answer:**

See Applicant’s answer to Interrogatory No. 1.

Respectfully submitted,

BABASLINGS LIMITED

By:



---

Robert Stoll  
Brian A. Coleman  
Anthony J. Palumbo  
DRINKER BIDDLE & REATH LLP  
1500 K Street, N.W., Suite 1100  
Washington, D.C. 20005-1209  
Tel: (202) 842-8800  
Fax: (202) 842-8465

*Counsel for Applicant Babaslings Limited*

**VERIFICATION**

I, Daniel G. Lucas, state that I am a Director of Applicant Babaslings Limited, that I have read the foregoing responses to Opposer's First Set of Interrogatories to Applicant, and that the responses are true and accurate to the best of my own knowledge, information and belief.

By: DANIEL G. LUCAS

**CERTIFICATE OF SERVICE**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

<hr style="border-top: 1px solid black;"/>	:	
Opposer,	:	
v.	:	Opp. No. 91-205,483
		Serial No. 79/103,197
BABASLINGS LIMITED,	:	
Applicant.	:	
<hr style="border-top: 1px solid black;"/>		

**APPLICANT’S OBJECTIONS AND RESPONSES TO  
OPPOSER’S REQUEST FOR PRODUCTION OF DOCUMENTS**

Pursuant to Rule 34 of the Federal Rules of Civil Procedure and Trademark Rules 2.116 and 2.120, Applicant Babaslings Limited (“Applicant”) makes the following objections and responses to Opposer’s Request for Production of Documents (“Opposer’s Requests”).

These objections and responses are based upon the best documents and information presently available to Applicant and are made without prejudice to the rights of Applicant to make additional or modified objections and responses should better or further documentation or information subsequently become available to Applicant. These responses also are made without prejudice to any right of Applicant to offer evidence on its behalf or to object to the relevance, competence, or admissibility on any ground of any evidence or witness offered by Applicant, and these responses do not constitute an admission of competence or admissibility of evidence of evidence or a waiver of objection on any grounds.

**DEFINITIONS AND INSTRUCTIONS**

Applicant objects to the Instructions and Definition forming a part of Opposer’s Request for Production of Documents as overly broad, harassing, unduly burdensome and as imposing greater obligations than those required by the Federal Rules of Civil Procedure and the Trademark Rules of Practice.

## OBJECTIONS AND RESPONSES TO REQUESTS

1. Produce all communications between Applicant and any of Applicant's customers located in the United States from 2002 to the present.

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all communications." Applicant objects to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is irrelevant to the claims or defenses in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

2. Produce all contracts between Applicant and persons or entities located in the United States from 2002 to the present.

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all contracts." Applicant objects to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is irrelevant to the claims or defenses in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

3. Produce all documents related to products sold by Applicant which were shipped to the United States from 2002 to the present.

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all documents." Applicant objects

to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is irrelevant to the claims or defenses in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

4. Produce all documents which support your denial in paragraph 1 of your Answer that Opposer is the company behind the popular sling baby carriers sold under the name or mark BABA SLINGS.

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all documents." Applicant objects to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is irrelevant to the claims or defenses in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control. Applicant objects to this Request as Applicant is not required to disclose the entirety of its proposed evidence in support of its case during discovery.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

5. Produce all documents in support of your denial in paragraph 3 of your Answer that Applicant "had authority to sell Opposer's baby carrier products in Europe under the derivative design mark theBabaSling appearing in the Application."

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all documents." Applicant objects to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is

irrelevant to the defense in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control. Applicant objects to this Request as Applicant is not required to disclose the entirety of its proposed evidence in support of its case during discovery.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

6. Produce all documents in support of your denial in paragraph 4 of your Answer that Applicant's "licenses has never included the right to sell any products in the United States under the BABA SLINGS mark or under the derivative design mark theBabaSling."

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all documents." Applicant objects to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is irrelevant to the defense in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control. Applicant objects to this Request as Applicant is not required to disclose the entirety of its proposed evidence in support of its case during discovery.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

7. Produce all documents in support of your denial in paragraph 5 of your Answer that "Applicant has no rights in the BABA SLINGS mark itself and is at best a geographically limited licensee of the derivative design mark theBabaSling appearing in the Application."

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all documents." Applicant objects

to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is irrelevant to the defense in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control. Applicant objects to this Request as Applicant is not required to disclose the entirety of its proposed evidence in support of its case during discovery.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

8. Produce all documents which support any of your affirmative defenses set out in your Answer.

**RESPONSE:**

Applicant objects on the basis that this request is overly broad, harassing and unduly burdensome, particularly insofar as it purports to encompass "all documents." Applicant objects to this Request to the extent that it is beyond the scope of the pleadings, and as such this Request is irrelevant to the defense in this proceeding and as not reasonably calculated to lead to the discovery of admissible evidence. Applicant objects to this Request as calling for documents/information outside of Applicant's custody, possession or control. Applicant objects to this Request as Applicant is not required to disclose the entirety of its proposed evidence in support of its case during discovery.

Subject to, and without waiver of the foregoing objections, Applicant shall produce representative, responsive, non-privileged documents to the extent the same exist and are in the possession or control of Applicant.

Respectfully submitted,

BABASLINGS LIMITED

By:  \_\_\_\_\_

Robert Stoll

Brian A. Coleman

Anthony J. Palumbo

DRINKER BIDDLE & REATH LLP

1500 K Street, N.W., Suite 1100

Washington, D.C. 20005-1209

Tel: (202) 842-8800

Fax: (202) 842-8465

*Counsel for Applicant Babaslings Limited*

**CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the foregoing Applicant's Objections and Responses to Opposer's Request for Production of Documents was served on the following address of record by first-class mail, postage prepaid, this 27th day of November 2012:

Mark Borghese  
BORGHESE LEGAL LTD  
10161 Park Rum Drive, Suite 150  
Las Vegas, NV 89145  
[mark@borgheselegal.com](mailto:mark@borgheselegal.com)



**EXHIBIT C**

**EXHIBIT C**

A wee baby sling that came a long way! Baba Sling's moments in the spotlight! 2nd place in Japan's leading baby Magazine, Practical Parenting's Mumpreneurs article & more



**Baba Slings in the Media**



As seen on November's 2008 edition of Practical Parenting

Please click on magazine cover image to read full article



Baba Slings make it to first place in Japan's leading baby magazine.

Baba Slings Ranked #2:

Baba Slings continue to be ranked highly in Japan's most popular baby magazines.

Find out where you can meet with us to get a live demonstration, view stock and get valuable baby sling wearing tips and advice



### Expos and Tradeshows



## Upcoming Events and Expo's

Come and see us for demos and info



### 2012 ABC KIDS EXPO

Louisville, Kentucky,  
USA

14-17 October 2012











Baba Slings is a registered trademark.  
All rights reserved. © Baba Slings 2008-2010

[terms and conditions](#)

*Want to know more about how the Baba Slings baby carrier was conceived? The gestation period, birth, hiccups and teething issues along the way. Find out about our mission, branding, name and company? And Baba Slings unique features.*



## about baba slings



[Our Story](#)



[Our Name](#)



[Our Logo](#)



[Our Company](#)



[Mission Statement](#)



[Baba Sling Features](#)





Baba Slings were designed by Mother of 5, Shanti McIvor, who whilst pregnant with her second child, did a lot of research on the subject of "attachment parenting" and "baby wearing". After learning of the immense benefits of carrying Baby, she started working on a design for a baby sling. And carried her own baby in the very first Baba Sling, and then after much interest from the general public she decided to start selling them at the local Eumundi Markets. Who would have thought that 13 years on Baba Slings is now the Top Selling baby sling in Japan and sought after the world over.

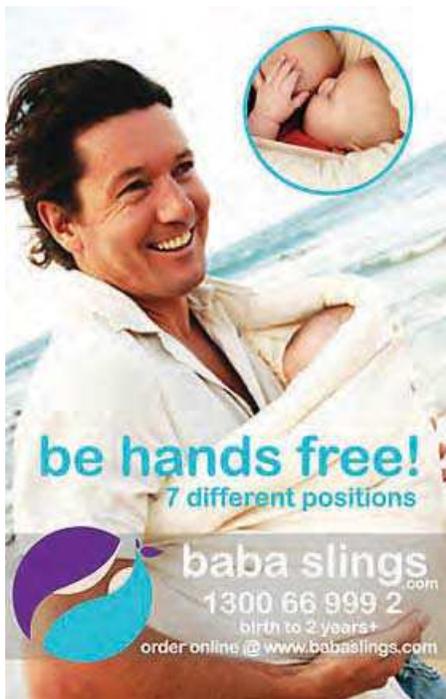
Baba Slings allow you several different comfortable positions to cater for your baby's changing moods and needs throughout the day . With discreet hands free breast feeding, you can have the life you want and remain connected to your little one as you go. They are fantastic for jet setters, public transport and parents at home with a family to run.

Baba Slings are for easy wearing with a specially imported Buckle and comfortable padding, + a safety strap & buckle. They are fully adjustable for both Mum and Dad, and have a double strapping system, for greater security. By putting no stress on baby's developing hips & spine you can have peace of mind that you are doing the very best for your Baby.

And not only that, they come in a range of colourful patterns and funky designs to suit all tastes, no wonder a mother recently said that she found her husband sexy when he wore the Baba Sling!



Baba Slings are Fully Adjustable, this is a very important point when looking at purchasing a Baby Sling or Baby Carrier. It means that not only can both Mum and Dad use it without having to purchase 2 different Slings, but also as Baby grows into Toddlerhood, the Baba Sling can be adjusted out to fit. Another important point is that Baba Slings can be tweaked to find the most comfortable fit whilst wearing baby.



## Our Story

“Necessity is the Mother of all Inventions”, well so the saying goes. However in the case of Baba Slings, “Invention” may not be quite the right word, as slings and baby carriers have been used for centuries. In fact for almost as long as humans have had to carry their young. In the case of Baba Slings, its conception began in 1999 whilst pregnant with my second child, Sai.

After looking at upright carriers, asymmetrical style slings, wrap arounds, backpacks, etc, I wanted to create a unique sling that was practical, easy to use, comfortable, multi-positioning, with a touch of style, and an extensive range of different fabrics for people to express their individuality. I wanted to create something that I would personally be able use, which I have done so with my subsequent 3 other children. With Breastfeeding in mind, I set out on my mission to provide people with high quality baby slings.

## Our Name

The name Baba Slings came to me after travelling to different parts of the world and noticing how universal the word Baba was! Of course there is the obvious-- 'baba' is one of very first sounds every infant makes regardless of the language spoken by the baby's parents. In different parts of the world the word has evolved into different meanings. In Russia it means Grandmother, in India, Grandfather, father or even teacher, father in parts of Africa, and the list goes on. What a perfect name for a Baby Sling, a word that has so many connections to family in many cultures around the world.



## Our Logo

The Baba Slings logo today is our 3rd attempt. And this one, we are very happy with! Designed by close friend Jacqui Rayner. It was inspired by a photo taken on the beach of a Mother bending down to kiss her baby in the Baba Sling. With the sweep of her hair, and the Baba Sling, it almost looked like a yin and yang symbol. The little straps at the top of the Sling, look similar to leaves. We wanted the nurturing nature of Baba Slings to be evident in the logo.

## Our Company

Baba Slings is very much a friend/family operated Company. For example all the photos on our website and promotional material were taken by a friend, of family and friends. We like to keep it in the family!!

The response to Baba Slings has been immense! With people contacting us from all over the globe daily we are very excited about the future developments!!



## Mission Statement

Our Mission is to provide families with comfortable, high quality and beautiful Baby Slings to aid in the very important transition from Birth to Toddlerhood.

Wherever in the world there is a need for a baby to be held close, Baba Slings want to be able to meet and embrace that need. We believe that it is therefore our highest obligation to do this environmentally and ethically.

We see it as our only choice and our absolute responsibility to tread as softly as possible on this

**Great Mother Earth.** To cause as little harm to all Earths children, whether they be human, animal, plant, material, sea or air.

All products and ranges stocked by Baba Slings, are made in No Sweat/ Fair Trade operations, using Organic materials wherever possible, and aiming to go entirely organic in the near future.

Our Mission is to supply Baba Slings and other product ranges designed, made, and owned by Baba Slings Pty Ltd Australia and to distribute exciting and ethically made and minded products from Companies within Australia and abroad.

Maybe as more babies experience the sweet connection of being carried, a whole new generation may emerge, one that is more balanced and in touch with their feelings and compassion for all beings on Earth.

### **Features:**

- Easy to adjust (both dad and mum can wear)
- In built safety strap and buckle
- Specially imported high quality side release ski buckle with divider for straps
- Double adjustable strapping system
- Comfortable foam shoulder padding
- 100% cotton
- Funky colours and patterns and plain colours
- Pocket
- Padded railings, greater comfort for baby
- Australian made (Some boutique are made overseas)
- Machine washable
- Meets highest quality control
- Extended use dependant upon comfortable weight bearing capability of parent
- Brilliant for sleeping and breast feeding babies
- Easy to put on, even easier to take off (don't have to wake up bub!)
- many different positions
- Increase the intimacy between you and little one
- Puts no pressure on baby's developing hips and spine.
- Supports neck and head
- Enhances prolaction flows, which aids in breast feeding
- Cuts down on crying and fussing, reduces reflux and colic
- Helps to complete baby's exterogestation period

Baba Slings is a registered trademark.  
All rights reserved. © Baba Slings 2008-2010

[terms and conditions](#)



Shanti with partner Ezra and their inspiration (L-R) Vyasa, Sharmila, Phoenix, Zach and Sai

# Highly slung

Wanting to keep her baby close inspired Shanti McIvor to design her own sling – now an international success

**WHO:** Shanti McIvor, 31, mum of Zach 15, Sai 9, Sharmila 6, Vyasa 2, and Phoenix, 7 months.

**WAS:** Student and home maker.

**NOW:** Inventor/owner of Babaslings.

Carrying your baby is really important. I tried a few carriers but they were cumbersome with lots of straps and buckles. I've modernised the hammock sling. You strap in your baby and off you go.

## When did the big idea strike?

After having my second child, I was looking at ways of bonding. With my eldest it'd been about four-hourly feeds and separate sleeping, but when Sai was a baby the thinking was changing.

## Starting out

After formulating the idea and a pattern, I put an ad in the paper to find some sewers. We started at a local hall. I borrowed \$1600 through a government local enterprise program, which I had to pay back. It took a while to find the right foam, buckles and wadding, and the sling has continued to evolve over the past nine years.

## Spreading the word

I grew up at the Eumundi markets and vowed I wasn't going to sell the slings there, but I did. I also attended baby expos and sold through mail and online.

## And now?

I thought it'd be great pocket money, but I started drawing an income soon. My sales have doubled every year. We now also have retailers and we'll expand into other products soon. Our Japanese

## Lessons learnt

- Be cautious about going into any partnership.
- Take time to develop a business plan.
- Make sure you have very good legal advice.
- Invest more money back into the business.
- Try to produce locally for products to be sold here in Australia.
- If you are lacking skills in an area, delegate to someone with expertise.



sales are booming. I'd love to get into a US chain store – the sky is the limit.

## How do the kids fit in?

I try to put five hours a day into the business. I have a part-time nanny and full-time cleaner, who help me with the cooking and the children. I have to travel to trade shows regularly. My eldest son is very helpful and comes to trade shows with me.

## The hardest part

I've had to spend quite a lot of money

protecting my product from copycat businesses. I've had people selling their own slings on eBay but using photos of mine. These are things I didn't think about when starting the business. I probably need a full-time solicitor.

## The best bits

One of the highlights was when my Japanese distributors came through our door. They've been wonderful for the business. Our sling has been ranked as the third most popular in Japan.

It's exciting travelling Australia and the world and attending expos. I also love getting emails from customers who have found the sling invaluable.

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## Operation Military Shower Shaw Air Force Base/ 3rd Army Headquarters

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### Community

I am a volunteer who is reaching out to my fellow military families who are expecting a baby during time of deployment or are facing financial hardships.



65

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Highlights ▾



**Operation Military Shower Shaw Air Force Base/ 3rd Army Headquarters** shared a link.

21 hours ago

Thank you [Baby Wingz](#) for sending your adorable baby booties for the October shower! These are adorable! Visit their couture line @<http://www.babywingz.com/Default.asp>





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### Baba Slings Embroidered Baby Carrier, Khaki

by [Baba Slings](#)

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- 100% cotton, machine washable

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Enter for a chance to win the weekly giveaway of a \$500 Amazon.com Gift Card in the [Amazon Baby Registry Sweepstakes](#). NO PURCHASE NECESSARY. Ends 3/15/2014.

### Product Information

#### Technical Details

Item Weight	1 pounds
Product Dimensions	63 x 33 x 1 inches
UPC	609722424943

#### Additional Information

ASIN	B007RZP35S
Customer Reviews	<a href="#">Be the first to review this product</a>
Best Sellers Rank	#215,272 in Baby (See top 100)
Shipping Weight	2 pounds (View shipping rates and policies)

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<



Babasling Original 100% Cotton Baby Carrier,



Babasling Lite 100% Cotton Baby Carrier,



Baba Slings Boutique Baby Carrier, Navy / Pink Batik



Hotslings Adjustable Pouch Baby Sling, Overcast,

>



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**Baba Slings Boutique Baby Carrier, Navy/Pink Batik**

**\$119.00**

Only 1 left in stock - order soon.



**Baba Slings Embroidered Baby Carrier, Purple**

**\$139.00**

Only 1 left in stock - order soon.



**Baba Slings 2-Tone Baby Carrier, Navy/Turquoise**

**\$109.00**

Only 1 left in stock - order soon.



**Baba Slings Baby Carrier, Maroon**

**\$99.99**

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**Baba Slings Embroidered Baby Carrier, Khaki**

**\$109.00**

Only 1 left in stock - order soon.

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[Baba Sling Giveaway!!!](#)

Posted: 04.11.11



Kev and I are always on the go, so a good baby carrier is a must. We have a lot it seems like, but we are always on the look out for something better. Then we got the [Baba Sling](#). We LOVE this sling! It is super simple to use, adjustable, and has the most comfy shoulder strap and padding around the edges. Rowan loves sitting in it and it comes in so many wonderful colors!!

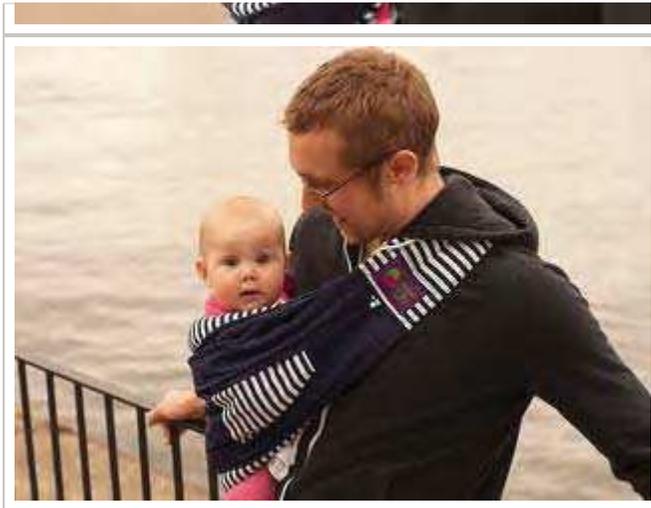




The lovely people at [Baba Slings](#) would like to give away 1 sling to 2 lucky readers. That doubles your chances of winning!! You may not have a baby yourself, but chances are you know someone who has one. This would make the best present for a shower, a birthday, or even for mother's day!







All you have to do is...

1. Visit [Baba Slings](#) and tell us what color you would chose from the [standard slings](#) in a comment below.
2. Bonus entry for visiting them on [facebook](#) and liking their page, then just leave a second comment letting us know you did so.

Trust me you will LOVE this awesome sling.



Comments (373)



[Vanessa](#)

04.11.11

My brother and wonderful sister-in-law just had a beautiful boy, and I would love to gift this to her for Mother's Day! I really love the khaki color, and it fits the theme of his nursery.



[Kristin](#)

04.11.11

We are expecting our second baby this fall and the orange one is what i would choose 😊



NatalieW

04.11.11

I have a 4.5 month old baby boy that loves to be held and snuggled all the time. I'd love to have a comfy sling like that for him. I'd pick Khaki.



Carly

04.11.11

I love the Jade color!



Carly

04.11.11

I also "liked" them on facebook.



Katrina

04.11.11

Orange! I really really hope I win this one for my 5 month old babe!!



hannah

04.11.11

Ugh, our sling is so awful. . .I have been looking for a new one. I love the lime!



[Tara](#)

04.11.11

I like the black sling! This would be perfect for baby #2!



[Lindsey](#)

04.11.11

Our baby will be here in September and the teal sling would go just perfect with the rest of his/her nursery theme!



[Tara](#)

04.11.11

like them on facebook



Marni

04.11.11

My closest friends just started a little family 😊 They plan on having more beautiful babies in the future, so I would pick the black one. Simple and easy to clean!



[Lindsey](#)

04.11.11

I also liked them on Facebook! 😊



[Jennifer H.](#)

04.11.11

I love the red one. That way, daddy could also wear it, but mommy could have a fun pop of color (way better than a bland ol' khaki one).



Katrina

04.11.11

I liked them on facebook.



[pamela](#)

04.11.11

i am loving the mocha! i am experiencing labor pains as we speak (not joking) so i would keep it for me! 😊



Leslie

04.11.11

We are having our second “only child” in November – 16 years from the first. Baby carriers have progressed a long way in 16 years. I’d choose the gold – I love the vibrant color!



Mrs. K

04.11.11

I would def go with yellow !



Stefanie

04.11.11

This sling looks great! I would choose black



[Rebekah](#)

04.11.11

We’ve been looking for a good baby carrier. I’ve used the Moby Wrap, but it’s just so much work to actually wrap. This looks great! I would choose the gold sling.



gillian

04.11.11

Oooh! I have been looking for a sling—I love the burnt orange color. Crossing my fingers!



[Rebekah](#)

04.11.11

I also liked them on Facebook.



[Jessica Marie](#)

04.11.11

I really like the gold sling! This would definitely come in handy in the future! Thanks for the giveaway!



Stefanie

04.11.11

I liked them on facebook!



[Kristin](#)

04.11.11

My good friends Emily and Danny just had their first baby on Saturday, and I would love to gift them the bright red one! Adorable!



[deni](#)

04.11.11

omg! I almost cry. this pictures are so adorable!  
ps. I would like to invite you to the first giveaway on my blog.  
xx  
Deni.



Marie

04.11.11

I like cream or navy, but I would chose probably black – universal colour....



Erica

04.11.11

I would have to pick black (probably the only one my husband would carry) This carrier looks fantastic, my 6 month old is 19lbs!!



Ashley

04.11.11

My fiance's sister is due in May and the Turquoise sling would be perfect for her! I also liked them on Facebook 😊



Erica

04.11.11

Liked them on Facebook too 😊



Ali

04.11.11

What a great sling! I have been looking for a good carrier. I like the khaki.



Amelia

04.11.11

great giveaway!

love your sunglasses in these pics 😊 super cute.

wow – so many colours to choose from! what a great surprise. I've narrowed it down to 3: navy, mocha, and purple. 3 colours I know my husband wouldn't mind wearing 😊



Meg Annan

04.11.11

I have a baby due in November & would LOVE the mocha-colored sling! Looks awesome!



Tess

04.11.11

Loving the pics of Rowan in the sling, she is a cutie. Would love to tote my 7 mo old in the jade sling!



kaitlyn

04.11.11

oh my! my sister recently had a baby and would love this! although I like the bright colors, I think my sister would like the black or brown ones 😊 easy to match any outfit with!



[Marta](#)

04.11.11

Looks like a comfy sling! I like the Orange one!



[Kara](#)

04.11.11

I love the mocha one! It looks so comfy! Our sling we have now stinks.



Ali

04.11.11

I liked them on facebook too!



[Kara](#)

04.11.11

Also liked on fb!



[Shayna](#)

04.11.11

Awesome! We don't have children yet, but would love love love to win it for the future. 😊 I would choose the black sling.



[Shayna](#)

04.11.11

I also liked them on facebook. 😊



Shelley J

04.11.11

ohhhhhhhhhh LOVE!! I like the brown one best.



Jessica

04.11.11

The Baba Slings site isn't working, otherwise I'd let you know what color I like...but for now I liked them on FB!



Jessi

04.11.11

how adorable!

i've been WANTING one of those bad boys... 😊

thanks so much and i hope i win! (i'd have to go with the army green... my hubby would rock that color well...)

jessi

[finnpuppy@gmail.com](mailto:finnpuppy@gmail.com)



[Shilah Will](#)

04.11.11

I love how they have SO MANY COLORS! I think I'd have to go with the red =]



[Shilah Will](#)

04.11.11

Andandand I liked them on facebook!



Lin

04.11.11

I love it and am due in September. I would choose black.



Maria

04.11.11

I would love the mustard yellow, BUT I don't think my hubby would.... or maybe he would... hm? It would be a hard decision between that one and the army green.

I think I am leaning more towards the army green!

Wish me luck!

[mvelis@aol.com](mailto:mvelis@aol.com)



Lin

04.11.11

Also liked on fb!



Claire J

04.11.11

Going for gold! I'm due to September and would love this sling. -c



[Pilar](#)

04.11.11

ooh! i would love to give this as a gift! the brown one is my favorite!



[Desiree](#)

04.11.11

I'd choose black, or maybe khaki! Both are so cute!!!



[Michelle](#)

04.11.11

Wonderful giveaway! I would probably go for the black or khaki!



[Desiree](#)

04.11.11

I liked them on Facebook as well through my personal page, Desiree Contin :fingers crossed: I'm due in October and having one of these would be AWESOME!



[Rhea](#)

04.11.11

Black or cream. 😊



[Rhea](#)

04.11.11

Liked them on Facebook too!



[Alix](#)

04.11.11

Oh my gosh! Great pictures, love the sling. My friend Chris and his wife Lauren are having a baby in about a month and I would love to give them the dark blue sling — it would match their son Jude's sailing-themed nursery so well!



[Caitlin](#)

04.11.11

Navy blue!!



[zzipper](#)

04.11.11

These looks so comfy.. definately one in black.. and I might have to get a second in orange..



[Caitlin](#)

04.11.11

Such a cute carrier! I like the black one



[lauren](#)

04.11.11

one of my good friends is having a baby, and i would love to give her a lovely sling as a shower gift. i think the teal one would suit her just fine.



[zzipper](#)

04.11.11

I "liked" them on FB!



[Brooke](#)

04.11.11

We're cooking up our first baby now and I've been on the lookout for a good carrier. I'd go with the black one. Thanks!



sophie

04.11.11

I LOVE the orange one! This would be wonderful for our upcoming second!



Cayla

04.11.11

The jade green one is awesome and would look great on my soon-to-be a mommy friend!



[Laura J.](#)

04.11.11

So tough to choose....I'd probably go with the cream!



Elisabet

04.11.11

I'd love the one in black, would be perfect for my 3 month old.-)



casey

04.11.11

Turquoise! yay



Rachael

04.11.11

I love the first yellow one...it will match my Jen-knitted tunnel scarf! Our first baby is about 11 weeks in the oven!



kathy

04.11.11

Love the mustard!



Elisabet

04.11.11

..and i "liked" them on facebook too:-)



Deb

04.11.11

I have a three month old and would love the orange embroidered one for her!



Mary Beth

04.11.11

My good friend is due in June, and I would love to surprise her with the Navy/lime 2-tone version! BTW-Your blog is great!



[Pineapple](#)

04.11.11

Kelly green!



Teresa

04.11.11

What a great way to tote my 2 month old around while chasing after her big brother! I would choose the orange . . . or the khaki . . . or the maroon.



[kelsey](#)

04.11.11

Awesome! I love the mocha color.



Bonnie

04.11.11

I really like the khaki.... my hubby and I would both look great sling'n our babes around!



Bonnie

04.11.11

I also 'liked' them on FB! Woo Hoo!



Katie

04.11.11

I would go with khaki since I don't know if I'm having a boy or a girl!



Natasha

04.11.11

I love the Lime! So bright and colorful.



Heather from the bar

04.11.11

The gold! My husband and I would both rock that while walking around with our little boy Declan!



Deb

04.11.11

I liked them on Facebook!



Kimberly

04.11.11

I'd love to have the brown sling. I have another sling, but it's super girly so my husband won't use it. He'd have no excuse with this!



Christine

04.11.11

I would go for the red!

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**Baba Slings** with [Joanne Schenach Ludwick](#).

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FAVORITES GO-TO ITEMS 2 MONTH OLD I CAN'T LIVE WITHOUT ANY OF THIS STUFF WINTER BABY IT'S COLD OUTSIDE

ON TWITTER

This. <http://t.co/UUKK0hVkJDo>

— @OurBeachBaby, a day ago

### A few of our favorite things {2 months old}:

#NaBloPoMo



10 MONTHS AGO

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ABOUT

Hi! I'm Tessa.

Questions? Email me ~ [tessa.ourbeachbaby@gmail.com](mailto:tessa.ourbeachbaby@gmail.com)



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1) **Zutano Pagoda Cozie Baby Hat:** As you all know, I LOVE Zutano. These fleece hats are perfect for layering up a baby. Not too tight, but nice and snug.

2) **Weleda Calendula Diaper Care Cream:** My mom used Weleda products on me when I was a baby, how cool is that? I love the smell of calendula, and I simply adore their diaper care cream. McCoy's bum likes it too!

3) **Pottery Barn Chamois Stroller Blanket:** Our dear friends gave us a green blanket when Drew was born, and it's become our go-to blanket. We use it 24/7! The baby sleeps with it tucked tightly over his swaddle blanket, it goes with us on walks, and when I feeding him. It's so warm and cozy, I often think we should get a second one!

4) **Baba Sling:** This has been a lifesaver for me since McCoy doesn't want to be put down, and won't sleep unless he's on top of me. I honestly have both the sling and the Bjorn with me at all times. After about an hour, it starts to hurt my shoulder, but then you just switch sides! He'll fall asleep in minutes when you tuck him into it.

5) **Padalily ~ Jungle Fever:** If you don't have a Padalily, you should get one. Super practical when lugging around the heavy car seat. Recently, McCoy has decided he LOVES the print of ours, and spends most of the time cooing at the animals. An added bonus that it can entertain the baby.

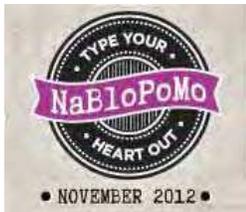
6) **Zutano Pagoda Cozie Newborn Jacket:** This jacket is great for when we bundle up for walks. It's not too thick, and keeps him nice and toasty in the car.

7) **JJ Cole Bundle Me:** I don't know what we would do without the Bundle Me. It's honestly the one "must have" winter item. We used it all the time with Drew in the stroller last winter on our chilly walks to the beach. I like it so much that I just ordered a bigger toddler size for Drew's stroller.

8) **Fisher Price My Little Lamb Cradle & Swing:** McCoy just started to like being in the swing. Super helpful when I'm cooking dinner or getting Drew organized. He even fell asleep in it today {hooray!}. I wish it had a plug instead of using extra large batteries...

9) **RoSK Cold Weather Pouch:** I purchased this a few weeks ago because of **Jennifer's** glowing recommendations. I couldn't be more thrilled that I did! We use it almost every day; over top of the Bjorn during our time at the freezing playground and it's also come in real handy over the bassinet stroller when we're out walking.

{And, we still use all the stuff from **last month's favorite things!**}



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 sesigsss said: You can find universal wall adapters instead of using up batteries for the swing! I usually have luck at Radio Shack but Best Buy or even Amazon should have them too.

 oneofourown likes this

 dagsemnott likes this

 definitelyjennifer said: so glad you love the pouch! don't you wish there was one in your size?

 altogetherbeautiful likes this



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**Heather Hogan Correa** · 11 months ago  
We're so glad you love ourRoSK Pouch!! Perfect for winter beach babies. Thank you for including us.

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**TessaHD** Mod → **Heather Hogan Correa** · 11 months ago  
Of course! Thanks for keeping our beach baby warm :)

| Reply Share ›

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**Have any moms done Baby Led Weaning with their ...**

2 comments · 8 months ago

Avatar **TessaHD** —Awesome! I'm going to email you when I have a minute. What did ...

**Buddies.**

1 comment · 6 months ago

Avatar **GreteI VS** —  
Xoxoxoxoxoxoo

**"My car is going too fast!!!!"**

1 comment · 2 months ago

Avatar **Laura Scimeca** —Drew: What's that?Sim: That's my pinkyDrew: Whats ...

**Lax bro.**

1 comment · 6 months ago

Avatar **GreteI von Schnauzer** —that is not a baby. that is a LITTLE BOY. Adorable!

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#### Baba Slings

Baba Slings ~ Ease of use, practicality and comfort combined with Stunning Designs means that you will not only be bonding with your little one, and providing everything that he or she needs, but it will be done in style! Your Style! No Compromise is needed, Baba Slings offer slings with attitude, let your Mama Lion roar with pride, or your inner Rock chic shine with Rockabilly, we have Tribal prints, Flower power or soft and subtle tones... Baba Slings have a sling for Everyone, including you Dad! x

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Naturally Family, Dollie Freddy, Debra Gaye Avery and 13 others like this.

**Debra Gaye Avery** I can't find this one on the online store?  
July 29 at 5:11am

**Baba Slings** Debra Gaye Avery we have a special shipment coming in soon, stay posted for more details! x  
July 29 at 6:36pm · Edited

**Debra Gaye Avery** Thankyou  
July 29 at 6:46pm via mobile · 1



# Baba Slings Instructions 1 Getting Started



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Ali Baba

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ba·ba  *noun* \ˈbä-(,)bä, -bə\

## Definition of BABA



: a rich cake soaked in a rum and sugar syrup —called also *baba au rhum*,

## Origin of BABA

French, from Polish, literally, old woman

First Known Use: 1826

## Other Food Terms

Reuben, calamari, chuck, curry, edamame, foie gras, hummus, leaven, nonpareil, peel

## Rhymes with BABA

aba, Kaaba, Labe, Saba, Sabah

## Learn More About BABA

 Spanish Central: Spanish translation of "baba"

 SCRABBLE®: Playable words you can make from "baba"

## Browse

• Next Word in the Dictionary: babacoote

BABA 0758

# **EXHIBIT D**

# **EXHIBIT D**

Commentary”).<sup>2</sup> The 1990 Commentary provided broad guidance on the Commission’s interpretation of the provisions of the FCRA, but specified that the interpretations were not trade regulation rules or regulations and did not have the force or effect of statutory provisions.<sup>3</sup>

## II. Basis for Removal of the 1990 Commentary

Since the publication of the 1990 Commentary, the FCRA has been amended several times in the ensuing years. The two most extensive amendments were the Consumer Credit Reporting Reform Act of 1996 (the “1996 amendments”) <sup>4</sup> and the Fair and Accurate Credit Transactions Act of 2003 (“FACT Act”).<sup>5</sup>

The 1996 Amendments expanded the duties of consumer reporting agencies (“CRAs”), and also increased the obligations of *users* of consumer reports, particularly employers. Most significantly, the 1996 Amendments imposed duties on a class of entities not previously treated by the FCRA—*furnishers* of information to CRAs—by including requirements related to accuracy and the handling of disputes by the entities that provided information to CRAs.

In 2003, the FACT Act <sup>6</sup> further expanded the FCRA.<sup>7</sup> It added several sections to assist consumers and businesses in combating identity theft and reducing the damage to consumers when that crime occurred, including granting consumers the right to request free annual reports from nationwide CRAs. The Commission, often in conjunction with the Federal financial agencies, issued numerous rules to

implement the various FACT Act provisions.<sup>8</sup>

As a result of these significant changes in the FCRA, as well as the passage of time, the 1990 Commentary has become partially obsolete.

In addition, on July 21, 2010, President Obama signed into law the Consumer Financial Protection Act of 2010 (“CFPA”).<sup>9</sup> Under the CFPA, much of the authority of the Commission and the Federal financial agencies to publish rules, regulations, or guidelines under the FCRA transfers to the CFPB. Although the CFPA provides for the transfer of existing regulations and guidelines to the CFPB, the Commission does not believe that it is appropriate to transfer the Commentary given its staleness. Indeed, in some respects, the Commentary is in conflict with the law as it has been amended. Accordingly, the Commission is rescinding 16 CFR 600.1, 600.2, and the Appendix to Part 600—Commentary on the Fair Credit Reporting Act.

Under 5 U.S.C. 553(b)(A), the requirement to provide prior notice and an opportunity for public comment does not apply to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. Further, under 5 U.S.C. 553(d)(2), the rescission may take effect immediately upon publication of this document in the **Federal Register**. Accordingly, the Commission rescinds 16 CFR 600.1, 600.2, and the Appendix to Part 600—Commentary on the Fair Credit Reporting Act, effective immediately.

## III. Regulatory Flexibility Act

Because these statements of general policy and interpretations are not “rules” subject to the Regulatory Flexibility Act, *see* 5 U.S.C. 601(2), the Commission is not required to publish any initial or final regulatory flexibility analysis under the Regulatory Flexibility Act as part of such action. *See* 5 U.S.C. 603(a), 604(b).

### List of Subjects in 16 CFR Part 600

Credit, Trade practices.

■ Accordingly, for the reasons set forth above, under the authority of 16 U.S.C. 1681s, the Commission amends Title 16, Chapter I, Code of Federal Regulations, by removing and reserving part 600.

<sup>8</sup> The Commission’s FACT Act rules are listed on the agency Web site at <http://www.ftc.gov/os/statutes/fcrajump.htm>.

<sup>9</sup> Title X, Public Law 111–203 (Dodd-Frank Wall Street Reform and Consumer Protection Act).

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

[FR Doc. 2011–18688 Filed 7–25–11; 8:45 am]

BILLING CODE 6750–01–P

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1500

[Docket No. CPSC–2010–0080]

### Children’s Products Containing Lead; Technological Feasibility of 100 ppm for Lead Content; Notice of Effective Date of 100 ppm Lead Content Limit in Children’s Products

**AGENCY:** U.S. Consumer Product Safety Commission

**ACTION:** Notice of statutory requirement.

**SUMMARY:** Section 101(a) of the Consumer Product Safety Improvement Act (“CPSIA”) provides that, as of August 14, 2011, children’s products may not contain more than 100 parts per million (“ppm”) of lead unless the Consumer Product Safety Commission (“CPSC,” “Commission,” or “we”) determines that such a limit is not technologically feasible. The determination can only be made after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children’s products. On February 16, 2011, we conducted a public hearing to receive views from all interested parties about the technological feasibility of meeting the 100 ppm lead content limit for children’s products and associated public health considerations. Through this document, we announce that children’s products must meet the statutory 100 ppm lead content limit on August 14, 2011, unless otherwise excluded under CPSC regulations.<sup>1</sup>

**DATES:** The 100 ppm lead content limit for children’s products is effective on August 14, 2011.

**FOR FURTHER INFORMATION CONTACT:** Dominique Williams, Directorate for Health Sciences, Consumer Product Safety Commission, Bethesda, MD 20814; telephone: (301) 504–7597; e-mail: [dwilliams@cpsc.gov](mailto:dwilliams@cpsc.gov).

### SUPPLEMENTARY INFORMATION:

<sup>1</sup> The Commission voted 3–2 to publish this notice, without changes, in the **Federal Register**. Chairman Inez M. Tenenbaum, Commissioners Thomas Moore and Robert Adler voted to publish the notice. Commissioners Nancy Nord and Anne Northup voted against publication of the notice. Chairman Tenenbaum and Commissioners Nord and Northup filed statements regarding the vote. The statements may be viewed at <http://www.cpsc.gov/pr/statements.html>.

<sup>2</sup> 55 FR 18804 (May 4, 1990). The 1990 Commentary followed a proposal published in August 1988. 53 FR 29696 (Aug. 8, 1988). It included eight interpretations that the Commission had issued in the 1970s (former 16 CFR 600.1 through 600.8).

<sup>3</sup> 16 CFR 600.2, citing 16 CFR 1.73.

<sup>4</sup> Title II, Subtitle D, Chapter 1, of the Omnibus Consolidated Appropriations Act for Fiscal Year 1997, Public Law 104–208 (Sept. 30, 1996).

<sup>5</sup> Public Law 108–159 (Dec. 4, 2003).

<sup>6</sup> *Id.*

<sup>7</sup> During the seven years between the 1996 Amendments and the FACT Act, there were a number of more modest revisions, the most significant of which was a 1999 amendment that specifically authorized the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of the Comptroller of the Currency, Office of Thrift Supervision, and National Credit Union Administration to promulgate regulations under the FCRA for the banks and other entities subject to their jurisdiction. Section 506 of the Gramm-Leach-Bliley Act (Pub. L. 106–102 (Nov. 12, 1999); FCRA § 621(e)).

## I. Background

Section 101(a)(2)(C) of the CPSIA (15 U.S.C. 1278a(a)(2)(C)) provides that, as of August 14, 2011, children's products may not contain more than 100 ppm of lead unless the Commission determines that such a limit is not technologically feasible. The Commission may make this determination only after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products. Section 101(d) of the CPSIA (15 U.S.C. 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

(1) A product that complies with the limit is commercially available in the product category;

(2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;

(3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or

(4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

On July 27, 2010, we published a notice in the **Federal Register** (75 FR 43942), requesting comment and seeking information concerning the technological feasibility of meeting the 100 ppm lead content limit for children's products that are not otherwise excluded from the lead content limits under 16 CFR 1500.87 through 1500.91. After initial consideration of the comments and information received in response to the July 27, 2010 notice, we published a notice in the **Federal Register** (76 FR 4641) on January 26, 2011, announcing that we would be conducting a public hearing to receive views from all interested parties about the technological feasibility of meeting the 100 ppm lead content limit for children's products and associated public health considerations. The hearing was held on February 16, 2011. On March 9, 2011, we published another notice in the **Federal Register** (76 FR 12944), reopening the hearing record to allow hearing participants to submit relevant studies and supplementary data in response to additional questions from certain Commissioners.

Participants who submitted comments and hearing testimony regarding the

technological feasibility of meeting the 100 ppm lead content limit and associated public health considerations included consumers, consumer groups, manufacturers, retailers, associations, and laboratories. Comments submitted in this proceeding are available at <http://www.regulations.gov>, under Docket No. CPSC-2010-0080. The video webcast of the hearing, as well as the presentations and written comments from the hearing, are available at the CPSC web site: <http://www.cpsc.gov/webcast/previous.html>. A transcript of the hearing and supplemental information provided by hearing participants are also available at <http://www.regulations.gov>, docket CPSC-2010-0080.

## II. Technological Feasibility of 100 ppm

We evaluated the technological feasibility of the 100 ppm lead content limit for children's products based on available technical information, written public comments, public hearing oral comments, and other available information. CPSC staff's analysis regarding the technological feasibility of materials and products to meet the 100 ppm lead content limit is contained in the staff briefing package available on the CPSC Web site at: <http://www.cpsc.gov/library/foia/foia11/brief/lead100tech.pdf> and <http://www.cpsc.gov/library/foia/foia11/brief/100ppmlead.pdf>. We evaluated the technological feasibility of meeting the 100 ppm lead content limit in materials such as plastics, glass, and metals; reviewed the economic impacts of reducing the lead content limit from 300 ppm to 100 ppm; and considered the public comments received in this proceeding, including comments on public health protectiveness, economic burdens, availability of compliant materials, and variability in test results. Based upon this analysis, the staff could not recommend that the Commission make a determination that it is not technologically feasible for a product or product category to meet the 100 ppm lead content limit for children's products under section 101(d) of the CPSIA. No such determination has been made by the Commission. Therefore, all children's products sold, offered for sale, manufactured for sale, distributed in commerce, or imported for sale in the United States must meet the 100 ppm lead content limit beginning August 14, 2011 as statutorily mandated by the CPSIA unless otherwise excluded under 16 CFR 1500.87 through 1500.91. With respect to bicycles and related products and youth motorized recreational vehicles, a stay of enforcement regarding the lead content in certain

parts, including metal components, is currently in effect until December 31, 2011 (76 FR 6765).

Dated: July 18, 2011.

**Todd A. Stevenson**,  
Secretary, Consumer Product Safety  
Commission.

[FR Doc. 2011-18510 Filed 7-25-11; 8:45 am]

BILLING CODE 6355-01-P

## COMMODITY FUTURES TRADING COMMISSION

### 17 CFR Parts 39 and 140

RIN 3038-AD00

### Process for Review of Swaps for Mandatory Clearing

**AGENCY:** Commodity Futures Trading  
Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commodity Futures Trading Commission (Commission or CFTC) is adopting regulations to implement certain provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). These regulations establish the process by which the Commission will review swaps to determine whether the swaps are required to be cleared.

**DATES:** Effective September 26, 2011.

**FOR FURTHER INFORMATION CONTACT:** Eileen A. Donovan, Special Counsel, 202-418-5096, [edonovan@cftc.gov](mailto:edonovan@cftc.gov), Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

### SUPPLEMENTARY INFORMATION:

#### I. Background

On November 2, 2010, the Commission published proposed regulations to implement certain provisions of the Dodd-Frank Act regarding the mandatory clearing of swaps.<sup>1</sup> The Commission is hereby adopting Regulation 39.5<sup>2</sup> to establish procedures for: (1) Determining the eligibility of a DCO to clear swaps; (2) the submission of swaps by a DCO to the Commission for a mandatory clearing determination; (3) Commission-initiated reviews of swaps; and (4) staying a clearing requirement.

Section 723(a)(3) of the Dodd-Frank Act provides that "it shall be unlawful for any person to engage in a swap unless that person submits such swap

<sup>1</sup> See 75 FR 67277 (Nov. 2, 2010).

<sup>2</sup> Commission regulations referred to herein are found at 17 CFR Ch. 1.

amending Class D airspace at Cabaniss Navy Outlying Field (NOLF), Corpus Christi, TX.

**DATES:** *Effective date:* 0901 UTC August 25, 2011.

**FOR FURTHER INFORMATION CONTACT:** Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 321-7716.

**SUPPLEMENTARY INFORMATION:**

**History**

On June 2, 2011, the FAA published in the **Federal Register** a final rule amending Class D airspace at Cabaniss NOLF, Corpus Christi, TX (76 FR 31821, Docket No. FAA-2010-1171). Subsequent to publication, an error was discovered in the latitude coordinates listed in the regulatory text. This action corrects that error. Class D airspace designations are published in paragraph 5000 of FAA Order 7400.9U dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR Part 71.1. The Class D airspace designations listed in this document will be published subsequently in the Order.

*Correction to Final Rule*

Accordingly, pursuant to the authority delegated to me, the latitude coordinates listed in the regulatory text for the Class D airspace area at Cabaniss NOLF, Corpus Christi, TX, as published in the **Federal Register** June 2, 2010 (76 FR 31821), (FR Doc. 2011-13559), are corrected as follows:

**ASW TX D Corpus Christi, TX [Corrected]**

*Cabaniss NOLF, TX*

On page 31822, column 1, line 49 of the regulatory text, remove 'lat. 27°38'15" N.,' and insert 'lat. 27°38'16" N. '; and on line 50 remove 'lat. 27°41'30" N.,' and insert 'lat. 27°41'22" N. '

Issued in Fort Worth, Texas, on August 2, 2011.

**Walter L. Tweedy,**

*Acting Manager, Operations Support Group, ATO Central Service Center.*

[FR Doc. 2011-20303 Filed 8-9-11; 8:45 am]

**BILLING CODE 4910-13-P**

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 Chapter II**

[CPSC Docket No. CPSC-2011-0052]

**Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies To Assess Conformity With the Limits on Phthalates in Children's Toys and Child Care Articles**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of Requirements.

**SUMMARY:** The Consumer Product Safety Commission (CPSC, Commission, or we) is issuing a notice of requirements that provides the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing pursuant to the phthalates limits in section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The Commission is issuing this notice of requirements pursuant to section 14(a)(3)(B)(vi) of the Consumer Product Safety Act (CPSA).

**DATES:** *Effective Date:* The requirements for accreditation of third party conformity assessment bodies to assess conformity with phthalates limits when tested in accordance with CPSC-CH-C1001-09.3, *Standard Operating Procedure for Determination of Phthalates*, and GB/T 22048-2008, *Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic* are effective August 10, 2011.

Submit comment by September 9, 2011. Comments on this notice should be captioned "Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with the Limits on Phthalates in Children's Toys and Child Care Articles."

**ADDRESSES:** You may submit comments, identified by Docket No. CPSC-2011-0052, by any of the following methods:

*Electronic Submissions:* Submit electronic comments in the following way:

*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through <http://www.regulations.gov>.

*Written Submissions:* Submit written submissions in the following ways:

*Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) preferably in five copies, to:* Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

*Instructions:* All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. Do not submit confidential business information, trade secret information, or other sensitive or protected information (such as a Social Security Number) electronically; if furnished at all, such information should be submitted in writing.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Carol Afflerbach, Compliance Officer, Office of Compliance and Field Investigations, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail [cafflerbach@cpsc.gov](mailto:cafflerbach@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

Section 14(a)(3)(B)(vi) of the CPSA, as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314, directs the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies (also known as "testing laboratories" or "laboratories") to assess children's products for conformity with "other children's product safety rules."<sup>1</sup> Section 14(f)(1) of the CPSA defines "children's product safety rule" as "a consumer product safety rule under [the CPSA] or similar rule, regulation, standard, or ban under any other Act enforced by the Commission, including a rule declaring a consumer product to be a banned hazardous product or substance." Under section 14(a)(3)(A) of the CPSA, each manufacturer (including the importer) or private labeler of products subject to those regulations must have products that are manufactured more than 90 days after

<sup>1</sup> The Commission voted 5-0 to publish this notice of requirements, with amendments, in the **Federal Register**. Chairman Inez M. Tenenbaum and Commissioners Thomas H. Moore and Robert S. Adler filed a joint statement regarding the vote. Commissioners Nancy A. Nord and Anne M. Northup filed individual statements. The statements may be viewed at <http://www.cpsc.gov/pr/statements/html>.

the **Federal Register** publication date of a notice of the requirements for accreditation, tested by a third party conformity assessment body accredited to do so, and must issue a certificate of compliance with the applicable regulations based on that testing. Section 14(a)(2) of the CPSA, as added by section 102(a)(2) of the CPSIA, requires that certification be based on testing of sufficient samples of the product, or samples that are identical in all material respects to the product. The Commission also emphasizes that, irrespective of certification, the product in question must comply with the applicable CPSC requirements (see, e.g., section 14(h) of the CPSA, as added by section 102(b) of the CPSIA).

This notice provides the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing pursuant to the following test methods:

- CPSC-CH-C1001-09.3, *Standard Operating Procedure for Determination of Phthalates*, issued on April 1, 2010 (“CPSC Test Method”). This is the most recent version of the test method, and it can be downloaded from the CPSC Web site at <http://www.cpsc.gov/about/cpsia/CPSC-CH-C1001-09.3.pdf>; and/or
- GB/T 22048-2008, *Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic*, issued on June 16, 2008 (“Chinese Test Method”).

The Commission is recognizing limited circumstances in which it will accept certifications based on product testing conducted before the publication of this notice of requirements. The details regarding those limited circumstances can be found in part VI of this document below.

Although section 14(a)(3)(B)(vi) of the CPSA directs the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies to assess conformity with “all other children’s product safety rules,” this notice of requirements is limited to test methods CPSC-CH-C1001-09.3, *Standard Operating Procedure for Determination of Phthalates*, and GB/T 22048-2008, *Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic*. The CPSC acknowledges that the test methods for determining phthalates content are not, by themselves, rules that are codified in the Code of Federal Regulations. However, section 108(d) of the CPSIA considers the phthalates content limits to be “consumer product safety standards” under the Consumer Product Safety Act. Section 14(a)(3)(B)(vi) of the CPSA directs the Commission to publish

notices of requirements for the accreditation of third party conformity assessment bodies to assess conformity with “other children’s product safety rules,” and section 14(f)(1) of the CPSA defines a “children’s product safety rule,” in part, as “a consumer product safety rule under [the CPSA].” Section 3(a)(6) of the CPSA, in turn, defines a “consumer product safety rule” as “a consumer products safety standard described in section 7(a) [of the CPSA] \* \* \* or a rule under this Chapter declaring a consumer product a banned hazardous product.” Accordingly, because the phthalates content limits are “consumer product safety standards” under the CPSA, it follows that they are also “consumer product safety rules” under section 3(a)(6) of the CPSA and, in turn, “children’s product safety rules” under section 14(f)(1) of the CPSA. Thus, the phthalates content limits are “children’s product safety rules” for which a notice of requirements for accreditation of third party conformity assessment bodies must be published. In addition, because the test methods would be used to assess conformity with the phthalates limits, it is appropriate for the notice of requirements to apply to the CPSC Test Method and the Chinese Test Method.

The CPSC also recognizes that section 14(a)(3)(B)(vi) of the CPSA is captioned: “All Other Children’s Product Safety Rules,” but the body of the statutory requirement refers only to “other children’s product safety rules.” Nevertheless, section 14(a)(3)(B)(vi) of the CPSA could be construed to require a notice of requirements for “all” other children’s product safety rules, rather than a notice of requirements for “some” or “certain” children’s product safety rules. However, whether a particular rule represents a “children’s product safety rule” may be subject to interpretation. Commission staff is continuing to evaluate which rules, regulations, standards, or bans are “children’s product safety rules.” The CPSC intends to issue additional notices of requirements for other rules which the Commission determines to be “children’s product safety rules.”

This notice of requirements applies to all third party conformity assessment bodies, as described in section 14(f)(2) of the CPSA. Generally speaking, such third party conformity assessment bodies are: (1) Third party conformity assessment bodies that are not owned, managed, or controlled by a manufacturer or private labeler of a children’s product to be tested by the third party conformity assessment body for certification purposes; (2) “firewalled” conformity assessment

bodies (those that are owned, managed, or controlled by a manufacturer or private labeler of a children’s product to be tested by the third party conformity assessment body for certification purposes and that seek accreditation under the additional statutory criteria for “firewalled” conformity assessment bodies); and (3) third party conformity assessment bodies owned or controlled, in whole or in part, by a government.

The Commission requires baseline accreditation of each category of third party conformity assessment body to the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Standard 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories.” The accreditation must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA), and the scope of the accreditation must include testing for any of the test methods identified earlier in this document for which the third party conformity assessment body seeks to be accredited.

(A description of the history and content of the ILAC-MRA approach and of the requirements of the ISO/IEC 17025:2005 laboratory accreditation standard is provided in the CPSC staff briefing memorandum, “Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 CFR part 1501 (Small Parts Regulations),” dated November 2008, and available on the CPSC’s Web site at: <http://www.cpsc.gov/library/foia/foia09/brief/smallparts.pdf>).

The Commission has established an electronic accreditation registration and listing system that can be accessed via its Web site at: <http://www.cpsc.gov/about/cpsia/labaccred.html>.

The Commission stayed the enforcement of certain provisions of section 14(a) of the CPSA in a notice published in the **Federal Register** on February 9, 2009 (74 FR 6396); the stay applied to testing and certification of various products, including the phthalates limits of section 108 of the CPSIA. On December 28, 2009, the Commission published a notice in the **Federal Register** (74 FR 68588), revising the terms of the stay. One section of the December 28, 2009, notice addressed: “Consumer Products or Children’s Products Where the Commission Is Continuing the Stay of Enforcement Until Further Notice,” due to factors such as pending rulemaking proceedings affecting the product or the

absence of a notice of requirements. The phthalates content testing and certification requirements for children's toys and child care articles were included in that section of the December 28, 2009 notice. The absence of a notice of requirements prevented the lifting of the stay in the December 28, 2009 notice with regard to testing and certifications of children's toys and child care articles for phthalates content. On February 8, 2011, the Commission published a notice in the **Federal Register** (76 FR 6765), continuing the stay of enforcement for testing and certification of children's products for which a notice of requirements for accreditation of laboratories had not yet been published.

The phthalates content testing and certification requirements for children's toys and child care articles were mentioned specifically as an example of a provision for which the stay would continue, pending publication of the notice of requirements. Thus, publication of this notice of requirements would have had the effect of lifting the stay on testing and certification requirements for phthalates content in children's toys and child care articles; however, on July 27, 2011, the Commission voted to stay enforcement of the testing and certification requirements of section 14 of the CPSA with respect to toys and child care articles subject to the phthalates content limits until December 31, 2011.

Accordingly, the Commission will enforce third party testing and certification requirements for products subject to the phthalates content limits if such products are manufactured on or after January 1, 2012. (Under the CPSA, the term "manufacturer" includes anyone who manufactures or imports a product.)

This notice of requirements is exempt from the notice and comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 553 (see section 14(a)(3)(G) of the CPSA, as added by section 102(a)(2) of the CPSIA (15 U.S.C. 2063(a)(3)(G))).

## II. Testing & Certification to Phthalates Limits—Prior Guidance Remains in Effect

The Commission approved a "Statement of Policy: Testing of Component Parts with Respect to Section 108 of the Consumer Product Safety Improvement Act" on August 7, 2009. On August 17, 2009, a Notice of Availability regarding the Statement of Policy was published in the **Federal Register** (74 FR 41400). The Statement of Policy can be viewed and downloaded from the CPSC Web site at:

<http://www.cpsc.gov/about/cpsia/componenttestingpolicy.pdf>. In brief, we believe that only those plastic parts or other product parts which could conceivably contain phthalates ("plasticized component parts") should be tested for phthalates. We consider it to be unnecessary to test and certify materials that are known not to contain phthalates or to certify that phthalates are absent from materials that are known not to contain phthalates.<sup>2</sup> In addition, we believe that when testing covered products, the assessment of the concentration of phthalates is to be based on testing of the plasticized component parts, rather than testing of the entire product, to avoid dilution of the concentrations of phthalates that can occur when the entire product is considered. The Statement of Policy remains in effect until further notice (except that the CPSC Test Method referenced in the Statement of Policy, CPSC-CH-C1001-09.2, has been superseded by CPSC-CH-C1001-09.3 as outlined in part VI of this document below).

The Commission voted to publish a "Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108" on February 13, 2009. On February 23, 2009, the staff guidance was published in the **Federal Register** (74 FR 8058). This staff guidance can be viewed and downloaded from the CPSC Web site at: <http://www.cpsc.gov/businfo/frnotices/fr09/draftphthalatesguidance.pdf>. The Commission may choose to update this staff guidance or initiate a formal rulemaking concerning the topics addressed by the guidance after receipt of the Chronic Hazard Advisory Panel report required by section 108(b)(2)(C) of the CPSIA. Until such time, this staff guidance remains in effect (except that the CPSC Test Method referenced in the guidance, CPSC-CH-C1001-09.1, has been superseded by CPSC-CH-C1001-09.3 as outlined in part VI of this document below).

Answers to frequently asked questions that provide guidance concerning the requirements of section 108 of the CPSIA can be viewed on the CPSC Web site at: <http://www.cpsc.gov/about/cpsia/sect108.html#faqs>. The Commission intends for this guidance to be useful and therefore the materials on this Web page may be modified

<sup>2</sup> Untreated/unfinished wood, metal, natural fibers, natural latex and mineral products are not expected to inherently contain phthalates and need not be tested or certified provided that these materials have neither been treated or adulterated with the addition of materials that could result in the addition of phthalates into the product or material.

periodically in the future. In order to receive automatic notification of any such updates, interested parties may sign up for the CPSIA email subscription list at: <https://www.cpsc.gov/about/cpsia/cpsialist.aspx>. The Commission notes that the phthalate content limits in section 108 of the CPSIA are statutory requirements and we may always take action with regard to products defined in this section of the statute that exceed those limits.

## III. Responses to Comments Received on the CPSC Testing Method

The Commission requested comments regarding the Statement in the Notice of Availability published in the **Federal Register** (74 FR 41400). We received several comments on the CPSC Test Method. We describe and respond to the comments in this section of the document. To make it easier to identify the comments and our responses, the word "Comment," in parentheses, will appear before the comment's description, and the word "Response," in parentheses, will appear before our response. We also have numbered each comment to help distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, or importance, or the order in which it was received.

(*Comment 1*)—Some commenters questioned the necessity to run the test in triplicate. Other test multiples from two to five were suggested. Some commenters asked whether the sample to be tested always needed to be ground to a powder. A commenter asked about the proper cleaning protocol of the cryogenic mill.

(*Response 1*)—We have examined all suggestions and comments pertaining to the CPSC Test Method and have updated our test method to address these issues (CPSC-CH-C1001-09.3). We adjusted the method to allow the third party conformity assessment body to choose an appropriate quality assurance program; thus, the third party conformity assessment body will determine the number of replicates to be tested. The CPSC Test Method allows, but does not require, third party conformity assessment bodies to pulverize the sample. Cryogenic mill equipment should be cleaned as thoroughly as any other laboratory equipment that comes into contact with a sample.

(*Comment 2*)—One commenter suggested that the official Chinese test method, GB/T 22048-2008, *Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl*

*Chloride Plastic*, should be added to the lists of acceptable extraction and analysis methods. The commenter also suggested that each plasticized component part should be cut into pieces no larger than 2 mm prior to the extraction step.

(*Response 2*)—We have reviewed the test method GB/T 22048–2008 and determined that it is an acceptable test method for inclusion in this notice of requirements. With regard to the 2 mm maximum size of pieces, we agree with this comment and have incorporated the dimension into the current edition of the CPSC Test Method (CPSC–CH–C1001–09.3).

(*Comment 3*)—Another commenter suggested that the CPSC Test Method include a description of the limit of detection (LOD) and limit of quantitation (LOQ). The commenter added that, on the last page of CPSC–CH–C1001–09.2, there appears to be an error in the DEHP calculation. Under column C, measured DEHP concentration by GC–MSW is 200 µg/ml. In the final calculation column, 200 µg/ml is mistakenly cited as 20 µg/ml.

(*Response 3*)—Detection and quantitation limits have not been outlined specifically at this point. Third party conformity assessment bodies should follow their own internal quality assurance program. These limits may be introduced in the future, following further validation and round robin studies. The DEHP calculation included a typographical error that was corrected for the current edition of the test method (CPSC–CH–C1001–09.3).

(*Comment 4*)—One commenter stated that grinding the sample into a powder is time-consuming, adds additional expense to the testing methods, and could introduce the possibility of significant interlaboratory variability.

(*Response 4*)—Grinding the sample into a powder is no longer required in the CPSC Test Method; however, third party conformity assessment bodies may continue to do so, if they wish.

(*Comment 5*)—One commenter asked how the CPSC Test Method prevents interferences that can lead to a false positive for the phthalates of interest. The commenter also asked if the detection method could be revised.

(*Response 5*)—We have updated the CPSC Test Method (to CPSC–CH–C1001–09.3) to include a vigorous qualitative assessment by trained staff to avoid false positives. Such steps include: Retention time matching with known standards and full-scan mass spectrum analysis. We will continue to consider new methods that could simplify or improve the analysis.

(*Comment 6*)—One commenter pointed out typographical inconsistencies found within the text of the method. Additionally, the commenter asked: What is the minimum signal-to-noise ratio required, and what are the reproducibility and detection limits of the method?

(*Response 6*)—We have corrected the typographical errors that might have caused confusion. Signal-to-noise, detection limits, and reproducibility requirements have not been outlined specifically at this point. Third party conformity assessment bodies should follow their own internal quality assurance program. Testing requirements may be adjusted following further validation and round robin studies.

(*Comment 7*)—One commenter asked if the chromatography was optimized.

(*Response 7*)—The gas chromatography parameters outlined have been successful at providing adequate separation while minimizing sampling time. However, due to the nature of DINP and DIDP, they will not completely separate chromatographically. DINP and DIDP are actually a mixture of compounds; DINP and DIDP contain some of the same phthalate species, leading to an overlap. We recommend following the selection monitoring analysis scheme outlined in the CPSC Test Method to quantify these compounds for instances when they are both present.

(*Comment 8*)—One commenter suggested that we create a flexible correlative policy that permits use of several methods suitable for the routine identification and measurement of total phthalate concentration, such as ASTM D7083–04, the Canada Product Safety Bureau method, the European Toy Safety Directive method, and GB/T 22048–2008, *Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic*.

(*Response 8*)—The current edition of the CPSC Test Method (CPSC–CH–C1001–09.3) allows alternative test methods. Additionally, any combination of the approved extraction and analysis methods listed may be used. We have included GB/T 22048–2008, *Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic*, as an additional test method in this notice of requirements. We have not included ASTM D7083–04 as an alternative detection method due to the lack of selectivity from using a flame ionization detector; this method may lead to false positives. We will review other suggested methods and

may include them as alternatives in future revisions of the test method.

#### IV. Accreditation Requirements

##### A. Baseline Third Party Conformity Assessment Body Accreditation Requirements

For a third party conformity assessment body to be accredited to test children's products for conformity with the test methods identified earlier in part I of this document, it must be accredited by an ILAC–MRA signatory accrediting body, and the accreditation must be registered with, and accepted by, the Commission. A listing of ILAC–MRA signatory accrediting bodies is available on the Internet at: <http://ilac.org/membersbycategory.html>. The accreditation must be to ISO Standard ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," and the scope of the accreditation must expressly include testing to the test method CPSC–CH–C1001–09.3, *Standard Operating Procedure for Determination of Phthalates*, and/or to the test method GB/T 22048–2008, *Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic*. A true copy, in English, of the accreditation and scope documents demonstrating compliance with these requirements must be registered with the Commission electronically. The additional requirements for accreditation of firewalled and governmental conformity assessment bodies are described in parts IV.B and IV.C of this document below.

The Commission will maintain on its Web site an up-to-date listing of third party conformity assessment bodies whose accreditations it has accepted and the scope of each accreditation. Once the Commission adds a third party conformity assessment body to that list, the third party conformity assessment body may commence testing children's toys and child care articles for phthalates content to support certification by the manufacturer or private labeler of compliance with the test method(s) identified earlier in part I of this document.

##### B. Additional Accreditation Requirements for Firewalled Conformity Assessment Bodies

In addition to the baseline accreditation requirements in part IV.A of this document above, firewalled conformity assessment bodies seeking accredited status must submit to the Commission copies, in English, of their training documents, showing how employees are trained to notify the

Commission immediately and confidentially of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the third party conformity assessment body's test results. This additional requirement applies to any third party conformity assessment body in which a manufacturer or private labeler of a children's product to be tested by the third party conformity assessment body owns an interest of 10 percent or more. While the Commission is not addressing common parentage of a third party conformity assessment body and a children's product manufacturer at this time, it will be vigilant to see if this issue needs to be addressed in the future.

As required by section 14(f)(2)(D) of the CPSA, the Commission must formally accept, by order, the accreditation application of a third party conformity assessment body before the third party conformity assessment body can become an accredited firewalled conformity assessment body. The Commission's order must also find that accrediting the firewalled conformity assessment body would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent conformity assessment body.

#### *C. Additional Accreditation Requirements for Governmental Conformity Assessment Bodies*

In addition to the baseline accreditation requirements of part IV.A of this document above, the CPSIA permits accreditation of a third party conformity assessment body owned or controlled, in whole or in part, by a government if:

- To the extent practicable, manufacturers or private labelers located in any nation are permitted to choose conformity assessment bodies that are not owned or controlled by the government of that nation;
- The third party conformity assessment body's testing results are not subject to undue influence by any other person, including another governmental entity;
- The third party conformity assessment body is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited;
- The third party conformity assessment body's testing results are accorded no greater weight by other governmental authorities than those of other accredited third party conformity assessment bodies; and

- The third party conformity assessment body does not exercise undue influence over other governmental authorities on matters affecting its operations or on decisions by other governmental authorities controlling distribution of products based on outcomes of the third party conformity assessment body's conformity assessments.

The Commission will accept the accreditation of a governmental third party conformity assessment body if it meets the baseline accreditation requirements of part IV.A of this document above and meets the additional conditions stated here. To obtain this assurance, CPSC staff will engage the governmental entities relevant to the accreditation request.

#### **V. How does a third party conformity assessment body apply for acceptance of its accreditation?**

The Commission has established an electronic accreditation acceptance and registration system accessed via the Commission's Internet site at: <http://www.cpsc.gov/about/cpsia/labaccred.html>. The applicant provides, in English, basic identifying information concerning its location, the type of accreditation it is seeking, and electronic copies of its ILAC-MRA accreditation certificate and scope statement, and firewalled third party conformity assessment body training document(s), if relevant.

CPSC staff will review the submission for accuracy and completeness. In the case of baseline third party conformity assessment bodies and government-owned or government-operated conformity assessment bodies, when that review and any necessary discussions with the applicant are completed satisfactorily, the third party conformity assessment body in question is added to the CPSC's list of accredited third party conformity assessment bodies at <http://www.cpsc.gov/about/cpsia/labaccred.html>. In the case of a firewalled conformity assessment body seeking accredited status, when staff's review is complete, staff transmits its recommendation on accreditation to the Commission for consideration. (A third party conformity assessment body that may ultimately seek acceptance as a firewalled third party conformity assessment body also can initially request acceptance as a third party conformity assessment body accredited for testing of children's products other than those of its owners.) If the Commission accepts a staff recommendation to accredit a firewalled conformity assessment body, the firewalled conformity assessment body

will be added to the CPSC's list of accredited third party conformity assessment bodies. In each case, the Commission will notify the third party conformity assessment body electronically of acceptance of its accreditation. All information to support an accreditation acceptance request must be provided in the English language.

Once the Commission adds a third party conformity assessment body to the list, the third party conformity assessment body may begin testing children's products to support certification of compliance with the phthalates content limits for which it has been accredited.

#### **VI. Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing to CPSC-CH-C1001-09, Standard Operating Procedure for Determination of Phthalates, and/or GB/T 22048-2008, Toys and Children's Products—Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic, Prior to the Effective Date**

For certifications of children's toy or child care articles subject to the phthalates content limits in section 108 of the CPSIA, the Commission will allow certifications to be based on prior testing under certain conditions. Firms that elect to voluntarily have the phthalates content of children's toys and child care articles tested by a third party conformity assessment body, using either the CPSC Test Method or the Chinese Test Method, before January 1, 2012, will not need to have those products retested. The Commission's acceptance of certifications based on prior testing under certain conditions should prevent testing backlogs at accredited third party conformity assessment bodies, making it less likely that the Commission will have to postpone the effective date for certification.

The Commission will accept a certificate of compliance to the phthalates limits in section 108 of the CPSIA based on testing performed by an accredited third party conformity assessment body (including a government-owned or -controlled conformity assessment body, and a firewalled conformity assessment body) if:

- At the time of product testing, the product was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an ILAC-MRA member at the time of the test. For firewalled conformity assessment bodies, the firewalled conformity assessment body must be one that the

Commission has accredited by order at or before the time the product was tested, even if the order did not include the test methods specified in this notice. If the third party conformity assessment body has not been accredited by a Commission order as a firewalled conformity assessment body, the Commission will not accept a certificate of compliance based on testing performed by the third party conformity assessment body before it is accredited, by Commission order, as a firewalled conformity assessment body;

- For tests conducted using the CPSC Test Method, the test was conducted on or after July 27, 2009. The Commission has chosen July 27, 2009, because it is the date the Commission posted a test method for testing component parts for phthalates on the Commission Web site: (<http://www.cpsc.gov/about/cpsia/CPSC-CH-C1001-09.2.pdf>). The test method was updated on April 1, 2010, to the current method (<http://www.cpsc.gov/about/cpsia/CPSC-CH-C1001-09.3.pdf>). The Commission will accept phthalates content certifications for products tested before January 1, 2012, if the product was tested using either CPSC-CH-C1001-09.2 or CPSC-CH-C1001-09.3. The Commission acknowledges that, on March 3, 2009, it released a test method that involved testing the entire product (<http://www.cpsc.gov/about/cpsia/CPSC-CH-C1001-09.1.pdf>) (“March 2009 test method”). The Commission will not accept phthalates content certifications for products tested using the March 2009 test method (CPSC-CH-C1001-09.1). The Commission considers testing the entire product to be less protective of children because mouthable component parts with high concentrations of phthalates in products with large quantities of nonplasticized parts would be able to pass the test because the total mass of the product would dilute the overall phthalate measure.

- For tests conducted using the Chinese Test Method, the test was conducted on or after June 18, 2008. The Commission has chosen June 18, 2008, because that is the date that the Chinese Test Method was issued.

- The third party conformity assessment body’s application for accreditation is accepted by CPSC by the mandatory effective date, as established by the Commission;

- The accreditation scope in the application for accreditation expressly includes one or both of the acceptable test methods identified earlier in part I of this document;

- The test results show compliance with the applicable current standards; and
- The third party conformity assessment body’s accreditation and inclusion of one or both of the test methods (identified earlier in part I of this document) in its scope remain in effect through the effective date for mandatory third party testing and manufacturer certification for the subject products’ respective standards.

Dated: July 29, 2011.

**Alberta E. Mills,**

*Acting Secretary, Consumer Product Safety Commission.*

[FR Doc. 2011-19678 Filed 8-9-11; 8:45 am]

**BILLING CODE 6355-01-P**

## COMMODITY FUTURES TRADING COMMISSION

### 17 CFR Part 35

**RIN 3038-AD21**

### Agricultural Swaps

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commodity Futures Trading Commission (“Commission” or “CFTC”) is charged with proposing rules to implement new statutory provisions enacted by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”). The Dodd-Frank Act provides that swaps in an agricultural commodity (as defined by the Commission) are prohibited unless entered into pursuant to a rule, regulation or order of the Commission adopted pursuant to certain provisions of the Commodity Exchange Act (“CEA” or “Act”). On February 3, 2011, the Commission requested comment on a set of proposed rules that would, among other things, implement regulations whereby swaps in agricultural commodities may transact subject to the same rules as all other swaps. The proposed rules for swaps in an agricultural commodity would repeal and replace the Commission’s current regulations concerning the exemption of swap agreements. After reviewing the comments submitted in response to the proposed rules, the Commission has determined to issue these final rules for swaps in an agricultural commodity in the form as originally proposed. The February 3, 2011, proposed rules also included provisions that would substantially amend the Commission’s regulations regarding commodity option

transactions. However, in this final rule the Commission is only issuing the rules for swaps in an agricultural commodity. The proposed rules for commodity option transactions will be addressed at a later date.

**DATES:** *Effective Date*—December 31, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Donald Heitman, Senior Special Counsel, (202) 418-5041, [dheitman@cftc.gov](mailto:dheitman@cftc.gov), or Ryne Miller, Attorney Advisor, (202) 418-5921, [rmiller@cftc.gov](mailto:rmiller@cftc.gov), Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

#### A. Dodd-Frank Act

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act.<sup>1</sup> Title VII of the Dodd-Frank Act<sup>2</sup> amended the CEA<sup>3</sup> to establish a comprehensive new regulatory framework for swaps and security-based swaps. The legislation was enacted to reduce risk, increase transparency, and promote market integrity within the financial system by, among other things: (1) Providing for the registration and comprehensive regulation of swap dealers and major swap participants; (2) imposing clearing and trade execution requirements on standardized derivative products; (3) creating robust recordkeeping and real-time reporting regimes; and (4) enhancing the Commission’s rulemaking and enforcement authorities with respect to, among others, all registered entities and intermediaries subject to the Commission’s oversight.

#### B. Proposed Agricultural Swaps Rules

Section 723(c)(3) of the Dodd-Frank Act provides that swaps in an agricultural commodity (as defined by the Commission)<sup>4</sup> are prohibited unless entered into pursuant to a rule, regulation or order of the Commission adopted pursuant to CEA section 4(c).

<sup>1</sup> See Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111-203, 124 Stat. 1376 (2010). The text of the Dodd-Frank Act may be accessed at <http://www.cftc.gov/LawRegulation/OTCDERIVATIVES/index.htm>.

<sup>2</sup> Pursuant to section 701 of the Dodd-Frank Act, Title VII may be cited as the “Wall Street Transparency and Accountability Act of 2010.”

<sup>3</sup> 7 U.S.C. 1 *et seq.*

<sup>4</sup> As discussed below, in accordance with the mandate of the Dodd-Frank Act, the Commission recently promulgated a final rule defining the term “agricultural commodity.” See 76 FR 41048, July 13, 2011.



# FEDERAL REGISTER

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Vol. 76

Tuesday,

No. 216

November 8, 2011

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Part III

## Consumer Product Safety Commission

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16 CFR Part 1107

Testing and Labeling Pertaining to Product Certification; Final Rule

**CONSUMER PRODUCT SAFETY COMMISSION****16 CFR Part 1107**

[CPSC Docket No. CPSC–2010–0038]

**Testing and Labeling Pertaining to Product Certification****AGENCY:** Consumer Product Safety Commission.**ACTION:** Final rule.

**SUMMARY:** The Consumer Product Safety Commission (“CPSC,” “Commission,” or “we”) is issuing a final rule that establishes protocols and standards with respect to certification and continued testing for children’s products. The final rule also establishes requirements for labeling of consumer products to show that the product complies with the certification requirements under section 14(a) of the Consumer Product Safety Act (“CPSA”). The final rule implements section 14(a)(2) and (i) of the CPSA, as amended by section 102(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”).

**DATES:** The rule will become effective on February 8, 2013 and applies to products manufactured after that date. The incorporation by reference of the publications listed in this rule is approved by the Director of the Federal Register as of February 8, 2013.<sup>1</sup>

**FOR FURTHER INFORMATION CONTACT:** Randy Butturini, Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; (301) 504–7562; email: [RButturini@cpsc.gov](mailto:RButturini@cpsc.gov).

**SUPPLEMENTARY INFORMATION:****I. Purpose of the Final Rule**

The purpose of this final rule is to reduce the incidents of deaths and injuries associated with children’s products. This will be accomplished by increasing the safety of children’s products. The likelihood of a noncompliant product being detected before it is introduced to the public will be increased. Consequently, consumer confidence in children’s products

certified to comply with the applicable product safety rules may be increased. Potentially, the number of recalls for children’s products could be reduced, and, with continued assessment of compliance, the scope of necessary recalls could be reduced. Further, third party testing during continuing production or importation can serve as an objective assessment of the effectiveness of a manufacturer’s or importer’s internal processes to ensure compliance, which would also serve to enhance the safety of children’s products in the market.

**II. Statutory Authority***A. The Consumer Product Safety Act, as Amended by the Consumer Product Safety Improvement Act of 2008*

Section 14(a)(1) of the CPSA, (15 U.S.C. 2063(a)(1)), as amended by section 102 of the CPSIA, establishes requirements for the testing and certification of products subject to a consumer product safety rule under the CPSA or similar rule, ban, standard, or regulation under any other act enforced by the Commission and which are imported for consumption or warehousing or distributed in commerce. Under section 14(a)(1)(A) of the CPSA, manufacturers and private labelers must issue a certificate, which “shall certify, based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA or any other Act enforced by the Commission.” CPSC regulations, at 16 CFR part 1110, limit the certificate requirement to importers and domestic manufacturers. Section 14(a)(1)(B) of the CPSA further requires that the certificate provided by the importer or domestic manufacturer “specify each such rule, ban, standard, or regulation applicable to the product.” The certificate described in section 14(a)(1) of the CPSA is known as a General Conformity Certification (GCC).

Section 14(a)(2) of the CPSA (15 U.S.C. 2063(a)(2)) establishes testing requirements for children’s products that are subject to a children’s product safety rule. (Section 3(a)(2) of the CPSA (15 U.S.C. 2052(a)(2)) defines a children’s product, in part, as a consumer product designed or intended primarily for children 12 years of age or younger.) Section 14(a)(2)(A) of the CPSA also states that, before a children’s product subject to a children’s product safety rule is imported for consumption or warehousing or distributed in commerce, the manufacturer or private

labeler of such children’s product must submit sufficient samples of the children’s product “or samples that are identical in all material respects to the product” to an accredited “third party conformity assessment body” to be tested for compliance with the children’s product safety rule. Based on such testing, the manufacturer or private labeler, under section 14(a)(2)(B) of the CPSA, must issue a certificate that certifies that such children’s product complies with the children’s product safety rule based on the assessment of a third party conformity assessment body accredited to perform such tests.

Section 14(i)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements. This provision applies to all consumer products that are subject to a product safety rule administered by the Commission. (On August 12, 2011, the President signed into law H.R. 2715, which amended both the CPSA and the CPSIA. Section 10(a) of H.R. 2715 redesignates what was identified as section 14(d) of the CPSA in the preamble of the proposed rule as section 14(i) of the CPSA; consequently, except where we are citing language from the proposed rule, the remainder of this document will refer to section 14(i) of the CPSA.)

Section 14(i)(2)(B) of the CPSA requires the Commission to establish protocols and standards for:

- Ensuring that a children’s product tested for compliance with a children’s product safety rule is subject to testing periodically and when there has been a material change in the product’s design or manufacturing process, including the sourcing of component parts;
- Testing of representative samples;
- Verifying that a children’s product tested by a conformity assessment body complies with applicable children’s product safety rules; and
- Safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

Section 14(i)(2)(B)(iii) of the CPSA provides for verification that a children’s product tested by a conformity assessment body complies with applicable children’s product safety rules. At this time, we are not imposing any verification obligations on manufacturers because we intend to conduct the verification ourselves under our inherent authorities while we gain more experience with the testing and certification requirements. When we find that a children’s product

<sup>1</sup> The Commission voted 3–2 to publish this final rule, with changes, in the **Federal Register**. Chairman Inez M. Tenenbaum, Commissioners Robert S. Adler and Thomas H. Moore voted to publish the final rule with changes. Commissioners Nancy A. Nord and Anne M. Northrup voted against publication of the final rule. Chairman Tenenbaum, Commissioner Adler, and Commissioner Moore issued a joint statement. Commissioner Nord and Commissioner Northrup issued statements. The statements can be found at <http://www.cpsc.gov/pr/statements.html>.

accompanied by a certificate of conformity does not pass the tests upon which the certification was based, we may initiate an investigation of the manufacturer, third party conformity assessment body, and any other relevant party in the supply chain, to determine the cause of the discrepancy.

To implement sections 14(a) and (d) (now renumbered by H.R. 2715 as section 14(i)) of the CPSA, as amended by section 102 of the CPSIA, we published a proposed rule in the **Federal Register** on May 20, 2010 (75 FR 28336). The proposed rule would:

- Define the elements of a “reasonable testing program” for purposes of section 14(a)(1)(A) of the CPSA;
- Establish the protocols and standards for continuing testing of children’s products under section 14(d)(2)(B)(i), (ii), and (iv) (renumbered as sections 14(i)(2)(B)(i), (ii), and (iv)) of the CPSA; and
- Describe the label that manufacturers may place on a consumer product to show that the product complies with the certification requirements for purposes of what was numbered previously as section 14(d)(2)(A) of the CPSA (now renumbered by H.R. 2715 as section 14(i)(2)(A) of the CPSA).

#### *B. H.R. 2715 and Its Impact on This Rulemaking*

On August 12, 2011, the President signed into law H.R. 2715. H.R. 2715 amended the CPSA and the CPSIA in several ways. For example, section 2, “Application of Third Party Testing Requirements,” of H.R. 2715, revised section 14(d) of the CPSA, in part, by:

- Renumbering the second paragraph of section 14(d) of the CPSA as section 14(i) of the CPSA. (When the CPSIA was enacted, it created, mistakenly, two paragraph (d)s in section 14 of the CPSA. The paragraph at issue in the proposed rule was the second of the two paragraphs numbered (d); H.R. 2715 contained a technical amendment to renumber the second paragraph (d) as a new paragraph (i) of section 14 of the CPSA);
- Revising section 14(i)(2)(B)(ii) of the CPSA to require the testing of “representative samples,” rather than the testing of “random samples”;
- Creating a new section 14(i)(3)(A) of the CPSA requiring, no later than 60 days after the date of enactment, that we “seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban,

standard, or regulation.” H.R. 2715 lists seven topics for public comment:

- The extent to which the use of materials subject to regulations of another government agency that requires third party testing of those materials may provide sufficient assurance of conformity with an applicable consumer product safety rule, ban, standard, or regulation without further third party testing;
  - The extent to which modification of the certification requirements may have the effect of reducing redundant third party testing by or on behalf of 2 or more importers of a product that is substantially similar or identical in all material respects;
  - The extent to which products with a substantial number of different components subject to third party testing may be evaluated to show compliance with an applicable rule, ban, standard, or regulation by third party testing of a subset of such components selected by a third party conformity assessment body;
  - The extent to which manufacturers with a substantial number of substantially similar products subject to third party testing may reasonably make use of sampling procedures that reduce the overall test burden without compromising the benefits of third party testing;
  - The extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations applicable under the CPSA;
  - The extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for testing consumer products subject to a third party testing requirement; and
  - Other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.
- Creating a new section 14(i)(3)(B) of the CPSA, requiring us to review the public comments and stating that we “may prescribe new or revised third party testing regulations if [we determine] that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations; and
  - Creating a new section 14(i)(4) of the CPSA, titled, “Special rules for small batch manufacturers,” to provide “alternative testing requirements” for

“covered products” manufactured by small batch manufacturers or to exempt small batch manufacturers from third party testing requirements. H.R. 2715 defines a “covered product” as “a consumer product manufactured by a small batch manufacturer where no more than 7,500 units of the same product were manufactured in the previous calendar year.” It defines a “small batch manufacturer,” in part, as “a manufacturer that had no more than \$1,000,000 in total gross revenue from sales of all consumer products in the previous calendar year.”

H.R. 2715 also contains (among other things) provisions on registration of small batch manufacturers and exclusions of certain materials from third party testing. For example, H.R. 2715 created a new section 14(i)(5)(A)(i) of the CPSA, which states that the third party testing requirements do not apply to “ordinary books or ordinary paper-based printed materials.”

The Commission has chosen to finalize those parts of the proposed rule that were not affected directly or significantly by H.R. 2715, and we will reserve other subparts or provisions in the final rule, pending our consideration and implementation of H.R. 2715. For example, because section 14(i)(2)(B)(ii) of the CPSA, as amended by H.R. 2715, now refers to the testing of “representative samples,” we have decided to remove § 1107.22 from subpart C of the final rule, which would have pertained to “Random Samples.”

### **III. Comments on the Proposed Rule and Our Responses**

Below, we describe and explain each subpart and section of the final rule, as well as describe and respond to the comments on the proposed rule. A summary of each of the commenters’ topics is presented, and each topic is followed by our response. For ease of reading, each comment will be prefaced by a numbered “Comment”; and each response will be prefaced by a corresponding numbered “Response.” Each “Comment” is numbered to help distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment’s value or importance or the order in which it was received. Comments on similar topics are grouped together.

#### *A. General Comments*

Several commenters addressed issues regarding testing and costs, generally. (Comment 1)—One commenter warned that because the overwhelming majority of consumer products sold in the United States are produced overseas,

nearly all of the work necessary to ensure compliance with the regulations will be performed overseas. The commenter stated that because the cost of compliance for foreign manufacturers can be relatively high—while the risks associated with noncompliance can be relatively low—it is important that our regulation balance the need for a high degree of assurance of compliance against the need to develop a practical regulatory structure that foreign manufacturers can and will implement.

(Response 1)—The final rule is designed not to be overly prescriptive, thereby giving manufacturers some flexibility in designing their testing and certification programs to be consistent with the statutory requirements. For example, the final rule allows the manufacturer to determine the number of samples that are tested, as long as the manufacturer has a high degree of assurance that the products represented by the samples are in compliance with all applicable children's product safety rules. Further, while the final rule requires that manufacturers document their compliance, it gives manufacturers the flexibility to determine how to maintain this information. In addition, the final rule does not require any documentation to be maintained in English or kept in the United States, except the certificate.

We also note that, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. H.R. 2715 directs us to seek public comment on seven specific issues, including the extent to which modification of the certification requirements may have the effect of reducing redundant third party testing by or on behalf of two or more importers of a product that is substantially similar or identical in all material respects, and other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable

consumer product safety rules, bans, standards, and regulations.

(Comment 2)—Two commenters stated that we should conduct a full cost-benefit analysis of the rule. One commenter added that costs of complying with the testing and certification rule, in combination with other requirements under the CPSIA and other rules administered by the CPSC, will result in a major rule with major implications to consumer product manufacturers, particularly children's product manufacturers, as well as to the entire supply chain. The commenter urged us to examine in greater detail, and to quantify, the full cost and burden of these rules. A third commenter implored us to consider the reduction in risk, if any, associated with each regulatory requirement and impose only those requirements that meaningfully enhance consumer safety in a way that makes increased costs and use of resources worthwhile.

(Response 2)—This rule is being promulgated under the Administrative Procedure Act and also section 3 of the CPSIA; neither authority requires us to conduct a cost-benefit analysis. Moreover, by allowing in CPSIA expedited rulemaking, Congress made it clear that it did not want the Commission engaging in any unnecessary delay in promulgating this rule. However, we agree that the final rule constitutes a major rule, as defined by the Congressional Review Act of 1996. While, in recognition of Congress's view as reflected in CPSIA, we decline to conduct a cost-benefit analysis for the final rule, we have changed the final rule to address some of the economic burden on manufacturers. Among the changes made to the final rule to reduce the burden are: (1) Reserving the subpart B requirements regarding a reasonable testing program;<sup>2</sup> (2) eliminating certain requirements of the proposed rule for children's products such as the remedial action plan; (3) reducing the recordkeeping requirements in several respects; and (4) allowing the use of in-house ISO/IEC 17025:2005 laboratories to reduce the frequency of third party periodic testing. By way of further example, with regard to the reduction in the recordkeeping requirements, the final rule does not require records to be

<sup>2</sup> It should be noted, however, that although we are not finalizing subpart B at this time, manufacturers of non-children's products that are subject to a product safety rule, ban, standard, or regulation are still obligated by the CPSA, as amended by the CPSIA, to certify that their products comply with all applicable safety rule[s] based on a test of each product or a reasonable testing program.

kept in the United States, nor does it require records to be translated into English, unless requested.

Additionally, we note that a cost-benefit analysis would not necessarily be confined to manufacturers or those in a supply chain (as implied by one commenter). We expect, for instance, that consumers will benefit from the testing and certification of consumer products, particularly if such testing revealed potential problems associated with a product or its components, or if such testing prompted a manufacturer to redesign or remanufacture the product to make it safer.

(Comment 3)—One commenter stated that some retailers are requiring many manufacturers to submit their products to as many as four different laboratories because the retailers want to see test results from specific laboratories. The commenter stated that we should clarify to retailers that this redundant testing is not necessary.

(Response 3)—The preamble to the proposed rule stated that retailers and sellers of children's products can rely on certificates provided by finished product certifiers—without conducting additional testing themselves—if those certificates are based on testing conducted by a CPSC-accepted third party conformity assessment body (75 FR at 28337).

#### *B. Proposed Subpart A—General Provisions*

##### 1. Proposed § 1107.1—Purpose

Proposed § 1107.1 would state that part 1107 establishes the requirements for a reasonable testing program for non-children's products; third party conformity assessment body testing to support certification and continuing testing of children's products; and labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(1), and (a)(2), (d)(2)(B) of the CPSA (15 U.S.C. 2063(a)(1), (a)(2), (d)(2)(B)).

We did not receive any comments on this section. However, because we have decided to reserve subpart B, which would pertain to the reasonable testing program for non-children's products, we have removed the reference to the "reasonable testing program for non-children's products." (We explain our decision to reserve subpart B of the proposed rule in part B.2 of this preamble below.)

Additionally, because H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSA to refer to testing of "representative" rather than "random" samples, we have, on our own initiative,

elect to simplify § 1107.1 to reflect the final rule's narrower purpose and have made minor, non-substantive changes to follow the language of the statute. This helps clarify which requirements in the statute this final rule is intended to address and which have been reserved for a later date. Additionally, proposed § 1107.1 was silent regarding procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body, even though proposed § 1107.24, "Undue influence," would contain such safeguards. Consequently, the final rule now mentions the establishment of procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. Thus, § 1107.1 now states that the part establishes the protocols and standards for ensuring continued testing of children's products periodically and when there has been a material change in the product's design or manufacturing process and safeguarding against the exercise of undue influence by a manufacturer on a third party conformity assessment body. It also establishes a program for labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(2) and (i)(2)(B) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)(2) and (i)(2)(B)).

## 2. Proposed § 1107.2—Definitions

Proposed § 1107.2 would define various terms used in the rule.

### a. CPSA

Proposed § 1107.2 would define "CPSA" to mean the Consumer Product Safety Act.

We received no comments on this definition and have finalized it without change.

### b. CPSC

Proposed § 1107.2 would define "CPSC" to mean the Consumer Product Safety Commission.

We received no comments on this definition and have finalized it without change.

### c. CPSIA

Proposed § 1107.2 would define "CPSIA" to mean the Consumer Product Safety Improvement Act of 2008.

We received no comments on this definition and have finalized it without change.

### d. Detailed Bill of Materials

Proposed § 1107.2 would define "detailed bill of materials" to mean a

list of the raw materials, subassemblies, intermediate assemblies, subcomponent parts, component parts, and the quantities of each needed to manufacture a finished product.

We received no comments on this definition. However, because the term "detailed bill of materials" appeared only in proposed § 1107.10(b)(1) (which would require a product specification as part of the reasonable testing program), and because the final rule now reserves subpart B, we have removed the definition of "detailed bill of materials" from the final rule.

### e. Due Care

Proposed § 1107.2 would define "due care" to mean the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances.

(Comment 4)—One commenter noted that the due care requirement only applies to a few specific provisions of the proposed rule, such as proposed § 1107.23(a) regarding "material change" in the product's design, manufacturing process, or sourcing of component parts. In some instances, this defined duty of "due care" would be coupled with a CPSC-created standard of "high degree of assurance." The commenter appreciated our recognition that both the "due care" standard of conduct and the "high degree of assurance" standard for compliance are anchored in the judgment and knowledge of the manufacturer. For that reason, the commenter felt that the due care requirement should have general applicability to all elements of compliance for implementation of the CPSIA's testing and certification requirements. The commenter stated that manufacturers should not have to wonder whether more than their exercise of reasonable judgment and practice, based on their manufacturing experience and sound knowledge of the product, is required for aspects of the rules that do not explicitly reference these standards.

(Response 4)—The definition of "due care" in § 1107.2 refers to the actions of a prudent and competent person. We expect that all parties will exercise prudence and competence in the testing and certification of products. The final rule emphasizes due care in particular sections, as noted by the commenter, because these are areas that require additional care in order to prevent noncompliant products from being produced and certified.

We recognize that manufacturers' knowledge of their products and their

manufacture can serve as a basis for determining what steps are necessary to achieve a high degree of assurance that their products comply with the applicable product safety rules. Based on that knowledge, manufacturers are uniquely situated to know what actions are necessary to exercise due care and demonstrate a high degree of assurance regarding their specific circumstances.

On our own initiative, we have revised the definition of "due care" in the final rule. The final rule's definition of "due care" includes a sentence stating that "Due care does not permit willful ignorance." This is not intended to be a substantive change because any party who is willfully ignorant of material facts, by definition, would not be exercising due care. However, the Commission wants to emphasize in the final rule that a party cannot purposely avoid knowing their business partner's testing and certification practices to avoid violating section 19 of the CPSA. A party will not be shielded from violating section 19 of the CPSA when that party knows or should know about testing and/or certification problems which may affect the ability of a consumer product to be compliant with all rules, bans, standards, or regulations. Certifiers and testing parties have an obligation to resolve known or knowable problems with testing and/or certification before relying upon or passing on test reports or certifications.

### f. High Degree of Assurance

Proposed § 1107.2 would define "high degree of assurance" as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."

(Comment 5)—Multiple commenters questioned the definition of a "high degree of assurance." One commenter would like the rule to define the term "high degree of assurance" in a more understandable or quantitative way. The commenter considered the term to be confusing and misleading and believed this could lead to unnecessary conflicts between manufacturers and conformity assessment bodies when a judgment has to be made in certain cases. The commenter wondered if this requirement is targeting the design area, manufacturing process control, quality control, or testing procedures.

Another commenter said that manufacturers would benefit from additional guidance on how to achieve a "high degree of assurance" through their testing programs. The preamble to the proposed rule referred to a 95 percent statistical significance level as constituting a "high degree" of

assurance, but the proposed rule would not mandate a 95 percent confidence threshold. The commenter asked what factors would permit a manufacturer to satisfy the “high degree of assurance” requirement with a statistical significance level below 95 percent and asked us to provide an example of a situation where a manufacturer could still achieve a high degree of assurance with less than 95 percent assurance.

Another commenter argued that the term “high degree of assurance” is subjective and subject to varied interpretations. The commenter suggested that a statistical confidence limit would help remove the subjectivity and set a specific threshold by which we can enforce our rules better. The commenter also was concerned that the wording may lead some manufacturers to believe that they do not have to test to the standard in all cases, as long as they foresee little risk of noncompliance, or assume that the risk is low of being discovered having noncompliant products in the marketplace. The commenter said the final rule should clarify that testing to applicable standards is required.

(Response 5)—The determination of a “high degree of assurance” for a given product will vary by industry, product, component part, and by manufacturer. Therefore, selecting an example using a hypothetical certifier would be of little value to manufacturers. We have intentionally defined the term in a manner that allows the manufacturer the flexibility to develop a testing program to ensure their product complies with all applicable children’s product safety rules. This rule provides broad protocols and standards for regulated firms to follow and adapt to their particularized needs given their products and processes. The use of quantitative values for the definition of “high degree of assurance” could lead to difficulties for some manufacturers. The preamble to the proposed rule stated: “We decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level because there may be difficulty in applying the statistical methods to all manufacturing processes” (75 FR 28344). The intent of the definition is to enable a manufacturer to have a degree of confidence, based on evidence (rather than only on a belief) that all of the products manufactured are compliant with the applicable product safety rules. Knowledge of a product’s design and how it is manufactured, control over component parts, and measurements showing consistent performance, are some elements that can be used to

demonstrate a “high degree of assurance.”

As for the commenter asking us to clarify that testing to applicable standards is required, § 1107.20 (a) of the final rule states that manufacturers must submit samples of a children’s product to a third party conformity assessment body for testing. We believe these statements are clear enough to convey that certification testing involves tests.

(Comment 6)—Two commenters agreed that a numerical target for defining what constitutes a high degree of assurance—in the context of programs based on good manufacturing practices (GMP)—is misplaced. One commenter noted that the explanation of the definition of “high degree of assurance” provided in the preamble to the proposed rule (75 FR at 28344) implies that we prefer the 95 percent statistical level of confidence for a high-degree-of-assurance approach and consider it the default. The commenter is concerned that the 95-percent-confidence-level language may prompt third party conformity assessment bodies and retailers to adopt standardized testing protocols that demand large sample sizes, which will be a particular burden for the initial certification and may not be warranted in many cases. The commenter expressed the belief that the goal, across a broad range of different products that are subject to different manufacturing requirements and material sourcing, must be a standard that correlates “a high degree of assurance” with an “evidence-based demonstration of consistent performance” that relies more appropriately upon process controls to assure conformance. The commenter indicated that, while generally accepted process controls may include statistical sampling as part of process control programs, in and of themselves, they are not preferable to good manufacturing practices. The commenter said that the final rule must be clear in this regard.

(Response 6)—Standards for GMPs are generally industry-specific in areas such as: Cosmetics, pharmaceutical operations, food handling, and medical devices. It is unlikely that any GMP-based program would be deemed workable or acceptable for all children’s product manufacturing methods.

A certifier’s determination that a product complies—with a high degree of assurance—with the applicable children’s product safety rules, may derive from statistically based testing, the application of good manufacturing practices, or other knowledge of the product and its manufacture. Because

GMP-based programs are industry-specific, we disagree with the commenter’s assertion that the programs are preferable to other accepted process controls in all manufacturing situations.

The final rule defines a “high degree of assurance” in general terms because the definition is intended to be applied to a wide variety of products that use many different manufacturing processes. Customizing the definition of “high degree of assurance” to fit one type of product or GMP-based program will necessarily increase the difficulty of manufacturers applying the definition to dissimilar products or manufacturing processes. Further, because GMP-based programs vary across industries—and the comments were not specific about which aspect(s) of a GMP program we should adopt, or which GMPs we should adopt—we cannot revise the definition, as requested by the commenter.

As for the commenter who interpreted the preamble to the proposed rule as expressing a preference for a 95 percent confidence level, we do not consider a numerically based definition of a “high degree of assurance” to be the default position. Defining a “high degree of assurance” with respect to a 95 percent probability or confidence level would be difficult to apply to all manufacturing processes for children’s products. Defining a “high degree of assurance” as a 95 percent, or higher, probability or confidence level could result in greater testing demands on small manufacturers. As discussed in the preamble of the proposed rule (75 FR at 28344), a statistical definition is not needed in order to provide an evidence-based high degree of assurance.

Regarding the concern that conformity assessment bodies and retailers may require large numbers of samples for certification testing, the children’s product certifier (not the conformity assessment body or retailer) specifies the number of samples to be tested. The final rule requires the number of samples to be sufficient to give the certifier a high degree of assurance that the tests conducted demonstrate accurately the ability of the product to comply with the applicable children’s product safety rules. As we previously stated in the preamble to the proposed rule:

The Commission wants to emphasize to retailers and sellers of children’s products that they can rely on certificates provided by product suppliers if those certificates are based on testing conducted by a third party conformity assessment body.

75 FR at 28337.

(Comment 7)—Two commenters contended that the proposed definition of a “high degree of assurance” lacks clarity. Both commenters said that the rule should have additional examples of what constitutes “a high degree of assurance.” One commenter acknowledged that the discussion in the preamble to the proposed rule makes clear that the definition mandates no specific formula (75 FR at 28344). However, the commenter noted that the preamble to the proposed rule gave no specific examples, other than the use of statistical methods. The commenter argued that the final rule should recognize other means of achieving this confidence level, including ways that do not rely solely on product testing or statistical methods. These methods include appropriate quality assurance processes and risk management. Quality assurance processes can include: Factory/supplier evaluations, design reviews, manufacturing process controls, process auditing, or similar controls or reviews. Risk management includes: Analysis of a given possible failure, the likelihood of the failure, and the potential consequences associated with the failure. The commenter argued that importers can use these activities to boost desired outcomes and reduce unexpected outcomes; and the commenter further maintained that the activities can be performed in a feedback loop that facilitates true root-cause analysis and correction, if there is a failure.

The commenters suggested substitute definitions for “a high degree of assurance” that are practically identical. One suggested definition reads: “A high degree of assurance means an evidence-based determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.”

Acceptable evidence-based determinations may be based on evidence derived through any appropriate process or control or combination of processes and/or controls, such as (but not limited to):

- Design validation;
- Manufacturing process control audits;
- In-process manufacturing controls, measurements, and tests;
- Component and material testing, as defined in 16 CFR part 1109;
- Finished product testing;
- Raw materials certification; and
- Other controls or processes that provide information about the safety or compliance of a product.

The other commenter’s suggested definition reads: “*High degree of assurance* means an evidence-based

determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. Acceptable determinations may be based on evidence derived through any appropriate tool or control methodology (or combination of tools and/or control methodologies), such as but not limited to:

- Design Validation
- Process Validation
- Manufacturing Process Control Audits
- Raw material validation and controls
- In-process manufacturing controls, measurements, and tests
- Component and material testing as defined at 16 CFR part 1109
- Finished Product Testing”

(Response 7)—The commenters are correct that certifiers can use process controls, mathematical techniques, simulations, and other aspects of a product and its manufacture, as part of the basis for determining whether a particular product complies with the applicable product safety rules with a high degree of assurance. The commenters also are correct that the preamble to the proposed rule (75 FR at 28344) provided statistically based examples in the definition of a “high degree of assurance.” However, a method on the commenters’ list may be adequate for one rule, but inadequate for another. As an example, *Design Validation* may be a good technique to ensure that a toy does not have a hole large enough to allow access to a sharp edge or point. However, *Design Validation* may be inadequate for controlling lead content because its techniques are ill-suited for controlling continuing production of component parts. As another example, component part testing is a useful technique for determining the chemical content of lead and the prohibited phthalates, but it is inadequate for determining compliance to the pacifier pull tests because the entire product is required to conduct the test. “A high degree of assurance” is defined in general terms because it is intended to be applied to a wide variety of products that use many different manufacturing processes. Providing a list of the intended applications as part of the definition would introduce the risk of a manufacturer applying techniques that are inappropriate for evaluating the applicable children’s product safety rule.

Therefore, we decline to amend the definition of “a high degree of assurance,” as suggested by the commenters. Specific examples are not universally applicable; and therefore,

they should not be included in the definition of “a high degree of assurance.” Any such list necessarily would be underinclusive or possibly confusing or misleading. Additionally, certification and periodic testing of children’s products must be based on tests of the finished product, or its component parts, sufficient to show compliance (or continuing compliance, in the case of periodic testing) with all applicable children’s product safety rules. A definition of a “high degree of assurance,” that includes methods other than testing, might lead some certifiers to conclude mistakenly that certification or periodic test requirements might be met by means other than testing.

(Comment 8)—One commenter suggested that the final rule allow a company’s prior safety record to replace product safety testing as evidence that a company has met the requirement for a high degree of assurance (“HDA”). The commenter wrote:

The “high degree of assurance” should be based on an overall assessment of the safety record of the company. It should NOT be based on the results of an individual product, even if recalled or deemed dangerous.

The commenter pointed out that its company had a very good safety record. The commenter added:

With this record over so many years, our company should be deemed to have satisfied this HDA requirement and be endorsed as having a reasonable testing program without further inquiry.

(Response 8)—Section 14(a)(2) of the CPSA makes clear that children’s product certification is based upon third party testing of the product and not a company’s safety record. For this reason, the final rule does not provide relief from the testing requirements in the statute. In addition, the commenter’s suggestion that a manufacturer should be allowed to rely upon its prior safety record to demonstrate a high degree of assurance would be a difficult concept to apply in practice because of the likely changes in any given manufacturer’s safety record over time and potential disagreements as to whether a product caused a safety problem, whether the safety problem resulted from product misuse, and whether safety issues had to occur at a particular rate of frequency before testing was warranted.

(Comment 9)—One commenter stated that a “high degree of assurance” could be provided best by using an accredited product certification program that meets the requirements of the International Standards Organization/International Electrotechnical Commission (ISO/IEC) Guide 65, *General requirements for bodies operating product certification*

systems, and the fundamentals of System 5 product certification requirements of ISO/IEC Guide 67, *Conformity assessment—Fundamentals of product certification*.

(Response 9)—The various activities a certification body undertakes, such as testing, conformity assessment, and surveillance can be used to demonstrate a high degree of assurance that a product complies with the applicable product safety rules. However, the techniques used by certification bodies are not the only means a manufacturer could use. Process control techniques, failure modes and effects analyses, and other quality assurance methods, depending upon the product under consideration, could be as effective as certification body methods. Because we want to give certifiers the flexibility to decide which methods apply best to their particular products, we decline to define a “high degree of assurance” using ISO/IEC Guide 65 and Guide 67 requirements. A manufacturer who wishes to use those requirements to ensure a high degree of assurance of compliance may do so. However, we reiterate that testing in support of certification of a children’s product must be performed by a CPSC-accepted third party conformity assessment body whose scope of accreditation includes the tests required for certification, and certification of a product cannot be delegated to another party, such as a certification body.

(Comment 10)—A commenter suggested that the language related to periodic testing intervals and sample sizes is inconsistent in the preamble to the proposed rule. The commenter conceded that it is difficult to specify the exact number of products that must be tested in order to reach a high degree of assurance that a product is compliant. The commenter noted that the response to comments section of the preamble to the proposed rule titled, *Additional Third Party Testing Requirements for Children’s Products*, stated that “the sample size for periodic testing will depend upon the number of samples that need to be tested to provide that statistical assurance” (75 FR at 28342). The commenter agreed with this statement but noted the inconsistency between the language used in that section and the language found in the response to comments section titled, *The Reasonable Testing Program*, which specifies that the testing intervals must provide “reasonable assurance” that the product meets the requirements of the applicable product safety rules (75 FR at 28338). The commenter noted that there is a difference between a “high degree of assurance” and “reasonable

assurance.” The commenter expressed the belief that the testing program should be statistically based, such that a confidence level of 95 percent must be achieved to indicate compliance. This requirement would eliminate the possibility of testing only a single sample to indicate compliance, the commenter asserted.

(Response 10)—In the preamble to the proposed rule, under the response to comments section, *Additional Third Party Testing Requirements for Children’s Products* (75 FR at 28342), we stated the following:

If a high degree of assurance is interpreted to be a statistical likelihood of not producing noncompliant products, the sample size for periodic testing will depend upon the number of samples that need to be tested to provide *that* statistical assurance (italics added) \* \* \*

The word “that” refers to “a high degree of assurance,” which appears at the beginning of the sentence. With respect to the other alleged inconsistencies mentioned in the comment, it is worth noting that the preamble to the proposed rule uses the phrase “high degree of assurance” 20 times; whereas, the codified text of the proposed rule does not use the term “reasonable assurance” at all. The term “reasonable assurance” appears only once in the preamble to the proposed rule, in the introduction to the response to comments section titled, *The Reasonable Testing Program*, where it is listed as one of the previous questions that we asked in the **Federal Register** notice announcing the December 2009 public workshop.

We also do not agree with the commenter that there should be a specific probability level (*i.e.*, 95 percent) in the definition of “a high degree of assurance.” As previously noted in the preamble to the proposed rule (75 FR at 28344), “we decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level because there may be difficulty in applying the statistical methods to all manufacturing processes.” Many manufacturing processes, such as low-volume and continuous manufacturing, are ill-suited to use a sampling technique for quality control purposes. In addition, for small-volume manufacturers, the number of samples required to achieve 95 percent confidence could be excessive, even to the point of requiring all of the products manufactured to be tested. Because the final rule’s testing requirements apply to a wide variety of products, manufacturers, and manufacturing processes, the rule must give manufacturers the flexibility to

determine the best way to comply with the testing requirements.

The intent of the definition is for a manufacturer to have a high degree of assurance based upon evidence (rather than only a belief) that all of the products manufactured are compliant with the applicable safety rules. Knowledge of the product’s design and how the product is manufactured, control over component parts, measurements showing consistent or inconsistent performance, the associated hazard, and many other elements such as these, can be used to determine the number of samples required for certification and for the periodic testing intervals, as noted in the final rule.

#### g. Identical in All Material Respects

Proposed § 1107.2 would define “identical in all material respects” to mean that there is no difference with respect to compliance to the applicable rules between the samples and the finished product.

(Comment 11)—Several commenters asked us to clarify the definition of “identical in all material respects.” One commenter said that the definition appears absolute in that it does not allow any “difference with respect to compliance.” The commenter indicated that such a definition would make testing requirements unnecessarily rigid and costly.

Another commenter contended that the definition of “identical in all material respects” cannot be absolute. One commenter would revise the definition to read: “‘*Identical in all material respects*’ means there is no difference between the sample and the finished product that could affect compliance to the applicable rules.” Another commenter suggested revising the definition of “identical in all material respects” to mean “to a high degree of assurance, there is no difference between the samples and the finished product that is material to compliance of the applicable rule.” One commenter suggested that the definition of “identical in all material respects” should mean “a manufacturer possess [sic] a reasonable belief that, there is no difference between the samples and the finished product is not materially compliant.”

(Response 11)—We do not regard the definitions suggested by the commenters to be improvements of the existing definition of “identical in all material respects.” For example, defining “identical in all material respects” to mean “there is no difference between the sample and the finished product that could affect compliance to the applicable rules”

appears to be so similar to the proposed definition that adopting the commenter's suggested definition would not alter the rule. Samples used for certification testing and the finished product may be different—just not different in any way that would affect the sample's ability to demonstrate compliance of the finished product. The definition of "identical in all material respects" is intended to emphasize that if anything other than the finished product is subjected to testing, then the characteristics of that sample must be identical to the testing of the finished product, insofar as complying with the applicable product safety rule. Otherwise, the test may not indicate that the finished product, in fact, complies with the applicable product safety rule.

The second definition suggested for "identical in all material respects" ("To a high degree of assurance, there is no difference between the samples and the finished product that is material to compliance of the applicable rule") also does not emphasize adequately that the finished product is what must comply with the applicable rules. In addition, using the phrase "to a high degree of assurance" in describing the similarity (with respect to conformance to the applicable rules), results in some doubt that the samples, in fact, are "identical in all material respects." Further, § 1107.20(a) of the final rule states that manufacturers must submit a sufficient number of samples of a children's product, or samples that are identical in all material respects to the children's product, to a third party conformity assessment body for testing to support certification. The number of samples selected must provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules. Using a "high degree of assurance" in the definition of "samples" would involve a double use of the term with no corresponding increase in clarity.

In a similar manner, the third definition suggested for "identical in all material respects," which uses the phrase "a reasonable belief," introduces doubt that the samples are identical to the finished product with respect to compliance. Additionally, "a reasonable belief" standard in the definition would result in an inquiry into the state of mind of a particular manufacturer and could lead to disagreements between the CPSC and manufacturers over whether a manufacturer's belief was "reasonable" in a specific instance. Further, the commenter did not explain or clarify their interpretation of the phrase

"materially compliant"; the absence of such an explanation or interpretation would result in additional uncertainty in the definition.

Nevertheless, on our own initiative, we have revised the definition of "identical in all material respects" to make minor clarifications to improve the definition's accuracy and consistency with the statute. For example, the proposed definition would refer to "compliance to the applicable rules;" the final definition now adds: "bans, standards, or regulations" after "rules," to be more consistent with section 14(f)(1) of the CPSA. We also have revised the phrase "between the samples and the finished product" to read: "between the samples to be tested for compliance and the finished product distributed in commerce," to reflect that, under the final rule, the items that must be "identical in all material respects" are the samples that are to be tested for compliance (as opposed to samples that are tested for any other purpose) and the product that is actually distributed in commerce.

(Comment 12)—One commenter urged us to state that the phrase "identical in all material respects" is intended to be consistent with the "objectively reasonable basis" standard from 16 CFR part 1633, and that we would consider individual subordinate mattresses that meet the requirements of 16 CFR 1633 to be "identical in all material respects" to the qualified prototype to which a specific mattress is subordinate.

(Response 12)—We agree with the commenter that "identical in all material respects" is consistent with a demonstration on an "objectively reasonable basis," as stated in 16 CFR § 1633.4(b)(3). We consider individual subordinate mattresses that meet the requirements of 16 CFR part 1633 to be "identical in all material respects" to the qualified prototype to which a specific mattress is subordinate.

#### h. Manufacturer

Proposed § 1107.2 would define "manufacturer" as "the parties responsible for certification of a consumer product pursuant to 16 CFR part 1110."

We received no comments on this definition and have finalized it without change.

#### i. Manufacturing Process

Proposed § 1107.2 would define "manufacturing process" as "the techniques, fixtures, tools, materials, and personnel used to create the component parts and assemble a finished product."

(Comment 13)—Two commenters noted that the proposed definition includes "personnel used to create the component parts and assemble a finished product." The commenters argued that this should not be construed to mean that any change in the employees who are involved in the production of a part or product is equivalent to a change in the manufacturing process.

(Response 13)—Regarding the commenters' suggestion on the definition of "manufacturing process," the commenters may be confusing a change in the manufacturing process with a material change that could affect compliance to an applicable product safety rule. The commenters are partly correct that any change in personnel involved with a manufacturing process does not necessarily constitute a material change with respect to the product's compliance. However, for manufacturing processes that rely on high levels of craftsmanship or technical expertise, such a personnel change could affect compliance and, therefore, might be considered a material change to the manufacturing process.

Therefore, we have finalized the definition of "manufacturing process" without change.

#### j. Production Testing Plan

Proposed § 1107.2 would define "production testing plan" as "a document that shows what tests must be performed and the frequency at which those tests must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable safety rules."

We received no comments on this definition, but, on our own initiative, we have chosen to remove it from the final rule. We have removed the definition because it is duplicative of the description and requirements of "a production testing plan" in § 1107.21(c)(2) of the final rule.

#### k. Third Party Conformity Assessment Body

Proposed § 1107.2 would define "third party conformity assessment body" to mean a third party conformity assessment body recognized by the CPSC to conduct certification testing on children's products.

We received no comments on this definition. However, on our own initiative, we have revised the definition by making editorial changes to describe more accurately our accreditation process and to indicate that the third party conformity assessment body's scope of accreditation must include the

applicable CPSC-required tests. Thus, the final rule now defines “third party conformity assessment body” as “a testing laboratory whose accreditation has been accepted by the CPSC to conduct certification testing on children’s products. Only third party conformity assessment bodies whose scope of accreditation includes the applicable required tests can be used for children’s product certification or periodic testing purposes.”

#### C. Proposed Subpart B—Reasonable Testing Program for Non-Children’s Products

Proposed subpart B would consist of one provision and would describe the “reasonable testing program” for non-children’s products. For example, proposed § 1107.10(a) would explain that, except as otherwise provided by a specific CPSC regulation or a specific standard prescribed by law, a manufacturer certifying a product pursuant to a reasonable testing program must ensure that the program “provides a high degree of assurance that the consumer products covered by the program will comply with all applicable rules, bans, standards, or regulations.” Proposed § 1107.10(b) would state that a reasonable testing program must consist of five elements: (1) Product specification; (2) certification tests; (3) a production testing plan; (4) a remedial action plan; and (5) recordkeeping. The proposal would describe, in greater detail, the requirements for each element of the reasonable testing program.

We received many comments on proposed subpart B. The comments addressed issues regarding the proposed provisions of a reasonable testing program on topics such as: product specifications, certification tests, samples for certification testing, production testing, remedial action, and recordkeeping. The commenters raised many concerns about the cost and burden of the proposal as well as practical issues, which illustrates the difficulty of drafting a regulation that can apply to many different types of products and manufacturing processes, yet still provide sufficient guidance to enable manufacturers to implement the requirements of a reasonable testing program effectively. Consequently, we are deferring action with respect to finalizing subpart B. We will reserve subpart B in the final rule and, except as stated otherwise in this preamble, continue evaluating the issues raised in the comments regarding a reasonable testing program. We note, however, that our deferral of action does not remove the responsibility of manufacturers,

under section 14(a)(1) of the CPSA to certify based on tests of their products or based on reasonable testing programs that their products comply with all rules, bans, standards, or regulations applicable to such products.

#### D. Proposed Subpart C—Certification of Children’s Products

Proposed subpart C would contain the requirements for the certification of children’s products. The proposed subpart C would consist of seven sections and would implement most requirements in section 14(i)(2)(B) of the CPSA.

##### 1. General Comments

Several commenters raised issues with respect to proposed subpart C generally, or on general concepts, such as testing.

(Comment 14)—One commenter argued that the terms “reasonable assurance” and “sufficient number of samples” are likely to result in widely disparate interpretations. The commenter urged that “reasonable assurance” should be defined as a statistically significant number with a confidence level of 95 percent, based on testing enough samples to provide statistical validity. The commenter said that setting a specific confidence limit would enable us to enforce this section by avoiding subjectivity and by creating uniformity and consistency among manufacturers and conformity assessment bodies.

The commenter noted that “upstream” controls (*i.e.*, processes, inspections, and tests conducted prior to or during product assembly intended to assure product quality), product risk assessments, and design analyses are reasonable tools for manufacturers to use but currently are not rigorous or specific enough to ensure “downstream” compliance. Until they are, compliance must be determined by final product testing, the commenter asserted.

(Response 14)—We decline to adopt the suggestion to set a 95 percent confidence level based on testing enough samples to provide statistical validity. Many manufacturing processes, such as those using continuous flow processes, are ill-suited to use a sampling technique for quality control purposes. In addition, for small-volume manufacturers, the number of samples required to achieve 95 percent confidence could be excessive, even to the point of requiring all of the products manufactured to be tested.

Because the final rule’s testing requirements apply to a wide variety of children’s products, as well as to

manufacturers of various sizes and different manufacturing processes, the rule must be flexible enough to allow the manufacturer to determine the best way to comply with the rule’s requirements. We are aware of numerous “upstream” quality assurance tools and processes that are widely used to ensure high levels of product performance. For example, techniques such as component part testing are particularly well-suited for determining compliance with the lead content limits for accessible parts on children’s products. Numerous international standards address quality control and assurance processes applied “upstream” in the product production process and can be used to extend the maximum periodic testing interval. Thus, we disagree with the commenter that none of these quality assurance tools and processes is rigorous or specific enough to ensure compliance.

(Comment 15)—One commenter recommended a system of product risk assessment that would tailor the third party certification schedule for low-volume firms, as follows:

Children’s products: High-risk children’s products would require third party certification annually. Low-risk children’s products would require third party certification every three years.

The commenter said that any test failure automatically would move the product into the next most stringent category. This system would focus the inspection of products on products that are the most dangerous to public safety. The commenter stated that an unintended consequence of this strategy would be to reward firms that make the safest products.

(Response 15)—The commenter appears to be applying the proposed low-volume exception to periodic testing (stated in proposed § 1107.21(d)) to certification testing. The low-volume exception did not apply to certification testing. There is no schedule for any manufacturer for when a product is subject to certification testing, regardless of production volume. Instead, periodic testing is required for children’s products to ensure continued compliance with a high degree of assurance.

Section 14(a)(2) of the CPSA requires certification testing for children’s products before they may be imported for consumption or warehousing or distributed in commerce. This initial testing of children’s products does not depend on product risk. Continuing compliance is demonstrated through periodic testing for children’s products, which specifies a maximum testing

interval, based on the implementation of a periodic testing plan by the manufacturer. The final rule allows a manufacturer to consider risk to the extent it permits consideration of “the potential for serious injury or death resulting from a noncompliant product” as a factor in determining the appropriate periodic testing interval under a periodic testing plan.

Regarding the commenter’s suggestion of devising a system of categorizing all children’s and non-children’s products subject to an applicable rule into risk categories, such a system would require a separate rulemaking effort and is beyond the scope of this rule.

(Comment 16)—One commenter noted that the proposed rule did not use recognized industry terminology consistently. The commenter noted that the proposed rule relies on the terms “test” or “testing,” as if all consumer product safety requirements could be evaluated by performing tests to ensure ongoing compliance. The commenter noted that, while full product testing is appropriate in some cases, current consumer product safety regulations imply or specify evaluation activities, not considered to be actual testing (*e.g.*, inspections, reviews, audits), may be appropriate.

The commenter noted that it recommended previously that we refer to Annex A of ISO/IEC 17000, *Conformity assessment—Vocabulary and general principles*, which provides a general description of the functional approach to activities that constitute conformity assessment, to address the question of the interpretation of the use of the terms “test” or “testing.”

(Response 16)—The word “test” was chosen because of its use in section 14(a) of the CPSA. “Certification tests” are tests on samples of the product that are identical in all material respects to the finished product. Section 14(i)(2)(B)(i) of the CPSA states that children’s products are subject to testing periodically and after a material change.

The words “test” and “testing” are used throughout the final rule to mean a process used to determine whether a product is compliant with the applicable product safety rules. The process is geared to the particular product and specific safety rule. As such, testing may include inspection of labels and manuals, audits, and measurements to determine compliance with the applicable product safety rules. We believe that the definition of “test” and “testing” are clear.

(Comment 17)—One commenter noted that we are not allowing the use of existing federally registered certification marks of third party

conformity assessment bodies as an acceptable substitute for a certificate of conformity. The commenter added that introducing the new certificate of conformity will cause immediate confusion in the marketplace. The commenter suggested that we should have to justify, through a comprehensive and independent study, why we are departing from the existing system and why our proposed system would be better and more reliable.

Another commenter stated that we should recognize certification marks issued by established third party certification programs as a substitute for the certificates of conformity described in the proposed rule when the product has been certified as compliant with associated product standards through a program that reflects CPSA requirements by an ISO/IEC Guide 65-accredited certification body.

(Response 17)—Certification marks are symbols that a manufacturer is authorized to affix to their product to indicate that the product has been certified by a certification body. Third party certification involves testing, declarations of conformance, factory inspections, and continuing surveillance activities. The certification body attests that the product complies with the specified product safety rules that were evaluated.

A certification mark does not contain the information required on a certificate by section 14(g) of the CPSA and cannot be used as a substitute for a Children’s Product Certificate. Section 14(a)(2) of the CPSA requires manufacturers of a consumer product that is subject to an applicable children’s product safety rule to issue a certificate certifying conformance of the children’s product to the applicable children’s product safety rules. Section 14(a)(2) of the CPSA does not allow a party other than the manufacturer, importer, or private labeler to issue a Children’s Product Certificate.

Since the CPSIA was enacted in 2008, we have not observed immediate confusion in the marketplace regarding certificates. As noted above, certification marks cannot be used as a substitute for certificates if there is confusion in the marketplace. Thus, because section 14(a) of the CPSA requires the manufacturer to issue a certificate of conformity, an independent study is not warranted.

Furthermore, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent

with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 18)—One commenter noted that a publisher of ordinary books may have varying titles and content, but all of the books are made of the same materials in the same manner. The commenter asserted that the differences between ordinary books are not material to compliance with the applicable rules. Accordingly, the commenter said that having accredited third party conformity assessment body testing for a finished book would constitute finished product testing for all other books (International Standard Book Numbers, or ISBNs) that do not materially differ from the tested book with respect to compliance with CPSC safety standards. The commenter said a publisher with a reasonable testing program and a product without material changes could rely on the component part certifications for all materials published within a 2-year period.

(Response 18)—Section 14(i)(5)(A)(i) of the CPSA, as amended by H.R. 2715, excludes ordinary books and ordinary paper-based printed materials from the third party testing requirements in 14(a)(2) of the CPSA. Additionally, the final rule reserves subpart B, which would pertain to a reasonable testing program for non-children’s products. Therefore, it is unnecessary for us to consider how third party testing results for a book might be extended to all other books.

(Comment 19)—One commenter asserted that only good design and comprehensive design review by qualified individuals will improve the safety of products. Therefore, the commenter suggested that we require “design hazard analysis” in the certification of children’s products section of the final rule. “Design hazard analysis,” according to the commenter, identifies potential safety hazards in a consumer product that result from the design of the product. It involves determinations made by skilled professionals including engineers, chemists, and biologists about the features of a product that might result in

safety hazards. The commenter asserted that the CPSC has the legal authority to require design hazard analysis of consumer products.

The commenter suggested the following changes:

- In Subpart C, *Certification of Children's Products*, insert a new subsection 1107.20(a), *Children's Product Certification*. (**Note:** The commenter may have meant to create a new subsection (a) and renumber the remaining subsections accordingly.) The new subsection would state:

Prior to submitting samples of a children's product for testing by a third party conformity assessment body, manufacturers must conduct a design hazard analysis and produce a design appraisal of the product that identifies and characterizes the potential hazards associated with that consumer product that are related to the design of a product. The design appraisal should include, at a minimum, an engineering, chemical, and biological analysis of the product, as appropriate to the type of product and the materials contained in the product.

- Insert in § 1107.26(c), Remedial Action, after “\* \* \* children's product safety rules”:

If the manufacturer knows or reasonably should know that the failure of the product is related to the product's design, the manufacturer shall conduct a revised design hazard review and produce a new design appraisal.

(Response 19)—We agree that designing safety into a children's product is an important part of a comprehensive quality control program. We decline, however, the commenter's suggestion to include in the final rule requirements mandating design hazard analyses for children's products. The current rulemaking is intended to implement the testing and certification requirements of section 14(a) and section 14(i)(2)(B) of the CPSA. Requiring a design hazard analysis goes beyond the statutory requirements because such an analysis would consider factors other than the factors required to demonstrate compliance with the applicable product safety rules. This action would extend the final rule to address activities that would occur before a product is manufactured.

Currently, given the range of products that are subject to section 14 of the CPSA, we have no practical means of identifying or evaluating individuals whose credentials and experience, under the commenter's suggested changes, would render them qualified to conduct design hazard analyses on products. Although the final rule does not require manufacturers to conduct a design hazard analysis on their products, manufacturers are free to

engage in such analyses when developing or manufacturing a product.

Further, as explained the section on remedial action in part III.D.7. below, we have removed from the final rule, the requirement for a remedial action plan for children's products.

(Comment 20)—One commenter suggested that final testing and certification should defer to the Occupational Safety and Health Administration (OSHA)-designated Nationally Recognized Testing Laboratory (NRTL) certification program by determining that such products, as they are manufactured and distributed for consumer use, are *per se* compliant with the proposed testing and certification rules. The commenter said we would still maintain our authority to recall products, seek civil penalties, and other remedies available to the Commission, if violations are found.

(Response 20)—Pursuant to section 14(a)(3)(C) of the CPSA, we have chosen to designate accrediting bodies that are full-member signatories to the International Laboratory Accreditation Cooperation—Mutual Recognition Arrangement (ILAC-MRA) to conduct third party testing. Given that children's products intended for the U.S. market are manufactured in nations throughout the world, we decided to avoid designating accreditation programs or entities that are recognized only in a specific region, nation, or locality. The reasons for this are: (1) To keep the program as simple as possible for use by manufacturers, private labelers, importers, testing laboratories, and other interested parties; (2) to establish uniform requirements regardless of location; (3) to establish a program that is manageable within agency resources; and (4) to maintain a degree of consistency in the procedures used by the designated accrediting bodies.

Moreover, the commenter appears to misstate testing requirements. Consumer products are not tested for whether they are compliant with the testing and certification rules (*i.e.*, parts 1107 and 1109), rather, consumer products are tested for compliance with the applicable rules, bans, standards, and regulations which the CPSC enforces. Moreover, section 14(i)(2)(B)(i) of the CPSA requires such testing periodically and when there has been a material change. Therefore, continued testing is required by the statute and “*per se* conformance” with the applicable product safety rules is not allowed. Additionally, section 14(a) of the CPSA requires manufacturers (including importers) to certify that their products comply with the applicable product safety rules. This responsibility cannot

be delegated to another party, such as a certification body.

The qualifications of testing laboratories performing certification tests are outside the scope of this final rule. Such qualifications are addressed in the various notices of requirements that we have published pursuant to section 14(a)(3) of the CPSA.

Finally, we acknowledge that the recently-enacted H.R. 2715 requires us to seek public comment on “opportunities to reduce the cost of third part testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation.” One topic which H.R. 2715 requires us to address pertains to “the extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations applicable under [the Consumer Product Safety Act].” Elsewhere in this issue of the **Federal Register**, we have published a notice inviting public comment on the issues identified in H.R. 2715, so the commenter's argument would be more appropriately raised and addressed in that proceeding. We note, however, that very few products covered under the OSHA-designated Nationally Recognized Testing Laboratory certification program would be children's products for which third party testing would be required. Moreover, those products that are subject to the OSHA certification program would likely be covered by CPSC regulations, if at all, for which the only requirement is a General Conformity Certificate based on a reasonable testing program. OSHA certification testing may be a sufficient basis for such certifications depending on the product and the type of testing involved. Given that CPSC does not have jurisdiction over products when the risks of injury associated with the consumer product could be eliminated or reduced to a sufficient extent by the actions of OSHA, there may be very little overlap between a particular product's results under OSHA's testing program and any CPSC required testing.

(Comment 21)—One commenter suggested an evidenced-based approach to certification, based on historical performance and risk for the product type and manufacturing process. The commenter suggested that an importer/retailer may implement a program requiring:

- Sample testing using materially identical components to be completed before production begins;

- Certification from samples selected during the start of production; and
- Periodic testing as the item remains in production.

At each of these stages, a representative set of samples would be pulled to cover all tests related to the applicable rules, bans, standards, and regulations.

The commenter suggested the following example:

For a child's solid rubber ball, more than 10,000 finished products that are materially identical could be made in less than one manufacturing shift. In this scenario, it would be appropriate to select samples when material changes occur and or meet historically defined frequency intervals in order to maintain and validate that products meet all rules, bans, standards, and regulations.

The commenter would like the CPSC to acknowledge that for children's products, samples selected from a lot of finished product over 10,000 pieces, but produced in a short time period, may be used to satisfy certification testing and periodic testing requirements.

(Response 21)—Section 14(a)(2) of the CPSA requires a manufacturer or importer of a children's product subject to a children's product safety rule to submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a third party conformity assessment body whose accreditation has been accepted by us to be tested for compliance with the applicable children's product safety rules. This requirement is also set forth in § 1107.20(a) of the final rule. Thus, the commenter's first two suggestions—to choose samples for testing using materially identical components, and to select samples during the start of production, would likely fulfill the statutory requirement to submit samples that are identical in all material respects to the product, for purposes of certification testing.

Section 14(i)(2)(B)(i) of the CPSA requires, in part, that we establish protocols and standards to ensure that a certified children's product is tested for compliance periodically. Section 1107.21 of the final rule details periodic testing requirements for children's products. Accordingly, the commenter's suggestion regarding periodic testing is required by the statute, and our expectation with regard to periodic testing is articulated in the final rule.

Regarding the commenter's suggestion regarding short-period production runs of children's products, the same samples may be used for certification and periodic tests. If a testing plan is designed and implemented to meet the

requirements of §§ 1107.20 and 1107.21, then the requirements to demonstrate the product's ability to meet all applicable children's product safety rules and ensure that continuing production is compliant may be met in this manner. If the manufacturer has a high degree of assurance of the children's product compliance, and the production run does not extend beyond the maximum periodic testing interval, then no third party periodic tests may be required. However, no children's product may enter into commerce without a Children's Product Certificate based on passing test results from a CPSC-accepted third party conformity assessment body certification.

(Comment 22)—Some commenters stated that the safety performance of a finished product may not be able to be based solely on the compliance of its component parts. The commenters asserted that some requirements can be evaluated only with finished product samples. The commenters asked us to clarify which products and which regulations would be amenable to component part testing. One commenter suggested that electrical safety standards and regulations (*i.e.*, fire and shock hazard testing) should not be allowed to rely solely on component part testing.

(Response 22)—The commenters are correct that some requirements can be evaluated only with finished product samples, and not with tests on component parts. However, both this final rule and the final rule on *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Requirements in Sections 14(a) and 14(i) of the Consumer Product Safety Act* (16 CFR part 1109) contain restrictions on the use of component part testing. For example, § 1107.20(c) of the final rule states that except where otherwise specified by a children's product safety rule, component part testing pursuant to 16 CFR part 1109 may be used to support the certification testing requirements of this section. The final rule for 16 CFR part 1109 states that if a certifier has doubts about whether component part testing is sufficient to demonstrate compliance with all the applicable rules, bans, standards, or regulations, those doubts should be resolved in favor of testing the finished product.

Therefore, the commenters' concerns are addressed by the requirements of the two rules.

(Comment 23)—One commenter expressed concern about the final rule's effect on laboratory testing capacity and

suggested removing references to statistical sampling and the use of ANSI/ASQ Z1.4, *Sampling Procedures and Tables for Inspection by Attributes* and Z1.9, *Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming*, for determining the number of samples required for certification testing, production testing, and periodic testing. The commenter said the frequency of testing and the number of samples tested should be set or determined by retailers and manufacturers to assure compliance with all applicable rules, bans, standards and regulations. The commenter stated that referencing the use of statistical sampling, confidence levels, and ANSI/ASQ Z1.4 & Z1.9 implies a very significant increase in the number of samples required for product testing.

(Response 23)—For manufacturers or importers using tests on samples of a product to ensure continued compliance to the applicable product safety rules, the rule permits manufacturers or importers to determine the frequency of testing and the number of samples tested to ensure compliance. Retailers only have testing or certification obligations if they are importers. The commenter did not explain how removing references to quality management and control standards and sampling procedures, which are not required, but may be used voluntarily by certifiers, would address the issue of third party conformity assessment body testing capacity. However, the proposed rule's reference to ANSI/ASQ Z1.4 and Z1.9 had the potential to mislead manufacturers because it would use the term "Acceptable Quality Level (AQL)." An AQL can be interpreted as an acceptable percentage of nonconforming products, which is not appropriate when applied to the case of compliance of products to health and safety standards. Therefore, we have deleted references to these standards in the final rule.

(Comment 24)—One commenter noted that the Labeling of Hazardous Art Materials Act (LHAMA) established the requirements for the labeling of art materials in ASTM D-4236, which is referenced in 16 CFR 1500.14(b)(8). The commenter asked that we: (1) Clarify the meaning of this provision with respect to the certification of art materials under section 14 of the CPSA; and (2) state whether LHAMA is a labeling rule under the Federal Hazardous Substances Act (FHSA) that would not require testing and certification to LHAMA under the CPSA. The commenter further proposed the use of existing facilities and procedures

allowed for LHAMA to certify compliance with the CPSIA.

(Response 24)—LHAMA requires that the manufacturer, importer, or repackager of art materials have a product's formulation reviewed by a toxicologist for its potential to cause chronic adverse health effects. A conformance statement on the product is used to certify that the product has been so reviewed. However, section 101 of the CPSIA introduces additional testing requirements for lead in children's products beyond what is required under LHAMA, so certification of art materials under LHAMA is not necessarily equivalent to testing for lead pursuant to section 101 of the CPSIA and section 14 of the CPSA.

Regarding whether LHAMA is a labeling requirement under the FHSA that would not require testing and certification, we note that LHAMA does not contain a performance standard similar to those in consumer product safety rules but rather, requires labeling in the form of a conformance statement that the product formulation has been reviewed by a toxicologist. The requirements of LHAMA are similar to the labeling requirements of the FHSA, of which LHAMA is a part. Therefore, third party testing for conformance to LHAMA is not required. Art materials designed or intended primarily for children 12 years of age or younger would have to be tested by a CPSC-accepted third party conformity assessment body to demonstrate compliance with the lead content limits, but they would not require third party testing and certification to the LHAMA requirements.

Regarding using facilities for LHAMA to certify to CPSIA requirements, section 14(f)(2)(C) of the CPSA states that a certifying organization, as defined in appendix A to 16 CFR 1500.14(b)(8), "meets the requirements" for consideration as a third party conformity assessment body "with respect to the certification of art materials and art products required under this section or by regulations prescribed under the Federal Hazardous Substances Act." Thus, an organization that is a certifying organization with respect to LHAMA is a third party conformity assessment body and may test children's art materials and art products for compliance with LHAMA. Thus, insofar as certifying organizations and LHAMA are concerned, no changes to the proposed rule are necessary. Accreditation requirements for testing for compliance with the CPSIA, other than LHAMA, are beyond the scope of this rulemaking and may be addressed in a separate rulemaking.

(Comment 25)—Multiple commenters noted that manufacturers have established first party testing laboratories that are accredited to ISO/IEC 17025:2005(E) (more commonly known as ISO/IEC 17025:2005 and how it will be referred to in the preamble), *General requirements for the competence of testing and calibration laboratories*. The commenters suggested that for manufacturers with such laboratories, we should allow test results from those facilities to be used for children's product certification purposes. Many commenters suggested that one half of the testing for certification should be allowed at in-house testing facilities; others recommended that the number of samples sent to third party conformity assessment bodies for certification purposes be reduced "to a minimum." Some commenters stated that we should recognize internal laboratories as a way to reduce dependence on third party conformity assessment bodies. The reasons for the suggestions include: A desire to reduce testing costs, to encourage other manufacturers to develop their own internal testing facilities, and to promote continuous product improvements.

(Response 25)—Section 14(a)(2) of the CPSA explicitly requires that testing of children's products be conducted by a third party conformity assessment body as a condition of certification. Further, third party conformity assessment bodies must have a CPSC-accepted accreditation for the scope of the testing undertaken in support of product certification. Unless the manufacturer's laboratory is a CPSC-accepted firewalled conformity assessment body, first party testing facilities, regardless of ISO/IEC 17025:2005 accreditation status, cannot be used for children's product certification purposes.

We note that, in response to these comments and concerns raised about cost, § 1107.21(d) of the final rule allows manufacturers using in-house testing laboratories accredited to ISO/IEC 17025:2005 to ensure continued compliance, to conduct periodic testing at a maximum testing interval of three years.

We further note that on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public comment on opportunities to reduce the cost of third party testing requirements, consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. Elsewhere in this issue of the **Federal Register**, we have published a notice

seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs, consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 26)—One commenter noted that carpets and rugs currently require flammability testing in accordance with 16 CFR parts 1630 and 1631 and suggested that there is no need for an additional flammability testing procedure for youth carpets and rugs.

(Response 26)—Section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products (or samples that are identical in all material respects) subject to a children's product safety rule for initial certification purposes. Further, section 14(f)(1) of the CPSA defines a "children's product safety rule" as a consumer product safety rule enforced by the Commission. Section 3(a)(2) of the CPSA defines a "children's product" as a consumer product designed or intended primarily for children 12 years of age or younger. Thus, because youth carpets and rugs are children's products and are subject to the consumer product safety rules 16 CFR parts 1630 and 1631, third party testing is required.

For these reasons, initial certification testing for youth carpets and rugs must be performed by a CPSC-accepted third party conformity assessment body whose accreditation includes the scope of the tests. Second, children's products are subject to requirements for periodic testing, material changes, undue influence, and recordkeeping in subpart C of the final rule. The test methods in 16 CFR parts 1630 and 1631 are still applicable.

(Comment 27)—One commenter stated that the statutory requirements for certificates in section 14(a) of the CPSA impose strict and detailed requirements for the contents and availability of certificates of conformity that document compliance of a children's product as demonstrated through test results. A certificate based on accredited third party conformity assessment body testing must be issued by the manufacturer and private labeler of any children's product that is subject to a CPSC rule, and it must comply not only with the requirements of section 14(g) of CPSA, but also with the requirements of a finished product certifier's reliance on component materials testing certification. Thus, a finished product certifier could rely on

a test report showing passing test results for one or more component materials used in the product, based upon accredited third party conformity assessment body testing conducted by another person.

The commenter stated that including this information in the certificate accompanying the finished children's product would create logistical nightmares for the manufacturers and private labelers of children's products. The commenter did not object to the "recordkeeping" requirements in proposed § 1107.26; however, the commenter urged us to note that compliance with these requirements should make it unnecessary for the manufacturer or private labeler of the finished children's product, to ensure that every certificate required under section 14 of the CPSA accompanies the product or shipment of products, is furnished to each distributor or retailer of the product.

The commenter also urged us to adopt certificate requirements that reflect the key concept in the tracking label provisions, which require that the manufacturer (as well as the "ultimate purchaser") of the finished children's product be able to "ascertain" certain information similar to what is required for certificates of conformity. The commenter suggested that certificates, like "tracking labels," for children's products under section 103 of CPSIA, could be mandated to use codes or other means to point all interested parties to a source where such information readily can be found. This code could be contact information, where the manufacturer or private labeler could include an Internet URL for the manufacturer's Web site, where the information could be accessed.

(Response 27)—Section 14(g)(1) of the CPSA and 16 CFR 1110.11 require specific information on each certificate. In addition, section 14(g)(3) of the CPSA states that the required certificate shall accompany the applicable product or shipment of products covered by the same certificate and a copy of the certificate shall be furnished to each distributor or retailer of the product. However, 16 CFR 1110.9 allows a manufacturer to file certificates electronically by providing an Internet URL for the manufacturer's Web site, where the information could be accessed, as the commenter suggested. We note that the listing of component parts or component part test results does not have to be included on the finished product certificate.

(Comment 28)—Multiple commenters mentioned the high costs associated with third party testing and noted that

the proposed rule under-recognizes the in-house quality assurance and testing capabilities of manufacturers.

(Response 28)—We are aware of many effective quality assurance techniques that are widely used to control quality in product manufacturing. However, section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products for initial certification. Unless the manufacturer's in-house testing facility is a CPSC-accepted firewalled conformity assessment body, data from those facilities cannot be used for children's product certification purposes. No exclusion is included in the statute for first party certification or periodic testing of children's products based on the costs of testing.

In response to these comments, and in response to concerns about the cost of third party testing, § 1107.21(d) of the final rule allows manufacturers who are implementing a production testing plan to ensure the compliance of continuing production, to conduct third party periodic testing at a maximum testing interval of two years. Further, the final rule allows manufacturers using in-house testing laboratories accredited to ISO/IEC 17025:2005 to ensure continued compliance by conducting third party periodic testing at a maximum testing interval of three years. We believe this balances the desire for unbiased objective test results with the cost concerns expressed in the comments.

Additionally, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires the CPSC to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

## 2. Proposed § 1107.20—General Requirements

### a. The Number of Samples

Proposed § 1107.20(a) would require manufacturers to submit a sufficient

number of samples of a children's product, or samples that are identical in all material respects to the children's product, to a third party conformity assessment body for testing to support certification. The proposal would require that the number of samples selected provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules.

(Comment 29)—Two commenters wanted more detail on what is meant by "a sufficient number of samples." The commenters expressed concern that, if the number is left to conformity assessment bodies, there will be too much variability among conformity assessment bodies about what is a sufficient number.

(Response 29)—A "sufficient number of samples" are the number of samples necessary to give the manufacturer or importer a high degree of assurance of the product's compliance with the applicable rules when tested. Because a high degree of assurance is based upon the manufacturer's or importer's knowledge of the product and its manufacture, a sufficient number of samples will vary based on those factors. For example, for products with highly consistent part-to-part manufacturing processes (*e.g.*, die casting), fewer samples may be necessary to give the manufacturer/importer a high degree of assurance of compliance. For processes with more variability (such as hand assembly), it is likely that more samples will be necessary to achieve the same high degree of assurance.

The commenters also may have misunderstood the role of conformity assessment bodies in the testing and certification requirements of the rule. The conformity assessment body does not specify the number of samples to be tested. The manufacturer or importer specifies to the conformity assessment body the number of samples to be tested.

Finally, on our own initiative, we revised the second sentence to say that the number of samples selected must "be sufficient to" provide a high degree of assurance. We added this language to be consistent with the requirement to "submit a sufficient number of samples" language in the first sentence of the section. This change is also consistent with section 14(a)(2)(A) of the CPSA, which requires a manufacturer to "submit sufficient samples of the children's product" for testing.

(Comment 30)—One commenter stated that the language covering

samples needs to be clarified. The commenter stated that the proposal would require testing with a “sufficient number of samples” to provide a “high degree of assurance” (for minimum certification testing), while maintaining that the sampling does not have to meet minimum standards of statistical confidence. However, the commenter noted that the comments accompanying the proposed rule recognize that “there may be difficulty in applying statistical methods to all manufacturing processes.”

The commenter further stated that if testing a “sufficient number of samples to provide a high degree of assurance” is required when applying a reasonable testing program to children’s products, then we should provide guidance on alternatives that certifiers may use to fulfill the duty to justify their plan, were they to choose anything less than a random statistical sample. The commenter noted that historically, we have relied on a sample of 12 or fewer units, without regard to the size of the production run and that certain statistical models used by auditors impose a maximum sample of 25 units, no matter the size of the cohort from which the samples are selected.

Based on these points, the commenter recommended that we delete the requirement to test a “sufficient number of samples to provide a high degree of assurance” under a reasonable testing program. The commenter said that the premise of a “reasonable testing program”—in order to differentiate it from the mandatory periodic testing required for children’s products not relying upon a reasonable testing program—must be that, for some specific products, testing will not be the basis for certifying to the applicable rule. The commenter stated that we appropriately acknowledged the implications of differences between product categories and industries attempting to develop programs when, in the preamble to the proposed rule, we observed: “A manufacturer may develop the scope and details of each element of a reasonable testing program based on knowledge and expertise regarding the product and its manufacturing processes” (75 FR at 28345). The commenter stated that this discretion also must extend to the sample selection method of test programs, provided that all population elements have a chance of selection and due care is exercised to avoid selection bias through documented procedures.

The commenter also stated that we should suggest separate regulations for specific products that may warrant prescribed methods, as has been done

with bicycle helmets. The commenter expressed the belief that this is the kind of evidence-based decision making we envisioned in rejecting a single definition of “high degree of assurance” within a reasonable testing program for non-children’s products.

(Response 30)—Although subpart B, describing a reasonable testing program, has been reserved in the final rule, the concept of certification testing and testing a sufficient number of samples to provide a high degree of assurance of compliance with applicable rules, bans, standards, and regulations remains in the final rule with regard to children’s products in § 1107.20(a). We disagree with the commenter’s assertion that “testing with a sufficient number of samples to provide a high degree of assurance” requires the testing method to meet minimum standards of statistical confidence. In the preamble to the proposed rule (75 FR at 28344), the discussion of a high degree of assurance intentionally avoided choosing a statistically based definition for the term. Therefore, the certifier is allowed to choose other means, using its knowledge of the product and how it is manufactured, to determine what would be a sufficient number of samples. A certifier may use statistical methods, but the determination of a sufficient number of samples to achieve a high degree of assurance is not required to be statistically based.

We decline to provide guidance on alternatives that certifiers may use to fulfill the duty to justify their plan if they were to choose anything other than a random statistical sample. With the wide variety of children’s products, manufacturers, and manufacturing processes that will be subject to the final rule, it would be impractical to attempt to provide guidance applicable to all or to attempt to provide individualized guidance for some or all products, as requested by the commenter. Because the certifier typically possesses greater knowledge of the product and how it is made than other parties possess, the certifier is in the best position to determine how to achieve a high degree of assurance that its products are compliant with all the applicable children’s product safety rules.

Regarding the commenter’s observation of the CPSC’s use of 12 or fewer samples, those samples were not used for children’s product certification purposes. Thus, tests run by CPSC staff are not germane to the discussion of product certification. Depending upon the manufacturer’s knowledge of a children’s product and its manufacture, a sufficient number of samples to provide a high degree of assurance of

compliance with the applicable children’s product safety rules may be greater, or fewer, than 12.

The commenter may be misunderstanding the rule as it relates to random samples. In proposed § 1107.22, the testing of random samples was required only during periodic tests of children’s products subject to an applicable children’s product safety rule. Pursuant to H.R. 2715, the testing of “random samples” to ensure continued compliance has been replaced with testing of “representative samples” to ensure continued compliance. Given the change in the statute, we have decided to remove § 1107.22 in the final rule. Regardless, certification testing in the proposed rule never required the selection of random samples for children’s products.

For children’s products, section 14(a)(2)(A) of the CPSA requires that every manufacturer or private labeler of a children’s product:

Submit sufficient samples of the children’s product, or samples that are identical in all material respects to the product, to a third party conformity assessment body accredited \* \* \* to be tested for compliance with such children’s product safety rule.

Therefore, the statute requires children’s products to be tested before they can be certified, and the statutory requirement for third party periodic testing applies.

We agree that there are instances in which it may be preferable to specify a testing program in a particular regulation, and several of our existing regulations require such programs. Should a particular standard at some point necessitate consideration of such an approach, we will provide due consideration of how to specify, within the statutory framework that requires third party certification and third party periodic testing, such a particular testing program.

(Comment 31)—One commenter expressed concern about the requirement to perform certification tests. The commenter said they did not believe that a requirement to test pre-production samples should be part of a reasonable testing program, adding that it may be impractical for seasonal items or short production runs. The commenter stated that preproduction samples cannot be tested because we will not accept the test results on samples as test results on the finished product. The commenter asked: if the preproduction samples fail and the retailer/importer has the product reworked by the manufacturer to correct any defects, and the production units pass tests to meet all applicable

standards, then why should it matter if the samples failed, as long as the final product meets the requirements? The commenter expressed the belief that sample testing should be optional, not required.

(Response 31)—Although subpart B, describing a reasonable testing program, has been reserved in the final rule, the concept of certification testing and testing a sufficient number of samples to provide a high degree of assurance of compliance with applicable rules, bans, standards, and regulations remains in the final rule with regard to children's products in § 1107.20(a). Section 1107.20(a) states that certification tests must be performed on samples that are identical in all material respects to the children's product distributed in commerce. Thus, finished children's product samples or preproduction samples are acceptable for certification test purposes if their performance for the test under consideration is the same as the finished product.

The commenter did not explain why they believe that certification tests may be impractical for seasonal or short production run items. Thus, we cannot respond to the commenter's concern. The final rule requires passing certification test results before a Children's Product Certificate can be issued.

With regard to the commenter's concern regarding a test failure of preproduction samples, the commenter may have misunderstood the requirements of certification testing. The commenter described a circumstance in which a manufacturer tested samples for compliance to a regulation. Upon receiving a failing test result, the manufacturer addressed the causes of the failing test results and conducted new certification tests on samples of the "corrected" product and received passing test results. This describes an acceptable process for initial product certification.

We disagree with the commenter's suggestion that certification tests should be optional. Section 14(a)(2) of the CPSA expressly refers to testing as being the basis of a certification and does not make such testing optional.

(Comment 32)—A commenter suggested that the final rule not require finished product/component part testing and should allow samples that are identical in all material respects to the finished product to be tested. The commenter added that testing on samples since the 1950s has not resulted in a recall for failing to comply with the applicable rule. Thus, requiring finished product/component testing would be extremely costly and burdensome and

would not increase safety. The commenter would revise the rule to make it clear that component parts that are materially similar to the finished part can be used for certification testing.

(Response 32)—We agree with the commenter regarding the testing of samples. Section 1107.20(a) states that samples must be identical in all material respects to the children's product.

We also agree with the commenter's suggestion that we clarify the rule; therefore, we have revised § 1107.20(c) to state that component part testing may be used for certification of a finished product.

(Comment 33)—One commenter expressed the belief that the manufacturer should determine the number of units to be tested, but added that they do not believe that statistical sampling is appropriate.

(Response 33)—A manufacturer may use statistical or qualitative means to determine how many units of a product are needed for certification testing to give the manufacturer a high degree of assurance that the product complies with the applicable rules. The manufacturer is not required to use statistical methods, but they should be prepared to describe how their technique shows the product's compliance.

(Comment 34)—One commenter noted that products using "food grade" materials have supplier certificates stating that these materials meet the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) and/or the packaging requirements for the Coalition of Northeastern Governors (CONEG). The commenter suggested supplementing these certificates with other analyses, as part of the certification (e.g., gas chromatography—mass spectrometry, GC-MS) and a reasonable testing program. The commenter said that such assurances also can be used, consistent with the Commission's authority under section 3 of the CPSIA, to reduce the burden of testing on manufacturers of consumer products. Because the proposed rule would acknowledge that children's product manufacturers who implement a reasonable testing program have a reduced third party test burden from the standpoint of third party periodic testing, the commenter said that such compliance assurances can be incorporated into a program for children's products as well.

(Response 34)—Section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products as a condition of certification. Additionally, those third party conformity assessment bodies must

have a CPSC-accepted accreditation for the scope of the testing undertaken in support of product certification. "Food grade" materials and CONEG requirements are not conducted by these laboratories and do not necessarily demonstrate compliance with the requirements of applicable children's product safety rules or compliance with the third party testing requirement in section 14(a)(2) of the CPSA. Accordingly, we cannot adopt those certifications in lieu of the certification required under section 14(a)(2) of the CPSA.

While manufacturer-supplied certificates stating that these materials meet FFDCA or CONEG requirements may not be used as the basis for a third party-supported product certification, they can be used as part of a production testing plan implemented to extend the maximum periodic testing interval from one year to two years if they are sufficient to demonstrate compliance with a children's product safety rule such as the lead content limits. We note that some food additives are GRAS, or "generally recognized as safe." However, these designations might not be based on scientific analyses or testing. Instead, the GRAS status for a material might be based on longstanding acceptance or belief.

Furthermore, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public comment on opportunities to reduce the cost of third party testing requirements, consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. H.R. 2715 directs us to seek public comment on seven specific issues, including the extent to which the use of materials subject to regulations of another government agency that requires third party testing of those materials may provide sufficient assurance of conformity with an applicable consumer product safety rule, ban, standard, or regulation without further third party testing. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715.

H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. Should new information

become available, the Commission may revisit this issue in the future.

#### b. The Interaction Between the Manufacturing Process and Samples

Proposed § 1107.20(b) would state that, if the manufacturing process for a children's product consistently creates parts that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. If the manufacturing process for a children's product results in variability in the composition or quality of children's products, a manufacturer may need to submit more samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules.

(Comment 35)—One commenter stated that phrases, such as "sufficient number of samples" and "variability in composition or quality," can be confusing. The commenter said that regular internal monitoring and periodic testing should be able to provide sufficient data and information to support any assessment of product quality.

(Response 35)—The commenter is correct that internal monitoring and testing can provide data to support the assessment of product quality. Because § 1107.20 applies to both tightly and loosely controlled manufacturing processes, we emphasize in § 1107.20(b) of the final rule that the number of samples needed to give the certifier a high degree of assurance of the product's compliance is affected by how well the product's manufacturing process controls those variables associated with compliance. A sufficient number of samples would be the quantity of samples selected for certification testing that gives the certifier a high degree of assurance that the product complies with all the applicable children's product safety rules.

"Variability in the composition or quality," for purposes of § 1107.20, means unit-to-unit differences of a product that can affect its compliance with the applicable children's product safety rules.

We have finalized this paragraph without change.

(Comment 36)—One commenter stated that regular internal monitoring and periodic testing should be able to provide sufficient data and information to support any assessment of product quality. The commenter noted that this procedure is commonly practiced by many manufacturers at present.

(Response 36)—Section 1107.20(b) of the final rule states, in part, that if the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. We interpret the comment to assert that internal manufacturing controls and regular testing should obviate the need for numerous samples for product certification. The commenter is correct in that the manufacturer's internal controls and testing can provide information to use in determining how many certification test samples would be required to give the certifier a high degree of assurance of the product's compliance with the applicable rule.

#### c. Component Part Testing

Proposed § 1107.20(c) would state that, except where otherwise specified by a children's product safety rule, a manufacturer may substitute component part testing for finished product testing pursuant to 16 CFR part 1109, if the component part, without the remainder of the finished product, is sufficient to determine compliance for the finished product.

(Comment 37)—One commenter requested that we make an explicit statement about component testing indicating that certain components are exempt from testing and certification. The commenter was concerned that, without specific language, the final customer will not accept component testing if exempt parts are not tested. The commenter recommended revising proposed § 1107.20(c) as follows:

(c) Except where otherwise specified by a children's product safety rule, a manufacturer may substitute component part testing for complete product testing pursuant to 16 CFR [part] 1109 if the component part, without the remainder of the finished product, is sufficient to determine compliance for the entire product. *Component part testing can be used to substantiate compliance for those children's products where part of the product has been exempted from testing pursuant to Section 1500.91.* (Italics indicate proposed language.)

(Response 37)—We agree that language similar to what the commenter suggested would be helpful, but we believe that the commenter's change is more appropriate in the rulemaking pertaining to component part testing, specifically with component part testing for the lead content of children's products under proposed 16 CFR 1109.12. Therefore, we have considered

this comment under the proposed rule for component part testing.

On our own initiative, we have revised § 1107.20(c) to state: "Except where otherwise specified by a children's product safety rule, component part testing pursuant to 16 CFR part 1109 may be used to support the certification testing requirements of this section." We made these changes to simplify the language in § 1107.20(c) and to remove descriptions of 16 CFR part 1109 to avoid potential confusion over what the final rule requires and what 16 CFR part 1109 mandates.

(Comment 38)—One commenter stated that raw (or base) material testing is critical to its ability to develop programs to comply with the law. The commenter noted that, although it is a component manufacturer, it has more than 384,000 stock-keeping units (SKUs). These hundreds of thousands of products could be seen as different combinations of a smaller population of subcomponents and raw materials. The commenter stated that it is through working with this smaller population of subcomponents and raw materials that they can effectively manage quality in areas such as lead levels.

(Response 38)—Component part testing of raw materials is beyond the scope of this rule and is considered in the final rule on *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements* (16 CFR part 1109). However, in that final rule, in many cases, raw materials or subcomponents may be considered component parts, as long as due care has been taken to ensure that no action subsequent to component part testing has adversely affected the raw materials' or subcomponents' compliance with the applicable product safety rules.

#### d. Remedial Action

Proposed § 1107.20(d) would state that, if a product sample fails certification testing, even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take remedial action. A manufacturer would not be allowed to certify the children's product until the manufacturer establishes with a high degree of assurance that the finished product complies with all applicable children's product safety rules.

(Comment 39)—Two commenters raised questions about what action must be taken when a product fails a test. One commenter interpreted the proposed rule to mean that all similar toys are

also not compliant, resulting in a factory shutdown. The other commenter noted that different products vary in design and manufacture, and if one product fails, it does not mean that other products would have the same problem.

(Response 39)—Section 1107.20(d) of the final rule states that if a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure. Generally, certification testing of a children's product requires all samples tested to pass the applicable children's product safety standard. Otherwise, the certifier cannot ensure with a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules. However, some regulations allow for some individual samples of a test set to exceed the limit but still comply with the regulation. For example, in the *Standard for the Surface Flammability of Small Carpets and Rugs* (FF 2–70) in 16 CFR part 1631, there is an allowance within the standard for a failure during a test and a prescribed action. Because the regulation specifies the procedure for dealing with a sample test failure, or through labeling, we would view such a properly labeled product as meeting the applicable product safety standard.

A test failure for one children's product applies only to that product and is not necessarily representative of all products in the factory. An exception to this might be a test on a component part used in many products. In that circumstance, the nature of the test failure and the component part's use in the other products would affect which products the failing test result applies. For example, if a component part over the lead content limit is inaccessible, the use of that component part would not make the children's product noncompliant.

Additionally, on our own initiative, we have revised § 1107.20(d) by adding the phrase: “to the applicable children's product safety rule(s)” after the phrase “if a product sample fails certification testing.” This change is for clarification purposes and is not intended to have a substantive effect on the final rule. We also replaced the phrase “take remedial action” with the phrase “take the necessary steps to address the reasons for the failure” because we have removed the remedial action plan requirement in § 1107.25 from the final rule. We discuss the removal of the

remedial action plan requirement in part III.D.7. of this document, below.

### 3. Proposed § 1107.21 Periodic Testing

#### a. General Periodic Testing Requirements

Proposed § 1107.21(a) would implement the periodic testing requirement in section 14(i)(2)(B)(i) (renumbered by H.R. 2715 from section 14(d)(2)(B)(i)) of the CPSA by requiring each manufacturer to conduct third party periodic testing at least annually, except as otherwise provided in proposed § 1107.21(b) and (d), or as provided in regulations under this title. The proposal also would explain that manufacturers may need to conduct third party periodic tests more frequently than on an annual basis to ensure a high degree of assurance that the product being tested complies with all applicable children's product safety rules and that more frequent third party periodic testing may help a manufacturer identify noncompliant products quicker and, as a result, may limit the scope of any potential product recall. In addition, more frequent third party periodic testing may reduce the manufacturer's liability for civil penalties resulting from a noncompliant product, reduce potential damage to a manufacturer's reputation, and increase the manufacturer's confidence in the effectiveness of the third party periodic testing.

(Comment 40)—One commenter asserted that the language of proposed § 1107.21 is not explicitly limited to children's products. The commenter recommended that the language in the final rule be revised so that the term “manufacturer” is changed to the phrase “manufacturer of a children's product” to clarify that § 1107.21 applies only to children's products. The commenter also stated that the same revision should be made throughout subpart C, wherever the term “manufacturer” appears without the qualifier “of a children's product.”

(Response 40)—We believe it is clear that Subpart C applies only to children's products. While we believe the commenter's suggested change is unnecessary, we have made other revisions to the text and have added a reference to manufacturers of children's product in § 1107.21(a) of the final rule to reiterate that the requirement applies only to children's products.

On our own initiative, we have revised § 1107.21 to reflect changes to the periodic testing frequency in § 1107.21(b), (c), and (d) of the final rule, to mention component part testing, and to make nonsubstantive

clarifications. For example, § 1107.21(a) of the final rule states: “All periodic testing must be conducted by a third party conformity assessment body.” The proposed rule had mentioned third party testing in proposed § 1107.21(b), but not in proposed § 1107.21(a), so adding this sentence to a revised § 1107.21(a) of the final rule reinforces the notion that periodic testing of children's products must be done by a third party conformity assessment body. We have reorganized § 1107.21 to state the general requirements at § 1107.21(a) and then identify different options for third party periodic testing frequencies at § 1107.21(b), (c), and (d). Thus, for example, we have modified and moved the annual periodic testing mentioned in proposed § 1107.21(a) to § 1107.21(b) in the final rule, and we have combined it with the periodic test elements that were at proposed § 1107.21(c). Consequently, § 1107.21(b) of the final rule states that a manufacturer must conduct third party periodic testing to ensure compliance with the applicable children's product safety rules at least once a year, except as otherwise provided in § 1107.21(c) and (d), or as provided in our regulations. (The final rule states that the periodic testing under § 1107.21(b) must be done “once a year,” as opposed to “annually,” to eliminate potential confusion in determining how to calculate the proper interval for periodic testing.) Under § 1107.21(b), the manufacturer must conduct periodic testing at least once a year when using a periodic test plan. Section 1107.21(b)(1) of the final rule (regarding the periodic test plan) is substantially the same as proposed § 1107.21(c)(1), except that the final rule states that manufacturers must develop a periodic test plan to “ensure with a high degree of assurance” that children's products continue to comply with all applicable children's product safety rules. (The proposed rule stated that the manufacturer must develop a periodic test plan to “assure that children's products” continue to comply.) Section 1107.21(b)(2), “Testing Interval,” is substantially the same as proposed § 1107.21(c)(2), except that, for consistency, the final rule refers simply to a “testing interval,” rather than a “periodic testing interval.” (The proposed rule had used different terms, such as “periodic testing interval,” “testing interval,” “interval,” and “interval for periodic testing,” for the same concept.)

(Comment 41)—One commenter supported third party testing for the initial certification for any new products and said that any major changes in

design, critical component changes, or meeting changing regulations should require recertification by third party testing bodies. The commenter also supported periodic testing by third party conformity assessment bodies of any products, providing that a much more refined and more specific requirement can be presented and confirmed by a proper authority. The commenter noted that it would be difficult and extremely risky to leave such a decision and ruling to the related parties. However, the commenter supported the earlier proposal of component part testing that certifies recognized components for toy production because it would enhance the elimination of certain repetitive and redundant testing on the finished product.

(Response 41)—The commenter was unclear what it meant by a “proper authority” or which parties are the “related parties” dealing with the difficulty and risk of periodic testing. In the final rule, the certifier (domestic manufacturer or importer) of a children’s product must determine the frequency of periodic testing and the number of samples to be tested. The frequency of testing (within specified maximum periodic testing intervals) and the number of samples required must be sufficient to give the certifier a high degree of assurance that continuing production or importation of the children’s product continues to meet the requirements of all applicable children’s product safety rules.

The commenter did not indicate what factors should be added to the periodic testing requirements to make them more refined or specific. Thus, we have no basis to modify the rule to account for such factors. Further, identifying or creating a “proper authority” to confirm periodic testing programs would present practical difficulties due to the number of products requiring periodic testing plans and the variety of manufacturing techniques used in their production. Because periodic testing requirements apply to many different types of children’s products and manufacturers, and because manufacturing techniques for those products vary widely, one set of refined or specific requirements for periodic testing is unlikely to be applicable to all children’s products that require periodic testing.

(Comment 42)—One commenter noted that some children’s products are not produced on a regular basis, and more than one year may pass between production runs. Because there are no production units on which to perform periodic testing, the commenter suggested that an “Inactive” product

status be created for a children’s product that has passed certification testing—but currently is not being produced. Once production resumes, periodic testing can be performed on the new units.

(Response 42)—A new “Inactive” status is unnecessary because periodic testing of children’s products is only required for continuing production after certification. If, in the commenter’s example, more than a year passes between production runs, when production recommences, the final rule requires periodic tests on new production runs to assure continued compliance. The certifier must use due care to ensure that no material change has occurred in the product’s design or manufacturing process, including the sourcing of component parts. Otherwise, new certification tests must be conducted on the newly manufactured product.

(Comment 43)—One commenter noted that while the proposed rule would accept the use of component part testing for certification purposes, it does not address its use for periodic testing. The commenter would revise proposed § 1107.21(c)(1) to include language allowing for the use of a component part testing program to meet the periodic testing requirements. The commenter stated that it could foresee customers requiring the development of a periodic testing program as a contractual requirement.

Another commenter remarked that the proposed rule does not recognize items that are exempt from testing pursuant to 16 CFR 1500.91, *Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act*.

(Response 43)—Section 1107.21(a) of the final rule states that manufacturers must conduct third party periodic testing. This testing is to ensure that children’s products manufactured after the issuance of a Children’s Product Certificate, or since the previous periodic testing was conducted, continue to comply with all applicable children’s product safety rules. Periodic testing can use component part testing to ensure compliance with some or all of the applicable children’s product safety rules. We have clarified the language of § 1107.21(a) of the final rule to state that component part testing may be used to meet the periodic testing requirements, subject to the conditions of § 1107.21.

Regarding items that are exempt from testing for lead content, those items are also exempt from any periodic testing requirements. In 16 CFR 1500.91, we

have determined that these materials fall under the lead content limit, and no testing is required.

(Comment 44)—One commenter stated that the testing frequency should be left to the manufacturer and to the market; and the commenter further asserted that a rule requiring manufacturers to test according to these standards every year is an unaffordable economic burden. The commenter indicated that it is unrealistic to imagine that testing cost savings from maintaining a reasonable testing program (as described in the proposed rule) will be useful because that program is “wasteful and gargantuan.” The commenter asserted that a firewalled conformity assessment body would be unrealistic for small businesses. The commenter also maintained that component part and composite testing likewise, will provide no relief. The commenter asked: If a firm has a good long-term record of safety, then why are they required to test according to the proposed rule?

(Response 44)—Section 14(i)(2)(B)(i) of the CPSA requires us to establish protocols and standards for ensuring that children’s products are subject to testing periodically. We have revised § 1107.21 to allow third party periodic testing: At least once per year for children’s product with a periodic testing plan; at least once every two years for children’s products with a production testing plan; or at least once every three years for a production testing plan using an ISO/IEC 17025:2005-accredited testing laboratory (and provided other requirements are met, including, but not limited to, using that lab to test to the children’s product safety rule(s) to which the product is subject). Allowing firms with a good long-term record of safety to forego testing their children’s products would not comply with the law, which requires periodic testing of children’s products, regardless of past performance.

Regarding the commenter’s assertion that children’s product manufacturers will not attempt to save on testing costs because implementing a reasonable testing program is “wasteful and gargantuan,” the final rule does not require manufacturers of children’s products to have a reasonable testing program in order to save on third party conformity assessment body testing costs. By increasing the manufacturer’s options to qualify for an extension of the maximum periodic testing interval, we hope that more manufacturers wishing to implement such a program will find it advantageous to do so.

Additionally, pursuant to H.R. 2715, elsewhere in this issue of the **Federal Register**, we have published a notice seeking comment on other techniques for lowering the cost of third party testing, consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

As for the commenter's remark about firewalled conformity assessment bodies, the final rule does not require that small businesses have a firewalled conformity assessment body.

Finally, regarding the commenter's statements on component part and composite part testing, we address those comments in the preamble to the final rule, *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements* (16 CFR part 1109).

(Comment 45)—One commenter stated that periodic testing is unnecessary because when a product is manufactured in China, the initial product sample is inspected by the China Entry-Exit Inspection and Quarantine Bureau to ensure that it complies with all European Union, United States, and China product safety standards. Additionally, the commenter observed, the China Entry-Exit Inspection and Quarantine Bureau will conduct the random sample in-line inspection to inspect a number of samples in the production twice a year. The commenter said that products that fail the inspection will not be allowed to be exported. The commenter said that the strict product safety inspections by China Entry-Exit Inspection and Quarantine Bureau are enough to have the high degree of product safety assurance and that a periodic testing requirement would be duplicative.

The commenter also said that periodic testing was unnecessary because, as the manufacturer, they have a high degree of self-discipline and strictly supervise their products' safety. Furthermore, the commenter stated that 90 percent of manufacturers have their own testing laboratories that conform to international laboratory standards and already have a series of internal product safety testing in place to maintain a high degree of product safety and quality assurance. In addition, the commenter stated that most customers require testing by the third party conformity assessment body per order before the manufacturer exports the goods to ensure a high degree of product safety.

(Response 45)—The final rule requires periodic testing to be conducted by a

CPSC-accepted third party conformity assessment body. China Entry-Exit Inspection and Quarantine Bureaus do not currently meet the conditions specified in the Consumer Product Safety Improvement Act for governmental conformity assessment bodies to participate in the CPSC's program. Further, the third party testing requirements apply irrespective of the level of a manufacturer's self-supervision of product safety.

With regard to internal testing facilities, these are considered first party laboratories, and their tests are not allowed for periodic test purposes, unless the laboratory is a CPSC-accepted firewalled conformity assessment body. However, if the third party laboratories testing the manufacturer's products for the customer are CPSC-accepted for the scope of the testing, test results from those laboratories may be used for fulfilling the periodic testing requirements. We note that internal testing facilities can be used to extend the maximum testing interval for periodic testing from one year to two years. Further, if the internal testing facility is ISO/IEC 17025:2005-accredited and other conditions are met, the maximum testing interval for periodic testing is extended to three years.

(Comment 46)—One commenter stated that the importer who purchases a product from a manufacturer and takes possession of the product prior to importation does not have full visibility and knowledge of the manufacturing process and must treat each shipment produced by the manufacturer as a discrete lot.

(Response 46)—An importer is responsible for issuing a Children's Product Certificate for the children's products they import. If a foreign manufacturer tests or certifies a children's product and provides the importer with the test results or certificate and other required documentation, then the importer, exercising due care, using the manufacturer's test data or certificate as a basis, may issue its own Children's Product Certificate.

In this circumstance, due care by the importer involves ensuring that the foreign manufacturer conducts periodic tests. If the foreign manufacturer does not certify the children's product, but the importer has documentation of the manufacture and testing of the children's product, then the importer is responsible for certifying the children's product and is subject to the requirement for periodic testing. However, if the importer has no knowledge of the manufacture of the

product, then it should treat each shipment as a discrete lot and subject it to certification testing because the importer does not know whether material changes have been made to the product since its last shipment. In this circumstance, the shipment that has undergone certification testing is not considered continuing production of the product, and is not subject to the periodic testing requirements.

#### b. Periodic Testing and Reasonable Testing Programs

Proposed § 1107.21(b) would state that if a manufacturer has implemented a reasonable testing program, as described in subpart B of this part (with the exception of the certification element which, for children's products, would have to comply with the requirements in proposed § 1107.20), it would have to submit samples of its product to a third party conformity assessment body for periodic testing to all applicable children's product safety rules at least once every two years. If a manufacturer's reasonable testing program fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, proposed § 1107.21(b) would state that we may require the manufacturer to meet the periodic testing requirements in proposed § 1107.21(c) or modify their reasonable testing program to ensure a high degree of assurance. One element of the reasonable testing program in proposed subpart B would be the "production testing plan" in proposed § 1107.10(b)(3); a production testing plan would describe what tests must be performed and the frequency with which those tests must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all applicable safety rules, bans, standards, or regulations.

(Comment 47)—One commenter recommended that we require children's products to be tested by a third party conformity assessment body at least every year, not every two years, as proposed. The commenter felt that many changes can occur over time in the manufacturing process, materials, test standards, and test protocols that could cause products tested infrequently to drift away from compliance with applicable children's product safety rules. The commenter felt that more frequent independent testing would be able to keep this in check better.

(Response 47)—We disagree with the commenter's inference that a production testing plan will not be capable of detecting "drift" in a product's

compliance with the applicable safety rules. We are aware of numerous forms of production testing techniques that have been implemented successfully to control product quality and ensure continuing compliance.

Manufacturers are free, however, to test their products more frequently than the rule would require.

Additionally, on our own initiative, we have reorganized § 1107.21 to move the requirements that were at proposed § 1107.21(b) to § 1107.21(c) of the final rule. Furthermore, because we have reserved subpart B (which would pertain to a reasonable testing program), we have removed references to a “reasonable testing program” in subpart C and replaced them with the key element of the “reasonable testing program,” which is the “production testing plan.” We decided to maintain the requirement for a production testing plan because children are a vulnerable population, and traditionally, we have had a greater interest in ensuring the safety of children’s products. Additionally, with the passage of the CPSIA, Congress indicated that it intended for children’s products to be subject to more stringent requirements than non-children’s products, as demonstrated by the requirements for third party testing and the protocols and standards for continuing third party testing for children’s products promulgated in this rulemaking.

Section 1107.21(c)(1) of the final rule states that if a manufacturer implements a production testing plan, as described in § 1107.21(c)(2), to ensure continued compliance of the children’s product with a high degree of assurance to the applicable children’s product safety rules, the manufacturer must submit samples of its children’s product to a third party conformity assessment body for periodic testing to the applicable children’s product safety rules at least once every two years. The 2-year period is derived from proposed § 1107.21(b) for manufacturers who have a reasonable testing program. Section 1107.21(c)(1) further states that a manufacturer may consider the information obtained from production testing when determining the appropriate testing interval (up to two years) and the number of samples needed for periodic testing to ensure that there is a high degree of assurance that the other untested children’s products manufactured during the testing interval comply with the applicable children’s product safety rules. The preamble to the proposed rule noted: “[t]he appropriate periodic testing interval may vary for a manufacturer depending on the

manufacturer’s knowledge of the product and its manufacturing processes” for the factors to consider when determining the periodic testing interval under proposed § 1107.21(c)(2) (renumbered to § 1107.21(b)(2) in the final rule) (75 FR at 28349). This concept applies equally to the information obtained from production testing. Information gained from production testing can be used to determine the appropriate testing interval (up to two years), and so we added this concept to § 1107.21(c)(1).

Section § 1107.21(c)(2) of the final rule describes the production testing plan, and it is substantially the same as the production testing plan in proposed § 1107.10(b)(3) (which is reserved in the final rule, along with the rest of subpart B). Section 1107.21(c)(2) explains that the production testing plan describes “the production management techniques and tests that must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable children’s product safety rules.” It further explains that a production testing plan may include: recurring testing or the use of process management techniques, such as control charts, statistical process control programs, or failure modes and effects analyses (FMEAs), designed to control potential variations in product manufacturing that could affect the product’s ability to comply with the applicable children’s product safety rules.

Section 1107.21(c)(2) also states that a manufacturer may use measurement techniques that are nondestructive and that are tailored to the needs of an individual product to ensure that a product complies with all applicable children’s product safety rules. Thus, the tests in a production testing plan under § 1107.21(c)(2) do not have to be the tests described in the applicable children’s product safety rule, and they do not have to be conducted by a CPSC-accepted third party conformity assessment body. However, the implementation of the production testing plan still requires some testing. Purely mathematical techniques, such as a Failure Modes and Effects Analysis only, or a computer simulation of the product alone, are not allowed. Purely mathematical techniques, without verifying measurements, may not characterize the product with sufficient fidelity to predict accurately its compliance to the applicable rules.

Section 1107.21(c)(2) of the final rule has revised the requirement in proposed § 1107.10(b)(3)(iii)(B), which stated:

“Any production test method used to conduct production testing must be as effective in detecting noncompliant products as the test used for certification” to “Any production test method used to conduct production testing must be effective in determining compliance” in the final rule. The language of the proposed rule could practically be interpreted to require the use of the test method mandated for certification because a manufacturer would be unclear about what “as effective” means and therefore, use the test method for certification. We changed the language in the final rule to clarify the point that production testing does not require the use of the test method for certification. Additionally, § 1107.10(b)(3)(iii)(C) of the proposed rule would state: “If a manufacturer is uncertain whether a production test is as effective as the certification test, the manufacturer must use the certification test.” This provision has been eliminated from the final rule because it is no longer necessary after the above clarification that production testing does not require use of the test method for certification.

Finally, § 1107.21(c)(3) of the final rule states that if a production testing plan fails to provide a high degree of assurance of compliance with the applicable children’s product safety rules, we may require the manufacturer to meet the requirements of § 1107.21(b) for a periodic testing plan to ensure a high degree of assurance of compliance. This is not a new requirement. Proposed § 1107.21(b) had the same requirement for manufacturers with a reasonable testing program. Because we have removed the reasonable testing program and reserved subpart B in the final rule, the periodic testing requirement is no longer linked to the reasonable testing program. However, we have moved this requirement to the production testing plan option in § 1107.21(c)(3) and the ISO/IEC 17025:2005-accredited laboratories option in § 1107.21(d) of the final rule.

(Comment 48)—A commenter strongly recommended that we recognize or endorse certain internal in-house testing facilities that conform to ISO 17025:2000 standard. The commenter felt that this recognition would greatly expedite testing procedures and the time for certain required testing and reduce costs and lessen dependence on the third party conformity assessment bodies. Another commenter stated that we should recognize internal laboratories as a way to reduce dependence on third party conformity assessment bodies. The reasons for the suggestions include:

Better monitoring of product safety, a desire to reduce testing costs, encourage other manufacturers to develop their own internal testing facilities, and promote continuous product improvements.

(Response 48)—We recognize that using ISO/IEC 17025:2005-accredited laboratories for testing purposes provides an added measure of assurance to production testing. The laboratories are accredited by an independent body as competent to perform specified tests. They are also recognized as having instituted a management system that establishes procedures and properly maintains records. Laboratory accreditation also establishes controls concerning data integrity, equipment calibration, and procedures to resist undue influence over testing results.

For these reasons, we have amended the final rule to include a new § 1107.21(d), which provides a maximum periodic testing interval of three years for a manufacturer using an ISO/IEC 17025:2005-accredited laboratory for production testing purposes. The laboratory must be accredited by an ISO/IEC 17011:2004(E) (more commonly known as ISO/IEC 17011:2004 and how it will be referred to in the preamble) (*Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*) accreditation body, and must use the same test method(s) used for certification testing when conducting testing to ensure continued compliance. We chose the 3-year time period because: (1) Having a laboratory accredited by an independent body as competent to perform specified tests provides an additional measure of assurance in the accuracy and the integrity of the testing results; (2) a laboratory accredited to ISO/IEC 17025:2005 must have implemented a management system that establishes and follows procedures, properly maintains records, and establishes controls concerning data integrity equipment calibration, and procedures to resist undue influence; and (3) using the same tests as the tests used for product certification provides a more direct assessment of compliance to the applicable children's product safety rules than process control techniques. Section 1107.21(d)(1) of the final rule also states that manufacturers must conduct testing using the ISO/IEC 17025:2005-accredited testing laboratory frequently enough to provide a high degree of assurance that the children's product continues to comply with the applicable children's product safety rules. In addition, section 1107.21(d)(1)

of the final rule states that a manufacturer may consider the information obtained from testing conducted by an ISO/IEC 17025:2005-accredited testing laboratory when determining the appropriate testing interval and the number of samples for periodic testing that are needed to ensure that there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable children's product safety rules.

Section 1107.21(d)(2) of the final rule states that if the continued testing described in § 1107.21(d)(1) fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, then we may require the manufacturer to comply with § 1107.21(b) or modify the testing frequency or number of samples required to ensure a high degree of assurance of continued compliance. Section 1107.21(d)(2) is substantially the same, in this respect, as proposed § 1107.21(b), in requiring the use of other third party periodic testing options if a manufacturer's testing program fails to provide a high degree of assurance of compliance, except that § 1107.21(d)(2) refers to "continuing testing," rather than a "reasonable testing program."

Section 1107.21(g) of the final rule describes the incorporation by reference of ISO/IEC 17025:2005 and ISO/IEC 17011:2004, as required by the Director of the Federal Register. This incorporation by reference is necessary because § 1107.21(d)(1) references ISO/IEC 17025:2005 and ISO/IEC 17011:2004.

(Comment 49)—Two commenters stated that periodic testing or auditing should be considered a regular internal function. One commenter stated that any manufacturer with qualified internal testing facilities should perform such duties easily and regularly to ensure product quality. Having a third party conformity assessment body conduct periodic testing would result in a significant cost impact and would create production delays and difficulties. The commenter suggested that we not specify the frequencies of testing under different manufacturing conditions. The commenter stated that product safety rules should apply to finished products.

Another commenter noted that a consistently good product testing record should reflect the competency of qualified internal testing facilities and expertise. Accredited and qualified in-house testing facilities should be able to handle this effectively and

economically. The commenter noted that smaller manufacturers may have to use the services of third party conformity assessment bodies per the agreed schedule, which needs to be defined and specified.

(Response 49)—The final rule requires periodic testing to be conducted by a CPSC-accepted third party conformity assessment body. If the "qualified internal testing facility" is a CPSC-accepted firewalled conformity assessment body, then tests from that conformity assessment body can be used for periodic testing purposes. Otherwise, an internal testing facility is considered a first party laboratory, and its test results would not be allowed for third party periodic testing purposes.

Regarding the commenter's assertion of significant costs, the commenter did not describe how third party testing would result in significant costs and production difficulties relative to internal testing. However, a manufacturer with internal testing facilities may use product test data from those facilities to increase its knowledge of the product and its manufacture, and thus, may reduce the number of samples required for periodic testing purposes as a means of controlling costs. Section 1107.21(c)(1) of the final rule states that if a manufacturer has implemented a production testing plan, the maximum testing interval for periodic testing is extended to two years. Additionally, under § 1107.21(d)(1) of the final rule, if the manufacturer uses an ISO/IEC 17025:2005-accredited testing laboratory for the production testing (and other requirements are met), the maximum testing interval is extended to three years. These methods may be used by a manufacturer to reduce the costs of third party conformity assessment body testing. (We explain the reasons for adding § 1107.21(d) to the final rule at part III.D.3.b. of the preamble.)

We agree with the commenter on the undesirability of specifying testing frequencies for different manufacturing conditions. Thus, the final rule specifies only the maximum testing interval for periodic testing and lists some factors to be considered by manufacturers in developing their periodic test plans. We also agree with the commenter that product safety rules should apply to finished products.

As noted above, pursuant to H.R. 2715, elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 50)—One commenter said we should clarify what level of detail or generality we would allow in mandating that a production test plan describe the tests to be conducted or the measurements to be tested. The commenter assumed that a manufacturer would have the flexibility to create a test plan that could be applied to multiple products. For example, the commenter suggested that a production testing plan could address testing by generic specifications of products, such as die-cast cars or fashion dolls. However, the commenter said that if we expect a production testing plan to specify the testing details for each product, then it would be so burdensome as to be economically not feasible.

(Response 50)—The use of production testing as a means to increase the maximum periodic test interval to two years is intended to be general in nature and flexible enough to be adaptable to many different products and manufacturing processes. It is the manufacturer's responsibility to tailor its production testing to its specific products. As stated in § 1107.21(c)(2) of the final rule, production testing is intended to ensure continued compliance of the product to the applicable children's product safety rules with a high degree of assurance. It is not required that a manufacturer's production testing plan specify all testing details for each product. However, § 1107.21(c)(2)(i) of the final rule specifies that a production testing plan must include a description of the process management techniques used, the tests to be conducted, or the measurements to be taken; the intervals at which the tests or measurements will be made; the number of samples tested; and the basis for determining that the combination of process management techniques and tests provide a high degree of assurance of compliance if they are not the tests prescribed for the applicable children's product safety rule. This is necessary because techniques and test methods other than those prescribed in the applicable children's product safety rules may be used in production testing and are needed to show the effectiveness of the production testing plan.

(Comment 51)—Two commenters stated that, although we acknowledged that a production testing plan could include procedures such as process management techniques, statistical process control programs, or failure mode analysis, the proposed rule would describe a rather rigid product testing plan. One commenter characterized the following two requirements as "a rigid

product testing plan": (1) The requirement for each site to have a separate production testing plan, and (2) the production testing interval should be short enough to ensure that, if the samples selected for production testing comply with an applicable rule, ban, standard, or regulation, there is a high degree of assurance that the untested product will comply with the applicable rule, ban, standard, or regulation. The commenter urged us to acknowledge more clearly that the elements of a production test plan enumerated in the rule are not the only elements that we will recognize and that other processes, such as statistical process control mechanisms, also may be used to show compliance.

One commenter suggested that the terms "production testing plan" and "remedial action plan" be replaced with "production testing plan or procedures" and "remedial action plan or procedures" because the use of the word "plan" may be interpreted too narrowly to allow for the range of methods that manufacturers may use to meet the requirements.

(Response 51)—Manufacturers may use production testing plans with any procedure that is effective in detecting noncompliant products (with the requirement that purely mathematical methods with no testing are not allowed). Statistical process control mechanisms, properly applied, are acceptable methods for production testing. The production testing plan implemented at each manufacturing site may be identical, if appropriate; but each site must have identifiable production testing specific to the products produced at that site. On our own initiative, we have added language to § 1107.21(c)(2)(ii) that clarifies this point. This is a matter of documentation, and the commenter has not provided a reason why this creates a problem. The final rule does not mandate a specific testing interval for all products. Rather, the requirement in the final rule is for production testing to be effective in detecting noncompliant products with whatever fixed or variable testing interval achieves a high degree of assurance of compliance to the applicable product safety rules.

We decline to adopt the suggestion to change "production testing plan" to "production testing plan or procedures." Dictionary definitions of "plan" and "procedure" are so similar that, to use both terms would be redundant. We believe that the description of a production testing plan in § 1107.21(c) of the final rule provides a sufficient description of its scope.

Additionally, because the final rule does not require a remedial action plan for children's products, the suggestion to replace the term "remedial action plan" with "remedial action plan or procedures" is no longer applicable.

(Comment 52)—One commenter supported the acknowledgement that the same production testing plan that is available to the manufacturing site and the importer of record (retailers) is sufficient. The commenter gave the example of a manufacturer who developed a production testing plan and demonstrated to their customers (the importers of record or retailers) that their production testing plan provides a high degree of assurance of compliance. The commenter said that importers could validate critical aspects of the plan through factory audits and evaluations, production inspections that ensure that the testing plan records are present and match the specifications, and periodic testing using a CPSC-accepted third party conformity assessment body.

(Response 52)—An importer can arrange for another party (e.g., a foreign manufacturer) to develop and conduct production testing for a product. The same production testing plan from another party may be used by multiple importers as a means of increasing the importers' maximum periodic test interval to two years. The importer, as the product certifier, must use due care to ensure that the implementation of a production testing plan ensures with a high degree of assurance that continuing production complies with the applicable product safety rules.

(Comment 53)—One commenter noted that proposed § 1107.21(b) would specify that if a manufacturer's reasonable testing program fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, we may require the manufacturer to meet the requirements of proposed § 1107.21(c) or modify its reasonable testing program to ensure a high degree of assurance of compliance. The commenter asked who would determine whether a reasonable testing program provides a high degree of assurance of compliance, and how.

(Response 53)—With regard to the language in proposed § 1107.21(b) referenced by the commenter, because we have reserved the reasonable testing program option for periodic testing in the final rule, we have moved that language to §§ 1107.21(c)(3) and (d)(2) (renumbered in the final rule) and modified it to refer to the production testing plan option with a maximum periodic testing interval of two years and/or the testing by an ISO/IEC

17025:2005-accredited testing laboratory option with a maximum periodic test interval of three years. With these changes in mind, we will decide, based on the available evidence, whether a children's product's production testing plan provides a high degree of assurance of continuing compliance to the applicable children's product safety rules.

(Comment 54)—One commenter noted that the voluntary establishment of a reasonable testing program for a children's product increases the period between periodic tests to—at least once every two years—from the requirement of annual periodic testing for children's products without a reasonable testing program. The commenter suggested that we consider the costs involved in establishing and maintaining a reasonable testing program, and noted that a reasonable testing program reasonably warrants a more relaxed periodic testing frequency standard, particularly when the manufacturing process inherently results in uniform production, with very little variability in the composition or quality.

The commenter also noted that the preamble to the proposed rule stated that not all periodic testing was required to be conducted by a third party conformity assessment body (75 FR at 28348). In addition, the commenter pointed out that the preamble to the proposed rule also stated that the appropriate periodic testing interval “may vary for a manufacturer depending on the manufacturer's knowledge of the product and its manufacturing processes” (75 FR at 28349).

The commenter urged us to permit a manufacturer of a children's product with a reasonable testing program in place to determine when to obtain third party conformity assessment body testing of ordinary children's books or other children's paper-based printed products under a testing frequency standard of at least once every four years. The commenter noted that third party conformity assessment body testing still would occur in response to a material change to the children's product.

(Response 54)—The final rule extends the maximum testing interval for periodic testing from one to two years for manufacturers who have implemented a production testing plan as a means of ensuring continued compliance of the product to the applicable children's product safety rules. The production testing plan in § 1107.21(c) of the final rule is the same production testing plan in the reasonable testing program described in

proposed § 1107.10(b)(3). This increase in the maximum testing interval was not based on the costs of third party testing or on the costs of implementing a production testing plan. When a manufacturer implements a production testing plan and conducts production testing, such testing provides more information about a product's manufacture and compliance with the applicable children's product safety rules, which justifies allowing a longer period of time between third party periodic tests. If a manufacturer uses an ISO/IEC 17025:2005-accredited testing laboratory for testing to assure continued compliance, the maximum third party periodic testing interval is extended to three years.

The commenter is correct that the preamble to the proposed rule stated that not every periodic test has to be done by a third party conformity assessment body if the manufacturer has implemented four elements of a reasonable testing program. However, § 1107.21(c) of the final rule states that a manufacturer who has implemented a production testing plan for a children's product must submit samples of the product to a third party conformity assessment body for periodic testing at least once every two years. We recognize that these two statements may be confusing, and we have clarified the text in § 1107.21(a) of the final rule to state that all third party periodic testing must be conducted by a CPSC-accepted third party conformity assessment body accredited to the scope of the tests required.

Additionally, on August 12, 2011, the President signed into law H.R. 2715 which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Regarding the commenter's suggestion on testing ordinary children's books or other children's ordinary paper-based printed materials, section 14(i)(4) of the CPSA, as amended by H.R. 2715,

excludes ordinary books from the third party testing requirements in section 14(a) of the CPSA. Additionally, we have decided to reserve, rather than finalize, subpart B, which would have pertained to a reasonable testing program for nonchildren's products. Therefore, it is unnecessary for us to address the commenter's suggestion.

#### c. Periodic Testing in the Absence of a Reasonable Testing Program

Proposed § 1107.21(c) would state that if a manufacturer has not implemented a reasonable testing program, as described in subpart B of this part, then all periodic testing would be required to be conducted by a third party conformity assessment body, and the manufacturer would be required to conduct periodic testing, described in proposed § 1107.21(c)(1) and (c)(2).

Proposed § 1107.21(c)(1) would require the manufacturer to develop a periodic testing plan to ensure that children's products manufactured after issuance of a children's product certification, or when the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules.

Proposed § 1107.21(c)(2) would require the periodic testing interval selected to be short enough to ensure that, if the samples selected for periodic testing pass the test, then there is a high degree of assurance that the other untested children's products manufactured during the interval comply with the applicable children's product safety rules. The interval for periodic testing may vary, depending upon the specific children's product safety rules that apply to the children's product. Proposed § 1107.21(c)(2)(i) through (c)(2)(ix) listed factors to be considered when determining the periodic testing interval.

On our own initiative, we made several editorial and complementary changes to proposed § 1107.21(c). In brief:

- We have renumbered proposed § 1107.21(c) as § 1107.21(b) in the final rule.

- In § 1107.21(b), we have revised the text to state the periodic testing options more clearly. Section 1107.21(b) now states that a manufacturer “must conduct periodic testing to ensure compliance with the applicable children's product safety rules at least once a year,” except as otherwise provided in § 1107.21(c) and (d) (the other periodic testing options in the final rule), or as provided in regulations under this title. Section 1107.21(b) of the final rule further states that if a manufacturer does not conduct

production testing under § 1107.21(c), or testing by a testing laboratory under § 1107.21(d), the manufacturer must conduct periodic testing pursuant to the periodic test plan requirements at § 1107.21(b)(1) and the testing interval requirements in § 1107.21(b)(2).

- In § 1107.21(b)(1) (formerly proposed § 1107.21(c)(1)), we have replaced “assure” with “ensure with a high degree of assurance.” We made this change to be consistent with other language used throughout the final rule. We also replaced “children’s product certification” with “Children’s Product Certificate,” for consistency throughout the final rule, and we eliminated the requirement of providing a basis for determining that the periodic testing plan provides a high degree of assurance that the product being tested continues to comply with all applicable children’s product safety rules. We eliminated the requirement that a manufacturer provide the basis for determining that a periodic test plan provides a high degree of assurance because manufacturers would need to demonstrate how their production testing plan provides a high degree of assurance if we requested that information. However, it is unnecessarily burdensome to require a manufacturer to provide the basis for this in every instance, when we may never inquire about the basis for a particular periodic test plan. Therefore, we have eliminated this requirement from the final rule. In addition, we have added language to § 1107.21(b)(1) to clarify that a manufacturer must have a periodic testing plan specific to each children’s product manufactured at a manufacturing site.

- In § 1107.21(b)(2) (pertaining to testing intervals), we have revised the text to refer to “testing interval” or “testing,” instead of “periodic testing interval” or “periodic testing.” “Testing Interval,” is substantially the same as proposed § 1107.21(c)(2), except that, for consistency, the final rule refers simply to a “testing interval,” rather than a “periodic testing interval.” (The proposed rule had used different terms, such as “periodic testing interval,” “testing interval,” “interval,” and “interval for periodic testing,” for the same concept.) We removed the word “periodic” because it is redundant in the context of the section, which addresses “periodic testing.” Additionally, § 1107.21(b)(2) states that the testing interval may vary, depending upon the specific children’s product safety rules that apply to the children’s product, “but may not exceed one year.” We added “but may not exceed one year” to clarify that, consistent with

§ 1107.21(b), the periodic testing must occur at least once a year.

- Section 1107.21(b)(2)(i) through (x) lists the factors to be considered in determining the testing interval. This list is almost identical to proposed § 1107.21(b)(2)(i) through (ix), except that the final rule separates the examples of nonmaterial changes that were at proposed § 1107.21(b)(2)(v). Proposed § 1107.21(b)(2)(v) would mention “Nonmaterial changes, such as introduction of a new set of component parts into the assembly process, or the manufacture of a fixed number of products.” Upon further consideration, we felt that the two examples were dissimilar, so § 1107.21(c)(2)(v) of the final rule now states: “Introduction of a new set of component parts into the assembly process”; and § 1107.21(c)(2)(vi) of the final rule states: “The manufacture of a fixed number of the products.” We have renumbered the remaining subparagraphs in § 1107.21(c)(2), accordingly.

#### d. Periodic Testing Frequency for Low-Volume Manufacturers

Proposed § 1107.21(d) would pertain to the periodic testing frequency for low-volume manufacturers. In brief, the proposal would not require a manufacturer to conduct periodic testing unless it has produced or imported more than 10,000 units of a particular product; instead, once that threshold has been reached, the manufacturer would be subject to the periodic testing requirements of proposed § 1107.21(a), and (b), or (c).

Several commenters addressed proposed § 1107.21(d). The comments spanned a range of issues. For example, one commenter said that the production or importation volumes for different children’s products may vary substantially, such as large electrical motorcycles and small stuffed toys, so the commenter said it is not reasonable to apply the same volume of 10,000 to all children’s products. The commenter asked whether periodic testing is necessary when a large number of products are produced in a short timeframe, for example, 100,000 toys produced in three months. Other commenters also focused on the 10,000 figure, asking whether the figure applies only to the number of children’s products produced, whether the number applies to each distinct product or to all children’s products made at a facility, or whether the figure of 10,000 units is too high or too low. (One commenter stated that its analysis of CPSC-announced recalls in 2009, showed that 47 percent of the recalls involved products of

10,000 units or less.) Yet another commenter interpreted the provision as an acknowledgement by the CPSC that the periodic testing frequency standard is not essential to safety because it dispenses with periodic testing altogether in the case of manufacturers who produce or import no more than 10,000 units of a product.

On August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 requires, among other things, that we seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. It also contains special rules for small batch manufacturers and directs us to consider alternative testing requirements or exempt small batch manufacturers from certain third party testing requirements. Given these new statutory obligations resulting from H.R. 2715, and, as part of the overall reorganization of § 1107.21, proposed § 1107.21(d) is being renumbered and reserved as § 1107.21(e), so that we may consider issues relating to cost, low-volume products, and small batch manufacturers more fully.

We are also reserving § 1107.21(f) for an amendment to this rule where, elsewhere in this issue of the **Federal Register**, we have published a proposed rule that would implement the “representative samples” provision in section 14(i)(2)(B)(ii) of the CPSA.

#### 4. Proposed § 1107.22—Random Samples

Proposed § 1107.22 would implement the testing of random samples requirement in former section 14(d)(2)(B)(ii) of the CPSA (renumbered by H.R. 2715 as section 14(i)(2)(B)(ii) of the CPSA), by requiring each manufacturer of a children’s product to select samples for periodic testing by using a process that assigns each sample in the production population an equal probability of being selected.

We received many comments on proposed § 1107.22. The commenters made numerous assertions, such as: Product samples should be reasonably representative of the product population; samples should not be golden samples; samples should be selected blindly; samples should not be selected with overt bias; and the rule should not use a statistical definition for random sample. Commenters also expressed concern over practical problems with the proposed section for random sampling. However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised section

14(i)(2)(B)(ii) of the CPSA, by replacing testing of “random samples” to ensure continued compliance with testing of “representative samples” to ensure continued compliance. Given this change in the statute, we have removed § 1107.22 from the final rule. Elsewhere in this issue of the **Federal Register**, we have published a proposed rule that would implement the “representative samples” provision in H.R. 2715.

#### 5. Proposed § 1107.23—Material Change a. General Requirements

Proposed § 1107.23(a) would state that if a children’s product undergoes a material change in product design or manufacturing process, including the sourcing of component parts, that a manufacturer exercising due care knows or should know that such material change could affect the product’s ability to comply with the applicable children’s product safety rules, the manufacturer must submit a sufficient number of samples of the materially changed product for testing by a third party conformity assessment body. Such testing would be required before a manufacturer could certify the children’s product. The extent of such testing would depend on the nature of the material change. Proposed § 1107.23(a) also would state that, when a material change is limited to a component part of the finished children’s product and does not affect the ability of the children’s product to meet other applicable children’s product safety rules, a manufacturer may issue a Children’s Product Certificate based on the earlier third party certification tests and on test results of the changed component part conducted by a third party conformity assessment body. For example, if the paint is changed on a children’s product, issuance of a Children’s Product Certificate may be based on previous product testing and on tests of the new paint for compliance to lead, heavy metal, and phthalate concentrations. Proposed § 1107.23(a) also would state that changes that cause a children’s product safety rule to no longer apply to a children’s product are not considered to be material changes. For example, assume that a children’s product consists of a cotton sweater with metal buttons and that the children’s product would be subject to the lead limits in section 101 of the CPSIA. If the manufacturer decided to use wooden buttons instead of metal buttons, the use of wooden buttons would eliminate the need to test the product for lead, and the change to wooden buttons, while arguably a

change in the product’s component parts, would not be a “material change” under proposed § 1107.23(a) for the purposes of complying with the lead content limits. However, for other children’s product safety rules, such as small parts, the change may be a material change.

Additionally, proposed § 1107.23(a) would require a manufacturer to exercise due care to ensure that reliance on anything other than retesting of the finished product after a material change would not allow a noncompliant children’s product to be distributed in commerce. A manufacturer should resolve any doubts in favor of retesting the finished product for certification. A manufacturer also would be required to exercise due care to ensure that any component part undergoing component-part-level testing is the same as the component part on the finished children’s product in all material respects.

We received several comments regarding “material change” and proposed § 1107.23, as well as the corresponding provision at proposed § 1107.10(b)(2)(ii). Although we have decided to reserve subpart B in the final rule, to the extent that comments on proposed § 1107.10(b)(2)(ii) were equally applicable to proposed § 1107.23, we have considered those comments here.

(Comment 55)—A commenter suggested that the definition of “material change” should be moved from proposed § 1107.10(b)(2)(ii) to the definitions in § 1107.2.

(Response 55)—Section 1107.10 has been reserved in the final rule. We agree with the commenter, and we have moved the definition of “material change” to § 1107.2 in the final rule, as this definition still applies to § 1107.23 regarding material changes in children’s products. Thus, § 1107.2 defines “material change” as “any change in the product’s design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product’s ability to comply with the applicable rules, bans, standards, or regulations.”

(Comment 56)—Some commenters suggested revising the proposed definition of “material change” to refer only to changes that “reasonably could affect” compliance.

(Response 56)—The commenters are concerned about a remote possibility that some set of circumstances could combine, such that a seemingly innocuous change could affect the product’s compliance to an applicable product safety rule. We realize that it

would be difficult for a manufacturer to identify every conceivable theoretical effect a change could have on a children’s product’s compliance. Therefore, manufacturers should exercise prudence and competence in determining the effects of a change to the product and in considering whether that change is material. This prudence and competence is encompassed in the manufacturer’s use of due care in evaluating the change.

We decline the commenters’ suggestion to modify the definition of “material change” because the definition now in § 1107.2 of the final rule includes the phrase “a manufacturer exercising due care.” Because the definition of “due care” includes the exercise of prudence and competence by the manufacturer, the addition of “reasonably could” is duplicative.

(Comment 57)—One commenter stated that different versions of the same product (e.g., color, packaging) should not require different tests.

(Response 57)—The commenter is correct that different versions of the same product that are not materially different do not require separate certification tests. The final rule defines a “material change” as any change in the product’s design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product’s ability to comply with the applicable rules, bans, standards, or regulations. Therefore, if the differences between various versions of the same product are not material changes, no additional testing is required. It is the manufacturer’s responsibility to determine if a difference between versions of a product constitutes a “material change.”

(Comment 58)—One commenter suggested that after certification testing of a product, if another product differs by a few minor components from the certified product, and proper proof of equivalent specifications are documented, a reduced sample size for certification should be allowed.

(Response 58)—In the circumstance described by the commenter, if a new product differs from an existing certified product by a few component parts, the manufacturer’s knowledge of the new product and its manufacture might be extensive enough to result in requiring fewer samples for certification testing than the number required for the existing certified product. We reiterate that if a new product is based on changes to an existing certified product, only the applicable product safety rules affected by the changes require

certification testing. The number of samples still must be sufficient to give the manufacturer a high degree of assurance of the new product's compliance with the applicable children's product safety rules. The certifier also may use component part testing as a means of reducing the number of finished samples needed for certification. If the changes from the existing certified product to the newer product are not material, then the certification tests on the existing certified product can be used for certification purposes on the newer product.

Thus, on our own initiative, we have revised § 1107.23(a) to make several clarifying changes to the paragraph. First, we have added language to the final rule to require the number of samples submitted to be sufficient to provide a high degree of assurance that the materially changed component part or finished product complies with the applicable children's product safety rules. This language was added because third party testing that occurs after a material change serves as recertification of the product for the applicable children's product safety rules affected by the material change. This language is essentially the same requirement contained in § 1107.20(a) of the final rule for initial certification of children's products. Additionally, § 1107.23(a) was revised to add the following: "A manufacturer of a children's product that undergoes a material change cannot issue a new Children's Product Certificate for the product until the product meets the requirements of the applicable children's product safety rules." Also, we added the following words to the first sentence: "and issue a new Children's Product Certificate." These are not intended to be substantive changes, but rather, meant to make clear what is already the case—that material changes require recertification based on passing test results. Finally, we have removed the language in proposed § 1107.23(a) that would require a manufacturer to exercise due care to ensure that reliance on anything other retesting of the finished product after a material change would not allow a noncompliant children's product to be distributed in commerce. This provision was removed because this issue is addressed in § 1109.5(a)(1) of the accompanying component part testing rule. We also removed the requirement that a manufacturer should resolve any doubts in favor of retesting the finished product for certification. This provision was removed because the issue is addressed in § 1109.5(c) of the

accompanying component part testing rule.

(Comment 59)—Two commenters raised issues related to products subject to 16 CFR part 1201, *Safety Standard for Architectural Glazing Materials*, although the issues they raised have wider implications that involve other products, including children's products. The products subject to that safety standard are glazing materials (glass) used or intended for use in doors and enclosures. The commenters noted that these types of glass normally are manufactured in a continuous process that is subject to numerous minor and ongoing adjustments to respond to atmospheric and other factors and to make sure that the tempering process continues properly. In addition, there can be numerous minor variations in format, size, and thickness of the glass, as well as other product characteristics that are a normal part of shifting from one product to another to meet customers' orders. This industry's current process of certification and quality control involves periodic third party "certification" testing to the requirements of 16 CFR part 1201 and uses alternate means for checking breakage performance of samples from subsequent production, such as a center punch test for tempered glass and the drop-ball and/or pummel test for laminated glass, in order to monitor ongoing compliance with the standard. If a potential failure of the standard is detected by these alternate tests, corrective action is taken, and product distribution is not resumed until a subsequent production test shows that the breakage performance has been restored.

The commenters requested clarification that the ongoing adjustments described above would not be "material changes" that would require recertification of the product. The proposed rule defines "material change" as one that "could affect the product's ability to comply with the applicable rules \* \* \*". One commenter requested that we state:

An adjustment to equipment or machinery made in order to maintain, achieve, or assure compliance with the applicable rules \* \* \* is *not* a material change within the meaning of section 1107.10.

The other commenter suggested the following addition to the rule:

Adjustments in the equipment or machinery to affect the product's ability to comply with any applicable rules or standards should not be considered a "material change" in the manufacturing process \* \* \* but will require the manufacturer, following those adjustments to subject the product to its production testing

plan and to achieve passing production test results before the manufacturer may resume production of that product.

(Response 59)—Although regulated non-children's products still must meet the certification requirements in section 14(a)(1) of the CPSA, we have reserved subpart B, including the reasonable testing program described in proposed § 1107.10. However, the broader issue presented by this commenter, which relates to adjustments in equipment or machinery, is applicable to children's products as well, so we will address this issue with regard to children's products.

In order for a change to be a "material change," it should be one that could adversely affect the product's ability to comply with the rule, ban, standard, or regulation. Minor and ongoing adjustments during manufacturing, especially in continuous flow processes, to maintain compliance with the applicable product safety rules are not considered material changes. However, we do not agree entirely with the commenters' suggested language because that language would include adjustments made to "achieve" compliance (*i.e.*, to change a product from noncompliance to compliance). Such a change would constitute a "material change"; thus, additional certification testing would be required.

(Comment 60)—One commenter suggested that, in proposed § 1107.10(b)(2), it also should be noted that testing of units within a common family of products should allow a test of one unit to represent all others within the family of products if the other models are materially the same. The commenter added that, regarding proposed § 1107.10(b)(2)(ii)(B), a manufacturer should not be required to conduct additional "certification" testing upon a change to the parts or materials, if the change does not affect the overall safety of the system. The commenter suggested that we revise the section to give manufacturers the ability to make changes to parts and materials without having to undergo costly and time-consuming certification testing. The commenter would allow manufacturers to conduct in-house testing that would show that the results of any change do not materially alter the performance of that part or system with regard to the safety elements in the applicable rule.

(Response 60)—Although regulated non-children's product must still meet the certification requirements in section 14(a)(1) of the CPSA, we have reserved subpart B, including the reasonable testing program described in proposed § 1107.10. However, the broader issue presented by this commenter related to

certification testing of units within a common family and when there has been a material change to a product is applicable to children's products as well, so we will address this issue with regard to children's products.

The final rule does allow what the commenter is suggesting—that testing of units within a common family of products be allowed to represent all of the other units within the family. Section 1107.20(a) of the final rule states that samples used for certification must be identical in all material respects to the finished children's product. If, as the commenter has stated, the tested units are identical in all material respects as others within the product family, then the test results can be applied to the other units within the product family.

Section 1107.23(a) describes testing requirements when there has been a material change in a children's product. If a change could adversely affect compliance with the applicable children's product safety rules, then it is considered a "material change," and retesting is required. If the commenter's phrase "does not affect the overall safety of the system" means that the change does not affect compliance with the applicable rules, then the change is not considered a "material change," and no recertification testing is required.

(Comment 61)—Some commenters stated that the requirement to submit a sufficient number of samples of a materially changed product for third party testing before certifying the changes would be costly and would inhibit manufacturers from making continuous product improvements. Ultimately, according to the commenters, this will reduce the safety of children's products.

(Response 61)—Section 14(i)(2)(B)(i) of the CPSA requires children's products to be subject to third party conformity assessment body testing when there has been a material change in the product's design or manufacturing process. These types of changes may introduce new hazards or may result in the product no longer being in compliance with the applicable children's product safety rules. After a material change to the product, only those applicable product safety rules that could adversely be affected require recertification. The samples selected must be of a sufficient number to provide a high degree of assurance that the test, conducted accurately, demonstrates the ability of the children's product to meet all applicable children's product safety rules.

Regarding continuous product improvements, changes that do not

adversely affect compliance to the applicable children's product safety rules are not "material changes" under the final rule and do not require recertification testing. However, manufacturers may wish to consider possible material change testing as part of their product improvement processes.

(Comment 62)—Three commenters characterized the testing requirements resulting from the proposed definition of "material change" as "overly burdensome" and "very unreasonable." The commenters differed in their reasons for arriving at this conclusion. One commenter characterized the proposed rule's material change testing requirements as too "open ended" because of imprecise language. The consequence of this lack of specificity, according to the commenter, is that "either you will always test or you take a big risk. This is completely unfair and unreasonable."

Another commenter expressed concern with the examples in proposed § 1107.23(c). Specifically, the commenter stated that manufacturing process changes, "such as new solvents to clean equipment or a new mold for an accessible metal component part of a children's product pose undue burdens on manufacturers without advancing safety goals." The commenter contended that "to require companies to develop new product specifications for every new solvent used in a facility or installation of a new mold made to the exact specifications as a prior mold" would require new third party testing, and this could not have been Congress' intent. The commenter suggested: "it should be left to the consumer product manufacturer to assess whether changes are likely to affect the ability of the particular product to meet a specific standard, ban, rule, or regulation."

The third commenter stated that the proposed definition is not clear and asked whether "using the same quality level of component part but just the different brand is a material change." The commenter stated that if third party testing of each such change is necessary, then "it is very unreasonable."

(Response 62)—The intent of § 1107.23 for children's products is not to be overly burdensome, but rather, to demonstrate the product's continued compliance with applicable children's product safety rules when a change in the product's design, manufacturing process, or component part sourcing has been made that could adversely affect a previously certified product's compliance. Because the final rule applies to a variety of products and manufacturing methods, it is impractical to anticipate every type of

product change that could occur to all affected products that might adversely affect compliance to an applicable product safety rule and provide specific language. Therefore, the final rule is written using general language to allow manufacturers the flexibility to determine, in each particular circumstance, whether a product change could adversely affect the product's compliance with an applicable children's product safety rule. Manufacturers should use their special knowledge of a product's design, components, and manufacturing processes to differentiate what changes may constitute a "material change," and require certification testing, as opposed to nonmaterial changes.

After initial certification of a product, a "material change" is a change that "could affect the product's ability to comply with applicable rules, standards or regulations." The ability to adversely affect compliance is what distinguishes a "material change" from nonmaterial changes. The final rule acknowledges that a manufacturer has special knowledge of its product design, components and, production processes, and the rule states that a "manufacturer exercising due care knows or should know" when a change is material. For example, a new solvent that does not contain any of the prohibited chemicals (lead and the prohibited phthalates), or a replacement mold shown to be made to the same specifications as a compliant mold, would not be examples of "material changes."

(Comment 63)—One commenter noted that proposed § 1107.10(b)(2)(ii)(A) would state that, for material changes that only affect product compliance to certain rules, certification may be based on the materially changed component, unless the change affects the finished product. If the change affects the finished product, then the certification must be based on the finished product. (The commenter is referring to proposed § 1107.10(b)(2)(ii)(A) and (C).) The commenter asked, when a disagreement arises, who makes the final determination of whether the material change affects the finished product's compliance?

(Response 63)—We have reserved subpart B, including the reasonable testing program described in proposed § 1107.10. However, the broader issue presented by this commenter relates to certification testing of units when there has been a material change is applicable to children's products as well, so we will address this issue with regard to children's products.

The commenter is correct that when a material change to a product occurs, only product safety rules affected by the material change would require recertification. If the material change solely affects a component part of a children's product and does not affect the ability of other component parts or the finished product to comply with applicable children's product safety rules, then § 1107.23(a) allows a manufacturer to base certification on earlier third party certification tests and on third party testing of the changed component part.

With regard to disagreements regarding whether the finished children's product is needed for certification after a material change, a manufacturer must use due care in determining whether testing the finished product or a component part is required. This due care is applied on a per-rule basis. Some rules, such as prohibited phthalate content, can be evaluated on component parts. Other rules, such as the safety standard for cribs, always require the use of the finished product for certification testing. Assuming the disagreement is between the manufacturer and the CPSC regarding whether a finished product is required for certification after a product change, we will decide, based on the available evidence, whether a material change requires samples of the finished product for certification.

#### b. Product Design

Proposed § 1107.23(b) would state that, for purposes of subpart C, the term "product design" includes all component parts, their composition, and their interaction and functionality when assembled. To determine which children's product safety rules apply to a children's product, a manufacturer should examine the product design for the children's product as received by the consumer. For example, if a children's product has a component part that contains lead or has a sharp edge, but is inaccessible when the product is assembled, then the lead and sharp edge requirements would not be applicable to the finished product. Changes to a product's design may result in a product being subject to additional children's product safety rules. For example, if a wooden button on a children's product is replaced with a plastic button, the wooden button previously excluded from testing for lead content has been replaced with a component part (the plastic button) that would be subject to testing for compliance with the lead content requirements.

We received no comments on this paragraph. However, on our own

initiative, we have revised the second sentence in § 1107.23(b) to state that a manufacturer should examine the product design for the children's product "as received or assembled by the consumer." We inserted the words "or assembled" because some children's product safety rules require the product to be tested in the finished product state in order to assess compliance with the applicable children's product safety rule. For example, assessing compliance with the inaccessibility requirements for the lead requirements mandates testing of the finished product in order to determine whether a component part of the product is accessible. The new language, "or assembled," was added to make it clear to the manufacturer that products must be tested as received or assembled by the consumer in those instances where the product is not received in assembled form.

#### c. Manufacturing Process

Proposed § 1107.23(c) would state that a material change in the manufacturing process is a change in how the children's product is made that could affect the finished children's product's ability to comply with the applicable children's product safety rules. For each change in the manufacturing process, a manufacturer should exercise due care to determine if compliance to an existing applicable children's product safety rule could be affected or if the change results in a newly applicable children's product safety rule. The following are some examples of a material change to the manufacturing process of a children's product:

- A new technique is used to fasten buttons to a doll's dress that could affect the children's product's ability to comply with the small parts rule;
- New solvents are used to clean equipment employed in the manufacture of children's products; the new solvents could affect the children's product's ability to comply with the lead content and phthalates requirements; and
- A new mold for an accessible metal component part of a children's product is introduced into the assembly line that could affect the children's product's ability to comply with requirements for sharp edges.

We received no comments on this paragraph and have finalized it without change.

#### d. Sourcing of Component Parts

Proposed § 1107.23(d) would state that a material change in the sourcing of component parts results when the replacement of one component part of a

children's product with another component part could affect compliance with the applicable children's product safety rules. This would include, but would not be limited to, changes in component part composition, component part supplier, or use of a different component part from the same supplier who provided the initial component part.

We received no comments on this paragraph. However, on our own initiative, we have revised the first sentence to replace the phrase "applicable children's product safety rules" with "applicable children's product safety rule." We made this change to avoid creating any misunderstanding of whether a material change results only if multiple children's product safety rules are affected; in other words, a material change can result, even if compliance with only one children's product safety rule is affected.

#### 6. Proposed § 1107.24—Undue Influence

Proposed § 1107.24(a) would implement the requirement to safeguard against undue influence, pursuant to section 14(i)(2)(B)(iv) of the CPSA, by requiring each manufacturer to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body.

##### a. Procedures To Safeguard Against the Exercise of Undue Influence

Proposed § 1107.24(a) would require the manufacturer to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity body.

(Comment 64)—Several commenters disagreed with the requirement in proposed § 1107.24(a) that manufacturers must establish procedures to safeguard against the exercise of undue influence on a third party conformity assessment body. One commenter noted that we already require third party conformity assessment bodies to train their staff to detect, avoid, and report undue influence. Another commenter stated that third party testing facilities already have these training programs in place. Two commenters asserted that third party conformity assessment bodies are not likely to be influenced unduly because their accreditation would be withdrawn.

(Response 64)—Section 14(i)(2)(B)(iv) of the CPSA requires us to establish, by rule, protocols and standards for safeguarding against the exercise of

undue influence by a manufacturer or private labeler on a third party conformity assessment body. This provision applies to manufacturers and private labelers as opposed to third party conformity assessment bodies. Consequently § 1107.24 of the final rule requires manufacturers of children's products to establish procedures to avoid actions that could undermine the integrity of laboratory test data. We have an interest in ensuring the integrity of laboratory test results used in the certification of children's products.

In a separate rulemaking, we will address the issue of requiring third party conformity assessment bodies to report undue influence.

(Comment 65)—Some commenters expressed concern regarding foreign manufacturers and the undue influence requirement. One commenter suggested that we will be unable to enforce the undue influence requirement on foreign manufacturers and importers. Another commenter said that the importer of record should not be responsible for undue influence initiated by people not directly employed by the importer of record. The commenter requested confirmation that importers will be responsible for training their employees only, and will not have the responsibility of training the employees of other companies, such as manufacturers, vendors, freight handlers, or laboratories.

(Response 65)—Section 1107.24 of the final rule requires “each manufacturer” to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. Section 1107.2 of the final rule defines a “manufacturer” as “the parties responsible for certification of a consumer product pursuant to 16 CFR part 1110.” Under 16 CFR part 1110, a foreign manufacturer is not required to certify a finished product; only a domestic manufacturer or the importer of a product made outside the United States is required to issue a finished product certificate. Thus, under § 1107.24, it is a domestic manufacturer or the importer who must establish procedures to safeguard against undue influence.

We agree that an importer is not directly responsible for training employees of other companies. This fact, however, does not absolve the importer issuing a finished product certificate of its duty to exercise due care when relying on test results provided by another company or third party conformity assessment body. A manufacturer or importer who issues a finished product certificate that is based

on test reports from a third party conformity assessment body over whom undue influence has been exercised provides a basis for the CPSC to deem the certificate invalid. We will hold the finished product certifier responsible for exercising due care that component part or finished product manufacturers or suppliers have not exercised undue influence over third party conformity assessment bodies.

(Comment 66)—Two commenters stated that because the term “undue” is undefined, nothing should be construed to prohibit a manufacturer from exercising its rights to challenge third party conformity assessment body test results based upon the manufacturer's belief that they are inaccurate.

(Response 66)—Section 1107.24 is not intended to preclude a manufacturer from challenging failing test results in appropriate circumstances. If a manufacturer has reason to think a test result received from a third party conformity assessment body is in error, it is appropriate to ask the third party conformity assessment body about the test result. Such inquiry does not constitute undue influence.

Additionally, § 1107.20(d) requires a manufacturer to investigate the reasons for a negative certification test result and to take action to address failing test results before a Children's Product Certificate can be issued. This investigation may involve discussions about the test results with the third party conformity assessment body.

#### b. Minimum Requirements

Proposed § 1107.24(b) would require the procedures described in § 1107.24(a) to include minimal requirements. Proposed § 1107.24(b)(1) would require safeguards to prevent attempts by the manufacturer to exercise undue influence on a third party conformity assessment body, including a written policy statement from company officials that the exercise of undue influence is not acceptable, and directing that appropriate staff receive annual training on avoiding undue influence and sign a statement attesting to participation in such training. Proposed § 1107.24(b)(2) would impose a requirement to notify the Commission immediately of any attempt by the manufacturer to hide or exert undue influence over test results. Proposed § 1107.24(b)(3) would impose a requirement to inform employees that allegations of undue influence may be reported confidentially to the Commission and describe to employees the manner in which such a report can be made.

(Comment 67)—Several commenters made remarks about training programs.

Two commenters stated that the training program and recordkeeping requirements (proposed § 1107.26(a)(5)) are burdensome and redundant because companies already have requirements to prohibit unethical behavior, such as exerting undue influence over third party conformity assessment body staff. Other commenters described this requirement as excessive and unreasonable. One commenter stated that the requirements for training are vague and urged us to describe what needs to be included. Another commenter raised questions about the content and form of the training, especially whether a written manual would be enough. Another commenter recommended deleting these requirements.

One commenter urged us to delete the requirement for appropriate staff to receive “annual training” on how to avoid undue influence. The commenter felt that an annual training mandate would be unnecessary and impose excessive costs and burdens on manufacturers of children's products.

(Response 67)—Section 14(i)(2)(B)(iv) of the CPSA requires us to establish protocols and standards, by rule, for safeguarding against the exercise of undue influence on third party conformity assessment bodies by a manufacturer or private labeler. Therefore, we decline the suggestion to delete these requirements from the final rule.

Section 1107.24 of the final rule implements the statutory mandate by requiring manufacturers to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. The rule does not prescribe the form or content of these programs in order to provide manufacturers flexibility in implementing the requirements. For example, manufacturers may wish to create written manuals and may include this training along with other forms of employee training. Manufacturers must keep records of employee participation in the training to be able to ensure that all relevant staff members receive this training pursuant to § 1107.26(a)(6).

We do agree, however, with the commenter who suggested that an annual training requirement reiterating previously presented procedures can impose costs and burdens the benefits of which are unclear. Thus, we have replaced the proposed requirement for annual training with a requirement for retraining when a substantive change to the rule is made regarding undue influence; this requirement appears as a new § 1107.24(b)(2), and we have

renumbered proposed §§ 1107.24(b)(2) and 1107.24(b)(3) as §§ 1107.24(b)(3) and 1107.24(b)(4), respectively, in the final rule. Manufacturers of children's products are free to modify their procedures and conduct retraining as often as they feel it is necessary to institute effectively their policies for safeguarding against the exercise of undue influence.

Additionally, on our own initiative, we have revised § 1107.24(b) of the final rule to make minor editorial or grammatical changes. We have revised § 1107.24(b)(1) to direct that "every appropriate staff member" receive training on how to avoid undue influence. The proposal would state that "appropriate staff receive annual training." By referring to "every appropriate staff member," the final rule clarifies that the emphasis is on training individuals rather than collections of individuals. Additionally, in § 1107.24(b)(4), we have replaced "Commission" with "CPSC" and replaced "to describe the manner" with "a description of the manner."

#### 7. Proposed § 1107.25 Remedial Action

Proposed § 1107.25 would require each manufacturer of a children's product to have a remedial action plan that contains procedures that the manufacturer must follow to investigate and address failing test results.

(Comment 68)—One commenter stated that requiring each manufacturer to have an actual remedial action plan to address failing test results is unnecessary because the remedial action will likely be different, depending upon the situation. Another commenter stated that because they are familiar with how to resolve compliance and quality issues, the preparation of a detailed written remedial action plan is a waste of time, money, resources, and intellect.

(Response 68)—The commenter is correct that, depending on the product and the nature of the test failure, remedial actions may take many different forms. The development of a remedial action plan before production commences could help in the determination of factors, such as lot size or what tracking information to maintain. These factors could help limit the number of production units subject to recall in the event that noncompliant products are introduced into commerce.

However, although it may be efficient and useful to have a formal process (such as the remedial action plan in proposed § 1107.25) to follow after receiving failing test reports, such preformulated plans are not essential,

either for certification or for ensuring continued compliance of consumer products. Ultimately, the manufacturer is responsible for ensuring that the product that they make complies with the applicable product safety rules. For some products and types of failing test reports, *ad hoc* methods may be as effective as preestablished plans in addressing the test failures and ensuring that products are compliant. For these reasons, we have removed the requirements for remedial action plans for children's products from the final rule. We encourage manufacturers who believe that remedial action plans would be advantageous for their product to develop such plans as part of their overall quality assurance system.

(Comment 69)—One commenter appreciated the acknowledgement that a remedial action plan could be a formal standard operating procedure (SOP), along with recordkeeping of each event. The commenter asked whether, when a particular component causes a product to become noncompliant with a rule, and the remedial action eliminates this specific component from the product, would certification have to be repeated. The commenter noted that documentation would be provided that the noncompliant component had been removed and that the product specification was revised. The commenter stated that there would be an SOP that requires a corrective action, along with documentation of the instance of noncompliance, to provide evidence that the product has been corrected and is compliant.

(Response 69)—As noted in our response to Comment 68, we have removed the requirement for a remedial action plan for children's products from the final rule. If a finished product has a noncompliant component part (such as an accessory item), and that item is removed from the finished product, the finished product certifier does not have to repeat certification testing on the newly constituted finished product because the certifier has certification test data demonstrating compliance with all applicable product safety rules for that product. The certifier should make sure that eliminating the noncompliant component part does not affect compliance with another applicable children's product safety rule for the finished product.

(Comment 70)—Several comments addressed the issue of retesting samples. Some commenters noted that often, a testing failure might result from a faulty laboratory test and not from a noncompliant product. The commenters said that the rule should allow retesting in appropriate situations when there is

suspicion about the manner in which a sample was handled or processed, or the certifier is challenging the results of a third party test.

One commenter asserted that if the manufacturer documents and supports any assertions related to the faulty test and the product's compliance, there should be no need for remedial action. Another commenter suggested that the implication in the rule is that any test failure, no matter how trivial, would trigger the need for remedial action, which would be costly. The commenter suggested that establishing tolerances for test results is necessary to reduce testing costs, as well as the burden of remedial actions, and at the same time ensure product safety. The commenter added that children's products are not so consistent that every test produces the same test result. The commenter asserted that retesting is a valid means of responding to a failing test result. Banning retesting out of fear that some unscrupulous parties will attempt to test the product into compliance will create severe problems.

(Response 70)—We have removed the requirement for a remedial action plan for children's products from the final rule. However, we recognize that an error or failure in the testing of a sample may lead to a failing test result, and therefore, investigating the test method and test execution is a legitimate avenue of investigation in those instances. Such an investigation can include examining the test procedures, sample preparation steps, equipment calibration, and other factors, in addition to tests on samples of the product as part of the investigation, which may affect test results, but are not indicative of a noncompliant product. Additionally, § 1107.20(d) of the final rule states that if a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure. A manufacturer cannot certify the children's product until the manufacturer establishes, with a high degree of assurance that the finished product does comply with all applicable children's product safety rules. While the final rule no longer refers to remedial action plans, a manufacture still "must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure." Retesting a product without investigating why the test yielded failing results, and taking whatever action addresses the situation (for

example, calibrating the testing machine before retesting, or correcting a manufacturing problem) to achieve passing results, is not acceptable for certification purposes because the certifier would not have a high degree of assurance that the products produced will be compliant with the applicable product safety rules.

Retesting should not be conducted to “shop” for passing test results or to keep testing the product until a sample finally passes (and disregarding all other tests that suggest the product is not in compliance).

With regard to establishing tolerances for test results, the acceptable values for test results are established in each rule, ban, regulation, or standard and are beyond the scope of this rule.

(Comment 71)—One commenter stated that some standards, such as the standard for the surface flammability of carpets and rugs (16 CFR part 1630), have alternative requirements for products that fail tests. The commenter suggested modifying the language to refer to a product that does not pass the applicable product safety standard, rather than a product that “fails” a test.

(Response 71)—In 16 CFR part 1630, the standard allows for a single failure in eight tests. Because there is an allowance in the standard for a failing test result, we would view such a product as compliant with the standard.

## 8. Proposed § 1107.26 Recordkeeping

### a. The Records To Be Kept

Proposed § 1107.26(a) would require a children’s product manufacturer to maintain records pertaining to:

- The Children’s Product Certificate for each product (proposed § 1107.26(a)(1));
- Each third party certification test (proposed § 1107.26(a)(2));
- The periodic test plan and periodic test results (proposed § 1107.26(a)(3));
- Descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values (proposed § 1107.26(a)(4));
- Undue influence procedures (proposed § 1107.26(a)(5)); and
- All remedial actions taken following a failing test result (proposed § 1107.26(a)(6)).

We did not receive any comments directly addressing proposed § 1107.26(a). However, on our own initiative, or to complement other changes in the final rule, we have revised § 1107.26(a) as follows:

- In § 1107.26(a)(1), we have changed “Records of the children’s product

certificate” to “A copy of the Children’s Product Certificate.” This change is intended to simplify the language in the codified text and use a consistent style throughout part 1107 when referring to the Children’s Product Certificate.

- We have finalized § 1107.26(a)(2) without change.
- In § 1107.26(a)(3), we have revised the recordkeeping elements to reflect changes to the periodic testing provision at § 1107.21. Thus, the final rule requires records of: (1) The periodic test plan and periodic test results; (2) a production testing plan, production test results, and periodic test results; or (3) testing results of tests conducted by a testing laboratory accredited to ISO/IEC 17025:2005 and periodic test results.

We have reserved § 1107.26(a)(4). We intend to place any recordkeeping requirement associated with the testing of “representative samples” at § 1107.26(a)(4). As we stated earlier in part III.D.4 of this document, the final rule removes § 1107.22 because H.R. 2715 amended the CPSA to change “random samples” to “representative samples.”

- We have renumbered proposed § 1107.26(a)(4) as § 1107.26(a)(5), and we have finalized it without change.
- We have renumbered proposed § 1107.26(a)(5) as § 1107.26(a)(6), and we have finalized it with one change to clarify that manufacturers must retain copies of the attestations required under § 1107.24(b)(1).
- We have deleted proposed § 1107.26(a)(6), which would pertain to records of all remedial actions. We have deleted this provision from the recordkeeping requirements because the final rule does not establish remedial action requirements for children’s products.

### b. The Location Where Records Are To Be Kept, the Recordkeeping Period, and the Records’ Availability in the English Language

Proposed § 1107.26(b) would require a manufacturer to maintain the records specified in subpart C at the location within the United States set forth in 16 CFR 1110.11(d) or, if the records are not maintained at the custodian’s address, at a location within the United States specified by the custodian. The manufacturer would be required to make these records available, either in hard copy or electronically, for inspection by the CPSC, upon request.

Proposed § 1107.26(c) also would require a manufacturer to maintain records (except for test records) for as long as the product is in production or imported by the manufacturer, plus five years. Test records would be required to

be maintained for five years. All records would be required to be available in the English language.

(Comment 72)—One commenter expressed concern about the recordkeeping requirements in proposed § 1107.10(b)(5) and asked for clarification of the phrase “for as long as the product is in production or imported.” The commenter noted that the requirements would lead to a massive undertaking for any manufacturer or importer, especially if all of the records must be maintained within the United States.

Another commenter stated that we should clarify the relationship between the requirement to maintain records and the proposed rule’s treatment of material changes requiring recertification, and thus, effectively creating a new product. To simplify the recordkeeping requirements, the commenter asked that the recordkeeping requirements apply “for as long as the product, *without a material change*, is in production or imported by the manufacturer plus five years” (emphasis in original). Otherwise, the commenter stated, manufacturers of long-running products would have to maintain records in perpetuity, which would increase costs without assisting safety or compliance.

(Response 72)—Although the final rule reserves subpart B (which includes proposed § 1107.10(b)(5)), the issues raised by the commenters are applicable to the recordkeeping requirement for children’s products, so we address this issue here for children’s products.

We agree that the burden of maintaining records for the life of a product, plus five years, could be unduly burdensome and difficult to implement, in cases where products undergo changes over time. Moreover, having a different time period for the retention of test reports versus other records may be confusing. Accordingly, we have revised the recordkeeping provision, such that all records must be maintained for at least five years from the date of their creation. If a product does not comply with an applicable children’s product safety rule in a significant way, it is likely that the noncompliant aspect of the product would become apparent within the 5-year period. This change should result in less confusion for the regulated community regarding how long records for a particular product must be maintained.

Additionally, on our own initiative, we have reorganized proposed § 1107.26(b) and (c), by combining them into § 1107.26(b) of the final rule. We

describe other changes in § 1107.26 immediately below.

(Comment 73)—Several commenters expressed concern about the requirement that records be maintained in English. Some commenters stated that we should allow records to be kept in the local language and only require translation into English by the manufacturer or importer when we request documentation. One commenter noted that the proposed rule will require millions of test reports and records to be created and maintained in English, even though only a small fraction of a percent of these test reports will ever be reviewed by the CPSC or other third parties. The commenter maintained that this would be very expensive for the manufacturer because they must find and hire English-speaking technicians to perform the testing.

The commenter also contended that this requirement could be potentially hazardous. The commenter posed this example:

For example, a quality assurance technician in Vietnam may be excellent at maintaining the quality of a product, and she may even have a passable grasp of English, but her English skills may not be sufficient to communicate precise technical findings in English. If she is nonetheless required to record her findings in English, then there is a risk the test results will be transcribed, described and maintained inaccurately. Thus, we ask that the Commission reconsider this English-only requirement in the proposed rule.

Another commenter asserted that a method for making documents available in English in the United States would need to be created to comply with the rule. The commenter contended that the requirement to have English language documents available within the United States does not offer additional confidence in product safety for U.S. consumers. Alternatively, the commenter suggested that a 3-year stay of the requirement that documents be maintained in English would allow a transition period to establish and implement appropriate infrastructure and processes for expanded recordkeeping.

(Response 73)—We agree that it would be burdensome in many cases for all records to be maintained in English. Therefore, § 1107.26(b) in the final rule allows records to be maintained in languages other than English, if the records in the original language can be provided immediately by the manufacturer to the CPSC, and if an accurate English translation can be provided within 48 hours, or within such longer period of time, as may be

negotiated with CPSC staff. Given this change to the final rule, we decline to adopt the suggestion that a 3-year stay of enforcement be implemented for this part of the rule.

(Comment 74)—Many commenters expressed concern about the requirement in proposed § 1107.26(b) that all records be maintained in the United States. Several commenters suggested that instead of requiring manufacturers to maintain records at a location within the United States, we should allow the records to be maintained outside the United States, so long as the records can be accessed from a location within the United States that is specified on the certificate. Some commenters noted that this requirement would be a burdensome and massive undertaking. One commenter did not believe that storing foreign manufacturing documents in the United States for every regulated product increases product safety. The commenter noted that these documents could be stored in their existing location and be submitted to the CPSC, upon request. Alternatively, the commenter suggested that a 3-year stay of the requirement that documents be maintained in the United States would allow a transition period to establish and implement appropriate infrastructure and processes for expanded recordkeeping.

Another commenter noted that ISO 9001, *Quality management systems—Requirements*, requires manufacturers to maintain these types of records at the factory where a product subject to certification is manufactured. Rather than requiring foreign manufacturers to maintain duplicate records in the United States, the commenter suggested that the final rule should harmonize CPSC requirements with ISO's, and require records to be made available to us for inspection, either in hard copy or electronically, through the U.S. subsidiary or other U.S. corporate entity, within a reasonable time after the CPSC requests them, pursuant to section 16(b) of the Consumer Product Safety Act.

(Response 74)—We agree that it may be burdensome and duplicative in many cases to maintain all records in the United States. To reduce this burden and still maintain prompt access to records when needed, § 1107.26(b) of the final rule no longer requires records to be maintained in the United States. However, all records must be made available, either in hard copy or electronically, such as through an Internet Web site, for inspection by the CPSC, upon request. Because the change eliminates the requirement that records

be kept in the United States, we decline to adopt the suggestion of a 3-year stay of enforcement of this part of the rule.

Regarding harmonization with the requirements of ISO 9001, the commenter did not specify which requirements in ISO 9001 should be harmonized. However, eliminating the requirement that records be maintained at a location within the United States would be consistent with sections 4.2.3.d of ISO 9001 (to ensure that relevant versions of applicable documents are available at points of use), and section 4.2.3.g of ISO 9001 (to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose).

(Comment 75)—One commenter stated that some of the required recordkeeping is “redundant and unnecessarily duplicative,” such as production testing plans for multiple factories. Fees for outsourcing these services could be significant and burdensome to many small businesses, the commenter asserted.

(Response 75)—Section 1107.21(c)(2) of the final rule sets forth the option to implement a production testing plan to increase the maximum periodic test interval, and § 1107.21(c)(2)(ii) of the final rule requires that each manufacturing site conduct separate production testing because the location at which a product is manufactured could have a material effect on the product's ability to comply with the applicable rules. Factors such as power quality, climate, personnel, and factory equipment could materially affect the manufacture of a product. Because it cannot be assumed that units of the same product manufactured in more than one location are identical in all material respects, the finished product certifier must conduct separate production testing for the product for each manufacturing site. We have taken other steps to reduce the recordkeeping burden, such as not requiring that records be kept in the United States, and we are eliminating the requirement that all records must be maintained in English.

(Comment 76)—One commenter noted that companies have established processes and formats and, in many cases, invested in information technology solutions to prepare and transmit these certificates in accordance with the law. The commenter added: “Retailers are relying upon such certificates as they can with the benefit of reduced liability under section 19 of the CPSA” as evidence that the products comply with all the applicable product safety rules. The commenter stated that

we need to clarify that the form of delivery of title, in and of itself, should not require additional testing, documentation, and certification. The commenter also asked us to clarify that retailers can rely upon domestically located supplier certifications without duplication of testing and certification requirements.

(Response 76)—A certificate must accompany the product, as specified in 16 CFR part 1110. Certificates can be in paper or electronic form, as described by the commenter. The commenter is correct that the issuance of a Children's Product Certificate means that the children's product has passed its certification tests. If the commenter is referring to additional third party tests requested by retailers after the issuance of a certificate, we emphasize, as we did in the preamble to the proposed rule, that retailers and sellers of children's products can rely on certificates provided by product certifiers without having to conduct additional testing, if those certificates are based on testing conducted by a CPSC-accepted third party conformity assessment body.

(Comment 77)—One commenter stated that the proposed recordkeeping requirements will have the largest immediate impact to the retail industry. The commenter stated that to meet these provisions, a process to centrally maintain records for an estimated 300,000 items per year would need to be created. The number of pages of documentation covering a portion of products for one large general merchandise retailer acting as importer of record, would range from a low of 375,000,000 pages to more than 1,000,000,000 pages per year. The commenter's estimate was based upon the following:

- Full product specification (150–200 pages);
- Certification testing (30–100 pages);
- Production testing plan (inspection records, testing documents, and production plans quality control documents) (1,000–3,000 pages); and
- Periodic testing (50–200 pages).

This estimate did not include records of remedial action, if necessary.

Another commenter stated that the standards of recordkeeping outlined in the proposed rule are clear and should not present an unreasonable burden on manufacturers or importers. The commenter asserted that any responsible firm would maintain these records even without the rule, and they further asserted that establishing a reasonable baseline for product safety recordkeeping is crucial to enforcement.

(Response 77)—We have revised the final rule to reduce costs associated

with recordkeeping requirements, such as reducing and simplifying the record retention period to five years from the date of creation for all records, eliminating the requirement that records must be maintained in English, and eliminating the requirement that records must be maintained in the United States. Moreover, removal of the remedial action plan requirement for children's products should further reduce the recordkeeping burden for manufacturers.

Even with these changes, the burden associated with the rule's recordkeeping requirements will vary among manufacturers or importers. As the commenters indicate, some manufacturers will consider the burden to be significant, whereas others will feel that the recordkeeping requirements are comparable to those at "any responsible firm." The recordkeeping burden could be fairly heavy for some products and relatively light for others, depending upon the complexity of the product, the number of product safety rules that are applicable to the product, and the amount of testing required. However, as stated in the preamble to the proposed rule (75 FR at 28360), documentation and recordkeeping are required to establish the identity of the product and to demonstrate that the product complies with the applicable safety rules, not only when it is certified, but also on a continuing basis after certification.

The final rule gives manufacturers and importers the flexibility to maintain records. The final rule does not require that the records be maintained in a specific CPSC format. While the final rule specifies what records or information must be maintained, a manufacturer may maintain the records—as the commenter suggested—within their own recordkeeping systems, if those systems meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

(Comment 78)—One commenter stated that manufacturers of children's furniture cannot provide any data on the cost of the recordkeeping requirements because they do not know yet the storage capacity that will be required to comply with the rule. Furniture manufacturers of non-children's products have reported that the cost of creating the system to collect their data on 16 CFR part 1303 compliance was approximately \$100,000, and the cost of records maintenance was in the range of \$30,000 to \$50,000 per year. Based on this, furniture manufacturers of children's products are certain that it will cost them in excess of \$100,000 to

build and program such a system. These furniture companies will require additional staff to maintain and update the system, and that will require the expenditure of at least \$30,000 to \$50,000 a year, per person.

(Response 78)—We acknowledge that there will be costs for tracking the data and maintaining the records, which could involve the development of software for tracking and managing the data and hiring additional staff. However, the final rule's recordkeeping requirements give manufacturers flexibility in determining how to meet them. Further, we have revised the final rule to reduce costs associated with recordkeeping requirements, such as reducing and simplifying the record retention period to five years from the date of creation for all records, eliminating the requirement that records must be maintained in English, and eliminating the requirement that records must be maintained in the United States.

(Comment 79)—One commenter stated that as long as the manufacturer can use existing documentation, then there should not be an undue burden on the regulated community to comply with third party testing requirements for children's products. However, the commenter noted that if we intend to require that the manufacturer maintain documentation in a different format, then there will be a cost associated with maintaining this information.

(Response 79)—The final rule does not require manufacturers to develop codes, numbering systems, or special data formats. A manufacturer is free to use any format, provided that the required information is available to the CPSC, when requested.

(Comment 80)—One commenter objected to the requirement that records must be maintained for five years. The commenter pointed out that the larger suppliers to the U.S. market, including chain stores, divide an order and ship separately to different states. Without giving details, the commenter implied that this would make the requirement to keep all required records for five years a heavy burden on manufacturers.

(Response 80)—This comment is from a trade association for a foreign manufacturer of children's products that may have misinterpreted the proposed rule. The proposed rule would require test records to be maintained for five years; other records would be maintained for as long as the product was in production or imported (without a material change), plus five years. In any event, a foreign manufacturer has no obligation to keep the records specified under § 1107.26, unless it

agrees contractually to maintain the records on behalf of the importer. Even under these circumstances, only the importer has the obligation to keep the records. The importer, as the certifier, is responsible for maintaining the records or having another party maintain the records on its behalf. As for the retailer in the distribution chain, they are not required to keep the records unless they are also the importer. An importer's obligation to maintain the records for the product is independent of how many different retailers distribute the product. Regarding the burden of keeping records for five years, the 5-year record retention requirement was selected to be consistent with the 5-year statute of limitations in 28 U.S.C. 2462. However, this requirement is not intended to supersede record retention times that are specified in existing regulations.

#### *E. Proposed Subpart D—Consumer Product Labeling Program*

##### 1. Introduction

Proposed subpart D, consisting of one section, would implement the label provision at section 14(i)(2)(A) of the CPSA. Section 14(i)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements in section 14(a) of the CPSA.

##### 2. General Requirements

Proposed § 1107.40(a) would allow manufacturers and private labelers of a consumer product to indicate, by a uniform label on or provided with the product, that the product complies with any consumer product safety rule under the CPSA, or with any similar rule, ban, standard or regulation under any other act enforced by the CPSC.

(Comment 81)—One commenter contended that allowing manufacturers to place an optional label on their products that states: “Meets CPSC Safety Requirements,” could give manufacturers who use such a label an unfair market advantage over manufacturers who choose not to include the label. The commenter stated that some manufacturers will not use the label because it will increase their product's cost. The commenter suggested that some consumers may choose the labeled product based upon a false assumption that a product without the label is somehow less safe. The commenter stated that some manufacturers will use the label as a misleading marketing tool or even alter

the font type or size of the label for marketing purposes.

(Response 81)—Section 14(i)(2)(A) of the CPSA requires us to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of section 14(a) of the CPSA. Section 1107.30 of the final rule (formerly proposed § 1107.40) implements this requirement. Use of the labeling program is at the discretion of the manufacturer or private labeler, and the manufacturer or private labeler must determine costs versus benefits for their particular products. The label specifications are designed to avoid giving consumers the false impression that the product is CPSC-tested, -approved, or -endorsed. Section 1107.30(d) of the final rule prohibits manufacturers or private labelers from implying, through manipulation of the font type, font size, or other means that the CPSC has tested, approved, or endorsed the product.

Other than renumbering this section, we have finalized paragraph (a) without change.

##### 3. Label Specifications

Proposed § 1107.40(b) would require the label to be printed in bold typeface, using an Arial font of not less than 12 points, be visible and legible, and state: “Meets CPSC Safety Requirements.”

(Comment 82)—One commenter stated that the final rule should not specify the features that must be used for the optional label indicating that a product meets the CPSC's safety requirements. The commenter did not think we should specify features such as size, color, font, or location because these will depend on the product. The commenter noted that there is the possibility that the specified text type and size will not be compatible with the different internal systems developed by retailers and manufacturers to meet the needs of the affected product. The commenter said that to specify any requirements other than what works with a firm's internal systems would have absolutely no benefit at all.

Another commenter expressed concern with the font size being “no less than 12 points” because that could be a problem on some small containers. The commenter said that we should use instead, the font size requirements in the Federal Hazardous Substances Act.

One commenter agreed with our approach of labeling products to indicate compliance with the rules. The commenter recommended that the CPSC's labeling program include guidelines for the type, style, color, and font of such labels and should consider

use of symbols or a mark, rather than words or initials, as proposed. Symbols also would help overcome language barriers for communicating compliance. The commenter said that the guidelines should allow variations in the label's size to accommodate products of different physical dimensions, but the general appearance of the label must remain consistent. They recommended that the labels appear as a permanent mark on the product packaging, as well as on the product itself.

(Response 82)—We agree with the commenters that specifying particular fonts and minimum sizes for the label could make adding a label difficult for some products. Depending on the product's characteristics, such as size, surface finish, and the presence of a smooth, flat area for the label, a label with a minimum font size may be difficult to apply. Therefore, § 1107.30(b) of the final rule (renumbered from proposed § 1107.40(b)) specifies that the label must be visible and legible and does not specify a font and a minimum size. This change will give manufacturers the flexibility to implement a labeling system tailored to their product.

The text of the message on the label remains: “Meets CPSC Safety Requirements.” The label may be affixed to the product or provided with the product to provide flexibility for the manufacturer or private labeler in their implementation of the labeling requirements. Because the labeling requirements will apply to all consumer products covered by an applicable product safety rule, it would be impossible to design a label that would work with every firm's internal system.

Regarding the labeling requirements in the Federal Hazardous Substances Act (FHSA), the commenter did not specify which labeling requirements should be used. The general labeling requirements for labeling certain toys and games in section 24(d) of the FHSA states that the label shall be displayed in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter. The changes to the final rule are consistent with the FHSA in this regard.

The final rule does not allow for the use of a symbol or mark because a symbol or mark might be misinterpreted as a CPSC certification mark or CPSC endorsement of the product. Additionally, the recommendation that a label be affixed to the product and its packaging may reduce the flexibility of manufacturers who choose to use the labeling program.

In reviewing the comments submitted regarding labels and the provisions of subpart D of the proposed rule, we noticed that proposed § 1107.40(d) (renumbered as § 1107.30(d) in the final rule) could be misunderstood to imply that an alternative label may be used in place of the label specified in proposed § 1107.40(b). We have revised § 1107.30(d) in the final rule to state that other labels, in addition to the label specified in § 1107.30(b), may be placed on the product, as long as the additional labels do not change the meaning of the label specified in § 1107.30(b).

(Comment 83)—One commenter argued that the requirement to provide only the statement: “Meets CPSC Safety Requirements,” is not adequate for indicating compliance. The commenter asserted that a registered certification mark is the only way to indicate adequately full compliance, and they noted further that the use of a registered certification mark is also used as a tool to address counterfeiting activities.

(Response 83)—The consumer product labeling program described in proposed § 1107.40 (renumbered as § 1107.30 in the final rule) is voluntary on the part of a manufacturer, importer, or private labeler. Section 14(a) of the CPSA requires the manufacturer, importer, and private labeler to issue a General Conformity Certificate or a Children’s Product Certificate for any product covered by an applicable product safety rule, regardless of whether a manufacturer elects to label their product under § 1107.30. A registered certification mark authorized by a certification body for a manufacturer to include with the product does not contain the information required by a certificate, as specified in 16 CFR part 1110, and it cannot be used in place of the certificate. Thus, we disagree with the commenter that certification marks are the only way to indicate full compliance. Other products, such as mattress sets, indicate compliance (in this case to 16 CFR part 1633) without the use of certification marks. Furthermore, we are aware of multiple instances of counterfeit certification marks on consumer products. As a result, we decline to revise the rule as suggested by the commenter.

#### 4. Conditions Under Which a Consumer Product May Bear the Label

Proposed § 1107.40(c) would allow a consumer product to bear the label if the manufacturer or private labeler has certified, pursuant to section 14 of the CPSA, that the consumer product complies with all applicable consumer product safety rules under the CPSA

and with all rules, bans, standards, or regulations applicable to the product under any other act enforced by the Consumer Product Safety Commission.

We received no comments on this paragraph and, other than renumbering § 1107.40 as § 1107.30, we have finalized it without change.

#### 5. Use of Other Labels

Proposed § 1107.40(d) would allow a manufacturer or private labeler to use another label on the consumer product, as long as such label does not alter or mislead consumers as to the meaning of the label described in proposed § 1107.40(b). A manufacturer or private labeler would not be allowed to imply that the CPSC has tested, approved, or endorsed the product.

In reviewing the comments submitted regarding labels and proposed subpart D, we noticed that proposed § 1107.40(d) (renumbered as § 1107.30(d) in the final rule) could be misunderstood to imply that an alternative label may be used in place of the label specified in § 1107.40(b). Therefore, on our own initiative, we have revised § 1107.30(d) to state that other labels, in addition to the label specified in § 1107.30(b), may be placed on the product, as long as the additional labels do not change the meaning of the label specified in § 1107.30(b).

#### F. Other Comments Received

Several commenters raised questions on whether the final rule should contain “safe harbors” (where certain actions are considered to be complying with a particular requirement), and questioned the rule’s effective date. Other commenters raised issues that were outside the scope of the rulemaking, such as whether a particular product was a “children’s product” or raised concerns on matters pertaining to the accreditation of third party conformity assessment bodies.

(Comment 84)—Two commenters suggested that the rule clearly should allow for recognition of “safe harbors” based upon adherence to national standards for good manufacturing practices, international ISO standards governing GMP, and industry-based GMP category-specific guidelines that manufacturers may use as evidence of their good faith commitment to attaining a high degree of assurance that their products meet or exceed applicable federal safety standards. The commenters noted that we have recognized that such programs may be considered evidence of meeting the requirements under the proposed rule but noted as well that we have not yet recognized our authority to provide for

such safe harbors, claiming the CPSIA did not make such specific provision (75 FR at 28339). According to the commenters, specific statutory authority is not a precondition to an agency acting under its rulemaking and enforcement authority to recognize such safe harbors. The commenters contended that we should provide such recognition.

(Response 84)—As we noted previously in the preamble to the proposed rule (75 FR at 28339), section 14 of the CPSA does not contain a safe harbor exception, nor does it establish any criteria by which the Commission could recognize testing programs for purposes of a safe harbor.

The final rule does not contain a safe harbor provision based upon a manufacturer’s participation in a voluntary or industry-sponsored program; nor have we recognized any such program to indicate compliance with the final rule. We note that ISO standards for good manufacturing practices are generally industry-specific in areas such as cosmetics, pharmaceutical operations, food handling, and medical devices, products largely beyond the CPSC’s jurisdiction. It is unlikely that any one GMP standard would be deemed workable or acceptable for all manufacturing methods for children’s products.

(Comment 85)—One commenter noted that the preamble to the proposed rule refers to a 95 percent statistical significance level as constituting a “high degree” of assurance. The commenter asked whether the CPSC would consider 95 percent probability or confidence level to be a safe harbor level.

(Response 85)—In the preamble to the proposed rule, the 95 percent probability level was discussed as an alternative definition of a “high degree of assurance” that we considered and subsequently rejected. We “decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level (or any other level of statistical confidence) because there may be difficulty in applying the statistical methods to all manufacturing processes” (75 FR at 28344). Therefore, we do not consider a 95 percent confidence level to constitute automatically a “high degree of assurance”; nor do we consider it to constitute a safe harbor level for purposes of compliance with the final rule. Determining what constitutes a “high degree of assurance” varies, depending upon the product manufactured and the manufacturing processes used. The determination must be made by individual manufacturers, based upon their knowledge of their products and manufacturing processes.

(Comment 86)—One commenter noted that, for most major retailers, the creation of a product begins with a design specification that originates 12 months or more prior to manufacture or import into the United States. The commenter said that retroactively applying all the requirements of the final rule would be unduly burdensome. The commenter added that manufacturers of compliant products that are currently on retailers' shelves may not have any or all of the components of a reasonable testing program. Generating this documentation "after the fact" is simply not possible. The commenter asked that the rule apply only to products whose development begins 180 days on or after adoption. Accordingly, products would begin to be certified based upon a reasonable testing program with all accompanying documentation approximately 18 months after adoption of the final rule.

One commenter suggested that we set the effective date at one year from the publication of the final rule because that is how long it would take their industry to change its manufacturing processes to be able to comply with the requirements of a reasonable testing program.

Another commenter said that they simply do not have the staff or the resources to get the third party testing done on all of the products that could fall within the definition of "children's product" and record it in a data collection and storage system (yet to be designed and implemented) within the 180-day timeframe mentioned in the preamble to the proposed rule. That commenter suggested that they needed at least 365 days, and therefore, they requested that we extend the stay of enforcement until February 2012.

(Response 86)—The preamble to the proposed rule indicated that a final rule would become effective 180 days after its date of publication in the **Federal Register** (75 FR at 28361). However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised the CPSIA in several different ways, and it also affected section 14(i)(2)(B)(ii) of the CPSA. H.R. 2715 also created a new section 14(i)(3)(B) of the CPSA, which requires us, no later than one year after H.R. 2715's date of enactment, to review the public comments (on opportunities to reduce the costs of third party testing requirements), and it permits us to "prescribe new or revised third party testing regulations," if we determine that "such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations."

Consequently, we have finalized those provisions that H.R. 2715 did not affect directly. We also have decided to make the final rule effective 15 months after date of publication in the **Federal Register** so that parties can begin taking steps to develop internal processes, such as recordkeeping, and so that we, and interested parties, can consider how H.R. 2715 interacts with the final rule.

We note that the effective date for the final rule is not calculated based on when development of a product begins, but rather, is calculated based on the date the product is manufactured. The requirements of the final rule apply only to products manufactured on or after the effective date of the final rule, and they do not apply retroactively to products already manufactured and certified.

(Comment 87)—One commenter expressed concern that the rule has the potential to multiply the current volume of product testing by several fold and that third party conformity assessment bodies will be unable to provide accurately and efficiently the increased testing capacity needed by retailers/importers to comply with this rule. The commenter asserted that currently, without the rule being in effect, retailers already are experiencing delayed turnarounds in product testing, and it is not uncommon to have special requests denied due to the current backlog in testing.

The commenter also expressed concern that the increased testing demand may affect laboratory execution, potentially resulting in incorrect laboratory results, which may cause compliant product to be lost, or may allow noncompliant product to enter commerce. The commenter said that if the capacity of the third party test conformity assessment bodies is exceeded, retailers' and manufacturers' ability to meet the rule's effective date could be jeopardized. The commenter asked that the third party conformity assessment body capacity issue be taken into consideration when establishing the effective date of the final rule.

(Response 87)—We are aware that implementation of section 14(a)(2) of the CPSA potentially could result in insufficient testing capacity at CPSC-accepted third party conformity assessment bodies. We note that in the majority of the notices of requirements that have issued since 2008, there have been very few claims of insufficient capacity, and when such issues have arisen, we have taken steps to address the matter (see 75 FR 34360, June 17, 2010). We intend to monitor and address, if possible, any capacity issues that arise after the final rule becomes effective.

(Comment 88)—One commenter objected to the application of the regulation to some juvenile furniture. The commenter stated that it is difficult to estimate the cost of testing for children's products when we have not yet decided on the definition of a children's product. Another commenter generally supported the idea of third party testing of children's products but was unclear about what products are included in the category of children's products.

(Response 88)—The final rule does not address what products fall within the definition of "children's products"; and therefore, the comment is outside the scope of the rule. However, after the comment was submitted, we issued an interpretative rule (now codified at 16 CFR part 1200) regarding the definition of children's product, providing the guidance the commenter is seeking.

(Comment 89)—One commenter wondered whether a manufacturer or importer of a children's product subject to a children's product safety rule for which no third party testing conformity assessment bodies have been accredited by CPSC, is required to certify the product based on such testing. The commenter also wondered whether an importer is prohibited from importing the children's product until we accredit third party testing conformity assessment bodies for the children's product safety rule.

(Response 89)—The final rule does not address the issuance of notices of requirements for accreditation of third party conformity assessment bodies; and therefore, the comment is outside the scope of the rule. However, if there are no CPSC-accepted third party conformity assessment bodies whose scope includes a rule applicable to a children's product, those products are not prohibited from being imported. The children's products must still comply with the requirements of the applicable children's product safety rules. For example, if a rule established a limit of X for a particular chemical in children's products, but there were no CPSC-accepted third party conformity assessment bodies to test for X, the children's product would still be subject to the limit of X for that particular chemical; the absence of a CPSC-accepted third party conformity assessment body would not mean that the limit no longer applies.

(Comment 90)—One commenter recommended that conformity assessment bodies should: (a) Comply with the standards in ISO/IEC Guide 65, or (b) in fulfillment of the requirements in ISO/IEC 17025:2005, during each audit review and resubmission of CPSC

Form 223, demonstrate independence from “\* \* \* financial and other pressures and influences that may adversely affect the quality of their work \* \* \*”; the commenter also suggested requirements for audits of conformity assessment bodies.

Another commenter expressed ongoing concern over the distinct possibility that accredited testing organizations, especially “firewalled” and “government laboratories,” could be subject to influence and threats to impartiality by outside or related interests. The commenter expressed concern that the new audit procedures stated that all types of third party conformity assessment bodies: Independent, firewalled suppliers, and government-owned or -controlled would be treated the same and were all called third party conformity assessment bodies. The commenter stated that these different types of conformity assessment bodies have different modes of operation, and they need to be treated differently by us in both the auditing and accreditation requirements. The commenter suggested that we require applicants to submit the evidence used to validate the fulfillment of ISO/IEC 17025:2005 requirements for the laboratory to “have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work,” not only as part of their application to the CPSC, but also on an ongoing basis, as part of each audit review and resubmission of CPSC Form 223.

Two commenters stated that the proposed rule fails to differentiate between firewalled and independent conformity assessment bodies. According to one commenter, a manufacturer can submit samples to its firewalled conformity assessment body even if its reasonable testing program fails to provide a high degree of assurance of compliance with the applicable children’s product safety rules. The commenter sought clarification of the provision that a manufacturer of children’s products with a reasonable testing program may submit samples to its firewalled conformity assessment body every two years.

(Response 90)—The final rule does not address the requirements for conformity assessment bodies; and therefore, the comments are outside the scope of the rule. Conformity assessment body requirements will be addressed in a separate rulemaking. Further, section 14(f) of the CPSA

defines third party, firewalled, and governmental conformity assessment bodies.

(Comment 91)—Two commenters recommended that we consider a number of steps to ensure that third party conformity assessment bodies are protected against undue influence. These included the following: (1) Adopting the requirements in Clause 4.2 of the ISO/IEC Guide 65; (2) using the OSHA NRTL program as a model for laboratory accreditation; and (3) requiring all laboratories applying to the Commission to submit evidence that they fulfilled ISO/IEC 17025:2005 section 4.1.5 b. One commenter made the recommendation for “firewalled” conformity assessment bodies. Another commenter would require annual reassessments of third party conformity assessment bodies.

(Response 91)—The final rule does not address undue influence requirements for third party conformity assessment bodies; and therefore, the comments are outside the scope of this rule. This rule establishes the requirements for manufacturers to safeguard against the exercise of undue influence on third party conformity assessment bodies.

(Comment 92)—Several commenters submitted comments on the concurrent rulemaking for component part testing in proposed 16 CFR part 1109.

(Response 92)—The final rule does not establish the requirements for component part testing; and therefore, these comments are outside the scope of this rule. We have, instead, considered those comments in that rulemaking. (*See Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party’s Finished Product Testing or Certification, to Meet Testing and Certification Requirements* (16 CFR part 1109)).

(Comment 93)—One commenter opined that an existing third party certification system under the OSHA NRTL program, in conjunction with testing being carried out in testing facilities accredited to ISO/IEC 17025, is the preferred method for product certification for the CPSC. The commenter recommended that we consider a similar program or an accredited certification program that meets the requirements of ISO/IEC Guide 65 and ISO/IEC Guide 67.

(Response 93)—The final rule does not address certification systems or accreditation, such as ISO/IEC Guides 65 and 67; and therefore, the comment is outside the scope of this rule.

(Comment 94)—Several commenters asked us to exempt silk from 16 CFR

part 1610. They argued that the regulation exempts plain surface fabrics weighing at least 2.6 ounces per square yard and fabrics made from acrylic, modacrylic, nylon, olefin, polyester, and wool, but not silk. The commenters stated that silk’s reaction to fire is comparable to wool and better than the synthetics that are exempted.

(Response 94)—The final rule does not address 16 CFR part 1610; and therefore, the comments are outside the scope of this rule.

(Comment 95)—One commenter noted that heavy element and phthalates testing use some chemicals. The commenter stated that, with increased testing, there will be more chemical waste, which may not be desirable.

(Response 95)—The final rule does not address testing methods for specific substances; and therefore, the comment is outside the scope of the rule.

(Comment 96)—One commenter suggested developing an exemption list for vinyl fabrics produced in accordance with 16 CFR part 1611, *Standard for the Flammability of Vinyl Plastic Film*, using a process similar to that used to develop the exemption list in 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*. In the latter case, testing over a number of years showed that certain types of fabrics always produce passing results when tested according to 16 CFR part 1610, and those types of fabrics eventually were exempted from the standard.

(Response 96)—The final rule does not address 16 CFR part 1611; and therefore, the comment is outside the scope of the rule.

(Comment 97)—One commenter disagreed that a standard of general application to all consumer products in a category should be considered a “children’s product safety rule” for purposes of the CPSIA.

(Response 97)—The final rule establishes the requirements for the testing and certification of children’s products and for the labeling of compliant consumer products. Determinations of whether a particular safety standard is a children’s product safety rule are outside the scope of this rule.

(Comment 98)—One commenter suggested that we consider developing training guidelines for the regulated community and testing laboratories that explain key elements of a reasonable testing program for non-children’s and children’s products. The guidelines could include helpful training aids and presentations to increase knowledge and understanding. The guidelines could include helpful examples and scenarios

for most common issues (e.g., developing a random sampling program) and even infrequent but complex issues (e.g., traceability for raw materials and product components).

(Response 98)—The final rule is limited to establishing the requirements for testing and certification for children's products and for labeling of consumer products as compliant; therefore, the comment is outside the scope of the rule. Further, we have reserved proposed subpart B (the reasonable testing program for non-children's products) for future consideration. We may consider establishing training programs in the implementation of the final rule.

(Comment 99)—One commenter noted that the proposed rule had to be worded very generally to be applicable to a wide range of products. This has had the effect of making it more difficult to understand how the rules will be applied in any specific industry. The commenter suggested that we conduct regional, industry-specific workshops to explain to the regulated manufacturers how these general rules will apply to their existing procedures and where new regulatory obligations exist.

(Response 99)—The final rule is limited to establishing the requirements for testing and certification for children's products and for labeling of consumer products as compliant; therefore, the comment is outside the scope of the rule. We may consider establishing regional industry-specific workshops in the implementation of the final rule.

(Comment 100)—One commenter recommended that the labels for toys be used to communicate not only compliance with the standards, but also the appropriate age range for the toy. The commenter said that the European Union uses a universal mark that indicates the inappropriate age ranges of a toy if it presents a choking hazard. The commenter said that the CPSC's program could expand on that concept, by recommending labeling that caregivers can use to separate toys intended for siblings of differing ages, while also preventing parents and other caregivers from buying toys that may be inappropriate for the age of the child. The commenter believes that this could help enhance toy safety by reducing children's exposure to inappropriate toys.

(Response 100)—The final rule does not address labeling for the appropriate ages ranges for a toy; therefore, the comment is outside the scope of the rulemaking. Section 14(i)(2)(A) of the CPSA requires us to implement a program by which a manufacturer may

label a product to comply with the certification requirements of section 14(a) of the CPSA. However, the CPSC staff has issued *Age Determination Guidelines: Relating Children's Ages to Toy Characteristics and Play Behavior*, T. P. Smith (Ed.) (2002) (which can be found on the CPSC Web site at <http://www.cpsc.gov/BUSINFO/adg.pdf>) which addresses the issue raised by the commenter.

(Comment 101)—One commenter asserted that the best approach would be to allow businesses to manage their compliance risks as best they can because " \* \* \* the prophylactic approach to testing adopted by the CPSC will inevitably put many small or micro businesses into bankruptcy \* \* \*. If the law does not permit the agency to adopt sensible rules that allow businesses to manage their compliance risk as best they can (where the standards remain in place, but the government stops trying to tell businesses HOW to comply), then the Commission must finally tell Mr. Waxman what he doesn't want to hear—that his law is broken and can't be fixed \* \* \*." The commenter then wrote: " \* \* \* I don't believe the agency can devise sensible regulations to fix this problem short of a legislative change."

(Response 101)—Comments about the merits of section 14 of the CPSA or the CPSIA are beyond the scope of this rulemaking. However, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision provides relief for small batch manufacturers. Another provision in H.R. 2715 requires the CPSC to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. H.R. 2715 directs the CPSC to seek public comment on seven specific issues, including other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires the CPSC to review the public comments and states that the CPSC may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 102)—One commenter, who manufactures die-cast metal toys, commented that the 90 ppm lead content limit is too low to allow use of the usual aluminum for casting their products, even though the same metal is used to make cooking utensils.

Furthermore, the commenter stated that it costs \$3,700 to test one unit and that the market will not absorb the costs of testing multiple units per batch. The commenter implied that these costs would cause it to go out of business or make its products in China. The commenter expressed the belief that it should not have to test using third party conformity assessment bodies because:

1. They are ISO 9001:2008 compliant.
2. They document all of their supplier receipts of metal, plastic, and powder paint materials.
3. They conduct a metal analysis for each production run with their spectrometer.

(Response 102)—The final rule does not address lead content and surface coating limits and; therefore, comments on the allowable concentration levels are outside the scope of this rule.

However, H.R. 2715 directs the CPSC to seek public comment on seven specific issues, including the extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations, and the extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for testing consumer products subject to a third party testing requirement. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715.

#### IV. Regulatory Flexibility Act

##### A. Introduction

We have examined the impacts of the final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would reduce any significant impact of a rule on small entities.

Several sections that were included in the proposed rule are not included in the final rule, but they are being reserved for future rulemaking. Proposed subpart B, pertaining to a reasonable testing program for non-children's products, is not included in the final rule, but we may address the issue in a future rulemaking. The proposed section pertaining to the

selection of random samples for children's products (§ 1107.22) is not included in the final rule, and it is addressed in a separate rulemaking published elsewhere in this issue of the **Federal Register**. Proposed § 1107.21(d), which would provide a partial exemption from periodic testing for low-volume products is not included in the final rule. The reason for omitting proposed § 1107.21(d) from the final rule is that H.R. 2715 asked us to examine means to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. It also contained special rules for small batch manufacturers and directed us to consider alternative testing requirements or to exempt small batch manufacturers from certain third party testing requirements. Given these new statutory obligations resulting from H.R. 2715, we are reserving § 1107.21(e) (formerly proposed § 1107.21(d)) so that we may consider issues related to cost, low-volume products, and small batch manufacturers more fully. Finally, proposed § 1107.25, which would establish requirements for remedial action for children's products, has not been included in the final rule.

Before promulgating a final rule, the Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis of the rule that analyzes the impact that the rule will have on small entities. The final regulatory flexibility analysis must contain:

- (1) A succinct 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 summary 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) 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;
- (4) 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
- (5) 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.

#### *B. Need for, and Objectives of, the Rule*

Section 14(a)(2) of the CPSA requires that every manufacturer of a children's product that is subject to a children's product safety rule certify that the product complies with the applicable children's product safety rule based on testing conducted by a third party conformity assessment body accredited to conduct such tests. The final rule establishes requirements and procedures for manufacturers to certify children's products under this section of the CPSA.

Section 14(i)(2)(A) of the CPSA requires that we initiate a program by which a manufacturer or private labeler may label a product as complying with the applicable safety rules. The statute also requires us to establish protocols and standards: (i) For ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. With the exception of items (ii) (standards and protocols for the testing representative samples), and (iii) (establish protocols and standards for verifying that a product tested by a conformity assessment body complies with applicable safety rules), the final rule implements these requirements.

The objective of the final rule is to reduce the number of children's products that are distributed each year that fail to comply with one or more children's product safety rules. The applicable children's product safety rules were established to reduce the unreasonable risk of injury or death due to foreseeable hazards associated with particular children's products.

#### *C. Comments on the Initial Regulatory Flexibility Analysis, and Our Responses*

The preamble to the proposed rule contained our initial regulatory flexibility analysis (76 FR at 28352 through 28360). Several commenters addressed issues pertaining to that analysis.

(Comment 103)—One commenter noted that in estimating the number of

firms that could be impacted by the proposed rule, the book publishing industry (NAICS code 511130) and printing industry (NAICS code 323117) were not included. The commenter recommended their inclusion for the final regulatory flexibility analysis.

(Response 103)—We acknowledge that the initial regulatory flexibility analysis inadvertently omitted these industries. However, the recently enacted H.R. 2715 exempts ordinary books and ordinary paper-based printed materials from the third party testing requirements, so the commenter's concern no longer applies.

(Comment 104)—One commenter indicated that the cost of complying with the reasonable testing program requirements for furniture will vary according to: (1) Whether the furniture is children's or non-children's furniture; (2) whether the furniture is produced domestically or imported; and (3) whether the manufacturer produces a high or low-volume of products. High-volume producers can rely on a component part certificate from their paint suppliers, and the cost of testing would be relatively low. Higher quality, lower volume producers would have greater difficulty because these items often are "made to order" and "as needed." These producers will use small batches of finishes issued in a number of different finishing materials, each of which would need to be tested.

(Response 104)—We agree that the costs of complying with the requirements will vary among products and manufacturers. Generally, the costs will be more significant for manufacturers of lower volume products. It should also be noted that proposed subpart B, which would contain the requirements applicable to non-children's products, is not being finalized at this time. Therefore, the final rule does not impose any requirements on non-children's furniture.

(Comment 105)—Two commenters expressed concern about costs. One commenter noted that reliance on third party conformity assessment body testing raises costs and imposes production delays. Another commenter, a charitable organization that makes wooden toys for donation to needy children, commented that it lacks the resources to pay for certification testing and would need to discontinue activities unless granted an exemption or some other type of relief.

(Response 105)—Section 14(a)(2) of the CPSA requires third party conformity assessment bodies to test children's products for compliance with applicable children's product safety

rules. We recognize that testing costs may be substantial and may have a significant adverse effect on some manufacturers, especially small businesses that may have limited financial resources. We also recognize that the testing will take time and could result in some delays in the production process.

Recently enacted H.R. 2715 requires us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. H.R. 2715 directs us to seek public comment on seven specific issues, including techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

H.R. 2715 also requires us to consider alternative requirements for the covered products of small batch manufacturers and, if no alternative requirements are available or economically practical, exempts small batch manufacturers from the third party testing requirements, with some exceptions. Covered products are those for which fewer than 7,500 units were produced in the previous year, and a small batch manufacturer is one whose gross sales revenue from all consumer products in the previous calendar year was less than \$1 million. In the case of toys, however, no alternative requirements or exemptions would be permitted for third party testing for the lead content of paint, small parts, and pacifiers. Where possible, we tried to reduce testing costs by allowing the use of component part testing.

(Comment 106)—One commenter noted that the initial regulatory flexibility analysis acknowledged that the examples used only considered the out-of-pocket testing costs. Costs not considered in the examples include: Samples destroyed or damaged in testing; transportation of the samples; administrative costs for managing testing; administrative costs for managing the testing data and recordkeeping; an allocation of general

management time; legal expenses, among other costs. The commenter estimated that, depending on the scale of the business, these costs will add 15 to 50 percent to the out-of-pocket testing costs.

The commenter also noted that the initial regulatory flexibility analysis considered the probability that some manufacturers or private labelers will have to test multiple samples to obtain the high degree of assurance required by the proposed rule. The commenter asserted that over the last 20 years of product testing at his company, multiple safety tests of the same product have not revealed anything useful. The commenter asserted that the testing rule is complex; that many small businesses will not have the skills necessary to understand what is expected of them in terms of compliance; and that many small businesses will exit the market for children's products.

(Response 106)—The initial regulatory flexibility analysis focused on the cost of third party testing because it will likely be the most significant cost for small manufacturers of children's products. Considering only the third party testing costs, the initial regulatory flexibility analysis found that the rule could have a significant impact on a substantial number of small entities. The initial regulatory flexibility analysis explicitly stated that the only costs considered in the analysis were the costs that the laboratories would charge to conduct the testing. The commenter is correct that the rule would impose other costs, including the cost of the samples destroyed in testing and freight, as well as the costs involved in administering and managing the testing and paperwork. The commenter's estimate that these costs would add 15 to 50 percent to the out-of-pocket testing costs, depending upon factors such as the product involved and the scale of the business, seems reasonable.

The commenter also is correct that the initial regulatory flexibility analysis considered the impact on firms that had to test more than one sample of a product in order for the manufacturer to obtain a high degree of assurance that the product complies with the applicable product safety rules. However, the final rule does not specify the number of samples that must be tested. It is possible that if the commenter, as asserted, has never found multiple tests on its products to reveal anything useful, then the products manufactured could be of such uniform composition and quality that the number of samples that the commenter will be required to submit for testing will be small. However, because the rule

requires that every children's product subject to a children's product safety rule be tested periodically by a third party conformity assessment body, the commenter might need to conduct more testing than the commenter believes is necessary.

We acknowledge that the rule is complex, and some small businesses might have to hire outside consultants, such as lawyers, statisticians, or quality control experts to help them comply with the regulations. As a result, some small firms may exit the market for children's products.

(Comment 107)—One commenter stated that the testing rule would accelerate the decline of domestic manufacturing firms, as more manufacturers go offshore to minimize the cost of testing. The commenter asserted that the furniture industry will have no choice but to close down more and more factories in the United States and take those jobs off shore to benefit from the lower testing costs. The commenter stated that some small manufacturers have abandoned plans to offer products intended for the youth market.

(Response 107)—The initial regulatory flexibility analysis noted that the costs of some third party tests are less expensive abroad than they are in the United States. For example, while typical prices for lead content tests range from \$50 to more than \$100 in the United States, the same lead content test, in some cases, can be obtained for as little as \$20 in China (75 FR at 28355). Higher third party testing costs in the United States would be an incentive for manufacturers to produce children's products abroad, to take advantage of the lower testing costs.

Given all of the factors that go into a decision by a manufacturer to produce consumer products abroad rather than in the United States, the impact of third party testing costs on such a decision might be small. It seems unlikely that the independent effect of higher third party testing costs, by itself, would result in a large number of factories in the United States closing down. With regard to small domestic manufacturers, it is possible that the third party testing costs associated with the children's furniture could lead some to manufacturers to reduce their children's furniture product lines or even cease their production of children's furniture. Any small manufacturer of children's furniture who qualifies as a small batch manufacturer might be offered relief by the alternative requirements or exemptions that are provided by H.R. 2715; however, matters regarding the small batch manufacturer's exception in

H.R. 2715 are outside the scope of this rulemaking. Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715, including other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations, pursuant to H.R. 2715.

(Comment 108)—One commenter stated that the cost to test a finish used in the furniture industry is about \$50 (which is consistent with the discussion of testing costs in the initial regulatory flexibility analysis). A youth bed, which is also subject to the lead content requirements of section 101 of the CPSIA, might require 29 tests at a third party testing facility, which would bring the total cost of lead testing to \$1,450. In addition, testing to the bunk bed standard would add \$600 to \$800 to the cost. A crib or toddler bed would cost an additional \$750 to \$765 (\$450 to \$520 in China) to test to the relevant children's product safety rules. The cost of testing other items of youth furniture, such as desks, entertainment centers, and bookcases, averages approximately \$235. These costs do not include the cost of the samples, freight, random sampling, or the cost for employees to track and administer the recordkeeping requirements.

(Response 108)—As described in the initial regulatory flexibility analysis (75 FR at 28352 through 28362), the testing of some children's products by third party conformity assessment bodies can be costly. The testing costs described by the commenter do not appear to be unreasonable estimates, based on cost estimates we obtained. In cases where the same component is used in more than one product, manufacturers may be able to reduce their testing costs by using component part testing. However, component part testing will not offer any relief from the costs of tests that must be performed on the finished product, such as tests for conformity to the crib and bunk bed standards.

(Comment 109)—One commenter stated that furniture manufacturers who deal in high-quality but lower volume furniture manufacturing may offer products with between 30 and more than 2,000 possible combinations of finishes. Many of these finishes are custom or made to order, so that a batch can range from a 5-gallon bucket to a 55-gallon drum. Each custom finish consists of at least 10 different materials. The manufacturer must create a panel for each possible combination of finishing materials and then have it analyzed by a third party testing facility.

An x-ray fluorescence (XRF) gun is then used to verify that the finished piece, in fact, complies with the lead-in-paint standard. It is estimated that 6 to 10 employees will be required to track the testing and compile the certificates of conformity. It is estimated that the cost to comply with the rule for non-children's products could range from \$200,000 to \$410,000, annually.

(Response 109)—We received many comments on proposed subpart B, which was concerned with reasonable testing programs for non-children's products. The comments raised many practical issues, which illustrates the difficulty of drafting a regulation that can apply to many different types of products and manufacturing processes and still provide sufficient guidance to enable manufacturers to implement the requirements effectively. Consequently, we are deferring action with respect to finalizing subpart B. Instead, we will reserve subpart B in the final rule and continue evaluating the issues raised in the comments.

It should be noted, however, that although we are not finalizing subpart B at this time, manufacturers of non-children's products that are subject to a product safety rule, ban, standard, or regulation are still obligated by the CPSA, as amended by the CPSIA, to certify that their products comply with all applicable safety rule, based on a test of each product or a reasonable testing program.

In the case of testing the lead content of paint, which the commenter mentioned, the use of component part or composite testing—as would be allowed by the final rule on component part testing—might allow some manufacturers to reduce their testing costs. For example, if the same 10 raw materials (and only those materials) are combined in different portions to produce 30 different finishes, a manufacturer could test the lead content of each of the materials, and if each of the materials met the lead content requirement, then the manufacturer would not need to test each of the 30 finishes separately.

(Comment 110)—One commenter stated that because the cost of testing and recordkeeping will be passed on to the consumer, this could create an “upside down” market in furniture, in which youth furniture is more expensive than adult furniture. This could lead some consumers to purchase “adult” furniture for children instead of purchasing youth furniture that has been third party tested.

(Response 110)—Section 14(a)(2) of the CPSA requires third party testing of children's products, including

children's and youth furniture. Depending upon the structure of the market and market conditions, some or all of the testing costs may be passed on to consumers. We cannot determine whether passing on these costs will make children's furniture—in any absolute sense—to be more expensive to purchase than adult furniture; but passing on these costs to consumers is likely to increase the relative price of children's furniture, and it could provide a price incentive for parents to substitute adult furniture for children's furniture.

(Comment 111)—One commenter stated that the proposed rule will impose significant new costs on the mattress industry because mattresses are already subject to an expensive mandatory testing program pursuant to 16 CFR part 1633. The commenter asserted that because most manufacturers of mattresses are small businesses, the proposed rule would have a substantially greater impact on the mattress industry, given the nature of the products, the types of standards that the products must meet, the destructive nature of the testing involved, and the cost of the samples tested.

The commenter also noted that mattress testing entails other costs, such as: the cost of the samples tested, the laboratory test fees, freight costs to ship samples to the laboratory, and the manufacturers' staff sent to witness the test. The total cost of conducting a full test for 16 CFR part 1633 can range from \$850 to \$1,650 per sample tested, plus added travel costs and salary expenses for company personnel to witness the test. The commenter urged us to take into account the significant new costs that the rules will impose on the mattress industry, which is comprised overwhelmingly of small businesses.

(Response 111)—We acknowledge that the rule could impose additional costs on some firms. However, section 14(a)(2) if the CPSA requires third party testing of children's products that are subject to an applicable children's product safety rule.

Additionally, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. H.R. 2715 directs us to seek public comment on seven specific issues. These issues include:

- The extent to which manufacturers with a substantial number of substantially similar products subject to third party testing may reasonably make use of sampling procedures that reduce the overall test burden without compromising the benefits of third party testing; and

- Other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Another provision of H.R. 2715 created a new section 14(i)(4) of the CPSA to provide for special rules for small batch manufacturers. The provision contemplates the possible development of alternative testing requirements for “covered products” made by “small batch manufacturers.” The provision also provides for possible exemptions of small batch manufacturers from the third party testing requirements and imposes certain limits on third party testing requirements. A covered product is a consumer product where no more than 7,500 units of the same product were manufactured by a small batch manufacturer in the previous calendar year, and a small batch manufacturer is a manufacturer that had no more than \$1 million in gross revenue from sales of all consumer products in the previous calendar year. Any small mattress manufacturer who meets the definition of a “small batch manufacturer” might benefit from this provision when it is implemented.

(Comment 112)—One commenter stated that the discussion of sample size is unrealistic. An example was used in

the initial regulatory flexibility analysis that provided the sample sizes that would be required to meet a specified statistical confidence level, assuming that both the historical variability (standard deviation) and the historical mean of the variable (lead content) are known. The commenter stated that continuously variable data on commonly available testing reports is generally not provided by the laboratories, and data for samples with a result below the method detection limit is generally provided in the form “< X ppm,” where X is the method detection limit. The commenter noted that these data cannot be included for calculations of the mean or standard deviation. The commenter stated that the example used is invalid, unless the data can be captured and tracked in full resolution, which is not the current state.

(Response 112)—To the extent that continuously variable data from testing results are unavailable, the discussion of sample size in the initial regulatory flexibility analysis may be unrealistic. Because the example is not widely applicable, and because we are not requiring that the periodic third party testing be used to provide a high degree of statistical assurance (e.g., 95 percent confidence) that no children’s products violate consumer product safety standards, we have omitted the example from the final regulatory flexibility analysis.

*D. Small Entities To Which the Rule Will Apply*

By regulation (16 CFR part 1110), the domestic manufacturer or importer is responsible for ensuring that a consumer product is tested properly, and, based on the testing results, must certify that the product conforms to all applicable consumer product safety rules. Manufacturers of children’s products that are subject to a children’s product safety rule must certify that the children’s products comply with all applicable children’s product safety rules, based on testing conducted by third party conformity assessment bodies that are accredited to conduct

such tests. The definition of a “children’s product” is broad, and it includes bicycles, books, furniture, apparel, jewelry, televisions, electronic games, toys, and so on, if designed or intended primarily for a child 12 years of age or younger. Virtually all children’s products are subject to one or more children’s product safety rules. For example, the lead content of paint and all non-excluded accessible component parts of children’s products are subject to limits. Therefore, virtually all manufacturers of children’s products will have to certify, based on tests by accredited third party conformity assessment bodies that their products comply with the lead content limits. We have excluded from the requirement to test for lead content a few materials that inherently do not contain lead. The excluded materials are limited to materials such as: most fabrics, precious metals, paper, gemstones, and a limited number of other items, and the list can be found at 16 CFR 1500.91. We also have issued a rule excluding from the lead content requirements (16 CFR 1500.87) inaccessible component parts in children’s products. Section 1(b)(3) of H.R. 2715 excludes certain used children’s products from testing for lead content. All other materials used in products intended for children must be tested for lead content.

In addition to the requirements to test for lead content, manufacturers must test for conformity with a wide variety of other children’s product safety rules. For example, there are product safety rules that establish standards for children’s products, such as toys, cribs, bicycles, bicycle helmets, youth all-terrain vehicles, bunk beds, baby walkers, and flammable clothing textiles. The CPSIA also limits the amount of six phthalates that can be present in children’s toys and child care articles; thus, many plastic component parts will need to be tested for phthalate content. A full list of the children’s product safety rules for which third party testing and certification will be required is given in Table 1.

TABLE 1—PRODUCT SAFETY RULES APPLICABLE TO CHILDREN’S PRODUCTS

16 CFR part # (or test method or standard)	Description
1420	All-Terrain Vehicles.
1203	Bicycle Helmets.
1512	Bicycles.
1513	Bunk Beds.
1500.86(a)(5)	Clacker Balls.
1500.86(a)(7) and (8)	Dive Sticks and Other Similar Articles.
1505	Electrically Operated Toys or Articles.
1615	Flammability of Children’s Sleepwear, Sizes 0 through 6X.
1616	Flammability of Children’s Sleepwear, Sizes 7 through 14.

TABLE 1—PRODUCT SAFETY RULES APPLICABLE TO CHILDREN'S PRODUCTS—Continued

16 CFR part # (or test method or standard)	Description
1610 .....	Flammability of Clothing Textiles.
1632 .....	Flammability of Mattresses and Mattress Pads.
1633 .....	Flammability (Open Flame) of Mattress Sets.
1611 .....	Flammability of Vinyl Plastic Film.
1219 .....	Full-Size Cribs.
1215 .....	Infant Bath Seats.
1216 .....	Infant Walkers.
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08, CPSC-CH-E1001-08.1 or 2005 CPSC Laboratory SOP).	Lead Content in Children's Metal Jewelry.
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08 or CPSC-CH-E1001-08.1).	Lead Content in Children's Metal Products.
Sec. 101 of CPSIA (Test Method CPSC-CH-E1002-08 and/or CPSC-CH-E1002-08.1).	Lead Content in Children's Non-Metal Products.
1303 .....	Lead Paint.
1220 .....	Non-Full-Size Cribs.
1511 .....	Pacifiers.
Sec. 108 of CPSIA (Test Method CPSC-CH-C1001-09.3 ) .....	Phthalate Content of Children's Toys and Child Care Articles.
1510 .....	Rattles.
1501 .....	Small Parts Rule.
1630 .....	Surface Flammability of Carpets and Rugs.
1631 .....	Surface Flammability of Small Carpets and Rugs.
1217 .....	Toddler Beds.
(ASTM F963) .....	Toys.

#### E. Number of Small Firms Affected

We estimated the number of firms that could be impacted, by reviewing every industry in the North American Industrial Classification System (NAICS), and selecting industries with firms that could manufacture or sell any children's product potentially covered by a consumer product safety rule. Firms are classified in the NAICS category that describes their primary activity. Therefore, firms that might manufacture or import consumer products covered by a safety rule as a secondary or tertiary activity may not have been counted. There is no separate

NAICS category for importers. Firms that import products might be classified as manufacturers, wholesalers, or retailers.

#### 1. Manufacturers

According to the criteria established by the U.S. Small Business Administration (SBA), manufacturers are generally considered to be small entities if they have fewer than 500 employees. Table 2 shows the number of manufacturing firms by the North American Industrial Classification System (NAICS) categories that cover most children's products that are subject

to a product safety rule. Although there are more than 26,000 manufacturers that would be considered small in these categories, not all of these firms are engaged in manufacturing children's products that are subject to a product safety rule. It would be expected that most firms engaged listed in the category, *Doll, Toy, and Game*, produce some products that are intended for children age 12 and younger. On the other hand, the *Surgical Appliance and Supplies Manufacturing* category includes crash helmets, but most other products in this category are not under our jurisdiction.

TABLE 2—MANUFACTURERS

NAICS Code	Description	Small firms	Total firms
31411 .....	Carpet and Rug Mills .....	244	262
315 .....	Apparel Manufacturing .....	7,126	7,195
316211 .....	Rubber and Plastic Footwear Manufacturing .....	43	45
316212 .....	House Slipper Manufacturing .....	1	1
316219 .....	Other Footwear Manufacturing .....	53	54
326299 .....	All Other Rubber Product Manufacturing .....	622	666
336991 .....	Motorcycle, Bicycle, and Parts Manufacturing .....	447	452
33712 .....	Household and Institutional Furniture Manufacturing .....	6,058	6,154
33791 .....	Mattress Manufacturing .....	427	441
339113 .....	Surgical Appliance and Supplies Manufacturing .....	1,817	1,916
33991 .....	Jewelry and Silverware Manufacturing .....	2,470	2,484
33992 .....	Sporting and Athletic Goods Manufacturing .....	1,707	1,748
33993 .....	Doll, Toy and Game Manufacturing .....	694	705
339942 .....	Lead Pencil and Art Good Manufacturing .....	124	129
339999 .....	All Other Miscellaneous Manufacturing .....	4,646	4,695
	Total Manufacturers .....	26,479	26,947

Source: U.S. Department of Commerce, Bureau of the Census, 2008 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Small Enterprise Employment Sizes for the United States, NAICS Sectors: 2008. (Available at: [http://www2.census.gov/econ/subs/data/2008/us\\_naicssector\\_small\\_empsize\\_2008.xls](http://www2.census.gov/econ/subs/data/2008/us_naicssector_small_empsize_2008.xls), last accessed on 16 August 2011.

In addition to the manufacturers in Table 3, there were 25,184 nonemployer businesses classified in NAICS 315 (Apparel Manufacturing) and 61,180 (classified in NAICS 3399 (Other Miscellaneous Manufacturers) in 2008. Nonemployer businesses are generally very small businesses with no employees. They are typically sole proprietorships, and they may or may not be the owner's principal source of income. The average receipts for the nonemployer businesses classified in *Apparel Manufacturing* was about \$31,000, and the average receipts for the nonemployer businesses classified *Other Miscellaneous Manufacturers* was about \$41,000.<sup>3</sup>

2. Wholesalers

Wholesalers would be impacted by the rule if they import any children's product that is subject to a product safety rule. Wholesalers who obtain their products strictly from domestic manufacturers, or from other wholesalers, would not be impacted by the rule because the manufacturer or importer would be responsible for certifying the products. Table 3 shows the number of wholesalers by NAICS code that would cover most children's products that are subject to a product safety rule. According to SBA criteria, wholesalers are generally considered to be small entities if they have fewer than

100 employees. Although there are more than 78,000 wholesalers that would be considered small in these categories, not all of these firms are engaged in importing children's products that are subject to a consumer product safety rule. A significant proportion of the firms classified as *Toy and Hobby Goods and Supplies Merchant Wholesalers* probably import at least some children's products. However, the only firms classified as *Motor Vehicle and Motor Vehicle Parts and Suppliers* that would be impacted by the final rule are those that import all-terrain vehicles intended for children 12 years old or younger.

TABLE 3—WHOLESALERS

NAICS Code	Description	Small firms	Total firms
4231	Motor Vehicle and Motor Vehicle Parts and Suppliers	17,734	18,769
4232	Furniture and Home Furnishing Merchant Wholesalers	11,353	11,844
42362	Electrical and Electronic Appliance, Television, and Radio Set Merchant Wholesalers.	2,444	2,591
42391	Sporting and Recreational Goods and Supplies Merchant Wholesalers	5,019	5,196
42392	Toy and Hobby Goods and Supplies Merchant Wholesalers	2,227	2,302
42394	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	7,363	7,447
42399	Other Miscellaneous Durable Goods Merchant Wholesalers	9,040	9,302
42432	Men's and Boy's Clothing and Furnishings Merchant Wholesalers	3,557	3,722
42433	Women's, Children's, and Infant's Clothing, and Accessories Merchant Wholesalers.	6,797	7,029
42434	Footwear Merchant Wholesalers	1,521	1,593
42499	Other Miscellaneous Nondurable Goods Merchant Wholesalers	11,203	11,490
	Total	78,258	81,285

Source: U.S. Department of Commerce, Bureau of the Census, 2008 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Small Enterprise Employment Sizes for the United States, NAICS Sectors: 2008. (Available at: [http://www2.census.gov/econ/susb/data/2008/us\\_naicssector\\_small\\_emplsize\\_2008.xls](http://www2.census.gov/econ/susb/data/2008/us_naicssector_small_emplsize_2008.xls), last accessed on 16 August 2011.

In addition to the wholesalers tabulated in Table 3, the U.S. Census Bureau estimated that there were 206,072 nonemployer businesses classified in NAICS categories that could include wholesalers of children's products. Nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about \$86,000.<sup>4</sup> An unknown number of nonemployer wholesalers could import children's products.

3. Retailers

Retailers that obtain their products from domestic manufacturers or

wholesalers will not be directly impacted by the rule because the manufacturers or wholesalers would be responsible for the testing and certification of the products. However, there are some retailers that manufacture or directly import some products; and therefore, they will be responsible for ensuring that these products are properly tested and certified. The number of such retailers is not known. Table 4 shows the number of retailers by NAICS code that would cover most children's products. According to SBA size standards, retailers are generally considered to be small entities if their annual sales are

less than \$7 million to \$30 million, depending on the specific NAICS category. Because of the way in which the data were reported by the Bureau of the Census, the estimates of the number of small firms in each category in Table 4 are based on similar, but different criteria. Although there are more than 100,000 firms that would be considered "small businesses" in these categories, it is not known how many of these firms are engaged in importing or manufacturing children's products. Many firms probably obtain all of their products from domestic wholesalers or manufacturers and would not be directly impacted by the rule.

<sup>3</sup> U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." Available at: <http://www.census.gov/econ/nonemployer/Revised%202008%20Data>

[%20With%202009%20Methodology%20Applied.xls](#) (last accessed 16 August 2011).

<sup>4</sup> U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics

Table." available at <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

TABLE 4—RETAILERS

NAICS Code	Description	SBA Size standard (millions of dollars of annual sales)	Criteria used for estimate of small firms (millions of dollars of annual sales)	Small firms	Total firms
441221 .....	Motorcycle, ATV, and Personal Watercraft Dealers .....	<30	<25	4,794	4,879
4421 .....	Furniture Stores .....	<19	<10	16,033	16,611
44813 .....	Children's and Infant's Clothing Stores .....	<30	<25	2,057	2,074
44814 .....	Family Clothing Stores .....	<25.5	<25	6,588	6,684
44815 .....	Clothing Accessories Stores .....	<14	<10	2,757	2,774
44819 .....	Other Clothing Stores .....	<19	<10	6,331	6,393
4482103 .....	Children's & Juveniles' Shoe Stores .....	<25.5	<25	227	230
4482104 .....	Family Shoe Stores .....	<25.5	<25	2,905	2,941
45111 .....	Sporting goods stores .....	<14	<10	14,388	14,545
45112 .....	Hobby, toy, & game stores .....	<25.5	<25	4,612	4,629
452 .....	General Merchandise Stores .....	<30	<25	6,873	6,971
45322 .....	Gift, Novelty, and Souvenir Store .....	<30	<25	19,297	19,339
454111 .....	Electronic Shopping .....	<30	<25	11,374	11,646
454113 .....	Mail Order Houses .....	<35.5	<25	5,281	5,645
4542 .....	Vending machine operators .....	<10	<10	3,796	3,887
	Total .....			107,313	124,700

Source: U.S. Census Bureau, 2007 Economic Census, Release date 11/02/2010.

In addition to the retailers tabulated in Table 4, the U.S. Census Bureau estimated that there were 324,918 nonemployer businesses classified in NAICS categories that could include retailers of children's products. Nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business retailers were about \$40,000.<sup>5</sup> An unknown number of nonemployer retailers could import children's products.

#### F. Compliance, Reporting, and Recordkeeping Requirements of Rule

The final rule establishes some requirements for the certification of children's products. It also establishes protocols and standards for ensuring that children's products are subject to testing periodically, when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts, and for safeguarding against the exercise of undue influence on a third party conformity assessment body by a children's product manufacturer or private labeler. The requirements are discussed in more detail below, and the impact that these could have on manufacturers is discussed in a later section of this preamble.

The final rule will impact virtually all manufacturers and importers of children's products because nearly all children's products are subject to some children's product safety rules. For example, the restrictions on lead content cover almost all children's products. Even products that contain some of the materials that have been excluded from the restrictions (see 16 CFR 1500.88) or that have been determined inherently not to contain lead in excess of the legal requirement (see 16 CFR 1500.91) might have to be tested for compliance with other rules. For example, although the fabric in wearing apparel might be excluded from the requirement to test for lead content, it may have to be tested for compliance with flammability requirements. Any other non-excluded objects on the apparel, such as buttons, snaps, zippers, or appliqués will also need to be tested for lead content.

In meeting the requirements of the final rule, manufacturers and importers can use component part testing, as provided by 16 CFR part 1109. This means, for example, that manufacturers could submit samples of paint that they are using on their products to a third party testing laboratory to be tested for lead and heavy metal content. This could reduce the amount of testing required because the results from the component part tests could be relied upon for demonstrating the compliance of all products on which that paint was used, rather than retesting the paint multiple times because it was used on multiple products. The final rule also allows manufacturers and importers to

rely upon testing of component parts that was procured by their suppliers, provided that the testing meets all of the requirements in 16 CFR part 1109. The requirements include that the testing be performed by a third party conformity assessment body whose accreditation has been accepted by the CPSC. To rely upon component part testing—whether conducted by the children's product manufacturer or by a supplier of the component part—there must be sufficient documentation so that the component part can be traced back to the party who procured the third party test results demonstrating that the component part complies with the applicable safety rules. Provisions in 16 CFR part 1109 also allow an importer to rely upon testing procured by, or a certificate issued by, a supplier of a finished good in issuing their own certificate for a product. Therefore, if a foreign manufacturer has tested and certified a children's product in accordance with the requirements of 16 CFR part 1109, an importer may rely upon that testing or certification in issuing their own certificate for the product.

#### G. Partial Exemption for Small Batch Manufacturers

H.R. 2715, which was enacted on August 12, 2011, provides some relief for small batch manufacturers from the third party testing requirements contained in the final rule. H.R. 2715 requires that we consider alternative requirements for small batch manufacturers. Until we determine what alternative requirements are suitable for

<sup>5</sup> U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." Available at: <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

small batch manufacturers, small batch manufacturers are not required to obtain third party testing results to confirm that their children's products conform to several children's product safety rules. However, small batch manufacturers are still subject to the third party testing requirements of the final rule with respect to the lead content of paint; full-size and non full-size cribs; pacifiers; small parts; children's metal jewelry; and baby bouncers, walkers, and jumpers.

H.R. 2715 defines a "small batch manufacturer" as a manufacturer who had no more than \$1 million in total gross revenue from sales of all consumer products in the previous calendar year (which will be adjusted annually by the percentage increase in the Consumer Price Index for all urban consumers).

We will implement the small batch manufacturer provision of H.R. 2715 in a separate proceeding.

#### H. Certification Tests

To certify that a children's product complies with all applicable children's product safety rules, the final rule requires that manufacturers submit samples of the product to a third party conformity assessment body whose accreditation has been accepted by the CPSC. The final rule requires that the number of samples submitted must be sufficient to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules. Fewer samples are needed if the manufacturing process consistently results in products that are uniform in composition and quality. More samples will be needed if there is more variability in the finished products. If any product fails certification testing, the manufacturer must investigate and address the cause of the failure, even if other samples passed the certification tests.

The cost of the third party testing is discussed in more detail later in part IV.N. of the preamble. Manufacturers also may incur costs for any consultants to provide advice for determining the number of samples that should be submitted for testing and to ensure that it was in compliance with the requirements. There also will be some administrative and recordkeeping costs associated with this requirement.

#### I. Periodic Third Party Testing

The final rule requires manufacturers and importers of children's products to periodically submit samples of their products to third party conformity assessment bodies whose accreditation

has been accepted by the CPSC for testing to ensure their products continue to comply with all applicable children's product safety rules. Manufacturers need to conduct periodic third party testing frequently enough to ensure, with a high degree of assurance, that the product continues to comply with all applicable children's product safety rules, but in no case can the interval between periodic tests exceed the maximum periodic testing interval applicable to the manufacturer.

Depending upon other testing procedures that a manufacturer may opt to use, one of three possible maximum periodic testing intervals will apply to a children's product manufacturer. The first option applies to manufacturers who do not conduct other production testing of a children's product. Manufacturers who do not undertake other production testing must conduct periodic third party testing of the product at least once a year. The final rule requires manufacturers to develop a periodic test plan that will ensure that the children's products manufactured after the certification, or since the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules. The periodic test plan must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples to be tested. Although the manufacturer has some discretion in determining the interval between periodic tests, the interval must be short enough to ensure that if the samples selected for periodic third party testing pass the tests, then there is a high degree of assurance that the untested products manufactured during the interval comply with all applicable children's product safety rules; and the interval must be no longer than one year.

The second option applies to manufacturers who implement a production testing plan (which can use first or third party testing). If a manufacturer has implemented a production testing plan that meets the requirement of § 1107.21(c) of the final rule, the manufacturer must conduct third party periodic testing at least once every two years. The production testing plan must describe the production management techniques and tests that must be performed to provide a high degree of assurance that products manufactured after certification continue to meet all applicable children's product safety rules. The production testing plan must also include additional information, such as the intervals at which tests must be conducted or measurements will be

made. The test methods used in the production testing plan need not be the same test methods used for certification, but they must be effective in determining compliance with the applicable children's product safety rules.

Manufacturers or importers who choose this second option, will need to ensure that their quality assurance or testing program meets the requirements of the final rule for production testing and that their testing program provides a high degree of assurance that all products manufactured or imported continue to comply with all applicable children's product safety rules. In addition, at least once every two years, this option requires the manufacturer or importer to submit samples to a CPSC-accepted third party conformity assessment body to be tested for conformity with all applicable children's product safety rules. The final rule does not specify how many samples must be submitted to the third party conformity assessment body, nor does it set forth what constitutes an appropriate periodic testing interval (other than stating it must not be greater than two years). However, the expectation is that this option will require less testing by third party conformity assessment bodies because, under this option, the (first party or third party) production testing provides the manufacturer or importer with a high degree of assurance that the products continue to comply with the applicable children's product safety rules and can provide manufacturers with information that can be used to determine the interval and number of samples required for the periodic third party testing.

The third option applies to manufacturers who conduct testing to ensure continuing compliance with the applicable children's product safety rules using a testing laboratory accredited to ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*, but whose accreditation has not been accepted by the CPSC. In most cases, these will be in-house testing laboratories. If a manufacturer conducts testing using such a testing laboratory, the manufacturer must conduct periodic third party testing at least once every three years. Any testing laboratory used under this option must be accredited by an accreditation body that is accredited to ISO/IEC 17011:2004, *Conformity assessment—General requirements for accrediting conformity assessment bodies*. The tests used under this option must be the same tests used for certification to the

applicable children's product safety rules. The testing must be conducted frequently enough to provide a high degree of assurance that the product continues to comply with all applicable children's product safety rules.

The final rule does not specify how many samples a manufacturer using the third option must submit to the third party conformity assessment body, nor does it set forth what constitutes an appropriate periodic testing interval (other than stating it must not be greater than three years). However, as with the second option, the intent behind including this option in the final rule is to reduce the cost that the rule imposes on children's product manufacturers, by reducing the amount of testing that they must obtain from third party conformity assessment bodies. The testing that the manufacturer performs in an ISO/IEC 17025:2005-accredited testing laboratory provides the high degree of assurance that the products comply with the applicable children's product safety rules, and it also can provide manufacturers with information that can be used to determine interval and number of samples required for the periodic third party testing.

Like the second option, the intent of the third option is to reduce the final rule's cost to manufacturers, by reducing the amount of testing that they must conduct using third party conformity assessment bodies. However, the manufacturers that are most likely to benefit from this third option are manufacturers who have their own in-house ISO/IEC 17025:2005-accredited testing laboratories. These are likely to be larger manufacturers, so this option is not expected to provide much relief to smaller manufacturers. To the extent that the smaller manufacturers compete with the larger manufacturers, this option may adversely affect the competitiveness of the smaller manufacturers relative to larger manufacturers because any cost reduction will disproportionately benefit larger manufacturers.

Under all periodic testing options, a manufacturer may need statistical or other knowledge in order to develop their testing plans, including determining the appropriate testing intervals and number of samples required to provide the manufacturer with a high degree of assurance that its children's products are in compliance with all applicable children's product safety rules. If these services are not available in-house, the firm may have to hire outside consultants. Additionally, firms will incur administrative and recordkeeping costs associated with the periodic testing requirement, in

addition to the cost of the third party testing, which is described in more detail later in this analysis.

#### *J. Third Party Testing Due to Material Changes*

If a children's product undergoes a material change in product design or manufacturing processes, including the sourcing of component parts that could affect the product's ability to comply with the applicable children's product safety rules, the final rule requires the manufacturer to submit samples of the materially changed product to a third party conformity assessment body for testing. The number of samples must be sufficient to provide a high degree of assurance that the materially changed product complies with all applicable children's product safety rules. The testing can be limited to the portion or component part of the finished product that was changed and for compliance with those children's product safety rules for which compliance might have been affected.

The primary cost of this requirement will be the cost of the third party testing. There also will be some administrative and recordkeeping costs associated with this requirement. The professional skills required by the manufacturer are the same skills required for the initial certification and periodic tests.

#### *K. Protection Against Undue Influence*

The final rule requires that each manufacturer of children's products establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. At a minimum, these procedures must include written policy statements from company officials that the exercise of undue influence is not acceptable and directing that every appropriate staff member receives training on avoiding undue influence and signs a statement attesting to their participation in the training. The procedures also must include a requirement to retrain the appropriate staff if there are substantive changes in the requirements for safeguarding against the exercise of undue influence. The training procedures must include a requirement to notify us immediately of any attempt by the manufacturer to hide or exert undue influence over test results, and a requirement to inform employees that allegations of undue influence may be reported confidentially to us and to describe how such a report can be made.

Firms will incur some costs in establishing the safeguards against undue influence. Although several

commenters stated that establishing these safeguards would be burdensome, none provided estimates of what the cost would be. The final rule gives firms great flexibility in meeting these requirements. For example, the final rule does not prescribe the form of the training, and firms may include this training along with other types of employee training.

#### *L. Recordkeeping*

The final rule requires manufacturers of children's products to keep the following records:

- A copy of the Children's Product Certificate for each product. The children's product covered by the certificate must be clearly identifiable and distinguishable from other products;
- Records of each certification test. The manufacturer must have separate certification test records for each manufacturing site;
- Records of one of the following for periodic tests of a children's product:
  - Periodic test plan and periodic test results;
  - Production testing plan, production test results, and periodic test results; or
  - Testing results of tests conducted by a testing laboratory accredited to ISO/IEC 17025:2005 and periodic test results.
- Records of descriptions of all material changes in product design, manufacturing processes, and sourcing of component parts, the certification tests, the test results, and the actual values of the tests, if any; and
- Records of the undue influence procedures, including training materials and training records of all employees trained on these procedures.

These records must be maintained for five years. The records must be made available for inspection by the CPSC, upon request. The records may be maintained in languages other than English, if the records can be provided immediately to us and translated accurately into English within 48 hours of a request by the CPSC or a longer period, as negotiated with CPSC staff.

We have estimated that, on average, it will take three to five hours for recordkeeping per product. However, the time needed for recordkeeping for any particular product could be substantially higher or lower. For example, recordkeeping for products that are subject to multiple standards, or products that require a substantial amount of testing, could need substantially more hours. For other products, such as those subject to only one standard, and for which little

testing is required, the number of hours needed for recordkeeping might be less.

#### M. Consumer Product Labeling Program

The final rule establishes a program by which any manufacturer or private labeler of a consumer product may label product as complying with the applicable certification requirements for the product. If the manufacturer has certified that a consumer product complies with all applicable consumer product safety rules, the manufacturer or private labeler may affix a label to the product which states that the product: "Meets CPSC Safety Requirements." The label must be visible and legible. This program is voluntary in that manufacturers and private labelers are not required to affix this label to their products. However, opting not to affix the label to the product would not relieve the firm of its responsibility to ensure that the products comply with the applicable safety rules and with all other provisions of the rule. This provision is not expected to have a significant impact on firms, however, because the program is voluntary, and the costs of adding or modifying a label on a product are expected to be low.

#### N. Cost of Third Party Testing and Potential Impact of the Rule

The costs of the third party testing requirements are expected to be significant for some manufacturers and are expected to have a disproportionate impact on small and low-volume manufacturers. This section discusses the cost of third party testing and the potential impact of the third party testing and other requirements of the final rule on manufacturers.

##### 1. Cost of Third Party Testing

The cost of third party testing is influenced by many factors, including the amount and skill of the labor required to conduct the tests, the cost of the equipment involved, the cost of transporting the product samples to the test facility, and the geographic area where the tests are conducted. Some tests require a substantial amount of time to conduct the tests, including the preparation of the samples. It might take a couple of days, for example, to test a bicycle for compliance with the bicycle standard (16 CFR part 1512). Similarly, a chemist testing the lead content of a product might be able to test only a few metal component parts per day, due to the amount of time required to prepare the samples and clean and calibrate the equipment between tests.

It should be noted that the price that a given manufacturer pays for testing is often the result of negotiations between

the testing laboratory and the manufacturer. Manufacturers who do a large volume of business with a testing laboratory frequently can obtain discounts on the testing laboratory's normal charges; but manufacturers who do only a small volume of business may not be able to negotiate a discount on the testing.

Information on the cost of third party testing to determine compliance with some children's product safety rules is provided below. The information was collected from a number of sources, including published price lists from some testing laboratories, conversations with representatives of testing laboratories, actual invoices provided by consumer product manufacturers, and public comments we received. The data are not based upon a statistically valid survey of testing laboratories. Additionally, the costs include only the costs that would be charged by the testing laboratory. Not included in the information are the costs of the samples consumed in destructive tests, the cost of shipping the samples to the testing laboratories, and any related administrative or recordkeeping activity. According to one commenter, these costs could add 15 to 50 percent to the third party testing costs.

##### 2. Lead Content and Lead-in-Paint

The cost per component part for testing lead content and lead-in-paint using inductive coupled plasma (ICP) analysis will range from a low of about \$20 per test, to more than \$100 per test. The lowest per-unit cost represents a substantially discounted price charged to a particular customer by a testing laboratory in China, and therefore, the price might not be typical. Within the United States, typical prices range from around \$50, to more than \$100 per test.

The cost of testing for lead content using X-Ray fluorescence (XRF) technology is significantly less expensive. Some firms have offered to screen products for lead content for as little as \$2 per test. These offers are generally directed to stores or businesses that want to check their inventory for conformity with the retroactive lead content requirements contained in the CPSIA. Some testing laboratories will charge for XRF testing at an hourly rate, which can cost around \$100. Ten to 30 tests can be conducted in an hour.

We have approved XRF test methods for determining the lead content of homogenous polymer products. Assuming that 10 to 30 tests can be conducted in an hour at a rate of \$100 per hour, the cost of XRF testing for

homogenous polymer products would be between \$3 and \$10 per test.

For testing the lead content of paint, we have approved the use of a specific XRF test method described in ASTM F2853 that uses energy dispersive XRF using multiple monochromatic beams. Generally, fewer tests can be conducted in an hour using this test method. If 6 to 12 tests can be conducted in an hour at a rate of \$100 an hour, then the cost of testing a paint for lead content using the approved XRF technique would be about \$8 to \$17.

Other than for homogenous polymer components and the lead content of paint, we have not approved the use of XRF techniques for testing any other materials. For other materials, such as metal components, manufacturers will need to use ICP analyses techniques to test for lead content.

##### 3. Phthalates

The cost of testing for phthalate content will range from around \$100 (a discounted price by a testing laboratory in China) to about \$350. These are the costs per component part, and they include testing for all six of the individual phthalates whose content is restricted.

##### 4. Bicycle Standard (16 CFR part 1503)

According to one testing laboratory, it takes one to two days to test a bicycle. The estimated price for testing one bicycle may range from around \$700, if the testing is performed in China, to around \$1,100, if the testing is performed in the United States. A manufacturer who needs several models of bicycles tested at the same time, might be able to obtain discounts on these prices. This does not include testing for lead or phthalates in nonmetal component parts. H.R. 2715, however, exempted the metal components of bicycles from the third party testing requirements for lead content.

##### 5. Bicycle Helmets

One testing laboratory quoted a price of \$600 for testing one model of a bicycle helmet to the CPSC bicycle helmet standard. A price list from another testing laboratory stated that conducting the certification testing to the Snell Foundation's bicycle helmet standard, which is similar to the CPSC standard, is \$830.

##### 6. Full-Size Cribs

As with bicycles, testing cribs requires a substantial amount of labor time to assemble the crib, take the appropriate measurements, and perform the required tests. The cost of testing a

full-size crib to the pre-2010 standard was about \$750 to \$1,200 for testing performed in the United States. The cost of testing a full-size crib to the current standard may be somewhat higher. The cost can vary, depending on the features of the individual cribs that require testing and among the various testing laboratories. Some manufacturers might receive discounted prices. This does not include testing the crib for lead and phthalates, which, to the extent necessary, would add to the cost of testing a crib to all applicable safety rules.

#### 7. Toys

The children's product safety rules applicable to toys, including the ASTM F963 standard made mandatory by the CPSIA, include a wide variety of tests, including tests for soluble heavy metals in surface coatings and for various physical and mechanical criteria. Based on the itemized prices on several invoices provided to us by testing laboratories or otherwise made public, the cost of the physical and mechanical tests range from about \$50 to \$245. The cost of the chemical test for the presence of heavy metals ranges from about \$60 to \$190 per surface coating. Again, these costs do not include testing for lead and phthalates, which add to the total cost.

The flammability requirements of ASTM F963 were not made mandatory by the CPSIA, but we were directed to examine the flammability requirements and consider promulgating rules addressing the issue. If some flammability tests are eventually required, the cost per test could be in the range of \$20 to \$50, based on some observed costs for the ASTM F963 flammability tests.

#### 8. Cost of Third Party Testing by Product

The cost to obtain the required third party testing for a product depends on the types and number of tests that must be performed, as well as the number of samples that are required to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the product to meet the applicable children's product safety rules or ensure continuing compliance with the applicable children's product safety rules. The cost of the testing also will be affected by the extent to which the manufacturer can use component part testing. Because of the wide variety of manufacturers and products that would be affected by the rule, we cannot provide comprehensive estimates of the impact of the rule on all manufacturers or products. The discussion below is

intended to provide only some perspective on the potential impact.

#### 9. Number of Samples Required

The final rule does not specify the exact number of samples that must be submitted to third party conformity assessment bodies, nor does it specify the testing interval, other than to provide maximum intervals. Instead, the final rule requires manufacturers to determine the number samples and the necessary testing interval based on factors such as: The variability of the product, manufacturing processes, and information obtained from other testing. However, it is likely that between certification testing, testing after a material change, and periodic testing, many manufacturers will need to submit more than one sample of a given product to third party conformity assessment bodies during a given year. Because some children's product safety rules require more than one unit of the product to complete all of the required tests, one sample may consist of multiple units of the product.

For purposes of certifying a children's product (including testing after a material change), the final rule requires manufacturers to submit enough samples to a third party conformity assessment body to provide a high degree of assurance that tests conducted for certification purposes accurately demonstrate the ability of the product to comply with all applicable children's product safety rules. In determining how many samples to submit, a manufacturer is to consider the variability in the product and manufacturing processes. If the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, such as with die casting, a manufacturer may be able to submit a relatively small number of samples to the third party conformity assessment body. If the manufacturing process for a children's product results in variability in the composition or quality of children's products, such as what might be expected with hand assembly, a manufacturer may need to submit a greater number of samples.

For periodic testing, the final rule requires that the number of samples selected must be sufficient to assess—with a high degree of assurance—the continuing compliance of the children's product with all applicable safety rules. Additionally, the testing interval for periodic testing must be short enough to ensure that, if the samples selected for periodic testing pass the test, there is a high degree of assurance that the other untested children's products

manufactured during the interval comply with the applicable children's product safety rules. Manufacturers who have implemented a production testing plan or test in an ISO/IEC 17025:2005-accredited testing laboratory may consider the information obtained from the testing in determining the testing interval and the number of samples that are needed.

#### 10. Hypothetical Toy Testing Example

To provide some information on what the magnitude of the third party testing costs may be for some manufacturers of children's products, this section discusses the potential cost of obtaining third party testing for a hypothetical toy. This example is hypothetical and is intended to illustrate some potential cost implications of the rule. The example is not intended to be representative of every product or manufacturer. The costs per test that are assumed in the examples are based on the cost of tests discussed above; but the actual costs can vary significantly between conformity assessment bodies. The testing costs for any particular manufacturer also depend upon factors such as the complexity of the products, the variation in the materials used, manufacturing processes used, opportunities to use component part testing, and so on. We used a similar example in the initial regulatory flexibility analysis. The discussion has been changed to reflect the fact that energy dispersive XRF analysis can be used to test for lead in paint in addition to XRF testing in homogenous polymer products. We also have modified the discussion to deemphasize references to statistical measurements because, although statistical measurements might be useful, the number of samples that must be tested need not be one that provides a particular confidence level, such as 95 percent confidence level that all products in a lot are compliant.

Toys must meet requirements concerning lead and phthalate content, as well as several physical and mechanical requirements, including the requirements of ASTM F963, which was made a mandatory standard by the CPSIA. In this example, we assume that the testing costs are at the low to middle part of the ranges discussed above, and we also assume that the hypothetical toy contains one metal component part that must be tested for lead content using ICP analysis (at \$50) and two plastic component parts for which XRF analysis can be used for determining the lead content (two tests at \$6 each). The plastic component parts also must be tested for phthalate content (two tests at \$225 each). Additionally, we assume

that the toy contains four different paints that must be tested for both lead content (\$13/test, assuming energy dispersive XRF analysis) and soluble heavy metals (\$125/test). Finally, we assume that the toy is subject to some mechanical requirements that include use and abuse testing (\$50 per test). Thus, the cost of testing the hypothetical toy for compliance to each applicable rule one time would be \$1,114: \$1,064 is associated with the chemical (lead, heavy metal, and phthalate) testing, and \$50 is associated with the mechanical testing (including use and abuse testing).

Having one sample tested by a third party conformity assessment body will probably not be sufficient to meet the requirements of the final rule. Therefore, the cost of the third party testing for the manufacturer of this hypothetical toy would be greater than \$1,114. For example, if four samples are needed, the cost would be \$4,456. The cost would be higher if some tests had to be conducted more than four times to provide the required high degree of assurance. The manufacturer might be able to reduce the third party testing costs if it is able to use component part testing for the chemical content tests.

For example, if the plastic resins, metal component part, and paints are used on other products, the manufacturer could test the component parts independently of the individual finished products and spread the cost of the chemical content tests over more than one finished product. If the average cost of the chemical content tests could be reduced by a factor of four through component part testing, then the cost of testing the toy in this example for conformity with all applicable safety rules one time would be \$316 (cost of chemical testing of \$1,064/4 and cost of the mechanical and use and abuse testing of \$50). However, the cost of third party testing for the manufacturer would likely be higher because testing one sample will seldom be sufficient to provide the required high degree of assurance. For example, if each component part required four tests, and the mechanical testing required must be repeated four times to provide the required high degree of assurance, then the cost of the third party testing for the hypothetical toy would be \$1,264.

11. Impact of Final Rule on Firms

Whether the third party testing costs would have a substantial adverse impact

on a firm depends upon the individual circumstances of the firm. One factor is the magnitude of the impact in relation to the revenue of the firm. A typical profit rate is about five percent of revenue. In other words, for every one dollar of revenue, only five cents might remain after paying all expenses. Therefore, a new cost that amounted to one percent of revenue could, all other things equal, reduce the profit by 20 percent and would be considered to be a significant impact by most firms. This would be consistent with what some other agencies consider to be significant. The Occupational Safety and Health Administration (OSHA), for example, considers an impact to be significant if the costs exceed 1 percent of revenue or 5 percent of profit.<sup>6</sup>

Some insight on the disparate impact that the final rule could have on small businesses can be provided by examining how the rule might impact three hypothetical toy manufacturers of different sizes. The costs associated with third party testing that the hypothetical manufacturers would face will be described, and the potential impact on the hypothetical manufacturers will be discussed. This discussion is summarized in Table 5.

TABLE 5—IMPACT OF RULE ON THREE HYPOTHETICAL FIRMS

		Hypothetical firm A—large manufacturer	Hypothetical firm B—small manufacturer	Hypothetical firm C—small batch manufacturer
1	Number of Different Products	1,000	100	10
2	Annual Production Volume per Product	100,000	10,000	1,000
3	Total Annual Production Volume (Row 1 × Row 2)	100,000,000	1,000,000	10,000
4	Revenue per unit sold	\$4	\$4	\$4
5	Total Annual Revenue (Row 4 × Row 3)	\$400,000,000	\$4,000,000	\$40,000
6	Cost of testing each product for compliance with all rule once	\$1,114	\$1,114	\$102
7	Cost of Testing Each Product 4 Times (Row 6 × 4)	\$4,456	\$4,456	\$408
8	Total Third Party Testing Cost (Row 7 × Row 1)	\$4,456,000	\$445,600	\$4,080
9	Cost of Samples (4 samples of 2 units of each product)	\$32,000	\$3,200	\$320
10	Recordkeeping (5 hours/product at \$36.43/hour)	\$182,150	\$18,215	\$1,822
11	Total Testing Cost for One Year (Sum of Rows 8 through 10)	\$4,670,150	\$467,015	\$6,222
12	Testing Cost as Percent of Revenue (Row 11/Row 5)	1.2%	11.7%	15.6%

12. Three Hypothetical Manufacturers

The first hypothetical manufacturer, Firm A, is a large toy manufacturer that offers 1,000 different toys with an annual production or sales volume of 100,000 units each. Its total annual production volume is then 100 million units (1,000 products × 100,000 units each), which is shown in Row 3 of Table 5. The second hypothetical manufacturer, Firm B, is a smaller toy

manufacturer offers 100 different products with an annual production or sales volume of 10,000 units each. Finally, the third hypothetical toy manufacturer is a small batch manufacturer that offers only 10 products that with an annual production or sales volume of about 1,000 units each.

13. Revenue

The average price of a toy is \$7 to \$8.<sup>7</sup> However, because the retailer and any wholesalers or distributors would also get a share of the revenue, the manufacturer would be expected to get a fraction of the retail price. Therefore, the revenue received by a manufacturer of a toy that retails for \$7 to \$8 might be about \$4 per unit. For some toys, the revenue per unit received by the

<sup>6</sup> OSHA, Assigned Protection Factors, Final Rule, Federal Register (71 FR 50121–50192), 24 August 2006.

<sup>7</sup> Retail sales of toys in the United States are about \$22 billion per year (Toy Industry Association press release dated 27 June 2011). A representative of the Toy Industry Association estimated that there are

about 3 billion individual toys sold annually in the United States. This suggests an average retail price of \$7 to \$8 (\$22 billion x 3 billion).

manufacturer might be lower, and for others it might be higher. To begin the example, we assume that the average revenue is \$4 per unit. The Total Annual Revenue of the Firm (Row 5) is found by multiplying the Revenue per unit (Row 4) by the Total Annual Production Volume (Row 3).

#### 14. Third Party Testing Costs

The final rule requires manufacturers to have children's products tested by a third party conformity assessment body before the products are distributed, periodically after that, and when there has been a material change in the product. In these hypothetical examples, we assume that the manufacturers must submit samples of their products to third party conformity assessment bodies annually, whether for initial certification of products, periodic testing, or recertification after a material change.

The cost of the third party testing for a toy is a function of the characteristics of the toy, such as the number and type of component parts, the materials used in its construction, and the specific toy standards and tests that apply to it. The cost of third party tests would not be expected to be affected by the size of the manufacturer (although some conformity assessment bodies might offer discounts to firms for whom they conduct a lot of testing). In the hypothetical example, we assume that the conformity assessment bodies will charge the manufacturer \$1,114 to test the toy for conformance with each applicable children's product safety rule (Row 6), which is the same cost used in the earlier discussion of the cost to test a hypothetical toy. In the case of Firm C, a small batch manufacturer, the third party testing costs may be lower. Unless we establish alternate requirements for small batch manufacturers, H.R. 2715 may effectively exempt the qualifying products of small batch manufacturers from many third party testing requirements, including the requirements for phthalates, heavy metal content of paints, and the lead content of substrates (but not from other requirements, such as lead-in-paint or children's metal jewelry). In the case of the toy example, Firm C will need to have the paints used tested for lead content and the toys themselves tested for small parts. Using the costs assumed in the hypothetical toy example, the cost to Firm C for testing each product once to the two applicable requirements would be \$102 (4 paints at \$13 each and for small parts at \$50).

This hypothetical example assumes that it is necessary to conduct each applicable test four times to provide the

manufacturer with the necessary high degree of assurance, whether for the initial certification of the product, or to meet the periodic testing requirement. Therefore, the total cost that the manufacturer will be charged by a third party conformity assessment body is \$4,456 per product for Firms A and B, and \$408 per product for Firm C (Row 7). Because each manufacturer produces more than one product, total third party testing costs (Row 8) is equal to the cost per product times the number of products produced multiplied by the number of products produced (Row 7  $\times$  Row 1).

In this hypothetical example, we further assume that, to conduct each test at least once, the manufacturer must submit two units of the toy to the conformity assessment body. In other words, a sample consists of two units of the product. The cost of the samples consumed by testing is the revenue that the manufacturer forgoes because the units were used for testing and not sold. Therefore, the cost of the samples consumed in the testing (given in Row 9) is calculated as the product of the 8 units required to conduct the tests, the revenue per product, and the number of different products (*i.e.*,  $8 \times \text{Row 4} \times \text{Row 1}$ ).

Although component part testing has the potential to reduce third party testing costs, component part testing is not considered initially in these examples. One reason we did not consider it is that it has not been determined how extensively component part testing will be used in practice. Component part testing generally might not be an option for component parts that are not used in multiple products, or for which only a small portion of the production is used in children's products. It also might not be applicable to some importers or manufacturers who obtain products from suppliers that do not have the capability for component part testing, or for which the manufacturer or importer, exercising due care, has not yet developed the degree of confidence in the supplier to rely upon test reports and records provided by the supplier.

#### 15. Recordkeeping

Firms will incur costs for preparing and maintaining the records and documentation required by the final rule. In this example, we assume that the recordkeeping will require approximately five hours per toy. Assuming that the total compensation, per hour, for the employees involved in

the recordkeeping is \$36.43,<sup>8</sup> the recordkeeping cost would be about \$182 per product. The total recordkeeping burden (given in Row 10) is the cost per product (\$182), multiplied by the number of products (Row 1). This estimate of the recordkeeping burden assumes that the manufacturer will not be required to acquire any additional equipment or software to comply with the recordkeeping requirements of the final rule.

#### 16. Total Testing Cost

The total cost of testing for one year is the sum of the cost of the third party testing, the cost of the samples consumed in the testing, the cost of the recordkeeping, and the cost of developing the sampling plans. This is given in Row 11 of Table 5.

Manufacturers may incur other costs that were not considered above. For example, the proposed rule contained provisions requiring manufacturers to select the samples for periodic testing, using techniques that would result in a statistical simple random sample. There will likely be costs associated with such requirements. These potential costs include: The cost of hiring consultants to design a sampling plan for selecting a sample that meets established requirements and the cost of the added time and effort that might be required in selecting such a sample. However, H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSIA by replacing the phrase: "the testing of random samples to ensure continued compliance" with the phrase: "the testing of representative samples to ensure continued compliance." Because of this change in the statute, we are not finalizing the section of the proposed rule pertaining to random samples. These costs will be addressed in more detail when we consider how to implement section 14(i)(2)(B)(ii) of the CPSA, as amended by the CPSIA and H.R. 2715.

#### 17. Impact on Hypothetical Firms

The impact of the testing costs on each of the hypothetical firms is summarized in Row 12 of Table 5. For the large manufacturer, Firm A, the testing costs could amount to 1.2 percent of the firm's revenue (total testing cost, divided by the total revenue) if the firm received about \$4 per product. This could be considered a

<sup>8</sup> This is based on the assumption that about half the labor is management or professional and the other half is sales or office labor. For all workers in private industry, the total hourly compensation for management, professional, and related occupations is \$50.08 and \$22.78 office and administrative occupations (Bureau of Labor Statistics, Employer Cost for Employee Compensations, March, 2011).

significant impact. (A typical profit is about 5 percent of total revenue. Thus, a 1.2 percent increase in costs could decrease profit for a typical firm by 24 percent.) If the average revenue that this firm received is somewhat higher, however, the impact probably would not be considered significant.

For Hypothetical Firm B, a smaller manufacturer, the testing costs would amount to about 11.8 percent of the firm's revenue, if the firm received an average of \$4 for each unit produced. For the small batch manufacturer, Firm C, the testing costs would amount to about 15.6 percent of its revenue. In both cases (*i.e.*, Firms B and C), costs amounting to 11.8 percent and 15.6 percent, respectively, of revenue would be considered a significant impact. These hypothetical examples illustrate the disproportionate impact that the final rule may have on small businesses. As illustrated, the final rule could also

have a significant impact on even a large manufacturer. The significance of the impact increases as the production or sales volume of the manufacturer decreases.

The example of Firm C can be used to demonstrate the relief that H.R. 2715 may be able to provide to small batch manufacturers. If Firm C is unable to benefit from the testing exemptions provided by H.R. 2715, then Firm C would have faced the same per-unit testing costs as the other firms in this example: \$1,114 instead of \$102. Under that scenario, the total testing cost for Firm C would have been more than \$46,000, which would have exceeded its revenue of \$40,000.

Some small manufacturers probably have average revenues per product that exceed \$4. This might be the case especially if it is a specialty or niche market, in which only a few manufacturers participate, or if the

product requires a substantial amount of skilled labor to create. Table 6 shows what the impact would be on Firm C, the hypothetical small batch manufacturer, if it received an average of \$50 per unit for each unit it sold. Its total revenue would increase to \$500,000 per year. The cost of the samples consumed in testing would increase to \$4,000 (Row 9), which would increase the cost of testing to \$9,902 (Row 11). The testing costs would amount to about 1.9 percent of the firm's revenue, which might be considered significant, but it is much lower than it would have been if its revenue per unit was lower. It should be noted that if the manufacturer receives \$50 per unit sold of a product, the retail price is likely substantially higher (unless the manufacturer sells a substantial portion of the product directly to the final consumer).

TABLE 6—IMPACT ON HYPOTHETICAL FIRM C IF REVENUE PER UNIT IS \$50

		Hypothetical firm C—very small manufacturer
1	Number of Different Products	10
2	Annual Production Volume per Product	1,000
3	Total Annual Production Volume (Row 1 × Row 2)	10,000
4	Revenue per unit sold	\$50
5	Total Annual Revenue (Row 4 × Row 3)	\$500,000
6	Cost of testing each product for compliance with all rule once	\$102
7	Cost of Testing Each Product 4 Times (Row 6 × 4)	\$408
8	Total Third Party Testing Cost (Row 7 × Row 1)	\$4,080
9	Cost of Samples (4 samples of 2 units of each product)	\$4,000
10	Recordkeeping (5 hours/product at \$36.43/hour)	\$1,822
11	Total Testing Cost for One Year (Sum of Rows 8 through 11)	\$9,902
12	Testing Cost as Percent of Revenue (Row 12/Row 5)	1.9%

There also will be other costs that could be associated with the rule for which no quantification was attempted in the above hypothetical examples. One cost that was not considered is the additional administrative costs that are likely associated with the final rule's requirements; these include the cost of tracking when each product or component part needs to be tested. It also includes the cost of monitoring the suppliers and component parts that are used, the production techniques used, and any changes in product design to determine when products need to be tested due to material changes. There also may be administrative costs in matching up test reports to finished goods and giving the approval to ship products that the manufacturer has certified.

Another cost that could impact manufacturers for which quantification was not attempted is the cost of

receiving test reports that indicate inaccurately that the product did not comply with a children's product safety rule. When a manufacturer receives a test report that indicates inaccurately that a product does not meet a standard, the manufacturer could assume that the test was accurate and needlessly dispose of, or attempt to rework, the products covered by the test result; or, it might suspect that the test report was inaccurate and investigate the reason for the test failure. This could involve retesting samples of the product by other conformity assessment bodies and having the conformity assessment body that produced the inaccurate result attempt to determine if any error was made in testing the product. In any case, this could result in delays in shipping product and lost sales.

Component part testing may offer some manufacturers relief from some testing costs. Component part testing

may allow the cost of the third party testing to be spread over more units of the component part, which ultimately lowers the cost of third party testing per unit of the finished product. For example, if the hypothetical firms in the above examples were able to reduce the cost of third party testing by a factor of four using component part testing, in several (but not all) of the scenarios examined, the impact on those small firms could be reduced to the point that it would no longer be considered significant. However, component part testing is not likely to be an option for all manufacturers, for all component parts, or for all tests. Moreover, although it can reduce the cost of the third party testing, it may not reduce other costs associated with the final rule, such as the cost of samples, the cost of the recordkeeping, and other administrative costs.

It should be noted that the examples above were for illustration purposes only. The number of times a product may have to be tested for certification purposes or for periodic testing purposes may be more or less than four times. The cost of testing some toys and other children's products could be higher or lower than the cost used in the above examples. The cost would be higher, for example, for products that had more component parts or for which the variability in the test results is greater, which could require more samples to be tested. The cost of testing could be lower for products that are subject to fewer safety rules or that contain fewer component parts. For some articles of apparel, for example, the only tests required might be for flammability and lead content on some component parts, for which component part testing might be possible. Although the examples suggest that some small businesses will be significantly adversely impacted by the final rule, some small businesses may have sufficient volume, sufficiently low testing costs, or sufficiently high revenue that the impact will not be significant.

#### 18. Possible Market Reactions and Caveats

Manufacturers can be expected to react to a significant increase in their costs due to the final rule in several ways. Some manufacturers might attempt to redesign their products to reduce the number of tests required, by reducing the features or the number of component parts used in the products that require testing. Manufacturers and importers could also be expected to reduce the number of children's products that they offer or, in some cases, exit the market for children's products entirely. Some may go out of business altogether.

The requirements of the final rule could be a barrier that inhibits new firms from entering the children's product market, unless they expect to have relatively high-volume products. This could be an important factor for firms that expected to serve a niche market, such as firms with products intended for children with special needs. Although H.R. 2715 may provide significant relief to small batch manufacturers, the requirements could still be a barrier for some small batch manufacturers, home-based manufacturers, and craftspeople. The requirement for third party testing when there is a material change in a product's design or manufacturing process could cause some small or low-volume manufacturers to forgo or delay

implementing some improvements to a product's design or manufacturing process in order to avoid the costs of third party testing.

Although component part testing has the potential to reduce the costs of testing, component part testing might not be an option for all products or manufacturers. Component part testing most likely is an option for component parts that are common to multiple products (e.g., paints, bolts of a standard size). The potential for component part testing to reduce the cost of testing would be less for products that have component parts that are unique to the particular product. Component part testing is also not likely to offer significant cost savings for low-volume component parts or for component parts from which the component part manufacturer derives only a small percentage of revenue on regulated or children's products. Moreover, to use component part testing, the manufacturer must be able to trace each component part for which component part testing was used, to the party who procured the test. Maintaining this traceability will involve some administrative and recordkeeping costs, which will reduce the potential benefit of component part testing.

Manufacturers may be able to mitigate the adverse impacts if they are able to raise their prices to cover these costs. However, because few companies have perfectly inelastic demand curves, most firms will likely have to absorb some of the cost increases that result from the final rule.

#### O. Conclusion

The final rule will have a significant adverse impact on a substantial number of small businesses. The provisions of the rule that are expected to have the most significant impact are provisions related to requirements for the third party testing of children's products and the associated administrative and recordkeeping requirements. The impact is expected to be disproportionate on small and low-volume manufacturers. This is because testing costs are relatively fixed. Therefore, the impact of testing costs, per unit, will be greater on low-volume producers than on high-volume producers.

H.R. 2715 may provide significant relief from the third party testing costs to certain manufacturers who meet the definition of a "small batch manufacturer." However, although the impact will be substantially reduced, some small batch manufacturers may still be significantly impacted by the requirements in the final rule.

The other provisions of the rule related to protections against undue influence over a conformity assessment body and the voluntary consumer product labeling program are likely to have less significant impacts on small businesses.

#### P. Federal Rules Which May Duplicate, Overlap, or Conflict With the Final Rule

The final rule implements certain provisions of the CPSIA pertaining to the certification and continued testing of children's products for compliance with children's product safety rules. Certain children's product safety rules contain some requirements for certification tests and reasonable test programs. However, any duplication, overlap, or conflict should be minimal. For example, the third party certification tests required by the final rule would satisfy the requirements for certification tests in any existing children's product safety rule. Any production testing required by an existing children's product safety rule can be used to increase the maximum period between periodic tests according to the provisions of the final rule.

#### Q. Alternatives for Reducing the Adverse Impact on Small Businesses

We recognize that the final rule will have a disproportionate impact on small and low-volume manufacturers. To a large degree, the impact is not avoidable because the CPSA, as amended by the CPSIA, requires that the certification of children's products be based on test results from accredited third party conformity assessment bodies. However, we have incorporated into the final rule, some provisions that are intended to lessen the impact on small businesses. These include: Provisions allowing for longer maximum intervals between periodic testing if the manufacturer conducts certain other testing; allowing manufacturers to use component part testing; and permitting manufacturers and importers to rely upon the certifications issued by other parties as a basis for issuing their own finished product certificates, as provided by 16 CFR part 1109.

We also identified and considered several alternatives that could have reduced the impact on small businesses, but which for reasons discussed below, were not adopted in the final rule. These include: Providing additional testing relief for low-volume products; reducing the number of samples that must be tested by third party conformity assessment bodies; basing the frequency of third party testing on the risk of injury from the product; and allowing

the use of XRF testing for lead content for more materials.

#### R. Provisions Incorporated in the Final Rule

##### 1. Longer Maximum Periodic Testing Interval if the Manufacturer Conducts Other Testing

The final rule provides for a longer maximum periodic testing interval if the manufacturer implements a production testing plan, as provided for in § 1107.21(c) of the final rule. The manufacturer may consider the information obtained from the production testing in determining the appropriate interval and number of samples required for third party periodic testing, provided that third party periodic testing occurs at least once every two years. If the manufacturer conducts testing in an ISO/IEC 17025:2005-accredited testing laboratory in accordance with § 1107.21(d) of the final rule, the maximum periodic testing interval is three years. However, this provision is expected to be of benefit primarily to larger manufacturers.

##### 2. Component Part Testing

The final rule allows firms to conduct component part testing pursuant to the requirements in 16 CFR part 1109. This can reduce the cost to manufacturers where one component part might be common to more than one product. Such component parts might include paints, polymers used in molding different parts, and fasteners. In these cases, the component parts might be received in larger lots than the production lots of the products in which they are used. Therefore, the testing costs for those component parts will be spread over more units than if they were required to be tested on the final products only.

##### 3. Reliance on Certifications by Other Parties

The final rule allows manufacturers and importers to rely upon testing obtained by or certifications made by another party as the basis for their own certificates, as allowed by 16 CFR part 1109. These certifications can be for component parts or for finished products. This provision would be of value to importers, who may base their own certificate of conformity on the certificate for a finished product issued by a foreign manufacturer, provided that the requirements of 16 CFR part 1109 are met.

#### S. Alternatives That May Further Reduce the Impact on Small Businesses

##### Additional Testing Relief for Low-Volume Manufacturers of Children's Products

The proposed rule would include a provision that would provide some relief to low-volume manufacturers of children's products, by exempting products from the periodic testing requirement until 10,000 units of the product have been manufactured or imported. Once 10,000 units have been manufactured or imported, the periodic testing requirements would apply to the product. This provision did not relieve the manufacturer or importer from the obligation to have the product tested by a third party conformity assessment body for: (1) Certification purposes, and (2) when there had been a material change in the product's design or manufacturing processes or sourcing of component parts. Thus, the manufacturer would have still been obligated to submit samples to a third party conformity assessment body to demonstrate that the product conforms with the applicable children's product safety rules prior to introducing the product and when there has been a material change. The provision only relieved the manufacturer from the periodic testing requirements until 10,000 units of the children's product had been manufactured or imported.

On August 12, 2011, H.R. 2715 was enacted into law. H.R. 2715 has the potential to provide substantial relief to "small batch manufacturers," which H.R. 2751 defines as manufacturers that had no more than \$1 million in total gross revenue from sales of all consumer products in the previous calendar year. H.R. 2751 also defines "covered product" as a consumer product manufactured by a small batch manufacturer where no more than 7,500 units of the same product were manufactured in the previous calendar year. Because the provisions for small batch manufacturers in H.R. 2715 may provide relief to many of the same manufacturers at which the low-volume exemption in the proposed rule was aimed, we decided to defer action on the low-volume exemption.

For most small batch manufacturers, the relief provided by H.R. 2715 may be greater than the relief that would have been provided by the low volume-exemption from the proposed rule because the H.R. 2715 provides small batch manufacturers with relief from both certification and periodic testing, with some exceptions, while the low volume exemption in the proposed rule only provided some relief from periodic

testing. However, the partial exemption from periodic testing that the proposed rule would provide for products where fewer than 10,000 units had been imported or manufactured could provide some relief for some manufacturers of low-volume products that are not categorized as small batch manufacturers by H.R. 2715. There are likely some manufacturers that have low-volume products, but that also have gross sales that exceed \$1 million. These manufacturers will receive no relief from the small batch manufacturer exceptions in H.R. 2715, but would have been provided some relief by the low-volume exemption in the proposed rule. Consequently, including the partial exemption from periodic testing for low-volume products from the proposed rule, could provide some relief to manufacturers of low-volume products that do not meet the definition of a small batch manufacturer.

We have decided to reserve the provision of the proposed rule that would provide partial relief from periodic testing for low-volume products. The reason is that H.R. 2715 directed us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. It also contains special rules for small batch manufacturers and directs us to consider alternative testing requirements or to exempt small batch manufacturers from certain third party testing requirements. Thus, given these new statutory obligations resulting from H.R. 2715, we are reserving § 1107.21(e) so that we may consider how to address cost, low-volume products, and small batch issues more fully.

##### 1. Reduce the Number of Repeated Third Party Tests Required for Certification

The final rule requires that manufacturers submit samples of children's products to third party conformity assessment bodies to: (1) Certify that they comply with all applicable children's product safety rules before they are distributed; (2) after material changes; and (3) periodically to ensure continued compliance with all applicable children's product safety rules. The number of samples required is not specified, but would be based upon factors, such as the degree to which the manufacturing processes create products that are uniform in composition and quality, the testing interval, and the number of samples required to ensure with a high degree of

assurance that a certified product continues to comply with all applicable children's product safety rules. It is likely that most manufacturers will need to have a product third party tested multiple times for both certification and periodic testing purposes.

An alternative that could provide some relief to small businesses is to require, for purposes of certifying a product, manufacturers to submit sufficient units of the product to conformity assessment bodies to ensure that the product can be tested for compliance with each applicable children's safety rule, at least once, or as many times as required by the specific regulation, if different. The same requirement could apply to periodic testing: At least once during the periodic testing interval established by the rule (*e.g.*, once a year) manufacturers would be required to submit sufficient units of the product to ensure that each applicable children's product safety rule is evaluated at least once. In some cases, all of the required tests could be performed on one unit of the product. In other cases, more than one unit of the product might be required to test the product to all applicable children's product safety rules. For example, more than one unit of a toy might be required to subject the toy to each use and abuse test that is applicable to the toy; the tests specified in the bicycle helmet standard require eight helmets. Nevertheless, each test would only need to be conducted one time. This could reduce the financial burden of the third party testing requirements on small businesses.

Under this alternative, manufacturers could still be required to have a high degree of assurance that their children's products complied with all applicable children's product safety rules. However, the testing or inspections needed to provide the manufacturer with a high degree of assurance of compliance could be first or third party testing, or by other process control means, at the option of the manufacturer. The purpose of the required third party tests would be to provide objective evidence of compliance.

We did not accept this alternative because, although it arguably would provide a greater level of evidence of compliance than what existed before the enactment of the CPSIA, it would not require enough third party testing to provide a high degree of assurance that children's products complied with all applicable children's product safety rules. An analysis of CPSC compliance data for children's shoes found several examples where test results for one

sample of an article indicated compliance with the lead content requirements, but tests results for a different sample of the same article showed lead levels that exceeded the standard.<sup>9</sup> This suggests that testing one sample may not always be sufficient to detect noncomplying products.

## 2. Allow Increased Use of XRF Analysis

XRF analysis is a testing technique that can be used to measure the heavy metal content of materials. The cost of using XRF analysis testing is generally less expensive than using ICP analysis. Currently, we have approved XRF analysis for determining the lead content of homogenous polymer products and one type of XRF analysis (energy dispersive XRF using multiple monochromatic beams using the test method in ASTM F2853–10) for paints. We have not approved the use of XRF analysis for determining the lead content of metal component parts. However, allowing the use of XRF analysis for determining the lead content of metal component parts could substantially reduce the cost of the third party testing. The reduction could be especially significant for manufacturers of children's products that have a lot of metal component parts.

We decided not to allow the expanded use of XRF analysis to determine lead content at this time. However, we are continuing to evaluate the potential use of XRF analysis, and should we determine that XRF analysis can be sufficiently accurate in determining lead content, in a separate rulemaking, we could consider expanding the allowable use of XRF analysis for third party testing. Moreover, H.R. 2715 directed us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable children's product safety rule. Further, H.R. 2715 directs us to seek public comment on the extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for testing consumer products subject to a third party testing requirement. Therefore, we may consider alternatives to reduce the cost of third party testing requirements more fully at a later date.

<sup>9</sup> CPSC Memorandum to the Commission, from John W. Boja, Howard N. Tarnoff, Mary F. Toro, and Marc J. Schoem, "The Technological Feasibility of Reducing the Lead Content to 100 ppm: Compliance Data" (29 June 2011).

## 3. Basing the Frequency of Periodic Testing on Risk of Injury or Illness

The final rule requires that periodic testing be performed at least once every one to three years, depending on the other testing that a manufacturer opts to perform. An alternative that would reduce the burden of the rule on some small businesses is to lengthen the time period between required periodic tests for products, component parts, or rules for which the risk of serious injury or illness from a violation of a children's product safety rule is low. This would reduce the burden on some manufacturers because it could reduce the amount of required third party testing.

This alternative was not accepted because, given the number of children's product safety rules and the large number and wide variety of children's products to which they apply, its administration would be complex and would require a large investment of resources to analyze and rank the risk of serious injury or illness that could result from each product or product category failing to comply with each applicable children's product safety rule and then determining the appropriate periodic testing requirements for the product or product category.

## 4. Alternatives Not Considered Because They Would Conflict With the Statute

We are aware of some alternatives that could reduce the burden of the rule but that were not considered in this rulemaking because adopting the alternative would conflict with the statute. For example, although we have been able to exempt some materials from the testing requirements that inherently do not contain lead in excess of the limits established by the CPSIA, we are not able to exempt materials from testing that can exceed those limits even if the health hazard associated with the materials or component parts is believed to be minimal. Likewise, we are not able to exempt from the testing requirements products for which compliance with the applicable safety rule is thought to be very high even without a mandatory third party testing requirement.

## V. Paperwork Reduction Act

The final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The preamble to the proposed rule contained a discussion of the estimated burden associated with the rule's collection of

information requirements (75 FR at 28360 through 28361).

Several commenters addressed issues relating to the Paperwork Reduction Act discussion.

(Comment 113)—Some commenters noted that the preamble to the proposed rule states that we will likely request access to records only when we are investigating potentially defective or noncompliant products. The commenters concluded that having to integrate multiple systems to compile data should not be needed, as long as companies can provide the data upon request. One commenter noted that proposed § 1107.10 (b)(5)(i)(C) would require not only records of each certification test, but also “a description of how the product was certified as meeting the requirements, including how each applicable rule was evaluated, the test results and the actual values of the tests.”

One commenter stated that it receives more than a thousand finished good test reports annually from CPSC-accepted third party labs. These reports often run 50 to 125 pages in length and contain hundreds of data points and assessments. The commenter asserted that adding additional descriptive text to explain “how” the product was certified, simply adds no value. The commenter concluded that if the test report references an ASTM standard, and the results are acceptable, that should be sufficient without additional explanations.

(Response 113)—The final rule reserves subpart B, which would contain proposed § 1107.10 and requirements for a reasonable test program for non-children’s products, including the recordkeeping requirements. Therefore, the final rule does not impose any recordkeeping requirements related to non-children’s products.

With respect to children’s products, the recordkeeping requirements at § 1107.26 of the final rule do not require descriptive text to explain “how” the children’s product was certified. The certification test methods are prescribed for children’s products. It should only be necessary for the manufacturer or importer to identify and store the new requirements that are not already part of their current recordkeeping systems and to be certain that the remaining documentation can be produced, upon request, in a manner that identifies clearly the requisite parts.

(Comment 114)—Several commenters addressed our estimated resource requirements to manage the general recordkeeping requirements for testing and certification. One commenter stated

that the toy industries’ experience in meeting the recordkeeping requirements of the interim enforcement policy is that the requirements are extremely burdensome, and the recordkeeping requirements contained in the proposed rule are much more extensive and will be even more costly. The commenter stated that our estimate of 200,000–300,000 hours to manage recordkeeping, equating to no more than 200 people across all industries impacted by the CPSIA, is much too low. Within the toy industry alone, the commenter estimated 10 times that many persons have been engaged along the global supply chain to manage the data and recordkeeping associated with the CPSIA’s existing requirements. Although we referenced a calculation of 100,000 to 150,000 products to which the recordkeeping requirements would apply, the commenter stated that companies typically certify each SKU, and there is recordkeeping for every version, even if it is identical in all material respects.

One commenter estimated that the true number of toys and games was closer to 2.5 million. The commenter’s estimate was based on a listing of 808,465 toys and games on a popular commercial Web site (on August 3, 2010), plus its estimate that the Web site only lists about one-third of the toys available. Given some specialty and other submarkets, the commenter thought that the final number of items in the *Toys, Games, and Educational* items category could be in excess of 4 to 5 million individual products or stock-keeping units. The commenter also provided an estimate of 8 million apparel items available for children. However, the commenter did not provide the method or data sources it used for the latter estimates. Another commenter noted that its company had about 1,700 individual products annually, requiring testing, certification, and recordkeeping, or more than 1 percent of the CPSC’s entire estimated number of products across all affected industries.

(Response 114)—We acknowledge that our original estimate of the number of products that would be impacted was low, and we have increased significantly our estimate of the recordkeeping burden associated with the testing and certification requirements of the final rule. Based on the comments, and other research, we have revised our estimate of the number of children’s products. In the categories of toys, art and creative materials, furniture, and jewelry, we estimate that there are perhaps 241,000 different products. There are additional products

in other categories, such as nursery or juvenile products, nontraditional toys (e.g., video games), CDs, bicycles, ATVs, party favors, and greeting cards intended for children, and some educational materials that could be affected by the final rule for which specific estimates have not been made. The estimates do not consider that some products might be produced at more than one location or certified by more than one importer. Therefore, we concluded that there could be 300,000 non-apparel products that are covered by the rule.

The original estimate did not account for the very large number of apparel products that would be covered by the final rule. The number of apparel products intended for children, including footwear, is estimated to be about 1.3 million. This would bring the total number of children’s products to about 1.6 million.

The final rule has been changed to address some of the burdens mentioned by the commenters, such as not requiring records to be kept in the United States or translated into English, unless requested.

Elsewhere in this issue of the **Federal Register**, we have published a notice seeking public comment on the issues in H.R. 2715, including other methods of lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 115)—One commenter asserted that its company’s testing program has been highly effective for more than 26 years, but it does not maintain the records that would be required by the proposed rules, and it would be very costly to do so. One commenter questioned whether the extensive recordkeeping on every item was necessary for the proper performance of the CPSC’s functions.

Another commenter echoed the concern that the cost of the recordkeeping requirements would be high without providing any clear benefit to the agency’s mission or product safety. The commenter estimated that a major retailer would need to maintain records on 300,000 distinct products, which would cost the retailer \$22 million annually, using the estimated per product recordkeeping burden employed in the notice of proposed rulemaking. Another commenter stated that we should reduce the reporting burden by allowing manufacturers or importers to maintain their own recordkeeping systems if they meet the traceability requirements and ensure

that products are certified properly before they enter into commerce.

(Response 115)—With respect to recordkeeping requirements for reasonable testing programs for non-children's products, we have reserved subpart B, which would contain requirements for reasonable testing programs for non-children's products. Therefore, the final rule does not impose any recordkeeping requirements on manufacturers of non-children's products.

With respect to children's products, we acknowledge that the recordkeeping requirements could require considerable resources to track the data and manage recordkeeping. As a result, the costs associated with the recordkeeping requirements could be a significant expense for some firms. However, as stated in the preamble to the proposed rule, the purpose of the documentation and recordkeeping requirements in the rule is to establish the identity of the product and to demonstrate that each product complies with the applicable rules when it is certified and on a continuing basis thereafter. Additionally, we note that retailers are not required to comply with the recordkeeping requirements of the rule, unless they are also the importer of the product.

We also have revised the final rule to reduce the costs associated with the recordkeeping requirements. For example, the final rule does not require manufacturers to maintain the records at a location in the United States, as long as they can provide the records to us, after receiving a request to do so. Also, with the exception of the certificates of conformity, the records will not have to be maintained in the English language.

Finally, the final rule does not require that the records be in a specific format. The final rule specifies the records or information that is required. However, manufacturers may maintain the records within their own recordkeeping systems if, as suggested by the commenter, they meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

(Comment 116)—Several comments provided estimates on the amount of time required for recordkeeping or information from which estimates could be derived. One commenter (a large toy manufacturer) stated that they had added six full-time employees to manage the data and recordkeeping associated with the CPSIA's existing testing and certification requirements, and they further indicated that they had 1,700 products tested annually for which recordkeeping would be

required. The test reports are from 50 to 125 pages in length and require maintaining for all products tested. The commenter estimated that their company accounted for greater than 1 percent of all the hours that the CPSC had estimated for all children's products. The commenter concluded that, based on this estimate, the actual number of hours required for recordkeeping by all companies would be higher than the CPSC's estimate.

Another commenter estimated that the recordkeeping will require about 2.25 hours per test submitted; but due to varying lot sizes and requirements, they estimate that multiple tests per year could be required on a product. They estimate that the burden will be 3 hours for one category of products that it manufactures and 5 hours for another, with an average across their product line of 3.5 hours.

One commenter said that the time required for recordkeeping would be higher for manufacturers that specialize in high quality, but low volume products. The commenter estimated that it would take 6 to 10 employees to track the testing data and compile it into certificates of conformity, or about 6 to 10 times the per-product labor required by the high volume, mass production manufacturers. The commenter estimated about 3 to 7.5 hours of recordkeeping would be required for high-quality, low-volume products.

(Response 116)—Based on these comments, we have determined that for many children's products, substantially more than 2 hours will be required for the associated recordkeeping. For products, such as toys, jewelry, children's furniture and other children's products, which are subject to third party testing to several different standards, we have determined that 5 hours is a reasonable estimate.

More hours will be required for some products to which many rules apply. Simpler products with few, or only one, applicable rule should require fewer hours for recordkeeping. For apparel and footwear products, we have determined that it is reasonable to use a lower estimate of the number of hours required for recordkeeping, such as 3 hours. This estimate recognizes that there could be substantial recordkeeping required for some items, such as those that require testing for flammability and that contain various components (*e.g.*, zippers, snaps, buttons, accessories) while other items, might require little testing.

*Title:* Testing and Labeling Pertaining to Product Certification.

*Description:* The final rule implements section 102(b) of the CPSIA,

which requires certification of compliance for children's products subject to a children's product safety rule. A certification that a children's product complies with the applicable children's product safety rules must be supported by testing by an approved third party conformity assessment body. The final rule imposes recordkeeping requirements related to those testing and certification mandates. The recordkeeping requirements are intended to allow identification of each product and establish that each product is certified properly, before it enters commerce. In addition, the recordkeeping requirements require certification that a product has been retested properly for conformity with all applicable rules on a continuing basis, including after a material change in the product's design or manufacturing processes, including the sourcing of component parts.

Each manufacturer or importer of a children's product subject to a children's product safety rule would be required to establish and maintain the following records:

- A copy of the Children's Product Certificate (§ 1107.26(a)(1));
- Records of each certification test (§ 1107.26(a)(2));
- Records of the periodic tests (§ 1107.26(a)(3));
- Records of descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, the certification tests run, and the test values (§ 1107.26(a)(5)); and
- Records of undue influence procedures (§ 1107.26(a)(6)).

*Description of Respondents:* The recordkeeping requirements apply to all manufacturers or importers of children's products that are covered by one or more children's product safety rules promulgated and/or enforced by the CPSC. We reviewed every industry category in the NAICS and selected those industry categories that included firms that could manufacture or sell such children's products. Using data from the U.S. Census Bureau, we determined that there are more than 37,000 manufacturers, almost 80,000 wholesalers, and about 128,000 retailers in these categories. However, not all of the firms in these categories manufacture or import children's products that are covered by children's product safety rules. Therefore, these numbers would constitute a high estimate of the number of firms that are subject to the recordkeeping requirements.

*Estimate of the Burden:* The hour burden of the recordkeeping

requirements will likely vary greatly from product to product, depending upon such factors as the complexity of the product and the amount of testing that must be documented. We do not have comprehensive data on the universe of products that will be impacted. Therefore, estimates of the hour burden of the recordkeeping requirements are somewhat speculative.

The preamble to the proposed rule (75 FR at 28361) estimated that, on average, approximately 2 hours would be needed for recordkeeping per product; although we recognized that, for some products, particularly those subject to more than one standard or rule, would need a substantial amount of testing, and thus, the recordkeeping burden could be much higher than 2 hours. Conversely, products subject to one standard or that need little testing, could have a recordkeeping burden of less than 2 hours.

Based on the comments we received on the proposed rule, however, we have revised the estimated number of children's products that are affected, as well as the hourly recordkeeping burden estimate. We now estimate that approximately 300,000 non-apparel children's products will be covered by the rule and that an average of 5 hours will be needed for the recordkeeping associated with these products. We also estimate that there are approximately 1.3 million children's apparel and footwear products and that will require an average of 3 hours for the recordkeeping. Thus, the total hour burden of the recordkeeping associated with the final rule is 5.4 million hours (300,000 × 5 hours plus 1,300,000 × 3 hours).

Additionally, for the proposed rule, to calculate the cost of the recordkeeping burden, we used the total hourly compensation for private sector workers in management, professional, and related occupations, which is \$48.91 per hour. This is based on the expectation that much of the recordkeeping will be done by chemists, engineers and quality control managers. Most commenters did not mention the occupational mix of the workers that would be involved in the recordkeeping associated with the rule. However, one commenter stated that the rule would result in an increase in his clerical and management staff. Therefore, to recognize that clerical, professional, and management staff will be involved in meeting the recordkeeping requirements of the rule, we will assume that personnel in "management, professional, and related occupations" will be responsible for half of the recordkeeping, while personnel in "office and administrative

support" occupations will be responsible for the other half. As of March 2011, these categories would average \$36.43 per hour (<http://www.bls.gov/news.release/ecec.t09.htm>).<sup>10</sup> At \$36.43 per hour (*i.e.*, the revised hourly compensation rate), the total cost of the recordkeeping associated with the testing and certification rule is approximately \$197 million (5.4 million hours × \$36.43 = \$196,722,000).

*Estimate Limitations:* There are some limitations to the above estimates that warrant mentioning.

While the estimates of the number of products are more accurate than the original estimates, they are not based on a well-designed survey or comprehensive database. Additionally, the extent to which some products might be certified by multiple importers, or are manufactured at different sites, has not been established.

Recordkeeping for the flammability of children's sleepwear might be captured in the OMB submission on another rule, but the recordkeeping associated with the lead content rules should be captured here. However, no adjustment for this has been made because we have not tried to separate children's sleepwear from other apparel items.

The recordkeeping considered here is best thought of as the recordkeeping mandated by the testing and certification requirements of section 102 of the CPSIA. It would be impossible to separate the time associated with the initial certification, from the time related to periodic testing and documenting material changes, especially because it often involves issuing a new certificate.

For finished goods manufacturers who also perform their own component testing, it is difficult to separate the recordkeeping burden associated with component part testing from the recordkeeping burden associated with the testing and labeling rule. This could lead to an overestimate of the costs associated with the testing and labeling rule and possibly result in underestimates associated with the component part testing rule. Better estimates may be possible if the recordkeeping burden is reevaluated after the rules are finalized.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have applied to the U.S. Office of Management and Budget

<sup>10</sup> U.S. Department of Labor, Bureau of Labor Statistics, "Employer costs for Employee Compensation—March 2011, Table 9" (8 June 2011). Available at: <http://www.bls.gov/news.release/ecec.t09.htm>. Last accessed 8 July 2011.

(OMB) for a control number for this information collection, and we will publish a notice in the **Federal Register** providing the number when we receive approval from the OMB.

## VI. Environmental Considerations

This final rule falls within the scope of the Commission's environmental review regulations at 16 CFR 1021.5(c)(2), which provides a categorical exclusion from any requirement for the agency to prepare an environmental assessment or environmental impact statement for product certification rules.

## VII. Executive Order 12988

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, of new regulations. The final rule is issued under authority of the CPSA and the CPSIA. The CPSA provision on preemption appears at section 26 of the CPSA. The CPSIA provision on preemption appears at section 231 of the CPSIA. The preemptive effect of this rule would be determined in an appropriate proceeding by a court of competent jurisdiction.

## VIII. Effective Date

The preamble to the proposed rule indicated that a final rule would become effective 180 days after its date of publication in the **Federal Register** (75 FR at 28361). However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised the CPSIA in several different ways and also affected section 14(i)(2)(B)(ii) of the CPSA. H.R. 2715 also created a new section 14(i)(3)(B) of the CPSA, which requires us, no later than one year after H.R. 2715's date of enactment, to review the public comments (on opportunities to reduce the costs of third party testing requirements) and directs us to "prescribe new or revised third party testing regulations" if we determine that "such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." Consequently, we have finalized those provisions that H.R. 2715 did not affect directly. We also have decided to make the final rule effective on February 8, 2013 so that parties can begin taking steps to develop internal processes, such as recordkeeping, and so that we and interested parties can consider how H.R. 2715 interacts with the final rule.

## List of Subjects in 16 CFR Part 1107

Business and industry, Children, Consumer protection, Imports,

Incorporation by reference, Product testing and certification, Records, Record retention, Toys.

Accordingly, 16 CFR part 1107 is added to read as follows:

**PART 1107—TESTING AND LABELING PERTAINING TO PRODUCT CERTIFICATION**

**Subpart A—General Provisions**

Sec.

1107.1 Purpose.

1107.2 Definitions.

**Subpart B—[Reserved]**

**Subpart C—Certification of Children's Products**

1107.20 General requirements.

1107.21 Periodic testing.

1107.23 Material change.

1107.24 Undue influence.

1107.26 Recordkeeping.

**Subpart D—Consumer Product Labeling Program**

1107.30 Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met.

**Authority:** 15 U.S.C. 2063, Sec. 3, 102 Pub. L. 110–314, 122 Stat. 3016, 3017, 3022.

**Subpart A—General Provisions**

**§ 1107.1 Purpose.**

This part establishes the protocols and standards for ensuring continued testing of children's products periodically and when there has been a material change in the product's design or manufacturing process and safeguarding against the exercise of undue influence by a manufacturer on a third party conformity assessment body. It also establishes a program for labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(2) and (i)(2)(B) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)(2) and (i)(2)(B)).

**§ 1107.2 Definitions.**

Unless otherwise stated, the definitions of the Consumer Product Safety Act and the Consumer Product Safety Improvement Act of 2008 apply to this part. The following definitions apply for purposes of this part:

*CPSA* means the Consumer Product Safety Act.

*CPSC* means the Consumer Product Safety Commission.

*Due care* means the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Due care does not permit willful ignorance.

*High degree of assurance* means an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.

*Identical in all material respects* means there is no difference with respect to compliance to the applicable rules, bans, standards, or regulations between the samples to be tested for compliance and the finished product distributed in commerce.

*Manufacturer* means the parties responsible for certification of a consumer product pursuant to 16 CFR part 1110.

*Manufacturing process* means the techniques, fixtures, tools, materials, and personnel used to create the component parts and assemble a finished product.

*Material change* means any change in the product's design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules, bans, standards, or regulations.

*Third party conformity assessment body* means a testing laboratory whose accreditation has been accepted by the CPSC to conduct certification testing on children's products. Only third party conformity assessment bodies whose scope of accreditation includes the applicable required tests can be used for children's product certification or periodic testing purposes.

**Subpart B—[Reserved]**

**Subpart C—Certification of Children's Products**

**§ 1107.20 General requirements.**

(a) Manufacturers must submit a sufficient number of samples of a children's product, or samples that are identical in all material respects to the children's product, to a third party conformity assessment body for testing to support certification. The number of samples selected must be sufficient to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules.

(b) If the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety

rules. If the manufacturing process for a children's product results in variability in the composition or quality of children's products, a manufacturer may need to submit more samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules.

(c) Except where otherwise specified by a children's product safety rule, component part testing pursuant to 16 CFR part 1109 may be used to support the certification testing requirements of this section.

(d) If a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure. A manufacturer cannot certify the children's product until the manufacturer establishes, with a high degree of assurance that the finished product does comply with all applicable children's product safety rules.

**§ 1107.21 Periodic testing.**

(a) *General requirements for all manufacturers.* All manufacturers of children's products must conduct periodic testing. All periodic testing must be conducted by a third party conformity assessment body. Periodic testing must be conducted pursuant to either paragraph (b), (c), or (d) of this section or as provided in regulations under this title. The testing interval selected for periodic testing may be based on a fixed production interval, a set number of units produced, or another method chosen by the manufacturer based on the product produced and its manufacturing process, so long as the applicable maximum testing interval specified in paragraph (b), (c), or (d) of this section is not exceeded. Component part testing pursuant to 16 CFR part 1109 may be used to support the periodic testing requirements of this section.

(b) A manufacturer must conduct periodic testing to ensure compliance with the applicable children's product safety rules at least once a year, except as otherwise provided in paragraphs (c), and (d) of this section or as provided in regulations under this title. If a manufacturer does not conduct production testing under paragraph (c) of this section, or testing by a testing laboratory under paragraph (d) of this section, the manufacturer must conduct periodic testing as follows:

(1) *Periodic Testing Plan.* Manufacturers must develop a periodic

testing plan to ensure with a high degree of assurance that children's products manufactured after the issuance of a Children's Product Certificate, or since the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules. The periodic testing plan must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples tested. At each manufacturing site, the manufacturer must have a periodic testing plan specific to each children's product manufactured at that site.

(2) *Testing Interval.* The testing interval selected must be short enough to ensure that, if the samples selected for testing pass the test, there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable children's product safety rules. The testing interval may vary depending upon the specific children's product safety rules that apply to the children's product, but may not exceed one year. Factors to be considered when determining the testing interval include, but are not limited to, the following:

(i) High variability in test results, as indicated by a relatively large sample standard deviation in quantitative tests;

(ii) Measurements that are close to the allowable numerical limit for quantitative tests;

(iii) Known manufacturing process factors which could affect compliance with a rule. For example, if the manufacturer knows that a casting die wears down as the die nears the end of its useful life, the manufacturer may wish to test more often as the casting die wears down;

(iv) Consumer complaints or warranty claims;

(v) Introduction of a new set of component parts into the assembly process;

(vi) The manufacture of a fixed number of products;

(vii) Potential for serious injury or death resulting from a noncompliant children's product;

(viii) The number of children's products produced annually, such that a manufacturer should consider testing a children's product more frequently if the product is produced in very large numbers or distributed widely throughout the United States;

(ix) The children's product's similarity to other children's products with which the manufacturer is familiar and/or whether the children's product has many different component parts compared to other children's products of a similar type; or

(x) Inability to determine the children's product's noncompliance easily through means such as visual inspection.

(c)(1) If a manufacturer implements a production testing plan as described in paragraph (c)(2) of this section to ensure continued compliance of the children's product with a high degree of assurance to the applicable children's product safety rules, the manufacturer must submit samples of its children's product to a third party conformity assessment body for periodic testing to the applicable children's product safety rules at least once every two years. A manufacturer may consider the information obtained from production testing when determining the appropriate testing interval and the number of samples needed for periodic testing to ensure that there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable children's product safety rules.

(2) *Production Testing Plan.* A production testing plan describes the production management techniques and tests that must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable children's product safety rules. A production testing plan may include recurring testing or the use of process management techniques, such as control charts, statistical process control programs, or failure modes and effects analyses (FMEAs) designed to control potential variations in product manufacturing that could affect the product's ability to comply with the applicable children's product safety rules. A manufacturer may use measurement techniques that are nondestructive and tailored to the needs of an individual product to ensure that a product complies with all applicable children's product safety rules. Any production test method used to conduct production testing must be effective in determining compliance. Production testing cannot consist solely of mathematical methods (such as an FMEA, with no additional components, or computer simulations). Production testing must include some testing, although it is not required that the test methods employed be the test methods used for certification. A manufacturer must document the production testing methods used to ensure continuing compliance and the basis for determining that the production testing plan provides a high degree of assurance that the product being manufactured continues to comply with all applicable

children's product safety rules. A production testing plan must contain the following elements:

(i) A description of the production testing plan, including, but not limited to, a description of the process management techniques used, the tests to be conducted, or the measurements to be taken; the intervals at which the tests or measurements will be made; the number of samples tested; and the basis for determining that the combination of process management techniques and tests provide a high degree of assurance of compliance if they are not the tests prescribed for the applicable children's product safety rule;

(ii) At each manufacturing site, the manufacturer must have a production testing plan specific to each children's product manufactured at that site;

(iii) The production testing interval selected for tests must ensure that, if the samples selected for production testing comply with an applicable children's product safety rule, there is a high degree of assurance that the untested products manufactured during that testing interval also will comply with the applicable children's product safety rule. Production testing intervals should be appropriate for the specific testing or alternative measurements being conducted.

(3) If a production testing plan as described in this paragraph (c) fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, the CPSC may require the manufacturer to meet the requirements of paragraph (b) of this section or modify its production testing plan to ensure a high degree of assurance of compliance.

(d)(1) For manufacturers conducting testing to ensure continued compliance with the applicable children's product safety rules using a testing laboratory accredited to ISO/IEC 17025:2005(E), "General requirements for the competence of testing and calibration laboratories," periodic tests by a third party conformity assessment body must be conducted at least once every three years. Any ISO/IEC 17025:2005(E)-accredited testing laboratory used for ensuring continued compliance must be accredited by an accreditation body that is accredited to ISO/IEC 17011:2004(E), "Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies." The test method(s) used by an ISO/IEC 17025:2005(E)-accredited testing laboratory when conducting testing to ensure continued compliance must be the same test method(s) used for certification to the applicable children's product safety rules.

Manufacturers must conduct testing using the ISO/IEC 17025:2005(E)-accredited testing laboratory frequently enough to provide a high degree of assurance that the children's product continues to comply with the applicable children's product safety rules. A manufacturer may consider the information obtained from testing conducted by an ISO/IEC 17025:2005(E)-accredited testing laboratory when determining the appropriate testing interval and the number of samples for periodic testing that are needed to ensure that there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable children's product safety rules.

(2) If the continued testing described in paragraph (d)(1) of this section fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, the CPSC may require the manufacturer to meet the requirements of paragraph (b) of this section or modify the testing frequency or number of samples required to ensure a high degree of assurance of continued compliance.

(e) [Reserved]

(f) [Reserved]

(g) The Director of the Federal Register approves the incorporations by reference of the standards in this section in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy of the standards 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: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland; Telephone +41 22 749 01 11, Fax +41 22 733 34 30; <http://www.iso.org/iso/home.html>.

(i) ISO/IEC 17011:2004(E), "Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies," First Edition, September 1, 2004 (Corrected version February 15, 2005);

(ii) ISO/IEC 17025:2005(E), "General requirements for the competence of testing and calibration laboratories," Second Edition, May 15, 2005.

(2) [Reserved]

#### § 1107.23 Material change.

(a) *General Requirements.* If a children's product undergoes a material change in product design or manufacturing process, including the sourcing of component parts, which a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable children's product safety rules, the manufacturer must submit a sufficient number of samples of the materially changed children's product for testing by a third party conformity assessment body and issue a new Children's Product Certificate. The number of samples submitted must be sufficient to provide a high degree of assurance that the materially changed component part or finished product complies with the applicable children's product safety rules. A manufacturer of a children's product that undergoes a material change cannot issue a new Children's Product Certificate for the product until the product meets the requirements of the applicable children's product safety rules. The extent of such testing may depend on the nature of the material change. When a material change is limited to a component part of the finished children's product and does not affect the ability of other component parts of the children's product or the finished children's product to comply with other applicable children's product safety rules, a manufacturer may issue a new Children's Product Certificate based on the earlier third party certification tests and on test results of the changed component part conducted by a third party conformity assessment body. A manufacturer must exercise due care to ensure that any component part undergoing component part-level testing is identical in all material respects to the component part on the finished children's product. Changes that cause a children's product safety rule to no longer apply to a children's product are not considered to be material changes.

(b) *Product Design.* For purposes of this subpart, the term "product design" includes all component parts, their composition, and their interaction and functionality when assembled. To determine which children's product safety rules apply to a children's product, a manufacturer should examine the product design for the children's product as received or assembled by the consumer.

(c) *Manufacturing Process.* A material change in the manufacturing process is a change in how the children's product is made that could affect the finished children's product's ability to comply

with the applicable children's product safety rules. For each change in the manufacturing process, a manufacturer should exercise due care to determine if compliance to an existing applicable children's product safety rule could be affected, or if the change results in a newly applicable children's product safety rule.

(d) *Sourcing of Component Parts.* A material change in the sourcing of component parts results when the replacement of one component part of a children's product with another component part could affect compliance with the applicable children's product safety rule. This includes, but is not limited to, changes in component part composition, component part supplier, or the use of a different component part from the same supplier who provided the initial component part.

#### § 1107.24 Undue influence.

(a) Each manufacturer must establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body.

(b) The procedures required in paragraph (a) of this section, at a minimum, must include:

(1) Safeguards to prevent attempts by the manufacturer to exercise undue influence on a third party conformity assessment body, including a written policy statement from company officials that the exercise of undue influence is not acceptable, and directing that every appropriate staff member receive training on avoiding undue influence, and sign a statement attesting to participation in such training;

(2) A requirement that upon substantive changes to the requirements in this section regarding avoiding undue influence, the appropriate staff must be retrained regarding those changed requirements.

(3) A requirement to notify the CPSC immediately of any attempt by the manufacturer to hide or exert undue influence over test results; and

(4) A requirement to inform employees that allegations of undue influence may be reported confidentially to the CPSC and a description of the manner in which such a report can be made.

#### § 1107.26 Recordkeeping.

(a) A manufacturer of a children's product subject to an applicable children's product safety rule must maintain the following records:

(1) A copy of the Children's Product Certificate for each product. The children's product covered by the certificate must be clearly identifiable

and distinguishable from other products;

(2) Records of each third party certification test. The manufacturer must have separate certification tests records for each manufacturing site;

(3) Records of one of the following for periodic tests of a children's product:

(i) A periodic test plan and periodic test results;

(ii) A production testing plan, production test results, and periodic test results; or

(iii) Testing results of tests conducted by a testing laboratory accredited to ISO/IEC 17025:2005(E) and periodic test results.

(4) [Reserved];

(5) Records of descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values; and

(6) Records of the undue influence procedures, including training materials and training records of all employees trained on these procedures, including attestations described at § 1107.24(b)(1).

(b) A manufacturer must maintain the records specified in paragraph (a) of this section for five years. The manufacturer

must make these records available, either in hard copy or electronically, such as through an Internet Web site, for inspection by the CPSC upon request. Records may be maintained in languages other than English if they can be:

(1) Provided immediately by the manufacturer to the CPSC; and

(2) Translated accurately into English by the manufacturer within 48 hours of a request by the CPSC, or any longer period negotiated with CPSC staff.

#### **Subpart D—Consumer Product Labeling Program**

##### **§ 1107.30 Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met.**

(a) Manufacturers and private labelers of a consumer product may indicate, by a uniform label on, or provided with the product, that the product complies with any consumer product safety rule under the CPSA, or with any similar rule, ban, standard or regulation under any other act enforced by the CPSC.

(b) The label must be visible and legible, and consist of the following statement:

#### **Meets CPSC Safety Requirements**

(c) A consumer product may bear the label if the manufacturer or private labeler has certified, pursuant to section 14 of the CPSA, that the consumer product complies with all applicable consumer product safety rules under the CPSA and with all rules, bans, standards, or regulations applicable to the product under any other act enforced by the Consumer Product Safety Commission.

(d) A manufacturer or private labeler may use a label in addition to the label described in paragraph (b) on the consumer product, as long as such label does not alter or mislead consumers as to the meaning of the label described in paragraph (b) of this section. A manufacturer or private labeler must not imply that the CPSC has tested, approved, or endorsed the product.

Dated: October 21, 2011.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2011-27678 Filed 11-7-11; 8:45 am]

**BILLING CODE 6355-01-P**

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

**The Proposed Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

**PART 39—AIRWORTHINESS DIRECTIVES**

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

**Rolls-Royce plc:** Docket No. FAA–2013–0029; Directorate Identifier 2013–NE–01–AD.

**(a) Comments Due Date**

We must receive comments by June 4, 2013.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to Rolls-Royce plc (RR) RB211–535E4–B–37 series turbofan engines.

**(d) Unsafe Condition**

This AD was prompted by recalculating the life of certain life limited parts operated to certain flight profiles. We are issuing this AD to prevent the failure of critical rotating parts, which could result in uncontained failure of the engine and damage to the airplane.

**(e) Compliance**

Comply with this AD within the compliance times specified, unless already done.

(1) Within 30 days after the effective date of this AD for engines that have operated to Flight Profile D or E, recalculate the life of the low-pressure (LP) turbine disc stage 2, intermediate-pressure (IP) compressor rotor shaft (stage 1 to 6), high-pressure (HP) compressor rear rotor shaft assembly, and HP turbine disc installed on that engine. Use the part lives, prorated life formulas, and flight profiles in Appendices 2, 4, and 5 of RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AG875, dated December 13, 2012, to make that calculation.

(2) Within 30 days after the effective date of this AD for engines that will operate to Flight Profile D or E, assign the Maximum Approved Lives defined in Appendix 2 of RR Alert NMSB No. RB.211–72–AG875, dated December 13, 2012, to the LP turbine disc Stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, and HP turbine disc based on the flight profile that will be flown.

(3) For engines that have only operated to, and will continue to operate to, Flight Profile

C, as defined in Appendix 5 of RR Alert NMSB No. RB.211–72–AG875, dated December 13, 2012, no further action is required by this AD.

(4) For engines that incorporate an LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD that have an engine shop visit (ESV) after the effective date of this AD, remove each part from service before the part exceeds the part life assigned in paragraph (e)(2) of this AD.

(5) For those engines that incorporate an LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD, that do not have an ESV after the effective date of this AD before the part exceeds the part life assigned in paragraph (e)(2) of this AD, remove the part from service at the next ESV.

**(f) Installation Prohibition**

After the effective date of this AD, any LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD that is re-installed in any engine after the effective date of this AD must be removed from service before the part exceeds the part life assigned in paragraph (e)(2) of this AD.

**(g) Definitions**

For the purpose of this AD, ESV is whenever engine maintenance performed prior to reinstallation requires the separation of a pair of major mating engine module flanges. Separation of flanges solely for the purpose of shipment without subsequent internal maintenance, is not an ESV.

**(h) Alternative Methods of Compliance (AMOCs)**

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

**(i) Related Information**

(1) For more information about this AD, contact Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: [robert.green@faa.gov](mailto:robert.green@faa.gov); phone: 781–238–7754; fax: 781–238–7199.

(2) Refer to EASA AD 2012–0265, dated December 18, 2012, for related information.

(3) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936 or email from [http://www.rolls-royce.com/contact/civil\\_team.jsp](http://www.rolls-royce.com/contact/civil_team.jsp), or download the publication from <https://www.aeromanager.com>. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on March 29, 2013.

**Colleen M. D'Alessandro,**

*Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 2013–07935 Filed 4–4–13; 8:45 am]

**BILLING CODE 4910–13–P**

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Parts 1112 and 1226**

[Docket No. CPSC–2013–0014]

**Safety Standard for Soft Infant and Toddler Carriers**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for soft infant and toddler carriers in response to the direction under Section 104(b) of the CPSIA.<sup>1</sup>

**DATES:** Submit comments by June 19, 2013.

**ADDRESSES:** Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

Other comments, identified by Docket No. CPSC–2013–0014, may be submitted electronically or in writing:

<sup>1</sup> The Commission voted 2–1 to approve publication of this proposed rule. Chairman Inez M. Tenenbaum and Commissioner Robert S. Adler voted to approve publication, and Commissioner Nancy A. Nord voted against publication. Commissioner’s statements concerning this or any other Commission action may be viewed by clicking on a specific Commissioner’s name and selecting “Statements” on the Commission’s Web site at <http://www.cpsc.gov/en/About-CPSC/Commissioners/>, or obtained from the Commission’s Office of the Secretary.

**Electronic Submissions:** Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

**Written Submissions:** Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

**Instructions:** All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

**Docket:** For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC-2013-0014, into the "Search" box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:**

Gregory K. Rea, Project Manager, Director, Division of Mechanical Engineering, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2258; email: [grea@cpsc.gov](mailto:grea@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background and Statutory Authority**

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission 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 and toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The term "durable infant or toddler product" is defined in section 104(f)(1) of the CPSIA as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years."

In this document, the Commission is proposing a safety standard for soft infant and toddler carriers. "Infant carriers" are specifically identified in section 104(f)(2)(H) of the CPSIA as durable infant or toddler products. The Commission has identified at least four types of products that fall within the product category of "infant carriers," including: Frame backpack carriers, handheld infant carriers, slings, and soft infant and toddler carriers. This proposed rule addresses hazards associated only with soft infant and toddler carriers. Recently, the Commission issued a proposed rule on handheld infant carriers (77 FR 73354 (Dec. 10, 2012)). Hazards associated with frame backpack carriers and slings will be addressed separately in future rulemaking proceedings.

Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The proposed rule is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2236-13, "Standard Consumer Safety Specification for Soft Infant and Toddler Carriers" (ASTM F2236-13), without alteration. The ASTM standard is copyrighted, but it can be viewed as a read-only document during the comment period on this proposal only, at: <http://www.astm.org/cpsc.htm>, by permission of ASTM.

**II. Product Description**

*A. Definition of a Soft Infant and Toddler Carrier*

ASTM F2236-13 defines "soft infant and toddler carrier" as "a product, normally of sewn fabric construction, which is designed to contain a full term infant to a toddler, generally in an upright position, in close proximity to the caregiver." Additionally, soft infant

and toddler carriers are generally designed to carry a child "between 7 and 45 pounds." ASTM F2236-13 explains that soft infant and toddler carriers are "normally 'worn' by the caregiver with a child positioned in the carrier and the weight of the child and carrier suspended from one or both shoulders of the caregiver. These products may be worn on the front, side, or back of the caregiver's body, with the infant either facing towards or away from the caregiver." Typically children are carried in soft infant and toddler carriers on the front of a caregiver, but some products on the market can be configured to carry a child upright on a caregiver's front, back, or hip.

Two broad classes of soft infant and toddler carriers are available in the United States: Structured and nonstructured. Structured soft infant and toddler carriers contain straps and waist belts that connect, to the seat area of the carrier and each other, with buckles, straps, and other mechanical fasteners. The straps, belts, and seating area of these products are often stiffened with padding and typically have a heavy textile covering. Nonstructured products, such as the mei-tai design, consist of a flat, textile center that acts as the seat area with waist straps and very long (5 to 6 feet) upper straps. The upper straps wrap over the caregiver's shoulders, cross in the back, and are brought around the waist to the front of the caregiver. The upper straps are then secured over the child's legs to form the leg openings and secure the child in an upright position. ASTM F2236-13 does not distinguish between products based on whether they are structured or nonstructured; requirements apply equally to all types of soft infant and toddler carriers.

The definition of a "soft infant and toddler carrier" is intended to distinguish it from other types of infant carriers that are also worn by a caregiver but that are not covered under ASTM F-2236-13, specifically slings (including wraps), and framed backpack carriers. Soft infant and toddler carriers are designed to carry a child in an upright position. Slings are designed to carry a child in a reclined position; although some slings may also be used to carry a child upright. Thus, the primary distinction between a sling and a soft infant and toddler carrier is the sling's design that allows for carrying a child in a reclined position. Different hazard patterns arise from carrying a child in a reclined position. Accordingly, slings are not included in the standard for soft infant and toddler carriers. Like soft infant and toddler carriers, framed backpack carriers are intended to carry

a child in an upright position, but are distinguishable because typically, they are constructed of sewn fabric over a rigid metal structure and are solely intended for carrying a child on the caregiver's back.

#### B. Market Description

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that at least 39 firms supply soft infant and toddler carriers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm has an unknown supply source. Insufficient information is available on the remaining three firms to categorize them.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers. Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand, meaning that about 70 percent of the products were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ( $.51 \times .70 \times 4.1$  million births per year). Typically, soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We estimate use into a child's second year under the assumption that approximately 25–50 percent of caregivers continue to use these products. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by new mothers. Thus, we estimate that approximately 2.6–3.2 million households have soft infant and toddler carriers available for use annually.

### III. Incident Data

CPSC's Directorate for Epidemiology, Division of Hazard Analysis is aware of 93 incidents related to soft infant and toddler carriers—reported over a period of nearly 13 years—beginning in January 1999 through early September 2012.

Two incidents involved a fatality, and 91 incidents were nonfatal.

#### A. Fatalities

Two suffocation fatalities were reported to CPSC from January 1999 to September 2012. The first fatality involved a 5-week-old male who fell asleep in the soft infant and toddler carrier after a feeding. About 20 minutes after the feeding, he appeared unresponsive. The official cause of death was listed as positional asphyxia. The second fatal incident occurred when a 2-month-old female fell asleep in a soft infant and toddler carrier worn by her parent. The parent lay down on a couch to sleep for the night while still wearing the carrier with the infant inside. The parent awoke the next morning to find the child unresponsive with her face pressed into the parent's chest. Staff could not directly attribute the two reported fatalities to product design or mechanical failure of the soft infant and toddler carrier.

#### B. Nonfatalities

Approximately 33 percent (30) of the 91 nonfatal incidents involved reports of an injury to an infant during use of a soft infant and toddler carrier. A majority of the injuries resulted from falls from the carrier. All of the injuries in which the age of the victim was available were reportedly sustained by infants who were 1 month to 13 months old. However, most of the incidents involved infants 6 months and younger. Although the remaining 61 nonfatal incidents reported that no injury had occurred, many of the descriptions indicated the potential for a serious injury or death.

Eight of the nonfatal incident reports involved skull fractures as a result of the child falling out of the product. Five skull fracture injuries reportedly required hospitalization; the three remaining skull fracture injury reports did not mention any hospitalizations. Some of the remaining injuries reported included: Collarbone and limb fractures, contusions, abrasions, blisters, and scratches.

#### C. Hazard Pattern Identification

The primary hazard associated with use of a soft infant and toddler carrier is falling, either caregivers falling while wearing the carrier and injuring the child in the carrier, or children falling or facing the risk of falling from the carrier due to fastener problems, large leg openings, stitching or seam problems, or straps that slip. A majority of the reported incidents summarized in Table 1 below, and all seven of the recalls described in section III.E,

involved an actual fall or potential risk of a child falling from a carrier.

Staff classified the 93 reported incidents by the issues—product feature, design element, or failure—primarily responsible for the incident and summarized this data in Table 1, below. An explanation of the categories represented in Table 1 follows.

*Fastener problems:* Twenty-five of the 93 incidents (27 percent) were related to fastener problems, such as snaps breaking/unexpectedly releasing, or buckles breaking/detaching/pinching/unexpectedly releasing. Six injuries, but no fatalities, were included among these reports.

*Structure, fit, and position issues:* Fourteen of the 93 incidents (15 percent) were related to aspects of the leg- and torso-opening design, how the carrier held the infant, and where the carrier was positioned on the caregiver. Examples of scenarios reported include: An infant slipping down far into the carrier and suffering an injury when the caregiver went into a bent position; an infant falling out of the carrier when the caregiver bent forward; and leg circulation-related injuries. There were 10 injuries reported in this category. No reported fatalities were associated with this issue.

*Problems with large leg openings:* Twelve of the 93 incidents (13 percent) were related to leg openings that were too large and that allowed the infant to slip through completely and fall out of the carrier. While there were no fatalities among these reports, there were seven injuries; three involved infants who were hospitalized for skull fractures.

*Issues with stitching/seams:* Ten reports (11 percent) were received about stitching on the carrier coming undone or seams ripping, resulting in other components, like straps, detaching and creating a fall hazard. One injury was included among these reports.

*Design and finish-related issues:* Eight reports (nine percent) of inadequate back support, rough fabric, poor air flow in the carrier insert, and other design issues were received. No fatalities were noted, but two injuries were associated with these issues.

*Strap issues:* Eight incidents (nine percent) reported issues with straps, mostly about the adjuster breaking or slipping. No injuries or fatalities were reported in this category.

*Other issues:* Eleven reports (12 percent) were related to issues other than those described above. Two fatalities and four injuries, including two hospitalizations, were reported in this category. The two fatalities—one case of a parent falling asleep while

wearing the carrier with the infant inside, and the other case of an infant suffering respiratory distress while being carried around facing in—are included in this category. In each case,

CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. The remaining reports were of

unspecified falls, an nonspecific abrasion injury, and an incidental injury to the infant, due to a caregiver's fall.

TABLE 1—DISTRIBUTION OF REPORTED INCIDENTS BY HAZARD PATTERNS ASSOCIATED WITH SOFT INFANT AND TODDLER CARRIERS REPORTING PERIOD: JANUARY 1, 1999–SEPTEMBER 10, 2012

Issues	Total reports		Deaths		Injuries	
	Count	Percentage	Count	Percentage	Count	Percentage
Mechanical Issues .....	77	83	0	0	26	87
Fasteners .....	25	27	0	0	6	20
Structure, fit, and position .....	14	15	0	0	10	33
Large leg openings .....	12	13	0	0	17	23
Stitching/seams .....	10	11	0	0	1	3
Design and finish .....	8	9	0	0	2	7
Straps .....	8	9	0	0	0	0
Other .....	11	12	2	100	24	13
Consumer Comments .....	5	5	0	0	0	0
Total .....	93	100	2	100	30	100

Source: U.S. Consumer Product Safety Commission's epidemiological databases IPII, INDP, and DTHS.

Note: The percentages have been rounded to the 2nearest integer. Subtotals do not necessarily add to heading totals.

<sup>1</sup> (3 hosp.).

<sup>2</sup> (2 hosp.).

D. NEISS Data

In addition to the 93 incident reports received by the Commission, we estimated the number of injuries treated in U.S. hospital emergency departments using the CPSC's National Electronic Injury Surveillance System (NEISS). We estimate that over a 13-year-period, a total of 1,400 injuries related to soft infant and toddler carriers were treated in U.S. hospital emergency departments from 1999 through 2011. Because CPSC's NEISS data for 2012 will be finalized in spring 2013, partial estimates for 2012 are not available. The injury estimates for individual years are based on very small samples and are not reportable. According 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.

Moreover, due to the unreliability of the yearly estimates, a trend analysis is not feasible.

No fatalities were reported through NEISS. Although data extraction criteria included ages up to 4 years, all of the injured children were reported to be less than 2 years of age. A breakdown of the characteristics among the emergency department-treated injuries associated with soft infant and toddler carriers is presented in the bullets below.

- Hazard—Getting struck while in the carrier when caregiver fell (65%); falling out of the carrier (21%).
- Injured body part—Head (63%); face (11%).
- Injury type—Internal organ injury (48%); contusions/abrasions (19%); and fractures (12%).
- Disposition—Treated and released (79%); hospitalized (10%); and treated and transferred (9%).

E. Product Recalls

Seven product safety recalls, recalling 652,250 units, were announced between January 1, 1999 and June 17, 2010 that involved a fall hazard related to use of a soft infant and toddler carrier. These recalls related to 130 incident reports received by the CPSC. A breakdown of the specific product defect necessitating the recall, product units involved, and the number of incident reports received is presented in the chart below. At the time the products were recalled, nine infants had been injured significantly in incidents that ranged from bruises to skull fractures. Additional information on these recalls can be found on the Commission's Web sites at: [www.cpsc.gov](http://www.cpsc.gov) or [www.saferproducts.gov](http://www.saferproducts.gov).

SOFT INFANT AND TODDLER CARRIER RECALL SUMMARY

[January 1, 1999 through June 17, 2010]

Manufacturer	Model	Year recalled	Units recalled	Reason	Incident reports	Injury reports
Evenflo Company & Hufco-Delaware, Inc..	Model 070 & 080 Snuggli® Front and Back Pack™.	1999	327,000 ....	Infant shifts to side & slips through leg opening, falls out.	13	One—fractured skull; two—bruises.
Baby Swede, LLC .....	Baby Bjorn .....	1999	240,000 (Recall to Re-pair).	Infants slip through leg openings—fall. Infants < 2 months—highest risk.	9	Six fractured skulls.
Baby Swede, LLC .....	Baby Bjorn Carrier Active.	2004	49,000 .....	Back support buckles detach from shoulder straps—pose fall hazard.	93	No injuries reported.

SOFT INFANT AND TODDLER CARRIER RECALL SUMMARY—Continued  
[January 1, 1999 through June 17, 2010]

Manufacturer	Model	Year recalled	Units recalled	Reason	Incident reports	Injury reports
Playtex Products, Inc ....	Playtex Hip Hammock	2005	32,000 .....	Shoulder strap detaches from Hammock, posing fall hazard.	2	No injuries reported.
Beco Baby Carrier, Inc	Beco Baby Carrier Butterfly.	2008	2,000 .....	Shoulder strap buckles unexpectedly release tension—straps slip through—pose fall hazard.	8	No injuries reported.
Optave, Inc .....	Action Baby Carrier .....	2008	250 .....	Chest strap can detach from shoulder straps, posing fall hazard to infant.	2	No injuries reported.
Regal Lager, Inc .....	CYBEX 2. GO Infant Carriers.	2010	2,700 U.S. 400 Canada	Shoulder strap slider buckle can break, posing fall hazard to infant.	3	No injuries reported.

#### IV. Soft Infant and Toddler Carrier International Standard and ASTM Voluntary Standard

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of “consumer groups, juvenile product manufacturers, and independent child product engineers and experts” to “examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products.” As a result of fall-related incidents and recalls of soft infant and toddler carriers, CPSC staff previously requested ASTM to develop voluntary requirements to address the hazards related to large leg openings. Through the ASTM process, we consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. The voluntary standard for soft infant carriers was first approved and published in April 2003, as ASTM F2236–03, *Standard Consumer Safety Performance Specification for Soft Infant Carriers*. It has been revised six times since then. The current version, ASTM F2236–13, renamed *Standard Consumer Safety Performance Specification for Soft Infant and Toddler Carriers*, was approved on March 1, 2013 and published in March 2013.

In addition to reviewing the ASTM standard, we reviewed the only international standard for soft infant carriers of which we are aware, EN13209–2:2005 *Child Use and Care Articles—Baby Carriers—Safety Requirements and Test Methods—Part 2: Soft Carrier*.

#### A. International Standard

CPSC evaluated requirements in ASTM F2236–13 and EN13209–2:2005 and determined that the requirements in ASTM F2236–13 are more stringent than EN13209–2:2005, and that they address the incidents seen in the data and reduce the risk of injury from these products. The few EN13209–2:2005 requirements without an ASTM F2236–13 counterpart address hazard patterns not found in the incident reports considered for this proposed rule.

#### B. Voluntary Standard—ASTM F2236

##### 1. History of ASTM F2236

Initially, ASTM F2236–03 addressed falls related to large leg openings. The standard’s bounded leg opening performance requirement limited the size of the leg opening to prevent infants from falling through large adjustable leg openings. The standard also established requirements to address sharp points and edges, small parts, lead in paints, wood parts, locking and latching of fasteners, dynamic load testing, static load testing, and product labeling. The scope of the standard was based on the manufacturers’ recommended use of the product with infants weighing 7 to 25 pounds.

The next update of the voluntary standard was published in March 2008. ASTM F2236–03 addressed fall issues with bounded leg openings that were too large but did not consider the ability of an *unbounded* leg opening to retain the occupant. An unbounded leg opening is created by placing the soft carrier on a caregiver’s torso, with a leg opening circumference comprised of carrier materials and the caregiver’s torso. Accordingly, to address

additional fall hazards, an unbounded leg opening performance requirement was added to ASTM F2236–08. ASTM F2236–08a was published in November 2008, to add general requirements included in other ASTM standards for durable children’s products that address hazards associated with toy accessories and flammability.

ASTM F2236–09 was published in April 2009. The statement that the child occupant must face the caregiver until the child can hold its head upright was moved in this version of the standard from the warning label to be an informational statement. ASTM F2236–10, published in December 2010, clarified further that the informational statement for a child to face the caregiver until the child can hold its head upright was unnecessary for soft infant carriers that have only one use position with the child facing the caregiver.

ASTM F2236–12 was published in December 2012. Several sections of the voluntary standard were revised based on input from CPSC staff. The scope was expanded to increase the upper weight limit of products within the scope of the standard from 25 to 45 pounds and to include specifically in the title of the standard the word “toddler.” ASTM F2236–12 also included a new definition in the terminology section of the standard for “carrying position,” to clarify procedures for dynamic and static load testing. Finally, the test methods for dynamic Noand static load testing were modified to increase the weight load required for testing to ensure adequate testing of products that are designed to carry heavier children.

## 2. Description of the Current Voluntary Standard—ASTM F2236–13

ASTM F2236–13 was published in March 2013. Together with the changes described in ASTM F2236–12, ASTM F2236–13 reflects the most significant revisions to the standard, to date. Revisions include modified and new requirements developed by CPSC staff, working with stakeholders on the ASTM subcommittee task group, to address the hazards associated with soft infant and toddler carriers. ASTM F2236–13 includes the following key provisions: Scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

**Scope.** The scope of the standard was updated in December 2012, to broaden the upper weight limit from 25 to 45 pounds for products falling within the standard. Expanding the scope of the standard ensures that all soft infant and toddler carrier products currently on the market are covered by the standard. The name of the standard was altered at the same time to include the word “toddler,” to clarify that toddlers can also be carried in these products. The scope of the standard also distinguishes soft infant and toddler carriers from other wearable infant carrier products, by describing that soft infant and toddler carriers are “normally of sewn fabric construction,” hold the child “generally in an upright position,” and “may be worn on the front, side, or back of the caregiver’s body.” Finally, the scope of the standard states that it does not apply to infant slings.

**Terminology.** Section 3.1 of the standard includes 14 definitions that help to explain general and performance requirements. Section 3.1.7 of the standard explains that a “leg opening” is the “opening in the soft carrier through which the occupant’s legs extend when the product is used in the manufacturer’s recommended use position.” Sections 3.1.4 and 3.1.13 of ASTM F2236–13, respectively, explain that a “dynamic load” is the “application of impulsive force through free fall of a weight,” and that a “static load” is a “vertically downward force applied by a calibrated force gage or by dead weights.” A new definition for “carrying position” was added in ASTM F2236–12, to clarify methods for dynamic and static load testing in section 7 of the standard. Also, a new definition for “fastener” was included in ASTM F2236–13, to aid in a new test for fastener strength and strap retention.

**General Requirements.** ASTM F2236–13 includes general requirements that

the products must meet, as well as specified test methods to ensure compliance with the general requirements, which include:

- Restrictions on sharp points or edges, as defined by 16 CFR §§ 1500.48 and .49;
- Restrictions on small parts, as defined by 16 CFR part 1501;
- Restrictions on lead in paint, as set forth in 16 CFR part 1303;
- Requirements for locking and latching devices;
- Requirements for permanent warning labels;
- Restrictions on flammability, as set forth in 16 CFR part 1610;
- Requirements for toy accessories, as set forth in ASTM F 963.

The flammability requirement in section 5.7 of the standard was changed in ASTM F2236–13 from a flammable solids requirement (16 CFR 1500.3(c)(6)(vi)) to meet the more stringent flammability requirement for wearing apparel (16 CFR part 1610). The flammability requirement was altered to be consistent with other wearable infant carriers made of sewn fabric, such as slings, to prevent a foreseeable fire hazard in all wearable infant carriers.

**Performance Requirements and Test Methods.** ASTM F2236–13 provides performance requirements and test methods that are designed to protect against falls from the carrier due to large leg openings, breaking fasteners or seams, and straps that slip, including:

**Leg Openings—**Tested leg openings must not permit passage of a test sphere weighing 5 pounds that is 14.75 inches in circumference.

**Dynamic and Static Load—**Beginning with the 2012 version of ASTM F2236, the dynamic load test was strengthened from requiring a 25-lb. shot bag to be dropped, free fall, from 1 inch above the seat area onto the carrier seat 1,000 times, to requiring testing with a 25-lb. shot bag, or a shot bag equal to the manufacturer’s maximum occupant weight limit, whichever is heavier. Also, the static load test was altered from requiring a 75-lb. weight for testing, to requiring a 75-lb. weight, or a weight equal to three times the manufacturer’s recommended maximum occupant weight, whichever is greater, to be placed in the seat area of the carrier for 1 minute. This revision means that products with a maximum recommended weight of 45 pounds must be tested to a 135-pound weight instead of 75 pounds, an 80 percent increase in the severity of the requirement.

Testing with the new required loads must not result in a “hazardous condition,” as defined in the general

requirements, or result in a structural failure, such as fasteners breaking or disengaging, or seams separating when tested in accordance with the dynamic and static load testing methods. Additionally, dynamic and static load testing must not result in adjustable sections of support/shoulder straps slipping more than 1 inch per strap from their original adjusted position after testing.

**Fastener Strength and Strap Retention—**ASTM F2236–13 added a new component-level performance requirement to evaluate the strength of fasteners and strap retention to help prevent falls. Products recalled due to an occupant fall hazard were caused by broken fasteners that passed the static and dynamic performance requirements in ASTM F2236–10. Accordingly, the new performance requirement, section 6.4 of ASTM F2236–13, states that load-bearing fasteners at the shoulder and waist of soft infant and toddler carriers, such as buckles, loops, and snaps, may not break or disengage, nor may their straps slip more than 1 inch when subjected to an 80-pound pull force. Adjustable leg opening fasteners must also be tested, but are subjected to lower loads, a 45-pound pull force, because these fasteners do not carry the same load as fasteners at the shoulders and waist. When tested, fasteners must not break or disengage, and adjustable elements must not slip more than 1 inch.

**Unbounded Leg Opening—**ASTM F2236–13 clarifies the unbounded leg opening test procedure to improve test repeatability. An unbounded leg opening must not allow complete passage of a truncated test cone that is 4.7 inches long, with a major diameter of 4.7 inches and a minor diameter of 3 inches. The test cone is pulled through the leg opening with a 5-pound force for 1 minute.

**Marking, Labeling, and Instructional Literature.** ASTM F2236–13 requires that each product and its retail package be marked or labeled with certain information and warnings. The warning label requirement was updated to address fall and suffocation hazards. The warning label must provide a fall hazard statement addressing that infants can fall through wide leg openings or out of the carrier. The following fall-related warnings must be addressed on the warning label: adjust leg openings to fit baby’s legs snugly; before each use, make sure all [fasteners/knots] are secure; take special care when leaning or walking; never bend at waist, bend at knees; only use this carrier for children between \_\_ lbs. and \_\_ lbs. Additionally, a suffocation hazard statement must

address that infants under 4 months old can suffocate in the carrier if the child's face is pressed tightly against the caregiver's body. The warning label must also address the following suffocation-related warnings: do not strap infant too tightly against your body; allow room for head movement; keep infant's face free from obstructions at all times. Products must also contain an informational statement that a child must face toward the caregiver until he

or she can hold his or her head upright. Instructional literature must be provided with all products that includes: assembly, use, maintenance and cleaning, and required warnings.

Additionally, ASTM F2236-13 now includes an example warning label that identifies more clearly the hazards, the consequences of ignoring the warning, and what to do to avoid the hazards. The format of the label was designed to convey more effectively these warnings

to the caregiver (Fig. 1). The rectangular shape of this label may be altered to fit on shoulder straps, if the manufacturer chooses not to place label in the occupant space; however, the label must be placed in a prominent and conspicuous location where the caregiver will see it when placing the soft infant and toddler carrier on their body.

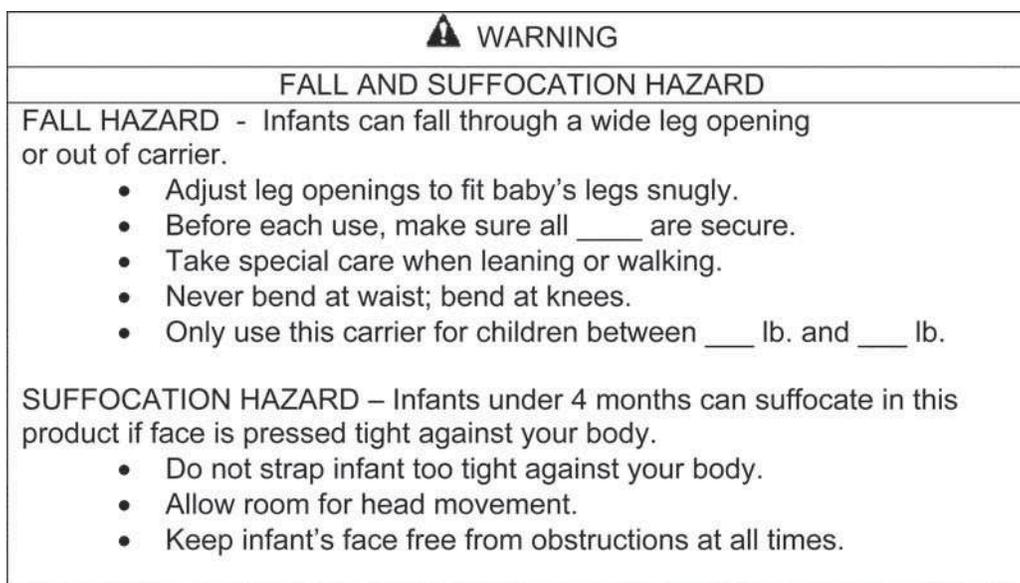


Figure 1. ASTM F2236-13 Example Warning label.

## V. Assessment of Voluntary Standard ASTM F2236-13

In this section of the preamble, we evaluate ASTM F2236-13 to determine whether adopting this voluntary standard as a mandatory standard will address the incidents described in section III of this preamble, or whether more stringent standards are required to reduce further the risk of injury associated with soft infant and toddler carriers.

### A. Large Leg Openings

Twenty-three percent of the injuries (7 of 30), including three hospitalizations, were caused when a child fell out of a large leg opening. The last incident occurred in 2005, involving a product purchased initially in 2000. The prevalence of this hazard led to product recalls in 1999 (see section III.E above) and led to the creation of ASTM F2236, whose first performance requirement (6.1 and corresponding test 7.1) was developed to limit the size of a soft infant and toddler carrier leg opening. New reports

involving the large leg opening hazard ceased within 2 years of the first version of ASTM F2236's publication in 2003. This, combined with CPSC detailed incident reviews, lead us to conclude that the current ASTM standard adequately addresses the large leg opening hazard scenario.

### B. Structure, Fit, and Position

Thirty-three percent of injuries reported to the CPSC (10 of 30) were related to the structure of the occupant seat area; fit of the occupant in the carrier; and the position of the soft infant and toddler carrier or the position of the wearer, or the position of the child in the seat area. These incidents occurred, for example, when an infant tucked down into the carrier and the caregiver bent at the waist breaking the child's leg; an infant fell out of the top of the carrier when the caregiver bent forward abrasions and/or blisters on infants from prolonged rubbing against the carrier while in use; and when infants suffered leg circulation-related injuries. New language in ASTM F2236-

13 requires that warning labels address ensuring that fasteners and knots are secure before each use, taking special care when leaning or walking, and bending at the knees, not at the waist, while wearing the carrier. The standard also includes requirements on the format of the label to enhance the label's effectiveness (Fig. 1).

Updated warning language on the product and in the instructional literature may address hazards arising from structure, fit, and position problems if consumers read, understand, and comply with the warnings. The diverse size of potential occupants, the broadrange of caregiver sizes and shapes, and numerous possible motions and activities that could lead to injury cannot be reliably replicated in a laboratory setting, making development of a repeatable test for structure, fit, and position types of injuries prohibitively difficult. A warning label would likely not address the hazard with circulation-related injuries because that hazard may be due to a design issue. The Commission will

continue to study incoming reports of leg circulation-related injuries and determine whether any additional action is necessary.

### C. Fasteners

Twenty percent of the injuries (6 of 30) were caused by fastener failures when a fastener suddenly broke or separated and the child fell to the ground. Although no hospitalizations resulted from breaking fasteners, three children suffered fractured collarbones, along with contusions and abrasions to heads and faces. The caregiver in a majority of the incidents was able to catch the child and prevent a fall. Fastener failures led to four of the five voluntary product recalls conducted since 2005.

ASTM F2236–13 addresses the hazards posed by fastener failures with a new performance requirement for fastener strength and strap retention, published in section 6.4 and a new test in section 7.7. New requirements state that all load-bearing fasteners, such as buckles, loops, and snaps may not break or disengage, nor may their straps slip more than 1 inch, when an 80-pound pull force is applied across the fasteners. An exception is made for adjustable leg opening fasteners, which must be subjected to a 45-pound pull force. Adjustable leg opening fasteners see substantially less load than other load-bearing fasteners during foreseeable use and abuse, such as fasteners securing shoulder and waist straps. The fastener strength and strap retention requirements do not apply to non-load-bearing fasteners that attach accessories, such as bibs, rain hoods, and toys to the soft infant and toddler carrier. The Commission believes that the inclusion of this new requirement in ASTM F2236–13 will adequately address the fall hazard related to fastener failures.

### D. Design and Finish

Seven percent of the soft infant and toddler injuries (2 of 30) are attributable to design and finish issues. Complaints include inadequate back support, rough fabric, poor air flow in the carrier insert, and one report of high lead levels in a zipper pull. The injuries consist of a pinched finger and a cut on the nose. ASTM F2236–13 includes language prohibiting sharp points and edges, but the standard does not specifically mention pinching. A pinching-shearing-scissoring hazard exists typically in products with rigid parts that move past one another; such a hazard does not generally exist with soft products. No changes to the voluntary standard for design and finish issues are

recommended at this time. Section 101 of the CPSIA requires that children's products, such as soft infant and toddler carriers, not contain lead content in excess of 100 parts per million. Accordingly, such requirement does not need to be repeated in ASTM F2236–13.

### E. Stitching/Seams

Although only three percent of the injuries (1 of 30) involve stitching and seams, 11 percent of the total soft infant carrier reports (10 of 93) describe incidents in which stitching became undone or seams ripped, resulting in other components, like straps, becoming detached. One injury was reported when a seam failed, causing a 4-month-old child to fall and receive minor contusions. The new fastener strength test, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236–13, respectively, all apply loads to soft infant and toddler carrier seams and sewn attachment points. The Commission believes that incidents related to ripping seams are adequately addressed by these new requirements in the voluntary standard, and therefore, we are not proposing any additional changes at this time.

### F. Straps

Although there were no injuries related to soft infant carrier straps, nine percent of the reported incidents (8 of 93) involve issues with straps. The problems reported include broken strap length adjustment mechanisms and straps that permit unexpected slippage. The new fastener strength and strap retention requirements, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236–13, respectively, all apply loads to soft infant and toddler carrier straps, and require that they not break or allow more than 1 inch of slippage. Accordingly, the Commission believes that incidents related to breaking and slipping straps are adequately addressed by these new requirements in the voluntary standard and is not proposing any additional changes at this time.

### G. Other

Thirteen percent of the injury reports (4 of 30), including two deaths, contain insufficient information for the CPSC to determine the exact nature of the product's contribution to the incident. This category includes two fatalities and four injuries, including two hospitalizations. The two fatalities discussed above in section III.A, both involving suffocation, are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to

determine that a specific factor contributed predominantly to the deaths. ASTM F2236–13 does, however, address in the warning label requirements a suffocation hazard arising from use of soft infant and toddler carriers. The new warning label requirements state that products must address the fact that infants under 4 months old can suffocate if their face is too tight against a caregiver's body, and the label also advises caregivers not to strap the infant too tightly against the body to allow room for head movement and to keep an infant's face free from obstruction at all times.

## VI. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for manufacturers of soft infant and toddler products to come into compliance, the Commission proposes that the standard become effective 6 months after publication of a final rule in the **Federal Register**. The Commission invites comment on whether 6 months will be sufficient time for soft infant and toddler carrier manufacturers to come into compliance with the rule.

## VII. Regulatory Flexibility Act

### A. Introduction

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that CPSC staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to

the requirements and the types of professional skills necessary for the preparation of reports or records; and

- identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

#### *B. Market for Soft Infant and Toddler Carriers*

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that there are at least 39 suppliers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm has an unknown supply source. Insufficient information is available to categorize the remaining three firms.<sup>2</sup>

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers.<sup>3</sup> Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand.<sup>4</sup> Thus, about 70 percent of soft infant and toddler carriers were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ( $.51 \times .70 \times 4.1$  million births per year).<sup>5</sup>

Many soft infant and toddler carriers have expanded their maximum weight

<sup>2</sup> Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm Web sites.

<sup>3</sup> The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, because the most recent survey information is from 2005, it may not reflect the current market.

<sup>4</sup> The data on secondhand products for new mothers was not available. Instead, data for new mothers and experienced mothers were combined and broken down into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage of soft infant and toddler carriers that were handed down or purchased secondhand.

<sup>5</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2009," *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. Number of live births in 2009 is rounded from 4,130,665.

limits in recent years to accommodate older children. Staff believes, however, that most adult users would not be comfortable carrying older, heavier children in soft infant and toddler carriers. This belief is supported by a lack of incident data for children over 2 years old. It appears that soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We do not know the proportion who continues to use these products into the second year; accordingly, we estimate risk under the assumption that approximately 25–50 percent will do so. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by new mothers. Therefore, approximately 2.6–3.2 million households have soft infant and toddler carriers available for use annually. Based on Epidemiology staff's estimate of 1,400 injuries treated nationally in emergency departments from 1999 to 2011, it is estimated that an average of 108 emergency department-treated injuries involving children under age 2 related to soft infant and toddler carriers are treated annually. Therefore, about 0.34–0.40 emergency department-treated injuries may occur annually for every 10,000 soft infant and toddler carriers available for use in the households of new (and second year) mothers.

#### *C. Reason for Agency Action and Legal Basis for the Draft Proposed Rule*

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards that are substantially the same as, or more stringent than, the voluntary standard for a durable infant or toddler product. CPSC staff worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2236–13, which forms the basis of the proposed rule.

#### *D. Requirements of the Proposed Rule*

The requirements of the proposed rule are set forth above in section IV.B.2 of this preamble, which describes ASTM F2236–13.

#### *E. Other Federal Rules*

Section 14(a)(2) of the CPSA requires every manufacturer and private labeler of a children's product that is subject to a children's product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory, that the product complies with all applicable children's product

safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards, by rule, for among other things, ensuring that a children's product is tested periodically and where there has been a material change in the product, and for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule).

Soft infant and toddler carriers will be subject to a mandatory children's product safety rule, so they will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule when the final rule and the notice of requirements become effective.

#### *F. Impact on Small Businesses*

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of soft infant and toddler carriers is small if it has 500 or fewer employees; and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 26 of the 31 domestic firms supplying soft infant and toddler carriers to the U.S. market are small firms—12 manufacturers, six importers, and eight firms whose supply source is unknown. Additional unknown small soft infant and toddler carrier suppliers may operate in the U.S. market as well.

*Small Manufacturers.* The expected impact of the proposed rule on small manufacturers will differ, based on whether their soft infant and toddler carriers are already compliant with ASTM F2236–10. Although ASTM F2236–12 was published in December 2012, and ASTM F2236–13 was published in March 2013, new standards are not in effect until 6 months after publication. Accordingly, firms are likely to be still testing to ASTM F2236–10. In general, firms whose soft infant and toddler carriers meet the requirements of ASTM F2236–10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months because this is the amount of time JPA allows for products in its certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice.

The impact on seven of 12 domestic manufacturers who comply with ASTM F2236–10 is expected to be small. Firms already in compliance with ASTM F2236–10 may require slight, if any, modifications, in order to bring their product(s) into compliance with the current voluntary standard. Any strap/fastener modifications are expected to incur minimal costs, as are changes to the warning label.

Meeting ASTM F2236–13's requirements could necessitate some product redesign for five of the 12 domestic manufacturers who are not believed to be compliant with ASTM F2236–10. These redesigns would likely involve adding or changing straps, fasteners, or fabrics; and partial redesigns are generally less expensive than complete redesigns, based on past discussions with manufacturers. For the types of changes that might be required to be made to these products, staff does not believe that complete redesigns (*e.g.*, engineering time, prototype development, and tooling) would be required for any known products. Therefore, in most cases, the impact of the proposed rule is not expected to have a significant effect on products that are not believed to be compliant with ASTM F2236–10.

It is possible that some firms whose soft infant and toddler carriers are neither certified as compliant, nor claim compliance with ASTM F2236–10 (or a similar standard), in fact, are compliant with the standard. CPSC staff has identified many such cases with other infant and toddler products. To the extent that some of these firms may supply compliant soft infant and toddler carriers and have developed a pattern of compliance with the voluntary standard, the direct impact of the proposed rule will be less significant than described above.

Eight small firms have unknown supply sources, three of which appear to be compliant with ASTM F2236–10. If these firms are manufacturers, they will be affected as described above. If these firms are distributors or wholesalers, the impact will be similar to the impact on importers, as discussed below.

In addition to the direct impact of the proposed rule, indirect impacts exist. These impacts are considered indirect because they do not arise directly as a consequence of the proposed rule's requirements. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will

include any physical and mechanical test requirements specified in the final rule. Because lead and phthalates testing are already required for soft infant and toddler products, they are not included in this discussion.

Staff estimates that testing to the ASTM voluntary standard could cost about \$500–\$600 per model sample. On average, each small domestic manufacturer supplies two different models of soft infant and toddler carriers to the U.S. market annually. Therefore, if third party testing is conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$1,000–\$1,200 annually. Based on a review of firms' revenues, the impact of third party testing to ASTM F2236–13—if only one soft carrier sample per model is required—is unlikely to be significant. However, these costs could be more significant if multiple models are needed for testing.

*Small Importers.* Most importers would not experience significant impacts as a result of the proposed rule. Five of the six small importers are believed to be compliant with the voluntary standard. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and would likely comply with the final mandatory standard as well. The remaining importer might need to find an alternate source of soft infant and toddler carriers if its existing supplier does not come into compliance with the requirements of the proposed rule. Alternatively, the firm may discontinue importing soft infant and toddler carriers altogether and perhaps substitute another product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience the associated costs if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers who must perform the testing themselves if more than one sample per model is required. In addition, the impacts could be higher than those incurred by domestic manufacturers if importers have to test each batch imported in the case where the foreign manufacturer does not conduct testing.

#### G. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative would be to set an effective date later than the proposed 6 months, which is generally

considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant soft infant and toddler carriers and spread the associated costs over a longer period of time.

#### VIII. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has "little or no potential for affecting the human environment," it will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

#### IX. Paperwork Reduction Act

The proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- A title for the collection of information;
- A summary of the collection of information;
- A brief description of the need for the information and the proposed use of the information;
- A description of the likely respondents and proposed frequency of response to the collection of information;
- An estimate of the burden that shall result from the collection of information; and
- Notice that comments may be submitted to the OMB.

*Title:* Safety Standard for Soft Infant and Toddler Carriers

*Description:* The proposed rule would require each soft infant and toddler carrier to comply with ASTM F2236–13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*. Sections 8.1 and 9.1 of ASTM F2236–13 contain requirements for marking, labeling, and instructional literature that are disclosure requirements, thus falling within the definition of "collections of information" at 5 C.F.R. 1320.3(c).

*Description of Respondents:* Persons who manufacture or import soft infant and toddler carriers.

*Estimated Burden:* We estimate the burden of this collection of information 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
1226 .....	39	2	78	1	78

Our estimate is based on the following:

Section 8.1 of ASTM F2236–13 requires that all soft infant and toddler carrier products and their retail packaging be marked or labeled as follows: the manufacturer, distributor, or seller name, and either the place of business (city, state, mailing address including zip code), or telephone number, or both; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 39 firms that supply soft infant and toddler carriers in the U.S. market. All 39 firms are assumed to use labels on their products and on their packaging already, but they might need to make some modifications to 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 soft infant and toddler carrier; therefore, the estimated burden hours associated with labels is 1 hour × 39 firms × 2 models per firm = 78 hours annually.

We estimate the hourly compensation for the time required to create and update labels is \$27.92 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” September 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$2,177.76 (\$27.92 per hour × 78 hours = \$2,177.76). No operating, maintenance, or capital costs are associated with the collection.

Section 9.1 of ASTM F2236–13 requires that all soft infant and carrier products provide instructions that are easy to read and understand. Where applicable, instructions for assembly, use, maintenance and cleaning of the product, and warnings, must also be included. Soft infant and toddler carriers are products that do not generally require installation but require instruction for proper use, fit, and adjustment on a caregiver’s body. Under the OMB’s regulations (5 CFR 1320.3(b)(2)), the 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” are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are “usual and customary.” Therefore, because we are unaware of soft infant and toddler carriers that lack any instructions to the user about proper use, fit, and assembly, we estimate tentatively that there are no burden hours associated with section 9.1 of ASTM F 2236–13 because any burden associated with supplying instructions with soft infant and toddler carriers would be “usual and customary” and would not fit within the definition of “burden” under the OMB’s regulations.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to submit comments regarding information collection by May 6, 2013, to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- Whether the collection of information is necessary for the proper performance of the CPSC’s functions, including whether the information will have practical utility;
- the accuracy of the CPSC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

**X. Preemption**

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is

identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

**XI. Certification and Notice of Requirements (NOR)**

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children’s products subject to a children’s product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children’s product safety rule to which a children’s product is subject. The proposed rule for 16 CFR part 1226, “Safety Standard for Soft Infant and Toddler Carriers,” when issued as a final rule, will be a children’s product safety rule that requires the issuance of an NOR.

Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which codifies 16 CFR part 1112. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children’s product safety rule in accordance with Section 14(a)(2) of the CPSA. The final rule also codifies all of the NORs that the CPSC has published to date. All new NORs, such as the soft infant and toddler carrier standard,

require an amendment to part 1112. Accordingly, the proposed rule would amend part 1112 to include the soft infant and toddler standard along with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for soft infant and toddler carriers would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it can apply to the CPSC to have 16 CFR part 1226, *Safety Standard for Soft Infant and Toddler Carriers*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

CPSC staff previously conducted an analysis of the potential impacts on small entities of the proposed rule for part 1112, and published an Initial Regulatory Flexibility Analysis (IRFA) in 77 FR 31086, 31123–26 (May 24, 2012). The IRFA concluded that the requirements in part 1112 would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under Section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would likely not pursue accreditation for this purpose.

Amending part 1112 to include the NOR for the soft infant and toddler standard would also not have a significant adverse impact on small laboratories. Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the soft infant and toddler standard. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the soft infant and toddler standard to their scope of accreditation. As a consequence, the Commission could certify that the proposed NOR for the

soft infant and toddler standard will not have a significant impact on a substantial number of small entities.

The final NOR will base the CPSC laboratory accreditation requirements on the performance standard set forth in the final rule for the safety standard for soft infant and toddler carriers and the test methods incorporated within that standard. The Commission may recognize limited circumstances in which it will accept certification based on product testing conducted before the Commission's acceptance of accreditation of laboratories for testing soft infant and toddler carriers (also known as retrospective testing) in the final NOR. The Commission seeks comments on any issues regarding the testing requirements of the proposed rule for soft infant and toddler carriers and the accompanying proposed NOR.

## XII. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for soft infant and toddler carriers. We invite all interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

### List of Subjects

#### 16 CFR Part 1112

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

#### 16 CFR Part 1226

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations by amending part 1112 and adding a new part 1226, 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:** 15 U.S.C. 2063.; Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008)

■ 2. In § 1112.15 add paragraph (b)(36) to read as follows:

### § 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

\* \* \* \* \*

(b) \* \* \*

\* \* \* \* \*

(36) 16 CFR part 1226, Safety Standard for Soft Infant and Toddler Carriers.

■ 3. Add Part 1226 to read as follows:

### PART 1226—SAFETY STANDARD FOR SOFT INFANT AND TODDLER CARRIERS

Sec.

1226.1 Scope.

1226.2 Requirements for Soft Infant and Toddler Carriers.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

#### § 1226.1 Scope.

This part establishes a consumer product safety standard for soft infant and toddler carriers.

#### § 1226.2 Requirements for Soft Infant and Toddler Carriers.

(a) Each soft infant and toddler carrier must comply with all applicable provisions of ASTM F2236–13, Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, approved on March 1, 2013. 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/cpsc.htm>. 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: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) Reserved

Dated: March 29, 2013.

**Todd A. Stevenson,**

Secretary, Consumer Product Safety Commission.

[FR Doc. 2013–07687 Filed 4–4–13; 8:45 am]

BILLING CODE 6355–01–P

- (iv) Task 57-29-03-270-801-A-01, Gear Rib Forward Lug Attachment for the Main Gear Before Modification 32025J2211, of Subject 57-29-03, Inspection of the Gear Rib Forward and Aft Lug Attachment for the Main Gear, of Chapter 57, Wings, of the Airbus A318/A319/A320/A321 Nondestructive Testing Manual, Revision 89, dated August 1, 2011.
- (v) Task 57-29-04-270-801-A-01, Gear Rib Forward Lug Attachment for the Main Gear Before Modification 32025J2211, of Subject 57-29-04, Inspection of the Gear Rib Forward and Aft Lug Attachment for the Main Gear, of Chapter 57, Wings, of the Airbus A318/A319/A320/A321 Nondestructive Testing Manual, Revision 89, dated August 1, 2011.

(4) The following service information was approved for IBR on May 19, 2008 (73 FR 19975, April 14, 2008):

(i) Airbus Service Bulletin A320-57-1138, Revision 01, dated October 27, 2006.

(ii) Reserved.

(5) For Airbus service information identified in this AD, contact Airbus, Airworthiness Office—ELAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email: [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>.

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(7) You may view this service information that is incorporated by reference 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: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on December 26, 2013.

**John P. Piccola,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2014-04954 Filed 3-27-14; 8:45 am]

**BILLING CODE 4910-13-P**

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Parts 1112 and 1226

[Docket No. CPSC-2013-0014]

### Safety Standard for Soft Infant and Toddler Carriers

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer

Product Safety Commission (Commission, CPSC, or we) to promulgate consumer product safety standards for durable infant or toddler products. Durable infant and toddler standards must be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is issuing this final rule establishing a safety standard for soft infant and toddler carriers in response to the direction under section 104(b) of the CPSIA.

**DATES:** The rule will become effective September 29, 2014 and apply to product manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of September 29, 2014.

**FOR FURTHER INFORMATION CONTACT:** Julio A. Alvarado, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7418; email: [jalvarado@cpsc.gov](mailto:jalvarado@cpsc.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub L. 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission 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 and toddler products. Durable infant and toddler standards must be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” Section 104(f)(2)(H) of the CPSIA specifically identifies “infant carriers” as durable infant or toddler products.

The Commission has identified at least four types of products that fall within the product category of “infant carriers,” including: Frame backpack carriers, hand-held infant carriers, slings, and soft infant and toddler carriers.

On April 5, 2013, the Commission issued a notice of proposed rulemaking (NPR) for soft infant and toddler carriers. 78 FR 20511. The NPR proposed to adopt as a mandatory standard the current voluntary standard for soft infant and toddler carriers, ASTM F2236-13, “Standard Consumer Safety Specification for Soft Infant and Toddler Carriers” (ASTM F2236-13), without alteration.

The Commission is issuing a final mandatory safety standard for soft infant and toddler carriers. Pursuant to section 104(b)(1)(A) of the CPSIA, the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public to develop this standard, largely through the ASTM process. After publication of the NPR, ASTM approved two revised versions of F2236-13, F2236-13a, on November 1, 2013, and F2236-14, on January 1, 2014. The revisions included in ASTM F2236-14 clarify several issues raised in the comments received on the NPR. Furthermore, the Commission finds that the revisions included in ASTM F2236-14 adequately address the comments received on the NPR. Section V of the preamble below discusses clarifying changes to the standard. The final rule for soft infant and toddler carriers incorporates ASTM F2236-14, by reference, without alteration.

#### II. Product Description

##### A. Definition of a Soft Infant and Toddler Carrier

ASTM F2236-14 defines a “soft infant and toddler carrier” as “a product, normally of sewn fabric construction, which is designed to contain a full term infant to a toddler, generally in an upright position, in close proximity to the caregiver.” Additionally, soft infant and toddler carriers are generally designed to carry a child “between 7 and 45 pounds.” ASTM F2236-14 explains that soft infant and toddler carriers are “normally ‘worn’ by the caregiver with a child positioned in the carrier and the weight of the child and carrier suspended from one or both shoulders of the caregiver. These products may be worn on the front, side, or back of the caregiver’s body, with the infant either facing towards or away from the caregiver.” Typically, children

are carried in soft infant and toddler carriers on the front of a caregiver; but some products on the market can be configured to carry a child upright on a caregiver's front, back, or hip.

In the United States, soft infant and toddler carriers are available in two broad classes: Structured and nonstructured. Structured soft infant and toddler carriers contain straps and waist belts that connect to the seat area and other carrier components with buckles, straps, and mechanical fasteners. The straps, belts, and seating area of these products are often stiffened with padding and typically have a heavy textile covering. Nonstructured products consist of a flat, textile center with waist straps and very long upper straps (5 to 6 feet) that wrap around the caregiver and are secured by tying the ends of the straps, such as the mei-tai design. ASTM F2236–14 does not distinguish between products based on whether they are structured or nonstructured; therefore, requirements apply equally to all types of soft infant and toddler carriers.

ASTM F2236–14's definition of a "soft infant and toddler carrier" distinguishes soft infant and toddler carriers from other types of infant carriers that are also worn by a caregiver but that are not covered under ASTM F2236–14, specifically slings (including wraps), and framed backpack carriers. Soft infant and toddler carriers are designed to carry a child in an upright position. Slings are designed to carry a child in a reclined position. However, some slings may also be used to carry a child upright. Thus, the primary distinction between a sling and a soft infant and toddler carrier is that a sling allows for carrying a child in a reclined position. Different hazard patterns arise from carrying a child in a reclined position. Accordingly, slings are not covered by the standard for soft infant and toddler carriers. Like soft infant and toddler carriers, framed backpack carriers are intended to carry a child in an upright position. However, framed backpack carriers are distinguishable from soft infant and toddler carriers because typically, backpack carriers are constructed of sewn fabric over a rigid frame and are intended solely for carrying a child on the caregiver's back.

### III. Incident Data

The preamble to the NPR summarized incident data involving soft infant and toddler carriers reported to the Commission from January 1, 1999 to September 10, 2012. 78 FR 20513 (April 5, 2013). CPSC's Directorate for Epidemiology, Division of Hazard Analysis updated this information for

the final rule to include soft infant and toddler carrier-related incident data reported to the Commission from September 11, 2012 through July 15, 2013. During the September 11, 2012 to July 15, 2013 time frame, CPSC received 31 new incident reports related to soft infant and toddler carriers. Two of the incidents were fatal, and 29 were nonfatal. Twenty-four of the 29 nonfatal incidents involved injuries. The total count of reported incidents includes emergency department-treated injuries (*i.e.*, injuries reported through the National Electronic Injury Surveillance System (NEISS)).<sup>1</sup> CPSC staff cannot present national emergency department-treated injury estimates for the final rule due to insufficient numbers of NEISS incidents reported during the time period. The number of incidents occurring in 2012 and 2013 is subject to change because the CPSC continues to collect information about such incidents.

#### A. Fatalities

Both reported fatalities involved suffocation. One suffocation fatality occurred in 2010. The decedent was a 17-day-old infant who was being carried in a soft infant and toddler carrier—facing the mother—while the mother ran errands. The mother reportedly breast fed the victim while walking. The report is unclear about whether the victim was out of the carrier or in the carrier while being fed. The mother found the child nonresponsive in the carrier. The child was placed on life support, which was later removed due to the child's poor prognosis. The second suffocation fatality occurred in 2011. The decedent, a 4-month-old female, was placed prone to sleep on a bed while still in a soft infant carrier.<sup>2</sup>

#### B. Nonfatalities

Twenty-nine soft infant and toddler carrier-related nonfatal incidents were reported to the CPSC from September 11, 2012 to July 15, 2013. The incident reports demonstrate that an injury occurred in 24 of the 29 incidents. The children's age was unreported or

unknown in four of the 29 nonfatal incidents. For the remaining 25 incidents, the ages provided in the reports ranged from 1 month to 18 months, with 64 percent of the total reports involving children 6 months of age or younger.

Among the 24 nonfatal injuries reported, four incidents required hospitalization. Two of the four injuries requiring hospitalization, a skull fracture and a leg fracture, resulted from infants falling out of a soft infant and toddler carrier. The other two injuries that required hospitalization were head injuries to the infant resulting from the caregiver falling. Other injuries included contusions, abrasions, and lacerations, mostly of the head and face. Fourteen of the injuries resulted from falls, either from the caregiver falling while wearing the carrier or from the infant falling out of the carrier.

The remaining five incident reports stated problems with the product but indicated that either no injury had occurred or the report failed to provide information about any injury.

#### C. Hazard Pattern Identification

CPSC identified hazard patterns among the 31 new incident reports that were similar to the hazard patterns identified among the incidents considered for the NPR. The primary hazard associated with use of a soft infant and toddler carrier continues to be falling, either caregivers falling while wearing the carrier and injuring the child in the carrier, or children falling or facing the risk of falling from the carrier. Hazard patterns are grouped into the following categories in order of frequency of incident reports:

- Caregiver falls (11)<sup>3</sup>;
- structure, fit, and position issues (7);
- design and finish-related issues<sup>4</sup> (2), (which are also among the 7 in the previous category);
- strap issues (2);
- issues with stitching/seams (1); and
- other issues (10).

*Caregiver Falls:* Eleven of the 31 incidents (35 percent) reported injuries to the infant in the carrier, when the caregiver slipped or tripped and fell. All of these were emergency department-treated injury (NEISS data) reports.

*Structure, fit, and position issues:* Seven of the 31 incidents (23 percent) were related to aspects of the leg- and torso-opening design, how the carrier held the infant, and where the soft

<sup>1</sup> CPSC's NEISS database is a national probability sample of hospitals in the United States and its territories. Patient information is collected from each NEISS hospital for every emergency visit involving an injury associated with consumer products. From this sample, the total number of product-related injuries treated in hospital emergency rooms nationwide can be estimated.

<sup>2</sup> According to CPSC Human Factors staff, this scenario represents an unsafe sleep environment. The prone sleep position is a known risk factor for SIDS, and placing an infant to sleep face down on top of a bed may increase the risk of suffocation. Sleeping in the prone position on a bed with an infant still inside a carrier may further increase the suffocation risk.

<sup>3</sup> All of the fall incidents were emergency department-treated injury (NEISS data) reports.

<sup>4</sup> Finish-related issues concern items such as material smoothness and lead content.

infant and toddler carrier was positioned on the caregiver. Examples of scenarios reported include: an infant slipping far down into the carrier and suffering an injury when the caregiver bent over; an infant falling out of the carrier when the caregiver bent forward; and leg circulation-related injuries to the infant. Three injuries were reported in this category, including one hospitalization.

*Design-related issues:* Two of the reports included in the structure, fit, and position category above stated complaints about how the carrier fit on the caregiver and that the infant got too hot when the carrier was used with the carrier insert. A carrier insert is available with some soft infant and toddler carriers to help support a young infant's head and neck. No one reported injuries in this category.

*Strap issues:* Two of the 31 incidents (six percent) reported issues with straps, mostly regarding the adjuster breaking or slipping. Both incidents resulted in injuries, including one hospitalization for a skull fracture stemming from a fall when the strap came undone.

*Issues with stitching/seams:* One incident report (three percent) stated that stitching on a carrier component came undone. However, the infant sustained no injury.

*Other issues:* Ten incident reports (32 percent) involved non-product-related issues or provided insufficient information for CPSC staff to determine definitively how the product contributed to the incident. The two fatalities are included in this category—one case of an infant suffering respiratory distress while being carried facing inward, and the other case involved an infant put to sleep in a prone position on a bed while still in a soft infant and toddler carrier. In each case, CPSC staff concluded that insufficient information was reported to determine a predominant factor about the product that contributed to the death. Five reports were of incidental injuries sustained by infants while being carried around in a soft infant and toddler carrier. Examples of such incidents include an infant who hit a pole after a bus in which the child was riding suddenly accelerated and an infant who got hurt while being put into a carrier. The remaining three reports involved infants who fell out of the carrier, with no additional information specified.

#### D. NEISS Data

The soft infant and toddler carrier NPR presented a separate national injury estimate for the 13-year period from January 1999 through December

2011. However, insufficient emergency department-treated injuries associated with soft infant and toddler carriers in 2012 prevent derivation of reportable national estimates.<sup>5</sup> In addition, until NEISS data for 2013 are finalized in spring 2014, partial estimates for 2013 are not available. Hence, injury estimates are not presented separately in this final rule. However, the emergency department-treated injuries are included in the total count of reported incidents presented in section III.C above.

#### IV. Response to Comments

CPSC received five comments regarding the NPR, including comments from industry, consumer groups, trade associations, and consumers. The comments address eight separate issues related to fastener strength testing requirements, warning label revisions, and the effective date of the final rule. Two commenters generally supported the rule. Comments submitted in response to the NPR are available at: [www.regulations.gov](http://www.regulations.gov), by searching under the docket number of the rulemaking, CPSC–2013–0014. The Commission finds that revisions made to the ASTM voluntary standard, which are incorporated into ASTM F2236–14, approved on January 1, 2014, and published in January 2014, adequately address comments received on the NPR. Accordingly, the Commission will incorporate by reference the most recent version of the voluntary standard, ASTM F2236–14, as the mandatory standard for soft infant and toddler carriers.

We summarize the comments received on the NPR and CPSC's responses below. To make identification of the comments and our responses easier, we placed the word "Comment," in parentheses, before the comment's description, and the word "Response," in parentheses, before our response. Additionally, we have numbered each comment to help distinguish among comments. The number assigned to each comment is for organizational purposes only and does not signify the comment's value or importance, or the order in which we received the comment.

##### A. Fastener Strength

*(Comment 1)* Two commenters stated that the specified fastener strength test load of 80 pounds in section 7.7.2 of ASTM F2236–13 is too high for soft infant and toddler carriers whose manufacturer-recommended maximum occupant weight for the product is less

than 45 pounds. The commenters suggested using a sliding scale for the test load that would adjust the test load by 1 pound for every pound the carrier is rated above or below 45 pounds. For example, for soft infant and toddler carriers designed for a maximum occupant weight of 25 pounds, commenters recommended a fastener test load of 60 pounds (80 pounds minus 20 pounds) instead of an 80-pound force. One commenter stated that for carriers designed for very small occupants, it would be difficult for every load-bearing fastener to be designed to meet the 80-pound test load because such fasteners tend to be large and difficult to handle gently when close to a small infant.

*(Response 1)* The Commission disagrees with the commenters and declines to modify the final rule based on this comment. ASTM F2236–13 added requirements for fastener strength testing. Each unique load-bearing fastener, except load-bearing fasteners used for a leg opening adjustment, must not break or disengage when subjected to a tensile load of 80-pound force for 5 seconds. The force is applied to the straps or soft goods on either side of the fastener. Leg opening adjustment fasteners are tested to a 45-pound force.

As noted in the NPR, CPSC staff tested fasteners on 14 different soft infant and toddler carriers, including recalled carriers. The manufacturer's recommended maximum occupant weight of the carriers tested ranged from 20 pounds to 45 pounds. CPSC staff found that most of the tested fasteners failed at loads well above the 80-pound force used in the test, while some of the fasteners on recalled products (which were rated at 26-pound maximum occupant weight) failed at 22 pounds to 55 pounds. The Commission agrees with CPSC staff that lowering the test load to a 60-pound force on a carrier rated at 25 pounds does not provide a sufficient safety factor, considering that fasteners from some recalled carriers failed at 55 pounds during testing. Based on the test results, the Commission finds that an 80-pound test load is appropriate, even for carriers with maximum occupant weights below 45 pounds.

All of the buckle and strap fasteners on the 14 carriers that CPSC staff tested were made from plastic. CPSC staff concluded that the characteristics of the plastic used for the fasteners dictated the fastener's ability to withstand the test load. The plastic material on the fasteners that fractured at a lower load was much less ductile, resulting in the fastener fracturing instead of deforming. Accordingly, CPSC staff found that smaller fasteners were as capable as

<sup>5</sup> According 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.

larger fasteners at meeting the 80-pound test load. Staff concluded that fastener strength was not necessarily proportional to fastener size.

CPSC staff states that the 80-pound test load for the fastener pull test is not directly related to the maximum carrier weight rating. Rather, the 80-pound test load was established based on testing the strength of fasteners on carriers already on the market. Fasteners that meet the required test load are robust enough for expected use during the life of the product. Moreover, CPSC staff believes that it is reasonably foreseeable that some caregivers may use soft infant and toddler carriers with infants whose weight exceeds the manufacturer's recommended occupant weight.

For the reasons discussed, the Commission declines to modify the final rule based on this comment.

#### *B. Fasteners That Support the Head*

*(Comment 2)* Two commenters stated that fasteners that support the head should be exempt from load testing. Non-load-bearing fasteners intended to retain items such as, but not limited to, hoods, bibs, and toy rings are exempt from load testing in ASTM F2236–13. One of the commenters stated: “head support for new born babies is critical,” but to achieve a good, adjustable head support requires fasteners that are slim and easy to use. The commenter designs head support fasteners to carry a certain load; however, the commenter stated that these fasteners are not load bearing and should be exempt from load testing in section 6.4 of the standard.

*(Response 2)* ASTM balloted and approved two clarifying changes to Note 1 in section 6.4 of the standard, which have been incorporated into ASTM F2236–14. These changes address the commenters' concern. Note 1 exempts non-load-bearing fasteners from the fastener strength tests in section 6.4 and lists examples of non-load-bearing fasteners that are exempt. We note that the list in Note 1 is not exhaustive, but merely illustrative, and that other features attached to a soft infant and toddler carrier by a non-load-bearing fastener are also exempt from the fastener strength tests in section 6.4.

ASTM F2236–13, the proposed standard for adoption in the NPR, stated that fasteners intended to retain items such as “hoods, bibs and toy rings” were exempt from testing. The ASTM subcommittee for soft infant and toddler carriers was aware of a feature called a “sleeping hood” that is attached to a soft infant and toddler carrier by non-load bearing fasteners. The “sleeping hood” feature was intended to be captured in ASTM F2236–13 Note 1

with the phrase “hoods.” To clarify that non-load-bearing fasteners used to retain “sleeping hoods” are exempt from testing, ASTM changed the word “hoods” in Note 1 to “sleeping hoods.” This revision was approved and published in ASTM F2236–13a.

Subsequently, based on a manufacturer's concern that Note 1 was still unclear about whether head adjustment fasteners that were non-load bearing had to be tested, ASTM balloted and approved another modification to Note 1. The second modification was incorporated into ASTM F2236–14 and added “head adjustment fasteners” to the list of examples of fasteners exempt from testing in Note 1. The Commission agrees with the clarification and believes that these revisions to the voluntary standard address the commenters' concern.

To the extent that commenters are suggesting that any potential load-bearing fastener that supports the head should be excluded from the fastener strength test in section 6.4 of the standard, the Commission disagrees. CPSC found that on the 14 carriers tested, the uppermost fastener generally supports the infant's upper torso and shoulders, as well as the head, and therefore, the fastener is critical to securing the infant in the carrier. Load-bearing fasteners that support the head, upper torso, and shoulders are not exempt from fastener-load testing requirements. The commenter apparently does not intend to exempt this type of fastener from testing.

#### *C. Fastener Strap Slip During Load Testing*

*(Comment 3)* One commenter stated that the strap slippage requirement as articulated in the standard (ASTM F2236–13, paragraphs 6.4.1 and 6.4.2) can result in a technical failure of an otherwise safe product. The commenter found that during product testing, certain straps can slip more than 1 inch but in a direction that makes the straps become tighter, not looser. The commenter asserted that this does not compromise safety. The commenter suggested that the language in paragraph 6.4.1 should be changed from “. . . adjustable elements in straps shall not slip more than 1 in. (2.5 cm) when tested . . .” to “. . . adjustable elements in straps shall not loosen more than 1 in. (2.5 cm) when tested . . .”

*(Response 3)* The strap slippage requirement in section 6.4.1 of ASTM F2236–13, the standard referenced in the NPR, prevents the fastener straps from slipping an appreciable amount through the buckles during fastener strength testing. Significant slippage can

result in a minimal load being held by the fastener/strap and could result in the strap pulling out of the fastener or loosening to the point that the infant could fall out of the carrier. The commenter seeks to clarify that straps that tighten during the test do not constitute a test failure.

The Commission agrees that straps that tighten during testing should not fail the strap retention requirement in the standard. However, based on the CPSC staff's assessment, the Commission finds that use of the word “slip” in the standard is more accurate than “loosen.” The amount of strap “slip” through a fastener can be measured; whereas, CPSC staff is uncertain how to measure strap “loosening.” Additionally, the requirement for support/shoulder strap slippage during the dynamic and static load testing in paragraph 6.2 uses the same wording, which states: “adjustable sections of the support/shoulder straps shall not slip more than 1 in. (25 mm) per strap from their original adjusted position . . .” Therefore, the Commission will not replace the word “slip” with “loosen” in the final rule, as suggested by the commenter.

After publication of the NPR, ASTM balloted and approved a modification to the voluntary standard that addresses the commenter's concern about straps that tighten during testing. ASTM F2236–14 incorporates a revision to sections 6.2.2, 6.4.1, and 6.4.2 of the voluntary standard to state: “straps shall not slip, *in a manner that loosens the strap*, by more than 1 inch.” This modification was included in the voluntary standard, beginning with revision ASTM F2236–13a.

The Commission finds that the revisions now incorporated into sections 6.2.2, 6.4.1, and 6.4.2 of ASTM F2236–14 addresses the commenter's concern and clarifies when fasteners pass the fastener strength test requirement without substantively altering the test method.

#### *D. Warning Text Format*

*(Comment 4)* One commenter noted that in ASTM F2236–13, the text height requirement for the warnings provided with product instructions specified in section 9.2.2 needs to be modified to match the text height requirement for warning labels in section 8.3.1. The commenter stated that if this modification is not made, section 9.2.2 would require every letter of warning text to be at least 0.1” high, instead of only the upper case letters, as is the case in section 8.3.1.

*(Response 4)* The Commission agrees that the text height requirement for

warnings should be consistent throughout the standard. To address the

commenter's concern, ASTM balloted and approved the following modified

text in section 9.2.2, as follows (additions are shown by *italics*):

9.2.2 In warning statements, the symbol “” and the word WARNING shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case is at least 0.1 in. (2.5 mm) high.

Section 9.2.2 of the voluntary standard incorporates this revision, beginning with ASTM F2236–13a. The Commission believes that the revised language addresses the commenter's concern.

#### E. Suffocation Warning

(*Comment 5*) One commenter stated that the required warning statement should read: “Infants, especially those under four months, can suffocate in this product if face is pressed tight against your body,” rather than the warning statement in the proposed rule, as provided in the ASTM standard:

“Suffocation Hazard—Infants under 4 months can suffocate in this product if face is pressed tight against your body.” The commenter said that this warning language does not adequately warn the user of the risk of suffocation for infants over four months and that the suggested warning statement will alert parents and other caregivers to a risk to older babies as well.

(*Response 5*) The Commission disagrees that the proposed suffocation warning, as provided in the ASTM voluntary standard, does not adequately warn users of the risk of suffocation. The primary mechanism for suffocation in a soft infant and toddler carrier is the infant's face being pressed tightly against a caretaker's body, obstructing the nose and mouth and keeping the infant's head from moving. Infants younger than 4 months old are mostly at risk because they do not have the head control or the muscle strength to move their head away if their airway becomes obstructed. By 4 months of age, infants have increased neck strength and can hold their heads up and explore their surroundings while the caretaker is walking. Infants who are 4 months old can be carried in the outward-facing position in soft infant and toddler carriers that allow this carry position. At around age 6 months, infants begin to sit upright unassisted. Caretakers can carry infants of this age in a soft infant and toddler carrier on the hip or on the caregiver's back, depending on the caretaker's level of comfort. As children reach toddlerhood, caregivers can carry

children in this age group in a carrier on the hip or back depending on the carrier type. Given that infants from age 4 months and older have developed head control and muscular strength and can be placed in outward facing, hip, and back carry positions, their face is less likely to become pressed tightly into a caretaker's body. Therefore, the risk of suffocation for these children is low. The Commission has not received data indicating that a risk of suffocation exists for children 4 months and older.

Identifying explicitly children who are most at risk does not suggest that others are not at risk. However, guidelines for warning labels recommend focusing on the most likely and most serious risks (Laughery and Hammond, 1999; Wogalter, 2006). Warnings about low-probability events (*i.e.*, older infants suffocating in soft infant carriers) may reduce the believability or arousal strength of warnings that caution of more likely risks (*i.e.*, infants under 4 months suffocating in soft infant carriers). The Commission finds that the current ASTM warning label about the suffocation hazard is sufficient without modification.

#### F. Stability Warning

(*Comment 6*) One commenter stated: “we are concerned that raising the upper weight limits, for the purpose of ensuring that all soft infant and toddler carriers on the market are covered by the rule, brings in carriers that might have a greater risk of instability and falls due to the extra weight load relative to the weight and strength of the caregiver. We would urge the Commission to include an adequate alert to this risk in the required warnings and instructions.”

(*Response 6*) During the rulemaking, CPSC staff identified soft infant and toddler carriers on the market that have a manufacturer-recommended upper weight limit of 45 pounds. The Commission believes that expanding the scope of the standard to increase the upper weight limit from 25 pounds to 45 pounds is necessary for the standard to cover all products on the market.

However, for the Commission to include a warning statement about the greater risk of instability and falls involving products with higher weight limits, data must be available to demonstrate that carrying heavier children in soft infant and toddler carriers presents a greater risk of instability and falls. At this time, the available data do not support this position. Furthermore, the commenter did not provide data demonstrating that products with higher weight limits present a greater risk of instability and falls than carriers with a lower weight limit. Therefore, at this time, the Commission declines to modify the warning label as suggested by the commenter.

#### G. Product Marking

(*Comment 7*) One commenter recommended that the CPSC require that products manufactured after the effective date of the final rule be marked as compliant, so that consumers can identify clearly products that meet the new mandatory standard for soft infant and toddler carriers.

(*Response 7*) The Commission finds that sufficient incentive exists for compliant producers to label their products as compliant with the final standard for soft infant and toddler carriers. A final rule implementing testing, certification, and labeling of children's products in section 14 of the CPSA, as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107 (the 1107 rule), became effective on February 13, 2013. Under the 1107 rule, a manufacturer or importer may label a certified compliant product as “Meets CPSC Safety Requirements.” Because producers are already allowed to label compliant products as such under the 1107 rule, adding this option to the soft infant and toddler carrier standard would be redundant. The Commission declines to change to the final rule based on this comment.

#### H. Effective Date

(*Comment 8*) Two commenters address the 6-month effective date proposed in the NPR. One commenter,

representing several advocacy groups, expressed support for the 6-month effective date. Another commenter, a soft infant and toddler carrier manufacturer, recommended a 12-month effective date, stating that the manufacturing process can take up to 6 months, and the product may be stocked in a warehouse for additional months, depending on sales.

(Response 8) The final standard will not be applied retroactively to products manufactured prior to the effective date of the final rule. Thus, any products warehoused before the effective date will not be affected by the standard. Manufacturers should be able to comply with the mandatory standard within 6 months of the final rule's publication. Manufacturers whose products do not comply with the standard will require some product modification. However, product modification is expected to involve minor changes, such as adding or changing straps or fasteners. Moreover, ASTM F2236-13 was adopted by ASTM in March 2013, and became effective in September 2013. Although the Commission is adopting ASTM F2236-14 as the mandatory standard, no substantive changes have been made to the voluntary standard since ASTM F2236-13. Manufacturers that comply with ASTM F2236-13 have already made, or have begun to make, the necessary modifications. The Commission declines to change the effective date of the final rule based on this comment.

#### V. Summary of ASTM F2236-14

The Commission is issuing this final rule for soft infant and toddler carriers that incorporates by reference the most recent voluntary standard for soft infant and toddler carriers, ASTM F2236-14. Together with the changes made in ASTM F2236-12, ASTM F2236-13, and ASTM F2236-13a, ASTM F2236-14 reflects the most significant revisions to the standard to date. Revisions to the voluntary standard include modified and new requirements developed by CPSC staff, working with stakeholders on the ASTM subcommittee task group, to address the hazards associated with soft infant and toddler carriers. After the comment period for the NPR closed, the ASTM F15.21 Soft Infant and Toddler Carrier subcommittee held a teleconference on August 12, 2013, to discuss comments submitted on the NPR. The subcommittee discussed the basis for each comment and reached a consensus on revisions to be submitted for ballot. The subcommittee chair balloted the proposed revisions to ASTM F2236-13 for concurrent ASTM Main Committee F15 and Subcommittee

F15.21 consideration on August 23, 2013, with a 1-month comment period. The August 23, 2013 ballot contained three revisions to the voluntary soft infant and toddler carrier standard:

- Revisions to sections 6.2.2, 6.4.1, and 6.4.2 to clarify that during the dynamic load, static load, and fastener strength tests, straps shall not slip, in a manner that loosens the strap, more than 1 inch.
- A revision to Note 1 in section 6.4 to clarify that "sleeping hoods" are an example of non-load-bearing fasteners that are exempt from fastener strength testing.
- A revision to section 9.2.2 to clarify that the text height requirements for the warnings included with instructions in section 9.2.2 are the same as the text height requirements for warnings required in section 8.3.1 of the voluntary standard.

ASTM did not receive any negative votes on the balloted revisions to ASTM F2236-13. ASTM approved the balloted revisions on November 1, 2013, and subsequently published ASTM F2236-13a in November 2013.

On September 26, 2013, the ASTM F15.21 Soft Infant and Toddler Carrier subcommittee met to discuss results of the items balloted on August 23, 2013. One manufacturer wanted the voluntary standard to further clarify that fasteners used for adjusting the head portion of the carrier were exempt from fastener strength testing because such fasteners are not load bearing. As a result, the subcommittee chair developed a draft ballot item that proposed to add "head adjustment fasteners" to the list of examples of fasteners that are exempt from load testing listed in Note 1 of section 6.4. The subcommittee chair balloted the proposed revision to ASTM F2236-13a for concurrent ASTM Main Committee F15 and Subcommittee F15.21 consideration on November 6, 2013, with a 1-month comment period. ASTM did not receive any negative votes on the balloted revision, and approved the revised standard, ASTM F2236-14, on January 1, 2014. ASTM published ASTM F2236-14 in January 2014.

We summarize the provisions of ASTM F2236-14 below. Each revision to ASTM F2236-13 discussed above is described below in more detail in the relevant section of the standard where the change appears. ASTM F2236-14 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

*Scope.* The scope of the voluntary standard was broadened in December 2012 to include soft infant and toddler carriers with an upper weight limit of up to 45 pounds. Previously, it was unclear whether carriers with upper weight limits over 25 pounds fell within the standard. Expanding the scope of the standard clarifies that all soft infant and toddler carrier products currently on the market fall within the standard. The name of the standard was changed in 2012 to include the word "toddler," to clarify that toddlers can also be carried in these products. The scope of the standard also distinguishes soft infant and toddler carriers from other wearable infant carrier products. The scope provides that soft infant and toddler carriers are "normally of sewn fabric construction," hold the child "generally in an upright position," and "may be worn on the front, side, or back of the caregiver's body." Finally, the scope of the standard states that the standard does not apply to infant slings.

*Terminology.* Section 3.1 of the standard includes 14 definitions to help explain general requirements and performance requirements. Section 3.1.7 of the standard explains that a "leg opening" is the "opening in the soft carrier through which the occupant's legs extend when the product is used in the manufacturer's recommended use position." Sections 3.1.4 and 3.1.13 of ASTM F2236-14, respectively, explain that a "dynamic load" is the "application of impulsive force through free fall of a weight," and that a "static load" is a "vertically downward force applied by a calibrated force gage or by dead weights." Beginning in 2012, the standard included a new definition for "carrying position" to clarify methods for dynamic and static load testing in section 7 of the standard. Finally, in 2013, the standard was updated to include a new definition for "fastener" to aid in a new test for fastener strength and strap retention.

*General Requirements.* ASTM F2236-14 includes general requirements that the products must meet, as well as specified test methods to ensure compliance with the general requirements, which include:

- Restrictions on sharp points or edges, as defined by 16 CFR §§ 1500.48 and .49;
- restrictions on small parts, as defined by 16 CFR part 1501;
- restrictions on lead in paint, as set forth in 16 CFR part 1303;
- requirements for locking and latching devices;
- requirements for permanent warning labels;

- restrictions on flammability, as set forth in 16 CFR part 1610;
- requirements for toy accessories, as set forth in ASTM F 963.

The flammability requirement in section 5.7 of the standard was changed, beginning with ASTM F2236–13, from a flammable solids requirement (16 CFR 1500.3(c)(6)(vi)), to meet the more stringent flammability requirement for wearing apparel (16 CFR part 1610). Adopting the wearing apparel flammability requirement in the soft infant and toddler standard makes it consistent with other wearable infant carriers made of sewn fabric, such as slings, to prevent a foreseeable fire hazard in all wearable infant carriers.

**Performance Requirements and Test Methods.** ASTM F2236–14 provides performance requirements and test methods that are designed to protect against falls from the carrier due to large leg openings, breaking fasteners or seams, and straps that slip, including:

**Leg Openings**—Tested leg openings must not permit passage of a test sphere weighing 5 pounds that is 14.75 inches in circumference.

**Dynamic and Static Load**—Beginning with the 2012 version of ASTM F2236, the dynamic load test was strengthened from requiring a 25-pound shot bag to be dropped, free fall, from 1 inch above the seat area onto the carrier seat 1,000 times, to requiring testing with a 25-pound shot bag, or a shot bag equal to the manufacturer's maximum occupant weight limit, whichever is heavier. Additionally, the static load test was revised—from requiring a 75-pound weight for testing—to requiring a 75-pound weight, or a weight equal to three times the manufacturer's recommended maximum occupant weight, whichever is greater, to be placed in the seat area of the carrier for 1 minute. Such revisions to the dynamic and static load tests strengthen the test requirements, by requiring that products with a maximum recommended weight of 45 pounds be tested to a 135-pound weight instead of 75 pounds, which represents an 80 percent increase in the severity of the requirement.

ASTM F2236–14 requires that testing conducted with the new required loads must not result in a “hazardous condition,” as defined in the general requirements, or result in a structural failure, such as fasteners breaking or disengaging, or seams separating when tested in accordance with the dynamic and static load testing methods. Additionally, the standard provides that dynamic and static load testing must not result in adjustable sections of support/shoulder straps slipping more than 1

inch per strap from their original adjusted position after testing.

Section 6.2.2 of the standard on Support/Shoulder Strap Slippage was modified beginning with ASTM F2236–13a. The modification clarifies what constitutes passing or failing the strap slippage test. Section 6.2.2 was amended to state: “Adjustable sections of support/shoulder straps shall not slip, *in a manner that loosens the strap*, more than 1 in. (25 mm) per strap from their original adjusted position after dynamic and static load testing is performed in accordance with 7.2.1 and 7.2.2, respectively.” The amendment allows straps to tighten during testing but not loosen more than 1 inch, which is the intent of the testing.

**Fastener Strength and Strap Retention**—ASTM F2236–14 includes a new component-level performance requirement that was added to the standard in 2013 to evaluate the strength of fasteners and strap retention to help prevent falls from a carrier. Previously, soft infant and toddler carriers were recalled due to an occupant fall hazard caused by broken fasteners that passed the static and dynamic performance requirements in the then existing standard, ASTM F2236–10. Accordingly, the performance requirement in section 6.4 of ASTM F2236–14 states that load-bearing fasteners at the shoulder and waist of soft infant and toddler carriers, such as buckles, loops, and snaps, may not break or disengage; nor may their straps slip more than 1 inch when subjected to an 80-pound pull force. Adjustable leg opening fasteners must also be tested but are subjected to lower loads, a 45-pound pull force, because these fasteners do not carry the same load as fasteners at the shoulders and waist. ASTM F2236–14 requires that when tested, fasteners must not break or disengage, and adjustable elements must not slip more than 1 inch.

Similar to the strap slip requirement in the static and dynamic load testing section of the standard, ASTM also clarified the strap slip section of the fastener strength test section in ASTM F2236–13a. Sections 6.4.1 and 6.4.2 were amended to state: “Each unique fastener, except for leg opening adjustment fasteners as tested per 6.4.2, shall not break or disengage, and adjustable elements in straps shall not slip, *in a manner that loosens the strap*, more than 1 in. (2.5 cm) . . . .” This amendment allows straps to tighten during testing but not to loosen more than 1 inch, which is the intent of the testing.

Additionally, Note 1 to section 6.4 of the standard provides that the fastener

strength and strap retention testing apply only to load-bearing fasteners. ASTM F2236–13 stated: “Fasteners intended to retain items such as, but not limited to, hoods, bibs and toy rings, are exempt from these requirements.” ASTM approved two changes to the language in Note 1 to clarify that several non-load-bearing features, “sleeping hoods” and “head adjustment fasteners,” are included in the list of examples exempted from fastener strength testing when such features are non-load-bearing. Note 1 in section 6.4 of ASTM F2236–14 now provides that: “Fasteners intended to retain items such as, but not limited to, *sleeping hoods, head adjustment fasteners*, bibs and toy rings, are exempt from these requirements.”

**Unbounded Leg Opening**—The voluntary standard was updated in 2013 to clarify the unbounded leg opening test procedure to improve test repeatability. ASTM F2236–14 requires that an unbounded leg opening must not allow complete passage of a truncated test cone that is 4.7 inches long, with a major diameter of 4.7 inches and a minor diameter of 3 inches. The standard requires a test cone to be pulled through the leg opening with a 5-pound force for 1 minute.

**Marking, Labeling, and Instructional Literature.** ASTM F2236–14 requires that each product and its retail package be marked or labeled with certain information and warnings. The warning label requirement was updated in 2013 to address fall and suffocation hazards. ASTM F2236–14 requires that the warning label provide a fall hazard statement addressing that infants can fall through wide leg openings or out of the carrier. The standard requires the following fall-related precautionary statements be addressed on the warning label: Adjust leg openings to fit baby's legs snugly; before each use, make sure all [fasteners/knots] are secure; take special care when leaning or walking; never bend at waist, bend at knees; only use this carrier for children between \_ lbs. and \_ lbs. Additionally, ASTM F2236–14 requires that a suffocation hazard statement must address the fact that infants under 4 months old can suffocate in the carrier if the child's face is pressed tightly against the caregiver's body. The standard requires that the warning label must also address the following suffocation-related precautionary statements: Do not strap infant too tightly against your body; allow room for head movement; keep infant's face free from obstructions at all times. Products must also contain an informational statement that a child must face toward the caregiver until he

or she can hold his or her head upright. All products are required to come with instructional literature on assembly, use, maintenance, cleaning, and required warnings.

ASTM F2236-14 includes an example warning label that identifies more clearly the hazards, the consequences of

ignoring the warning, and how to avoid the hazards. The label format was designed to communicate more effectively these warnings to the caregiver (Fig. 1). Manufacturers may alter the rectangular shape of the label to fit on shoulder straps, if the

manufacturer chooses not to place label in the occupant space. However, the standard requires that the label be placed in a prominent and conspicuous location, where the caregiver will see the label when placing the soft infant and toddler carrier on their body.



Figure 1. ASTM F2236-14 Example Warning Label.

ASTM F2236-14 includes a 2013 revision to section 9.2.2 of the standard on Instructional Literature. Section 9.2.2 of the standard describes how the warning label is to be conveyed in the instructional literature. The text height requirements in this section should match the text height requirements for the on-product warning label in section 8.3.1, which was overlooked when publishing ASTM F2236-13. To correct this issue, ASTM F2236-14 includes the following revision to section 9.2.2, so that it is the same as 8.3.1: “In warning statements, the symbol “” and the word WARNING shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case is at least 0.1 in. (2.5 mm) high.”

## VI. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The NPR proposed that the final rule would become effective 6 months after publication of a final rule

in the **Federal Register**. Although we received one comment requesting a 12-month effective date (comment 8 in section IV.H), the Commission finds that a 6-month effective date is sufficient time to allow manufacturers to come into compliance. Manufacturers whose products are not compliant with the

standard will require some product modification; however, any necessary product modification is expected to involve minor changes, such as adding or changing straps or fasteners. Moreover, ASTM F2236-13 was adopted by ASTM in March 2013, and became effective in September 2013.

Although the Commission is adopting ASTM F2236–14, this version of the voluntary standard is substantially the same as ASTM F2236–13.

Manufacturers that are compliant with ASTM F2236–13 have already made or have begun to make the necessary modifications.

## VII. Regulatory Flexibility Act

### A. Introduction

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC prepare a final regulatory flexibility analysis (FRFA) when the Commission promulgates a final rule. 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:

- A succinct statement of the objectives of, and legal basis for, the rule;
- a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary 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;
- a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- a description of the steps the agency has taken to reduce 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 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.

### B. Market for Soft Infant and Toddler Carriers

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms primarily produce soft infant and toddler carriers, as well as substitute

products, such as slings. CPSC Economic Analysis (EC) staff believes that there are at least 54 suppliers of soft infant and toddler carriers to the U.S. market.<sup>6</sup> Thirty-nine domestic firms supply soft infant and toddler carriers to the U.S. market: 23 are domestic manufacturers; eight are domestic importers; and eight firms have unknown supply sources. In addition, 12 foreign firms supply soft infant and toddler carriers to the U.S. market. CPSC has insufficient information available to categorize the remaining three firms.<sup>7</sup>

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers.<sup>8</sup> Approximately 30 percent of soft infant and toddler carriers are handed down or purchased secondhand.<sup>9</sup> Thus, about 70 percent of soft infant and toddler carriers are acquired new. This estimate suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ( $0.51 \times 0.70 \times 4.1$  million births per year).<sup>10</sup>

Many soft infant and toddler carriers have expanded their maximum weight limits in recent years to accommodate older children. However, from the lack of incident data involving children older than 2 years, CPSC staff believes that most caregivers would not be comfortable carrying older, heavier children in soft infant and toddler carriers. Based on the incident data, it appears that soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to

<sup>6</sup> Staff conducted research to identify manufacturers and importers of soft carriers. From the time of the NPR to the final rule, several firms entered the market, raising the number of suppliers from 39 in the NPR to 54 presently.

<sup>7</sup> CPSC staff made these determinations using information from Dun & Bradstreet and ReferenceUSA.gov, as well as the firms' Web sites.

<sup>8</sup> The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from *American Baby* magazine's mailing lists. Also, because the most recent survey information is from 2005, the information may not reflect the current market.

<sup>9</sup> The data on secondhand products for new mothers was not available. Instead, data for new mothers and experienced mothers were combined and broken down into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage of soft infant and toddler carriers that were handed down or purchased secondhand.

<sup>10</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2009," *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. The number of live births in 2009 is rounded from 4,130,665.

use these products into the second year. While we do not know the proportion of caregivers who continue to use these products into the second year, we estimated the numbers of soft infant and toddler carriers in use by assuming that a portion of caregivers, e.g., 25–50 percent, will continue to use carriers in the child's second year. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by new mothers. Assuming that 25–50 percent of caregivers continue to use soft infant and toddler carriers in the second year, approximately 2.6 million ( $2.1 \text{ million} \times 0.25 \times 2.1 \text{ million}$ ) to 3.2 million ( $2.1 \text{ million} \times 0.50 \times 2.1 \text{ million}$ ) households have soft infant and toddler carriers available for use annually. Based on Directorate for Epidemiology staff's estimate of 1,400 injuries treated nationally in emergency departments from 1999 to 2011, an average of about 108 emergency department-treated injuries involve soft infant and toddler carriers annually.<sup>11</sup> Therefore, about 0.34 – 0.40 emergency department-treated injuries may occur annually for every 10,000 soft infant and toddler carriers available for use.

### C. Reason for Agency Action and Legal Basis for the Final Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. Staff recommends adopting the voluntary standard (ASTM F2236–14), without modification.

### D. Requirements of the Final Rule

The requirements of the final rule are set forth above in section V of this preamble, which describes ASTM F2236–14.

### E. Issues Raised by Public Comments

Section IV of this preamble contains a summary of the five comments received and the issues raised by the comments.

<sup>11</sup> Memorandum from Risana Chowdhury, Directorate for Epidemiology, dated March 11, 2013, Subject: Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates: 1999–September 10, 2012. CPSC staff cannot present national emergency department-treated injury estimates for 2012 due to insufficient numbers of NEISS incidents reported during the time period, and 2013 data is not yet available. Memorandum from Risana Chowdhury, Directorate for Epidemiology, dated September 23, 2013, Subject: Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries between September 11, 2012 and July 15, 2013.

#### F. Other Federal Rules

Two federal rules interact with the soft infant and toddler carrier mandatory standard: (1) *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107); and (2) *Requirements Pertaining to Third Party Conformity Assessment Bodies* (16 CFR part 1112). The regulation at 16 CFR part 1107 requires every manufacturer of a children's product that is subject to a children's product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Because soft infant and toddler carriers will be subject to a mandatory children's product safety rule, they will also be subject to the third party testing requirements of 16 CFR part 1107 when the soft infant and toddler carrier mandatory standard becomes effective.

In addition, 16 CFR part 1107 requires the third party testing of children's products to be conducted by CPSC-accredited laboratories. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. The NORs for existing rules are set forth in 16 CFR part 1112. The Commission is finalizing an amendment to 16 CFR part 1112 that establishes the requirements for the accreditation of testing laboratories to test for compliance with the soft infant and toddler carrier final rule.

#### G. Impact on Small Businesses

The FRFA is limited to the 39 domestic firms known to be marketing soft infant and toddler carriers in the United States because U.S. Small Business Administration (SBA) guidelines and definitions pertain to U.S.-based entities. Under SBA guidelines, a manufacturer of soft infant and toddler carriers is small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 32 of the 39 domestic firms supplying soft infant and toddler carriers to the U.S. market are small firms—18 manufacturers, six importers, and eight firms—whose supply source is unknown. Additional unknown small soft infant and toddler carrier suppliers may also operate in the U.S. market.

One purpose of the regulatory flexibility analysis is to evaluate the impact of a regulatory action and determine whether the impact is economically significant. While the SBA gives considerable flexibility in defining

“economically significant,” CPSC staff typically uses one percent of gross revenue as the threshold for determining “economic significance.” CPSC staff considers any impact that is one percent or more of gross revenue is considered economically significant. SBA has accepted the one percent of gross revenue threshold and this threshold is also commonly used by agencies in determining economic significance.<sup>12</sup>

*Small Manufacturers:* The expected impact of the final rule on small manufacturers will differ, based on whether manufacturers' soft infant and toddler carriers are already compliant with F2236–13. Although F2236–14 was published in January 2014, firms are still likely to be testing to F2236–13. However, because ASTM F2236–13, ASTM F2236–13a, and ASTM F2236–14 do not contain material differences, manufacturers in compliance with ASTM F2236–13 are likely to continue to comply with the voluntary standard.

The Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, has certified several soft infant and toddler carriers as compliant with the voluntary standard, and other manufacturers have claimed compliance with the voluntary standard. Based on this information, 11 of 18 domestic manufacturers comply with ASTM F2236–13. These 11 firms should not require any modifications to their products and, as such, the firms should not be impacted by incorporation of ASTM F2236–14 as the final rule.

Meeting ASTM F2236–14's requirements could require some modifications for seven of the 18 domestic manufacturers who are believed not to be currently compliant with ASTM F2236–13. Based upon past discussions with firms and Engineering Sciences staff, necessary modifications would likely involve adding or changing straps, fasteners, or fabrics and generally would be less expensive to accomplish than a complete product redesign. Therefore, in most cases, the impact of the final rule is not expected to have a significant effect on products that do not comply with ASTM F2236–13.

Under section 14 of the CPSA, soft infant and toddler carriers are also subject to third party testing and certification requirements. Once the

new soft infant and toddler requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107). Third party testing will pertain to any physical and mechanical test requirements specified in the soft infant and toddler carrier final rule; lead and phthalates testing is already required. Third party testing costs are in addition to the direct costs of meeting the soft infant and toddler standard.

Based on information from the durable nursery product industry and confidential business information supplied for the development of the third party testing rule, CPSC staff estimates that testing to a single ASTM voluntary standard could cost around \$500–\$600 per model sample. On average, each small domestic manufacturer supplies two different models of soft infant and toddler carriers to the U.S. market annually. Therefore, if third party testing to the requirements in the soft infant and toddler standard is conducted every year on a single sample for each model, third party testing costs associated for each manufacturer would be about \$1,000–\$1,200 annually. Based on an examination of estimates of firms' revenues from recent Dun & Bradstreet reports, the impact of third party testing is not likely to be economically significant if only one sample per model is required. However, if more than one sample is needed to meet the testing requirements, third party testing costs could have an economically significant impact on some small manufacturers (*i.e.*, testing costs could be one percent or more of gross revenue). CPSC staff does not know exactly how many samples each manufacturer will need to test to meet the “high degree of assurance” criterion required by 16 CFR part 1107.

*Small Importers:* Most importers will not experience significant impacts as a result of the final rule. CPSC staff believes that four of the six small importers are compliant with the voluntary standard. The remaining importers may need to find an alternate source of soft infant and toddler carriers if their existing suppliers do not come into compliance with the requirements of the final rule. Alternatively, the firms may discontinue importing soft infant and toddler carriers altogether and perhaps substitute another juvenile product.

As is the case with manufacturers, all importers will be subject to third party

<sup>12</sup> U.S. Small Business Administration, Office of Advocacy. A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act and Implementing the President's Small Business Agenda and Executive Order 13272. May 2012, pgs. 18–20. [http://www.sba.gov/sites/default/files/rfaguide\\_0512\\_0.pdf](http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf).

testing and certification requirements, and consequently, they will experience the associated costs, if their supplying foreign firm(s) does not perform third party testing. The resulting costs could potentially have a significant impact on a few small importers that must perform the testing themselves, particularly if more than one sample per model is required.

Eight small firms have unknown supply sources, three of which appear to be compliant with ASTM F2236–13 and should not be impacted by the incorporation of ASTM F2236–14 as the mandatory final rule. The remaining five firms may need to make small changes to their products to be compliant with ASTM F2236–14. Due to the nature of the product, the modifications should be limited to changes in straps or fasteners and should not have a significant impact.

**H. Alternatives**

One alternative would be to set an effective date for the final rule later than the staff-recommended 6 months, which

is generally considered sufficient time for suppliers to come into compliance with a durable infant and toddler product rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant soft infant and toddler carriers and spread the associated costs over a longer period of time. However, given that the changes to meet the standard are not substantial, CPSC staff believes that 6 months is sufficient.

**VIII. Environmental Considerations**

The Commission’s regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has “little or no potential for affecting the human environment,” the rule will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The final rule for soft infant and toddler carriers falls within the categorical exemption.

**IX. Paperwork Reduction Act**

This rule contains information collection requirements that are subject

to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The preamble to the proposed rule (78 FR at 20520 through 20521) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. OMB has assigned control number 3041–0162 to this information collection. We did not receive any comment regarding the information collection burden of the proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated manufacturers subject to the information collection burden is now estimated at 54 manufacturers rather than the 39 manufacturers initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified 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
1226 .....	54	2	108	1	108

Our estimate is based on the following:

Section 8.1 of ASTM F2236–14 requires that all soft infant and toddler carrier products and their retail packaging be marked or labeled as follows: the manufacturer, distributor, or seller name, and either the place of business (city, state, mailing address, including zip code), or telephone number, or both; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 54 firms that supply soft infant and toddler carriers in the U.S. market. For PRA purposes, we assume that all 54 firms use labels on their products and on their packaging already. However, firms might need to make some modifications to their existing labels. We estimate that the time required to make these modifications is about 1 hour per model. Each of the 54 firms supplies an average of two different models of soft infant and toddler carriers. Therefore, we estimate the burden hours associated with labels to be 108 hours annually (1 hour × 54 firms × 2 models per firm = 108 hours annually).

We estimate the hourly compensation for the time required to create and update labels is \$27.71 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” September 2013, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, we estimate the annual cost to industry associated with the labeling requirements in the final rule to be \$2,992.68 (\$27.71 per hour × 108 hours = \$2,992.68). This collection of information does not require operating, maintenance, or capital costs.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this final rule to the OMB.

**X. Preemption**

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is

identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus implying that the preemptive effect of section 26(a) of the CPSA applies to final durable infant and toddler product final rules. Therefore, the final rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when the final rule becomes effective.

**XI. Certification and Notice of Requirements**

Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children’s products subject to a children’s product

safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a NOR for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The final rule for 16 CFR part 1226, "Safety Standard for Soft Infant and Toddler Carriers," is a children's product safety rule that requires the issuance of a NOR.

Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which codifies 16 CFR part 1112. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section 14(a)(2) of the CPSA. The final rule also codifies all of the NORs that the CPSC has published, to date. All new NORs, such as the soft infant and toddler carrier standard, require an amendment to part 1112. Accordingly, the final rule amends part 1112 to include the soft infant and toddler standard, along with the other children's product safety rules for which the CPSC has issued NORs. The final NOR is based on the CPSC's laboratory accreditation requirements on the performance standard set forth in the final rule for the safety standard for soft infant and toddler carriers and the test methods incorporated within this standard.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for soft infant and toddler carriers are required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1226, *Safety Standard for Soft Infant and Toddler Carriers*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

A FRFA was conducted as part of the promulgation of the original 16 CFR part 1112 (78 FR 15836, 15855–15858), as required by the Regulatory Flexibility Act. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse 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 expected to provide such services are those that anticipate receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the rule to include the NOR for the soft infant and toddler carrier standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the soft infant and toddler carrier standard. Most of these laboratories have already been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the soft infant and toddler standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the soft infant and toddler carrier standard will not have a significant impact on a substantial number of small entities.

#### List of Subjects

##### 16 CFR Part 1112

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

##### 16 CFR Part 1226

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations by amending part 1112 and adding a new part 1226, 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:** 15 U.S.C. 2063; Pub. L. No. 110–314, section 3, 122 Stat. 3016, 3017 (2008)

■ 2. In § 1112.15 add paragraph (b)(37) to read as follows:

**§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?**

\* \* \* \* \*

(b) \* \* \*

(37) 16 CFR part 1226, Safety Standard for Soft Infant and Toddler Carriers.

\* \* \* \* \*

■ 3. Add Part 1226 to read as follows:

#### **PART 1226—SAFETY STANDARD FOR SOFT INFANT AND TODDLER CARRIERS**

Sec.

1226.1 Scope.

1226.2 Requirements for soft infant and toddler carriers.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, Sec. 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

##### **§ 1226.1 Scope.**

This part establishes a consumer product safety standard for soft infant and toddler carriers.

##### **§ 1226.2 Requirements for soft infant and toddler carriers.**

(a) Each soft infant and toddler carrier must comply with all applicable provisions of ASTM F2236–14, Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, approved on January 1, 2014. 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/cpsc.htm>. 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: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) [Reserved]

Dated: March 24, 2014.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2014–06771 Filed 3–27–14; 8:45 am]

**BILLING CODE 6355–01–P**

impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify controlled airspace at Lampson Field, Lakeport, CA.

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

#### PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for 14 CFR Part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

##### § 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9X, Airspace Designations and Reporting Points, dated August 8, 2013, and effective September 15, 2013 is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

\* \* \* \* \*

#### AWP CA E5 Lakeport, CA [Amended]

Lampson Field, CA  
(Lat. 38°59'26" N., long. 122°54'03" W.)  
Sutter Lakeside Hospital Heliport, CA Point  
in Space Coordinates  
(Lat. 39°06'09" N., long. 122°53'19" W.)

That airspace extending upward from 700 feet above the surface within a 4-mile radius of Lampson Field, and within a 5-mile radius of the Point in Space serving the Sutter Lakeside Hospital Heliport.

Issued in Seattle, Washington, on July 17, 2014.

**Christopher Ramirez,**

*Acting Manager, Operations Support Group,  
Western Service Center.*

[FR Doc. 2014–17371 Filed 7–22–14; 8:45 am]

**BILLING CODE 4910–13–P**

#### CONSUMER PRODUCT SAFETY COMMISSION

#### 16 CFR Parts 1112 and 1228

[Docket No. CPSC–2014–0018]

#### Safety Standard for Sling Carriers

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for sling carriers in response to the direction under Section 104(b) of the CPSIA.

**DATES:** Submit comments by October 6, 2014.

**ADDRESSES:** You may submit comments related to the Paperwork Reduction Act (PRA) aspects of the marking, labeling, and instructional literature of the proposed rule to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to: [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

You may submit other comments, identified by Docket No. CPSC–2014–0018, by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal

eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above. *Written Submissions:* Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

*Instructions:* All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

*Docket:* For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number CPSC–2014–0018, into the "Search" box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Hope E J. Nesteruk, Project Manager, Division of Human Factors, Directorate for Engineering Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301–987–2579; email: [hnesteruk@cpsc.gov](mailto:hnesteruk@cpsc.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub. L. 110–314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission 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 and toddler products. These standards are to be "substantially the same as" applicable

voluntary standards or more stringent than the voluntary standard if the Commission concludes 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.” Section 104(f)(1)(H) provides that the term “durable infant or toddler product” includes “infant carriers.”

Section 104 also requires manufacturers of durable infant or toddler products to comply with a registration program that the Commission establishes. Section 104(d).

In this document, the Commission is proposing a safety standard for sling carriers. Section 104(f)(2)(H) of the CPSIA lists “infant carriers” as one of the categories of durable infant or toddler products identified for purposes of section 104. As indicated by a review of ASTM’s standards and retailers’ Web sites, the category of “infant carriers” includes hand-held infant carriers, soft infant carriers, frame backpack carriers, and sling carriers. The Commission has issued final rules for hand-held infant carriers (78 FR 73415 (December 6, 2013)) and soft infant carriers (78 FR 20511 (April 5, 2013)) and a proposed rule on frame backpack carriers (79 FR 28458 (May 16, 2014)). In the Commission’s product registration card rule identifying additional products that the Commission considered durable infant or toddler products necessitating compliance with the product registration card requirements, the Commission specifically identified infant slings, or sling carriers, as a durable infant or toddler product. 76 FR 68668 (December 29, 2009). The durability of infant slings is discussed in section II.B. of this document.

Because the voluntary standard on infant slings, ASTM 2907–14a, “Standard Consumer Safety Specification for Sling Carriers,” refers to “infant slings” as “sling carriers,” the notice of proposed rulemaking refers to infant slings as “sling carriers.” The terms are intended to be interchangeable and have the same meaning.

Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. CPSC staff participated in the ASTM sling carrier subcommittee meetings and task group meetings and worked with

the ASTM sling carrier task groups to develop ballot language for revisions to the sling carrier voluntary standard. The proposed rule is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2907–14a, “Standard Consumer Safety Specification for Sling Carriers” (ASTM F2907–14a), without change.

The ASTM standard is copyrighted, but the standard is available as a read-only document during the comment period on this proposal only, at: <http://www.astm.org/cpsc>, by permission of ASTM.

## II. Product Description

### A. Definition of Sling Carrier

ASTM F2907–14a “Standard Consumer Safety Specification for Sling Carriers” defines a “sling carrier” as “a product of fabric or sewn fabric construction, which is designed to contain a child in an upright or reclined position while being supported by the caregiver’s torso.” These products generally are intended for children starting at full-term birth until a weight of about 35 pounds. The designs of infant slings vary, but the designs generally range from unstructured hammock-shaped products that suspend from the caregiver’s body, to long lengths of material or fabric that are wrapped around the caregiver’s body. Infant slings normally are worn with the infant positioned on the front, hip, or back of the consumer, and with the infant facing toward or away from the consumer. As stated in the sling carrier definition, these products generally allow the infant to be placed in an upright or reclined position. However, the reclined position is intended to be used only when the infant is worn on the front of the consumer. The ability to carry the infant in a reclined position is the primary feature that distinguishes sling carriers from soft infant and toddler carriers, another subset of sling carriers.

The Commission identified three broad classes of sling carrier products available in the United States:

- Ring slings are hammock-shaped fabric products, in which one runs fabric through two rings to adjust and tighten the sling.
- Pouch slings are similar to ring slings but do not use rings for adjustment. Many pouch slings are sized rather than designed to be adjustable. Other pouch slings are more structured and use buckles or other fasteners to adjust the size.
- Wrap slings are generally composed of a long length of fabric, upwards of six

yards long, and up to two feet wide. A wrap sling is completely unstructured with no fasteners or other means of structure; instead, the caregiver uses different methods of wrapping the material around the caregiver’s body and the child’s body to support the child. Wrap-like slings mimic the manner in which a wrap supports the child but use fabric in other manners, such as loops, to reduce the need for caregivers to learn wrapping methods. Ring slings, modifications of wraps and pouch slings, and other products that meet the definition of a sling carrier contain parts that are also considered durable from an engineering perspective and suggest they were selected for long-term use. In addition, the test methods in ASTM F2907–14a combine to ensure that slings meet a minimum level of durability.

ASTM F2907 does not distinguish among the type of slings. The voluntary standard’s requirements apply equally to all slings.

### B. Sling Carrier Use

ASTM F2907–14a states that sling carriers generally are intended for children starting at full-term birth, until a weight of about 35 pounds (15.9 kg). According to the data tables used to produce the 2000 Centers for Disease Control and Prevention (CDC) U.S. growth charts, the median (50th percentile) weight of a child does not exceed 35 pounds until about 46 months for boys and 49 months for girls (CDC, 2000). Moreover, the 5th percentile bodyweight of a child does not exceed 35 pounds until about 65 months for boys and 69 months for girls. This means that more than half of all 3-year-olds are likely to be at or below the maximum weight of 35 pounds, and that even some 5-year-olds are likely to be at or below this upper weight limit. Although the Commission believes that sling carriers are most likely to be used with infants, it seems reasonably foreseeable that some portion of the user population will use these carriers with preschool-aged children.

Evidence suggests that sling carriers are often reused for multiple children. For example, according to a 2005 survey conducted by the American Baby Group (2006 *Baby Products Tracking Study*), nearly one-third (31 percent) of mothers who own slings had a sling that was handed down or purchased secondhand. Preliminary data from CPSC’s Durable Nursery Products Exposure Survey found that 21 percent of sling owners acquired the sling used. The Survey also found that after the owner discontinued use of the sling,

only 4 percent threw away the sling; 96 percent of owners stored the sling for future use, sold the sling, gave the sling away, or returned the sling to the original owner. These results suggest that most sling owners at least perceive sling carriers to have a future useful life, even if the sling had been used previously.

The Commission is aware of several online Web sites, forums, and “babywearing” groups dedicated to buying, selling, and trading previously used sling carriers. (“Babywearing” is commonly used to describe the wearing or carrying of a baby in a sling or similar carrier.) For example, a simple search of sold listings for a used “baby sling” on eBay resulted in more than 1,700 listings during a roughly 3-month period. Although some of the products in these ads do not meet the definition of a “sling carrier,” a brief examination of the most recent 200 sales suggests that a very large percentage of these products would be considered a sling carrier. Thus, many consumers appear to be purchasing slings secondhand.

**C. Market Description**

The Commission has identified 47 suppliers to the U.S. market, but there may be hundreds more suppliers that produce small quantities of slings. (The Commission made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm Web sites.) Web sites such as Etsy show thousands of listings for artisans producing slings and wraps (although each firm may have multiple listings), which accounts for additional suppliers who are not among the 47 suppliers identified. Sling carriers are distributed by a variety of methods, such as mass merchandisers, small specialty juvenile products stores, and Internet-only distributors.

Of the 47 sling carrier suppliers identified, 33 companies are based in the United States: 25 are manufacturers, and four are importers. Available information does not identify the supply source for four firms. There are also 14 foreign companies that export directly

to the United States via Internet sales or directly to U.S. retailers.

A sling carrier is an uncomplicated product to produce, typically requiring only fabric, thread, rings (and in some cases, fasteners), and a sewing machine. A common scenario for a sling manufacturer starts with a mother using various slings or soft carriers and then deciding to make her own design in her home. Some of these home businesses grow into larger businesses that become more specialized and sophisticated, typically designing and marketing their own products but having the product manufactured overseas. However, the newer home businesses may be relatively unsophisticated and may not be aware of the sling carrier voluntary standard effort or know that sling carriers may be subject to existing federal regulations on children’s products.

According to a the 2006 *Baby Products Tracking Study*, 17 percent of new mothers own sling carriers. As noted previously, approximately 31 percent of sling carriers were handed down or purchased secondhand. Thus, about 69 percent of sling carriers were acquired new. (The data collected for the *Baby Products Tracking Study* do not represent an unbiased statistical sample. American Baby Products surveyed potential respondents from its mailing lists to generate a sample of 3,600 new and expectant mothers. Additionally, because the most recent survey information is from 2005, the data may not reflect the current market.) This information suggests annual sales of about 471,000 sling carriers (.17 × .69 × 4 million births per year), with prices ranging from \$30 to around \$150. (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, “Births: Final Data for 2009,” *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.)

However, this sales estimate may be a substantial underestimate for two

reasons: (1) Industry sources state that slings have increased in popularity since the survey was done in 2005; and (2) other products like wraps, pouches, and some soft carriers, which fall under the standard, may not have been included in the *Baby Products Tracking* study. Based on discussions with an industry representative, sales of these other products that fall under the proposed rule for sling carriers could increase the Commission’s sales estimate to about 600,000 to 1 million units annually.

**III. Incident Data**

The Commission is aware of a total of 122 incidents (16 fatal and 106 nonfatal) related to sling carriers, which were reported to have occurred from January 1, 2003 through October 27, 2013. Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Given that reporting is incomplete, the Commission strongly discourages drawing inferences based on the year-to-year increase or decrease shown in the reported data. (The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the National Electronic Injury Surveillance System (NEISS). These reported deaths and incidents do not provide a complete count of all deaths and incidents that occurred during that time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to sling carriers.)

Among the incidents in which age was reported, all but one of the children were 12 months old or younger; the age of the oldest child was reported to be 3 years. Some incident reports did not indicate the age because there was no injury involved or age was unknown. Table 1 provides the age breakdown as reported in the 122 incidents.

**TABLE 1—AGE DISTRIBUTION AS REPORTED IN SLING CARRIER-RELATED INCIDENTS**

[01/01/03–10/27/13]

Age of Child	All Incidents		Fatal and Nonfatal Injuries	
	Frequency	Percentage	Frequency	Percentage
Unreported*	31	25	1	1
One—Three Months	70	57	54	77
Four—Six Months	11	9	8	11
Seven—Nine Months	7	6	4	6
Ten—Twelve Months	2	2	2	3
Three Years	1	1	1	1

TABLE 1—AGE DISTRIBUTION AS REPORTED IN SLING CARRIER-RELATED INCIDENTS—Continued  
[01/01/03–10/27/13]

Age of Child	All Incidents		Fatal and Nonfatal Injuries	
	Frequency	Percentage	Frequency	Percentage
Total .....	122	100	70	100

Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS.

Note: Percentages do not add to 100 due to rounding.

\*: Age was unknown or the incident reported no injury.

#### A. Fatalities

CPSC received reports of 16 fatalities associated with the use of a sling carrier that occurred during the period from January 1, 2003 through October 27, 2013. Eleven of the 16 decedents were 1-month olds; the remaining five were between 3- and 5-months old. Nine of the decedents were described as having died of smothering, (also known as “suffocation,” or “positional asphyxia.”) Suffocation can occur when babies are contained entirely within the pouch of a sling. Infants who are placed with their heads below the rim of the sling are likely to stay in the same position because they are surrounded by unyielding fabric under the tension of their weight, and are tightly confined within the product, typically with their faces directed towards or held against the parent’s body. The highest risk of suffocation occurs when the infant’s face (nose and mouth) is pressed against the mother’s body, blocking the infant’s breathing, and rapidly suffocating the baby within a few minutes. The cause of death was undetermined for the remaining decedents.

One fatal victim was 5 months old. The age range of the remaining 15 fatal victims was from birth to 3 months; 11 infants were ages 1 month and younger, and the remaining four were 3 months old. Infants younger than 4 months old are at a high risk for suffocation because they have relatively immature physiological systems controlling breathing and arousal.

#### B. Nonfatalities

Of the 106 sling carrier-related nonfatal incidents that were reported to have occurred from January 1, 2003 through October 27, 2013, 54 reports reflected an injury to the infant during use of the product. Age was unreported for one of the injured, and one report stated that a 3-year-old was injured. For the rest of the incidents, the child’s age ranged from 1 month to 11 months.

Among the 54 reported nonfatal injuries, nine were reported as involving hospitalizations. Among the hospitalizations, one injury was described as a permanent brain injury

due to breathing difficulties suffered by the infant. The rest of the hospitalizations were serious head injuries, such as a fracture and/or brain hemorrhage, which resulted from infants falling from the carrier. Eleven additional skull/face/wrist fracture injuries were reported, but none of these incidents was reported to involve hospitalizations. The remaining non-hospitalized injuries included closed-head injuries, contusions/abrasions, lacerations/scratches, among others. (A closed head injury is a head injury where the skull remained intact. A closed head injury can range from a minor bump to the head to a severe life threatening traumatic brain injury.) A majority of the injuries resulted from falls from the carrier; most of these falls resulted from the caregiver slipping, tripping, or bending over while carrying the infant in the sling. The remaining injuries were due to miscellaneous product-related issues or other caregiver missteps, such as the caregiver not allowing enough safety clearance for the child in the sling carrier while the caregiver performed daily activities.

The remaining 52 incident reports stated that no injury had occurred or provided no information about any injury.

#### C. Hazard Pattern Identification

The Commission considered all 122 reported incidents (16 fatal and 106 nonfatal) to identify hazard patterns associated with sling carriers. In order of frequency of incident reports, the Commission grouped the hazard patterns into the following categories:

1. Problems with the *positioning* of the infant in the sling carrier: Thirty-one of the 122 reported incidents (25 percent) were in this category. Among them were nine deaths due to smothering, one permanent brain impairment injury due to breathing difficulty, and two other injuries—one related to breathing difficulty and the other related to blood-circulation in the infant’s leg. The rest of the incidents reported that the infant suffered breathing problems while in the carrier or that the caregiver had difficulty safely

positioning the infant in the sling carrier to avoid the potential for suffocation.

2. *Caregiver missteps*: Twenty of the 28 incidents (23 percent) in this category were reported to have occurred when the caregiver slipped, tripped, or bent over, causing the infant in the sling to either fall with the caregiver or fall out of the carrier. Eight additional incidents among the 28 reported in this category occurred when caregivers dropped the infant during placement into/removal out of the carrier or failed to provide enough safety clearance for the infant in the carrier as the caregivers conducted their daily activities. Examples of the latter scenario include an infant getting struck by a door or a falling object, or an infant hitting a wall. Although these 28 incidents did not involve any fatalities, all but one incident resulted in an injury to the infant. These incidents included 11 reports of skull fractures and one report of bleeding in the brain. Other injuries included closed-head injuries, contusions of the head/leg/back, and a finger laceration.

3. *Undetermined or unspecified* cause: Twenty five reported incidents (20 percent) included seven fatalities, two hospitalized injuries, and 13 non-hospitalized injuries, with very little information available on the circumstances leading to the incidents. The official reports did not indicate a specific cause of death. Among the injuries, which included fractures of the skull/wrist, as well as other serious head injuries, most were reported through hospital emergency departments with very little scenario-specific information.

4. Problems with *buckles*: Twelve of the 122 incidents (10 percent) reported buckles releasing, slipping, or breaking, causing infants to fall or nearly fall. There was one hospitalization for a skull fracture and two non-hospitalized injuries. There were no fatalities in this category.

5. *Miscellaneous product-related* issues: There were nine incident reports (seven percent) in which consumers complained of a design flaw posing a possible strangulation hazard, a broken

component, rough fabric, or a sharp surface; or consumers indicated an unspecified product failure. Although these reports did not include any fatalities, there were six injuries reported in this category, including one skull fracture.

6. *Consumer comments:* There were 17 non-event reports (14 percent) of consumer comments or observations of perceived safety hazards. In most of these cases, the consumer did not own the sling carrier in question. None of these reports indicates that any event actually occurred.

#### D. Product Recalls

Since January 1, 2003, the CPSC has issued five consumer-level recalls involving sling carriers. All five recalls were for product defects that created a substantial product hazard and resulted in the recall of about 1.1 million sling carriers. Two of the recalled products posed a suffocation hazard, while three recalls were related to structural integrity and fall or potential fall hazards.

### IV. Other Standards

#### A. International Standards

The Commission identified one European standard that covers fabric carriers without rigid structure. In addition, a guideline for sling carriers is under development in Europe.

1. British Standard EN13209–2:2005, *Child Use and Care Articles—Baby Carriers—Safety Requirements and Test Methods—Part 2: Soft Carriers* (27 September 2005), is the European standard for soft, fabric carriers. However, EN13209 specifically states that the scope is intended for a “product [that] has holes designed to accommodate the child’s legs.” Sling carriers do not have holes through which a child’s legs pass. Although some individual requirements in the EN13209 standard may be more stringent than those in F2907–14a, the reported incidents do not suggest that these are prevalent hazard patterns associated with sling carriers. Therefore, the Commission does not believe that incorporating these more stringent requirements would further reduce the risk of injury associated with sling carriers.

2. CEN/TR 16512, *Child use and care articles—Guidelines for the safety of children’s slings*, is a guideline that is under development in Europe. However, because this guideline, once completed would not be a standard, CEN/TR 16512 is not an option for consideration. The Commission expects that this guideline, when published,

will contain recommendations similar to EN13209, but with recommendations adapted for the unique attributes of sling carriers.

The Commission notes that the ASTM F15.21 subcommittee has worked to make F2907 the most appropriate standard for the unique nature of sling carriers by harmonizing with other standards (e.g., EN13209 and ASTM F2236), when appropriate, but also addressing the uniqueness of sling carriers, when needed. The Commission believes that ASTM F2907–14a is the most comprehensive standard that addresses the incident hazard patterns and that F2907–14a adequately addresses the hazards identified to date.

#### Voluntary Standard—ASTM F2907

##### 1. Description of Standard

ASTM F2907, “Standard Consumer Safety Performance Specification for Sling Carriers,” establishes safety performance requirements, test methods, and labeling requirements to minimize the hazards to children presented by sling carriers. ASTM first published a consumer product safety standard for sling carriers in 2012. ASTM has revised the voluntary standard five times since then. The current version, ASTM F2907–14a, was approved on February 15, 2014, and published in March 2014. ASTM F15.21 subcommittee issued a ballot on May 16, 2014, that proposed a modification in the occupant retention test pass/fail criteria. According to the ballot, “the current Occupant Retention test criteria (section 6.3) are not accurately separating good ring slings from poorly-constructed ring slings.” The modification ASTM has proposed would increase from 1 inch to 3 inches the amount the ring sling attachment system may slip while still passing the standard. At the time of writing, the Commission does not have sufficient information to assess this change. Staff welcomes comments on the issue.

The current version of the sling carrier standard, ASTM F2907–14a, contains requirements to address the following issues:

- Laundering;
- Hazardous sharp points or edges;
- Small parts;
- Lead in paint;
- Wood parts;
- Locking and latching;
- Openings;
- Scissoring, shearing, and pinching;
- Monofilament threads;
- Flammability;
- Marking and labeling; and
- Instructional literature.

In addition, F2907–14a includes construction, quality, and durability test

methods that are specific to sling carriers in the static, dynamic, occupant retention, and restraint system tests. These test methods combine to ensure that slings meet a minimum level of durability.

- **Static load test:** This test checks that the sling can support the sling’s maximum recommended weight with a safety factor of three, by gradually applying a weight of three times the manufacturer’s maximum recommended weight, or 60 lbs., whichever is greater, in the support area of the sling, and maintain the weight for one minute.

- **Dynamic load test:** This test assesses the durability of the sling and proper functioning of the sling’s fasteners by dropping a 35-lb. load into the sling’s support area in each recommended carrying position every 4 seconds for up to 1,000 cycles.

- **Occupant retention test:** This test assesses whether the sling retains the occupant as the caregiver moves about. The test also assesses the sling’s durability. The sling is attached to a test torso, and a test mass is placed in the sling. The test torso will move up and down at a rate of two times per second (approximately a brisk walking speed). The sling is tested to determine whether the adjustment mechanisms (e.g. rings, knots) release.

- **Restraint system test:** This test assesses whether any child restraints used by the sling are sufficient. Each restraint system is tested with a 45-lb. force on the restraint and again with a CAMI dummy. The anchorages for the restraint system are not to separate from their attachment points during or after testing.

##### 2. Adequacy of Requirements in Addressing Identifiable Hazard Patterns

**Positioning.** The Commission identified positioning as the primary hazard pattern in 31 cases. This includes nine deaths due to smothering, one permanent brain impairment injury due to breathing difficulty, and two other injuries—one related to breathing difficulty and the other related to blood circulation in the infant’s leg.

As noted previously, the Commission identified suffocation/asphyxia related to positioning as a risk associated with sling carriers. Suffocation can occur when babies are contained entirely within the pouch of a sling. The highest risk of suffocation occurs when the infant’s face (nose and mouth) is pressed against the mother’s body, blocking the infant’s breathing and rapidly suffocating a baby within a few minutes. Furthermore, because of its shape and lack of support, a sling carrier can facilitate an infant being positioned

within the confines of the sling in a manner that causes acute neck hyperflexion (chin touching the chest). Infants found in this compromised position are likely to stay in the position because infant neck muscles are too weak to support the weight of their head. Infants who stay for prolonged periods of time in this position can experience compromised airflow to the lungs, resulting in an inadequate supply of oxygen to the brain. Oxygen deprivation to the brain can lead to loss of consciousness and death.

Although there is no performance test for positioning in ASTM F2907–14a, ASTM F2907–14a requires statements in the warnings and instructions for sling carriers to caution against the hazards identified by the Commission through examination of the sling carrier incidents. Section 8.3.3 of F2907–14a specifies the warnings that must appear on each sling and addresses each of the hazard patterns the Commission found in the suffocation data. In short, all sling carriers must: (1) Include a safety alert symbol



and the signal word “WARNING,” (2) warn that failure to follow the manufacturer’s instructions can result in “death or serious injury,” (3) state the minimum and maximum recommended weights for the sling, and (4) warn about the potential suffocation and fall hazards associated with sling carriers.

More specifically, according to ASTM F2907–14a, the warnings that pertain to suffocation and positioning must address:

- the risk of suffocation to infants younger than 4 months if the infant’s face is pressed against the caregiver’s body within the confines of the sling and the increased risk of suffocation to infants born prematurely or those with respiratory problems;
- the need to check often to make sure that the infant’s face remains uncovered, clearly visible to the caregiver, and away from the caregiver’s body at all times;
- the importance of making sure that the infant does not curl into a position with the chin resting on or near the infant’s chest, which can interfere with breathing even when nothing is covering the nose or mouth;
- the need to reposition the infant after nursing so the infant’s face is not pressed against the caregiver’s body; and
- the importance of never using the sling with infants smaller than 8 pounds, without seeking the advice of a healthcare professional.

Lastly, the warning label prescribed by ASTM F2907–14a must include a pictogram that illustrates proper and improper infant positioning within the sling. ASTM F2907–14a includes an example of the type of pictogram sought but does not specify a particular design.

Section 9 of ASTM F2907–14a specifies what instructional literature must be provided with the sling. This section requires that the instructions contain an image of each manufacturer’s recommended carrying position, include all of the warning statements that are required to appear on the sling, and provide several additional instructions.

ASTM subcommittees for other durable nursery product standards have also tried to address positioning hazards related to a C-shaped curl in an infant’s head, neck, and torso area; however, there has been no repeatable performance test identified. The Commission attempted to address the positioning hazard associated with sling carriers in a new manner, based on the recognition that a sling carrier is worn by the caregiver and involves direct contact with the caregiver, thereby allowing for the possibility of the caregiver seeing a child who is in distress. Specifically, the Commission explored a “face exposure” test that, at a minimum, could keep a sling from preventing the caregiver from observing the infant’s face. The Commission pursued this possible test with the ASTM task group but found that the available anthropomorphic mannequins, *e.g.*, CAMI dummies, do not accurately represent the manner in which a child sits in a sling, and that the variable nature of sling products makes the repeatability of a test questionable. Together with the ASTM task group, the Commission concluded that a test to address positioning hazards is technically infeasible at this point.

Ultimately, the Commission concluded that warning requirements about proper and improper infant positioning present in ASTM F2907–14a is the only feasible hazard-mitigation strategy at this time. The Commission will continue to consider possible performance requirements pertaining to this issue and will pursue such an approach with the ASTM Subcommittee in the future, if an approach becomes feasible. Because there is no feasible performance test and because the warning statements in ASTM F2907 were developed considering both known hazard patterns for sling carriers and established practices for warning labels, the Commission believes that the warnings and instructions published in

ASTM F2907–14a are adequate to inform caregivers about how to reduce the likelihood of positioning incidents.

Caregiver Missteps. Incidents involving caregiver missteps included 11 reports of skull fractures and one episode of bleeding in the brain. Other injuries included closed head injuries, contusions of the head/leg/back, and a finger laceration. The Commission determined that these incidents were related directly to the actions, often accidental, of the caregiver. Examples include a caregiver slipping or tripping while wearing the sling carrier with the child inside, or incidental contact occurring between the child and an object, such as a door or wall. Although these types of incidents cannot be addressed directly through a performance test, the standard addresses these incidents by alerting caregivers of the hazard and making sure that the sling contains the infant. ASTM F2907–14a requires the following statement to appear on the on-product label to address the fall hazard to infants associated with “caregiver missteps,” such as tripping or bending over:

FALL HAZARD—Leaning, bending over, or tripping can cause baby to fall. Keep one hand on baby while moving.

In addition, the occupant retention test in ASTM F2907–14a is intended to reduce the likelihood that the child will fall out of the sling due to a caregiver misstep. ASTM F2907–14a requires the test mass to be contained within the sling for the duration of the test.

Buckles. Twelve of the incidents involved buckles releasing, slipping, or breaking, and included a hospitalization for a skull fracture and two non-hospitalized injuries. ASTM F2907–14a addresses this hazard in several ways, using the static, dynamic, occupant retention, and restraint system tests. For the reasons described previously, the Commission believes that the performance tests in F2907–14a adequately address hazards associated with buckle failure.

## V. Effective Date

The Administrative Procedure Act (APA) requires that the effective date of the rule be at least 30 days after publication of the final rule, 5 U.S.C. 553(d). The Commission generally considers 6 months sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Six months is the period the Juvenile Products Manufacturers Association (JPMA) typically allows for products in JPMA’s certification program to shift to a new voluntary standard once that new voluntary standard is published. Therefore,

juvenile product manufacturers are accustomed to adjusting to new standards with this time frame. However, in this instance, a large number of very small suppliers potentially will experience significant economic impacts complying with the rule. In addition, because ASTM F2907 has only been in existence for approximately 2 years, there is relatively little information regarding compliance with the voluntary standard. Thus, the Commission is proposing a 12-month effective date. The Commission invites comment on whether 12 months is an appropriate length of time for sling carrier manufacturers to come into compliance with the rule.

## VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to review proposed rules for a rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes a general notice of proposed rulemaking. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA must contain:

- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
- identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

### 1. Reason for Agency Action and Legal Basis for the Proposed Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. The Commission

worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2907–14a, which the Commission proposes to incorporate by reference.

### 2. Compliance Requirements of the Proposed Rule

The Commission is incorporating by reference the current voluntary standard, with no revision, to form the proposed rule. Some of the more significant requirements of the current voluntary standard for sling carriers (ASTM F2907–14a) include static and dynamic load testing to verify the structural integrity of the sling carriers and occupant retention testing to help ensure that the child is not ejected from the sling carrier. The ASTM standard requires that the buckles, fasteners, and knots that secure the sling carrier remain in position before and after these three performance tests. There is also a separate restraint system test to help ensure that any restraints used by the sling do not release while in use.

The voluntary standard also includes:

- requirements for several features to prevent cuts (hazardous sharp points or edges, and wood parts);
- small parts;
- marking and labeling requirements;
- flammability requirements;
- requirements for the permanency and adhesion of labels; and
- requirements for instructional literature.

The updated warning statements provide additional details of the fall and suffocation hazards and are intended to address the primary fatality risk associated with infant slings, suffocation.

### 3. Other Federal Rules

Section 14(a)(2) of the Consumer Product Safety Act (CPSA) requires every manufacturer and private labeler of a children's product that is subject to a children's product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory, that the product complies with all applicable children's product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards by rule for, among other things, making sure that a children's product is tested periodically and when there has been a material change in the product, and safeguarding against the exercise of undue influence by a manufacturer or private labeler against a conformity assessment body. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, Testing and Labeling Pertaining to Product

Certification (16 CFR part 1107), became effective on February 13, 2013 (the 1107 rule). When the sling carrier rule is finalized, sling carriers will be subject to a mandatory children's product safety rule. Accordingly, sling carriers will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule. Slings are already subject to lead and phthalates testing under the 1107 Rule. This rule adds certain mechanical tests and other requirements to the third party testing requirement.

In addition, the 1107 rule requires certifiers to use CPSC-accredited laboratories to conduct the third party testing of children's products. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformance assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. The NORs for existing rules are set forth in 16 CFR part 1112. Consequently the Commission is proposing an amendment to 16 CFR part 1112 that would establish the requirements for the accreditation of testing laboratories to test for compliance with the sling carrier final rule.

### 4. Impact on Small Businesses

Of the 47 identified suppliers of sling carriers to the U.S. market, 33 are domestic firms. (We limit our analysis to domestic firms because U.S. Small Business Administration (SBA) guidelines pertain to U.S.-based entities.) Under SBA guidelines, a manufacturer of sling carriers is small if it has 500 or fewer employees, and importers and wholesalers are small if the importers or wholesalers have 100 or fewer employees. Based on these guidelines, 31 of the domestic firms supplying sling carriers to the U.S. market appear to be small businesses. These businesses consist of 23 manufacturers, four importers, and four firms with unknown supply sources.

Additionally, as noted previously, an unquantified number of producers supply baby slings to the U.S. market via Web sites such as Etsy. Although we have no information on these suppliers, based on the general nature of suppliers selling products on Etsy and similar markets, we assume that these suppliers are well within SBA criteria for small business. For purposes of analysis, we refer to these suppliers as "very small manufacturers" to distinguish them from the more established manufacturers, but this is not an official SBA designation.

Before preparation of a regulatory flexibility analysis, the Commission conducts a screening analysis to determine whether a regulatory flexibility analysis or a certification statement of no significant impact on a substantial number of small entities is appropriate for a proposed rule. The SBA gives considerable flexibility in defining the threshold for “no significant economic impact.” However, the Commission typically uses 1 percent of gross revenue as a threshold; unless the impact is expected to fall below the 1 percent threshold for the small businesses evaluated, the Commission prepares a regulatory flexibility analysis.

Because we were unable to demonstrate that the draft proposed rule would impose an economic impact less than 1 percent of gross revenue for the affected firms, the Commission did not prepare a certification statement, but conducted an IRFA.

#### Small Manufacturers

JPMA and the Baby Carrier Industry Alliance (BCIA) have advised some manufacturers of F2907–12, F2907–13a, F2907–13b, and F2907–14. These organizations are offering assistance to member manufacturers on testing and compliance with the ASTM sling carrier standards. However, the ASTM sling carrier standards are relatively new, and there is no established history of compliance among manufacturers.

As of January 2014, only two of the 23 known small manufacturers of sling carriers are listed on the JPMA Web site as certified compliant. Based on our review of small firm Web sites and a conversation with a small ring sling manufacturer, we have identified three additional firms (not JPMA certified) that have conducted testing to some version of the ASTM standard, for a total of five firms that have conducted testing to some version of the ASTM standard. These firms may have already experienced the impacts of the proposed rule and may not experience any additional impacts. The remaining firms are likely to incur some cost associated with the proposed rule.

Due to the nature of the product and the relative ease of production, the Commission believes that most of the physical changes needed to meet the standard, such as changing fabrics, changing stitching, adding reinforcements, changing buckles, changing rings, changing labels, and changing instructions, are unlikely to be costly. Because sling carriers are largely made of fabric, tooling costs are not usually a large factor.

Some manufacturers of ring slings are having difficulties with their products passing the occupant retention tests consistently. The problem appears to be variation in testing results based on how the sling is positioned on the test fixture. At this time, the precise cost of changes necessary to satisfy testing under the ASTM standard is unknown; and we cannot rule out the potential for costs high enough to lead to significant economic impacts, especially for the very small manufacturers.

According to one manufacturer, changes to warning labels required under the proposed rule may have an impact on very small suppliers. We do not have sufficient data to determine whether this impact is expected to be economically significant. For example, if the cost of printing and sewing in the labels is 30 cents per sling, then the impact would be 1 percent of the sales price for a \$30 sling. CPSC staff contacted a representative from the BCIA to obtain label prices but has no independent estimate at this time. An additional consideration is that the labels are relatively large and may reduce the appeal of the product if they cannot be readily concealed. However, this impact will apply to all sling manufacturers.

Another manufacturer also expressed concerns that minor deviations from the font sizes required by the standard on the labels could force manufacturers to redo portions of the testing. This phenomenon may diminish as businesses become familiar with the requirements. Testing costs are discussed below.

The majority of the costs associated with the proposed standard will probably be related to testing. Few of the sling carrier manufacturers have the technical capability or the equipment to conduct any testing in house; and most small and very small manufacturers probably will have to rely on third party testing during product development. Some small and very small manufacturers could experience significant costs simply testing to find out initially whether their products comply with the proposed standard and with any additional testing necessary to develop complying products.

In addition, under section 14 of the CPSA, sling carriers are subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, Testing and Labeling Pertaining to Product Certification (16 CFR part 1107). This will include any physical

and mechanical test requirements specified in the final rule; lead and phthalates testing, if applicable, are already required; hence, lead and phthalates testing are not included in this discussion.

According to a BCIA representative, third party testing to the ASTM sling carrier voluntary standard could cost around \$500 – \$1,050 per model sample, with \$700 as an average cost. Third party testing consists of two costs: the testing costs unique to F2907 associated with the dynamic load test, the static load test, the occupant retention test, and the restraints test; and the general testing costs associated with testing for flammability, small parts, sharp edges, instructions, and labels. The testing costs unique to sling carriers vary widely, from \$210 to \$650, depending on whether the testing is done in China or the United States and whether a discount, such as the discount negotiated by the BCIA for its members, is applied. The general testing costs may amount to \$300 to \$400. The very small firms that manufacture in the United States will probably also test in the United States to avoid logistical difficulties, thus incurring higher costs.

The \$700 estimate for average testing costs includes all the required testing, such as flammability, sharp edges, etc. If a very small manufacturer with one model only needed to conduct one third party test annually, the costs of testing would amount to \$700. A very small manufacturer producing 20 to 30 low-priced slings a month might have annual revenues of \$10,800 (30 slings per month × 12 months × \$30 per sling). Testing one sample at \$700 would amount to 6.5 percent (\$700/\$10,800) of annual revenue for this hypothetical very small manufacturer, which we would clearly classify as a significant economic impact. Even if this manufacturer could sell its slings for \$150, testing one sample at \$700 would amount to 1.3 percent of annual revenue of \$54,000 (360 slings × \$150 per sling).

As a comparison, third party testing costs for soft infant and toddler carriers (SITCs) were estimated at \$500 – \$600 per sample for the SITC standard, ASTM F2236–14. However, the higher testing costs for slings could reflect additional testing for occupant retention, which is not part of the SITC standard.

Based upon the previous example, even in the unlikely case that very small sling manufacturers are able to develop a complying product without incurring significant economic impacts, very small sling manufacturers are still likely to incur significant economic impacts complying with section 14 of the CPSA.

These types of impacts would apply to the very small producers marketing their products primarily via Etsy and other Web sites.

Although information on sales revenue is limited to half of all manufacturers, we estimate that most of the 23 small domestic manufacturers have substantially larger sales volumes than the example above, with annual sales ranging between \$200,000 and \$16 million. Thus, product development and testing costs would be a lower percentage of sales revenue than the example above. At the lower range of \$200,000 in revenues, significant economic impacts would occur if the producer had to test three models per year. Firms with revenues closer to the upper end of the range, \$16 million, would need to test more than 200 models per year to experience significant economic impacts from testing. The number of tests needed for product development purposes or to meet the “high degree of assurance” criteria under section 14 of the CPSA is not known.

About a third of firms (8 of 23) also have other product lines, which may cushion the impact of design changes and increased testing costs for sling carriers. These other products may be similar products, such as mei tais (a traditional Asian unstructured soft carrier falling under the SITC standard) or SITCs, or these other products may be completely unrelated juvenile products.

**Small Importers**

At this time, only one of the four importers identified is in compliance with F2907–12, F2907–13a or F2907–13b. Depending upon the costs of coming into compliance incurred by the importers’ suppliers and whether the importers’ suppliers are able to pass on the costs, the other three importers could experience a significant economic impact. Three of the four importers are owned by foreign parent companies that supply the importers’ slings. These parent companies must make the business decision to comply or to

discontinue U.S. operations. Two of the four importers could respond by simply discontinuing their sling product line altogether because these importers have varied product lines.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements. Consequently, these importers will experience the associated costs of compliance. The resulting costs could have a significant impact on these small importers.

As mentioned previously, four of the small domestic firms have unknown supply sources, and none of these supply sources has claimed compliance with any version of F2907. However, two firms have varied product lines and may be in a better position to comply without incurring significant economic impacts. The other two appear to be small firms specializing in slings, and therefore, these small firms may be impacted more heavily by compliance and testing costs.

**5. Alternatives**

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative would be to set an effective date later than 12 months. Setting a later effective date would reduce the economic impact on firms in two ways. First, firms would be less likely to experience a lapse in production, which could result if firms are unable to comply within the required timeframe. Second, firms could spread costs over a longer time period, thereby reducing their annual costs and the present value of their total costs. Given the large number of very small suppliers who potentially will experience significant economic impacts, a later effective date may warrant consideration. The Commission welcomes comments regarding an appropriate effective date.

**VII. Environmental Considerations**

The Commission’s regulations address whether we are required to prepare an environmental assessment or an

environmental impact statement. If our rule has “little or no potential for affecting the human environment,” our rule will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

**VIII. Paperwork Reduction Act**

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

*Title:* Safety Standard for Sling Carriers.

*Description:* The proposed rule would require each sling carrier to comply with ASTM F2907–14a, *Standard Consumer Safety Specification for Sling Carriers*. Sections 8 and 9 of ASTM F2907–14a contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

*Description of Respondents:* Persons who manufacture or import sling carriers.

*Estimated Burden:* We estimate the burden of this collection of information 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
1228	47	3	141	1	141

*Our estimates are based on the following:*

Section 8.1.1 of ASTM F2907–14a requires that the name and the place of business (city, state, mailing address, including zip code, or telephone

number) and Web site, if applicable, of the manufacturer, distributor, or seller be marked clearly and legibly on each product and its retail package. Section 8.1.2 of ASTM F2907–14a requires a code mark or other means that identifies

the date (month and year, as a minimum) of manufacture.

There are 47 known entities supplying sling carriers to the U.S. market. All 47 firms are assumed to use labels already on both their products

and their packaging, but the firms might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies an average of three different models of sling carrier; therefore, the estimated burden associated with labels is 1 hour per model  $\times$  47 entities  $\times$  3 models per entity = 141 hours. We estimate the hourly compensation for the time required to create and update labels is \$27.71 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," September 2013, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$3,907.11 (\$27.71 per hour  $\times$  141 hours = \$3,907.11). There are no operating, maintenance, or capital costs associated with the collection.

Section 9.1 of ASTM F2907-14a requires instructions to be supplied with the product. Sling carriers do not generally require assembly, but require instructions for proper use, fit, and adjustment on a caregiver's body, as well as maintenance, cleaning, and storage. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the 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" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because we are unaware of sling carriers that generally require some instructions for use, but lack any instructions to the user, we estimate tentatively that there are no burden hours associated with section 9.1 of ASTM F803-13 because any burden associated with supplying instructions with sling carriers would be "usual and customary" and would not be within the definition of "burden" under the OMB's regulations.

Based on this analysis, the proposed standard for sling carriers would impose a burden to industry of 141 hours, at an estimated cost of \$3,907.11 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by August 22, 2014, to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

#### IX. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury, unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as "consumer product safety rules." Therefore, the preemption provision of section 26(a) of the CPSA would apply to a rule issued under section 104.

#### X. Certification and Notice of Requirements (NOR)

The CPSA establishes certain requirements for product certification and testing. Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's

product is subject. *Id.* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1228, "Safety Standard for Sling Carriers," when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

To meet the requirement that the Commission issue an NOR for the sling carrier standard, the Commission proposes to amend an existing rule. The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as Part 1112). This rule took effect on June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section 14(a)(2) of the CPSA. The final rule also codifies all of the NORs that the CPSC had published to date. All new NORs, such as the sling carrier standard, require an amendment to part 1112. Accordingly, the proposed rule would amend part 1112 to include the sling carrier standard, along with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for sling carriers would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1228, *Safety Standard for Sling Carriers*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

As required by the RFA, staff conducted a final regulatory flexibility analysis (FRFA) when the Commission issued the part 1112 rule (78 FR 15836, 15855-58). Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse 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 that were 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.

Based on similar reasoning, amending the part 1112 rule to include the NOR for the sling carrier standard will not have a significant adverse impact on

small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the sling carrier standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the sling carrier standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the sling carrier standard will not have a significant impact on a substantial number of small entities.

**XI. Request for Comments**

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for sling carriers. We invite all interested persons to submit comments on any aspect of the proposed rule.

Comments should be submitted in accordance with the instructions in the ADDRESSES section at the beginning of this notice.

**List of Subjects**

*16 CFR Part 1112*

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

*16 CFR Part 1228*

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations 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)(39) to read as follows:

**§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?**

\* \* \* \* \*

(b)(39) 16 CFR part 1228, Safety Standard for Sling Carriers.

\* \* \* \* \*

■ 3. Add part 1228 to read as follows:

**PART 1228—SAFETY STANDARD FOR SLING CARRIERS**

Sec.

1228.1 Scope.

1228.2 Requirements for sling carriers.

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

**§ 1228.1 Scope.**

This part establishes a consumer product safety standard for sling carriers.

**§ 1228.2 Requirements for sling carriers.**

(a) Each sling carrier must comply with all applicable provisions of ASTM F2907–14a, Standard Consumer Safety Specification for Sling Carriers, approved on February 15, 2014. 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/cpsc.htm>. 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: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) [Reserved]

Dated: July 10, 2014.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2014–16792 Filed 7–22–14; 8:45 am]

**BILLING CODE 6355–01–P**

**DEPARTMENT OF ENERGY**

**Federal Energy Regulatory Commission**

**18 CFR Part 40**

[Docket No. RM14–15–000]

**Physical Security Reliability Standard**

**AGENCY:** Federal Energy Regulatory Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** Pursuant to the section regarding Electric Reliability of the Federal Power Act, the Federal Energy Regulatory Commission (Commission) proposes to approve Reliability Standard CIP–014–1 (Physical Security). The North American Electric Reliability Corporation, the Commission-certified Electric Reliability Organization, submitted the proposed Reliability Standard for Commission approval in response to a Commission order issued on March 7, 2014. The purpose of proposed Reliability Standard CIP–014–1 is to enhance physical security measures for the most critical Bulk-Power System facilities and thereby lessen the overall vulnerability of the Bulk-Power System against physical attacks. The Commission proposes to approve Reliability Standard CIP–014–1. In addition, the Commission proposes to direct NERC to develop two modifications to the physical security Reliability Standard and seeks comment on other issues.

**DATES:** Comments are due September 8, 2014. Reply comments are due September 22, 2014.

**ADDRESSES:** Comments, identified by docket number, may be filed in the following ways:

- *Electronic Filing through <http://www.ferc.gov/>:* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.
- *Mail/Hand Delivery:* Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

*Instructions:* For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document

**FOR FURTHER INFORMATION CONTACT:**

Regis Binder (Technical Information), Office of Electric Reliability, Division of Reliability Standards and Security, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (301) 665–1601, [Regis.Binder@ferc.gov](mailto:Regis.Binder@ferc.gov).  
Matthew Vlissides (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (202) 502–8408, [Matthew.Vlissides@ferc.gov](mailto:Matthew.Vlissides@ferc.gov).

**SUPPLEMENTARY INFORMATION:**

1. Pursuant to section 215 of the Federal Power Act (FPA), the