

Wednesday, October 21 9:00 am-10:30 am

210 Consumer Product Safety: Understanding and Avoiding the Pitfalls of the New Legislation and Regulations

Joe Beck

Partner, Consumer Product Safety Kilpatrick Stockton LLP

Christopher Fox

Vice President, Corporate Social Responsibility Hanesbrands Inc.

Alan Schoem

Senior Vice President
Marsh Risk Consulting Global Product Risk Practice

Joel Tennenberg

Litigation & Regulatory Counsel Toys "R" Us, Inc.

Faculty Biographies

Joe Beck

Joe Beck is a partner at Kilpatrick Stockton in Atlanta, where he concentrates on intellectual property litigation and product safety regulation issues. At Kilpatrick, Mr. Beck designed and helped quarterback one of the most successful recalls in Consumer Product Safety Commission ("CPSC") history involving an appliance that caused several deaths. As a result of this work, he was invited by the CPSC to make a presentation at the State Department to The U.S. Conference Board regarding recall techniques. At a subsequent public hearing in Washington, the vice chair of the CPSC referred to him as "one of the most knowledgeable persons in the country about consumer product recalls." Mr. Beck counsels a wide variety of clients regarding the new Consumer Product Safety Improvement Act.

Following active duty in the U.S. Army, he worked for Neighborhood Legal Services in Washington, DC before joining Kilpatrick Stockton in Atlanta.

Mr. Beck is an adjunct faculty member of the Emory University School of Law and has lectured at Harvard, Stanford and, at the request of the U.S. State Department, in Russia, India, Kosovo and Bosnia, among other countries. He is a former trustee at the Copyright Society of the USA and is on the board of directors of the Georgia First Amendment Foundation.

Mr. Beck received his BA from Emory University, his MA from George Washington University Law School and his JD from Harvard.

Christopher Fox

Christopher Fox is currently the associate general counsel and vice president of corporate social responsibility ("CSR") at Hanesbrands Inc. His current responsibilities include oversight of Hanesbrands Inc.'s worldwide CSR programs (environmental, safety, social compliance, and security) as well as Hanesbrands Inc.'s global business practices program.

Previous responsibilities included representation of Hanesbrands Inc.'s supply chain and asia business development groups. In this role, he worked and traveled extensively in India, China, and other parts of Southeast Asia. He has and continues to travel widely throughout Latin America and Asia.

Mr. Fox received his BA from the College of William and Mary and his JD/MBA from Wake Forest University.

Alan Schoem

Alan H. Schoem is a senior vice president in the global product risk practice within the risk consulting practice of Marsh in Washington, DC. This global practice specializes in providing professional consulting services for clients who encounter a product recall, product tampering, product contamination, product safety or liability issue. He works with companies on regulatory compliance, establishing procedures to conduct recalls, and minimizing risk and liability. While Mr. Schoem is primarily responsible for assisting clients who have Consumer Product Safety Commission-related issues, he also assists clients with automotive, food and other issues.

Prior to joining Marsh, Mr. Schoem served as director of the office of compliance at the U.S. Consumer Product Safety Commission (CPSC). Mr. Schoem also served at the CPSC in various capacities, including assistant general counsel for enforcement and director of the division of administrative litigation, which pursued recalls through litigation and pursued civil penalties for violations of commission rules and regulations. While at CPSC, Mr. Schoem helped create the CPSC's fast track product recall program under which firms expeditiously recall dangerous products without any government determination of hazard.

The ABA honored Mr. Schoem with the Mary C. Lawton Outstanding Government Service Award recognizing his efforts to facilitate recalls of hazardous products.

Mr. Schoem received a BA from the University of Maryland and a JD from the American University Law School in Washington, DC.

Joel Tennenberg

Joel S. Tennenberg is the litigation and regulatory counsel for Toys "R" Us, Inc., based in Wayne, New Jersey. His responsibilities include managing the company's commercial litigation and advising the company on various areas of regulatory compliance, including safety assurance, store operations, and marketing. Mr. Tennenberg led a cross-functional group within Toys "R" Us to address compliance with all aspects of the Consumer Product Safety Improvement Act of 2008.

Prior to joining Toys "R" Us, Mr. Tennenberg was an associate in the commercial litigation department at Anderson Kill & Olick, P.C. in New York City.

Mr. Tennenberg received his BA from Yeshiva University and is a graduate of the Benjamin N. Cardozo School of Law, Yeshiva University.



The CPSIA

- Enacted in reaction to the recalls of toys with lead paint and recalls of other children's products
- Imposes new requirements on all consumer products regulated by CPSC especially children's products
- · Gives CPSC new authority and additional resources
- Increases civil penalties to \$15 million and adds criminal penalties
- · Commission expanded to five members
- CPSIA is not risk-based
- The landscape has changed for all products regulated by CPSC

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Scope of the CPSIA

- Applies to ALL products regulated by the CPSC under all laws it enforces, i.e., CPSA, FHSA, FFA, PPPA and RSA.
- All products for which CPSC has issued mandatory safety standards or banning regulations must be tested and certified [Stay of enforcement until 2/10/10 for certain products].
- Children's Products must be tested by an accredited laboratory and be certified by the U.S. importer or domestic manufacturer [Stay of enforcement until 2/10/10 for certain products].

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CPSC's Approach to Interpreting and Enforcing the CPSIA

- Stays of Enforcement
- Lead Requirements
- Phthalate Requirements
- Tracking Labels

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Preemption

- Preexisting preemption provisions of the CPSA (15 USC § 2075), FHSA (15 USC §1261n), PPPA (15 USC § 1476) and FFA (15 USC § 1203) remain in effect and CPSC may not expand, contract, limit, modify or expand the scope
- CPSIA lead and phthalate restrictions preempt state law
- Prop 65 is not preempted-15 USC § 2075(b)

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Role of State Attorney Generals in Enforcing the CPSIA (Section 218)

- Pre CPSIA: Any interested person could sue to enforce a safety standard or banning regulation issued under the CPSA or an order under the CPSA (15 USC § 2073(a)
- **CPSIA:** State AGs may seek injunctive relief on behalf of their residents, among other things, to enjoin the sale of
 - products that violate CPSC issued safety standards, rules or bans
 - certain recalled products as announced by the Commission
 - banned hazardous substances under the FHSA
 - children's products that have not been certified as tested by thirdparty laboratories (stay of enforcement until 2/10/10)
 - children's products that lack tracking labels
 - products with safety marks if the use of those marks is unauthorized.
 - violations of stockpiling restrictions
- Advance notice to CPSC required

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Whistleblower Protection (15 USC § 2087)

- Protection for employees of manufacturers, private labelers, distributors and retailers who
 - Provide, caused to be provided or are about to provide or cause to be provided to
 - The employer, federal government or state AG information relating to any violation or act or omission the employee reasonably believes to be a violation of any provision of any law enforced by the CPSC
 - Testified or is about to testify in a proceeding concerning a violation
 - Assisted or participated or is about to assist in participation of a proceeding
 - Objected to or refused to participate in any activity, policy, practice or task that the employee reasonably believes to be a violation of a law enforced by CPSC.
 - Employee has 180 days from discharge or alleged discrimination to file complaint with Secretary of Labor
 - Secretary of Labor has 60 days from complaint receipt to initiate an investigation

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Whistleblower Protection (15 USC § 2087)

- Complainant must make a prima facie showing that protected behavior was a contributing factor to an unfavorable personnel action or complaint is dismissed
- No investigation or other action if employer demonstrates, by clear and convincing evidence, that the employer would have taken the same unfavorable personnel action in the absence of that behavior.
- To find a violation, Secretary of Labor must find complainant demonstrated the protected behavior was a contributing factor to unfavorable personnel action.
- Frivolous or bad faith complaints up to \$1000 in attorney's fees

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Will/Should the CPSIA be Amended?

- Do Stays of Enforcement afford adequate protection?
- CPSIA restricts risk-based decisionmaking
- Unintended Consequences
- Is it too late?

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Flammability

- Always test fabric; in some instances we also test finished garments.
- A new fabric cannot be adopted for use in our garments unless it is a Class 1.
- HBI testing policy requires that all fabrics we use are tested appropriately, even those fabrics that are exempt under the flammability laws. In addition we test every lot of our high cotton fleece.
- Continuing Guarantees

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Children's Products & Small Parts

- According to 16 CFR 1501.3(d) "children's clothing and accessories, such as shoelace holders and buttons" are exempt from small parts regulations – <u>BUT HBI TESTS ANYWAY</u>
- HBI Small Parts Testing Program (all kids garments sizes 0-18)
 - Design Stage
 - We try to "design-out" small parts hazards (either do not use them or make sure they are securely fastened
 - <u>DESIGN HAZARD ANALYSIS</u> identify all small parts (as defined in the Hazardous Substance Act) and identify any other product safety issues for all children's products.
 - <u>TEST TO FAILURE</u> all small parts (as defined in the Hazardous Substance Act) are subjected to test to failure testing; a style cannot be adopted for manufacturing unless it passes our rigorous standards (well above government and customer requirements).
 - Top of Production the first garment(s) off the production line are tested; if it passes, production can continue; if not, the inspector must identify the issue and fix it and re-test successfully before proceeding with manufacturing.
 - Manufacturing Stage testing is required on a daily basis top ensure the parts are being sewn on/applied correctly

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Impact to a Manufacturer

- Huge volume of additional testing performed (XRF/Wet-Testing) for HBI this has meant testing for lead in substrate and paint/surface coating; for others it has included things such as sharp points and phthalates.
- 2. Certificates of Conformity
 - a) Need a "system" to:
 - a) house test data
 - b) validate style being shipped against test results to ensure we are shipping compliant product
 - c) store certificates which can be accessed by customers and government
- Tracking information on labels we had to change all label and packaging specs to accommodate the tracking information. This was most difficult on our tagless garments that are pad stamped.

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Certificate Tracking System

Design Stage	Pre-Production Stage	Top of Production ¹	Ship from Manufacturing Facility
Get Affidavit from parts supplier Test component parts	Test component parts from bulk production lots	• Test all styles we manufacture in garment form (lead substrate and lead paint for all kids garments) ²	•System will confirm there is a valid test(s) from TOP for each style number. Exception reports will be generated and email alerts will be sent if a style cannot be validated.

- 1 Top of Production (TOP) the first few garments for every style we manufacture are pulled from the line and must go through safety testing and quality testing.
- 2 Flammability testing is done on fabric prior to garment being manufactured. Those test results are reviewed at TOP to ensure all fabric used in garment is Class 1.

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Challenges for HBI

- Testing volume
- Multiple shipping and P.O. systems
- Lack of system that correlates manufacturing style numbers to selling style numbers – need to build it
- Not able to track component part numbers in system.
 Only able to track at garment style level because not all business units use the same software to build the product specification sheets.
- Expense
- Man hours

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Key CPSIA Standards

Lead in Surface Coatings	90ppm	ALL STANDARDS APPLY TO:
Lead in Substrate Materials	300ppm	1. NEW SHIPMENTS 2. CURRENT INVENTORY
Phthalates	0.1%	

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Communication with Vendors

- 1. Establishing new standards and requesting identification of non-compliant items.
- 2. Review of internal and laboratory data.
- 3. One-on-one discussions with vendors.

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Other Challenges

- 1. Definitional
 - Intended primarily for 12 and under (Lead)
 - What is a "toy"? (Phthalates)
- 2. Execution of Stop Sales and Disposition of Non-Compliant Goods
- 3. Mixed Inventory
- 4. Harmonization with State Laws

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Beyond February 10, 2009

- 1. <u>August 2009</u> Lead standards: 90 ppm surface coating; 300 ppm substrate.
- 2. <u>August 2009</u> Tracking labels for goods manufactured after 8/14/09.
- 3. <u>August 2009</u> Registration cards and manufacturer's customer database for certain juvenile items produced after 8/14/09.
- 3rd Party Testing and Certification Required now for lead in surface coating and certain other requirements/products; remainder delayed until 2/10/10.

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 Recalls of dangerous products – once consigned to the fine print in Consumer Reports – are making headlines these days.

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 Although toys have received much attention, the U.S. Consumer Product Safety Commission (the federal agency with the strongest enforcement powers and the broadest mandate) has jurisdiction over countless other "consumer products" ranging from household appliances and furniture to swimming pools, bicycles and adult exercise equipment.

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 The law requires detailed reports of defective products, and injuries, signed by the Chief Executive Officer of the manufacturer, importer, distributor or retailer.

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 It is the view of the CPSC that Congress intended to encourage widespread reporting of potential product hazards. Accordingly, the CPSC takes the position that companies must report if the product **could** "create a substantial risk of injury to the public." See generally 16 CFR Part 1115.

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 The regulations provide that the Chief Executive Officer of the subject firm should sign any written reports to the Commission under § 15(b) unless this responsibility has been delegated by filing a written delegation of authority with the Commission's Office of Compliance and Enforcement Division of Corrective Actions.

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 That same law empowers the CPSC to order recalls and refunds, assess millions of dollars in fines and, in the case of knowing and willful violations, seek imprisonment of officers and directors.

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 Indeed, the CPSC may fine a company millions of dollars merely for failing to notify the Commission "immediately" – defined as 16 days from the time the company knew or should have known that a "defect" in its products could create a substantial risk of serious injury.

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 The time limit is short because all information about a safety "defect" – whether the source is an internal quality control report or a phone call from a consumer – is ordinarily imputed to the CEO within five days.

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A CPSC mandated recall can:

- subject management to second guessing by federal officials;
- compromise a firm's ability to defend itself in the likely wave of product liability lawsuits; and
- 3. imperil insurance coverage.

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 And while most recalls traditionally have been "under the radar" and often unnoticed, that is changing: the new CPSIA and growing public anger over lax product safety, especially for imported products, have already resulted in negative publicity for many U.S. firms.

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 At a minimum, adverse publicity about safety can erode the value of trademarks and reduce consumer goodwill and sales.

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 Unlike new product introductions that often are announced months in advance and preceded with advertising campaigns and vendor and consumer incentives, product recalls typically blindside firms.

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 Because the CPSC has instant access to thousands of hospital emergency room reports (and often is notified of potential defects by plaintiff's attorneys, public interest groups and consumers themselves), manufacturers and distributors of products may be almost literally "the last to know" of alleged defects and resulting injuries.

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 Given the time pressure on CEO's to notify the federal government "immediately", the novel challenge of retrieving rather than selling products from consumers – literally, "reversing engines" - not to mention the need to defend multiple product liability law suits, negotiate (and sometimes litigate) with insurers, and manage public relations, even large public companies (think: Firestone Tire and the Ford Explorer) can be severely damaged by a recall; smaller firms do not always survive the ordeal.

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 Should it become necessary to institute a recall, a number of departments within a company may become involved, including quality control, shipping, inventory, risk management, engineering, design and public relations. Because of the legal issues involved and the need to facilitate accurate and candid communication through use of the attorney-client and work product privileges, the legal department, assisted by outside counsel with experience in this area of the law, should be involved in all aspects of a recall.

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 Firms can reduce both the likelihood of a recall and the attendant costs by comparatively simple advance planning. The supplemental article elaborates on the foregoing information in this PowerPoint, and then discusses how to plan for a recall.

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[Code of Federal Regulations]
[Title 16, Volume 2]
[Revised as of January 1, 2009]
From the U.S. Government Printing Office via GPO Access
[CITE: 16CFR1608]

[Page 609-612]

TITLE 16--COMMERCIAL PRACTICES

CHAPTER II -- CONSUMER PRODUCT SAFETY COMMISSION

PART 1608_GENERAL RULES AND REGULATIONS UNDER THE FLAMMABLE FABRICS ACT--Table of Contents

Sec.
1608.0 Scope.
1608.1 Terms defined.
1608.2 Form of separate guaranty.
1608.3 Continuing guaranties.
1608.4 Guaranties furnished by non-residents of the U.S. no bar to prosecution.
1608.5 Salvage operations of common carriers and others.
1608.6 Reference to guaranty by Government prohibited.

Authority: Sec. 5, 67 Stat. 112, as amended, 81 Stat. 570, 15 U.S.C. 1194.

Source: 40 FR 59887, Dec. 30, 1975, unless otherwise noted.

Sec. 1608.0 Scope:

The rules and regulations in this part are applicable to all standards issued under the Flammable Fabrics Act.

Sec. 1608.1 Terms defined.

As used in the rules and regulations in this subchapter D, unless the context otherwise specifically requires:

- (a) The term act means the Flammable Fabrics Act, sec. 1 et seq., 67 Stat. 111-115, as amended, 68 Stat. 770, 81 Stat. 568-74 (15 U.S.C. 1191-1204, note under 1191).
- (b) The terms rule, rules, regulations, and rules and regulations, mean the rules and regulations prescribed by the Commission pursuant to section S(c) of the act.
- (c) The term United States means, the several States, the District of Columbia, the Commonwealth of Puerto Rico and the Territories and Possessions of the United States.
- (d) The terms marketing or handling means the transactions referred to in section 3 of the act.
- (e) The definition of terms contained in section 2 of the act shall be applicable also to such terms when used in rules promulgated under the act.

Sec. 1608.2 Form of separate guaranty.

The forms which follow are suggested forms of separate guaranties under section 8 of the act for use by guarantors residing in the United

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States. Representations contained in these suggested forms of separate guaranties with respect to reasonable and representative tests may be based upon a guaranty received and relied upon in good faith by the guarantor, tests performed by or for a guarantor, or class tests, where permitted under these rules. Where the forms are used as part of an invoice or other paper relating to the marketing or handling of products, fabrics, or related materials subject to the act, wording may be varied to limit the guaranty to specific items in such invoice or other paper. The name, address of the guarantor, and date on the invoice or other paper will suffice to meet the signature, address, and date requirements indicated on the forms.

(a) General form.

The undersigned hereby guarantees that reasonable and representative tests, made in accordance with procedures prescribed and applicable standards or regulations issued, amended, or continued in effect under the Flammable Fabrics Act, as amended, show that the product, fabric, or related material covered and identified by, and in the form delivered under this document conforms to the applicable standard or regulation issued, amended, or continued in effect.

Date:

Name____ Address

(b) Form for guaranty based on guaranty.

Based upon a guaranty received, the undersigned hereby guarantees that reasonable

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and representative tests, made in accordance with procedures prescribed pursuant to the Flammable Fabrics Act, as amended, show that the product, fabric, or related material covered and identified by, and in the form delivered under this document conforms to the applicable standard or regulation issued, amended, or continued in effect.

Date:

Name

Address

(Sec. 5 of the Act, 67 Stat. 112, as amended by 81 Stat. 570, 15 U.S.C. sec. 1194; sec. 8 of the Act, 67 Stat. 114, as amended by 81 Stat. 572, 15 U.S.C. sec. 1197)

Sec. 1608.3 Continuing guaranties.

(a) Any person residing in the United States may file with the Office of the Secretary of the Consumer Product Safety Commission a continuing guaranty under section 8 of the act applicable to any product, fabric, or related material marketed or handled by such person. When filed with the Commission, a continuing guaranty shall be fully executed in duplicate and execution of each copy shall be acknowledged before a notary public. Forms for use in preparing continuing guaranties to be filed with the Commission will be supplied by the Office of the Secretary of the Commission upon request. To remain in effect, such guaranties must be renewed every 3 years and at such other times as any change occurs in the legal business status of the person filing the guaranty. It is therefore required that any person who has filed a continuing guaranty with the Commission shall promptly advise the Commission in writing of any change in the legal status of the guarantor or in the address of the guarantor's principal office and place of business. Representations contained in the prescribed form of continuing guaranty with respect to reasonable and representative tests may be based upon (1) a guaranty received and relied upon in good faith by the guarantor, (2) tests performed by or for a guarantor, or (3) class tests, where permitted under these rules.

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(b) The following is the prescribed form of continuing guaranty for filing with the Commission: Continuing Guaranty Under the Flammable Fabrics Act for Filing With Consumer Products Safety Commission The undersigned, -----, a -----, a -----(Corporation, partnership, proprietorship) residing in the United States and having principal office and place of business at --------- (Street and number) -----, (City) ------, (State or territory, ZIP code) and being engaged in the marketing or handling of products, fabrics, or related materials subject to the Flammable Fabrics Act, as amended, and regulations thereunder, Hereby quarantee(s) that with regard to all the products, fabrics, or related materials [described as follows: _____1 (If guaranty is limited to certain products, fabrics, or related materials, list the general categories here. If guaranty is not so limited, leave these lines blank.) hereafter marketed or handled by the undersigned, and for which flammability standards have been issued, amended, or continued in effect under the Flammable Fabrics Act, as amended, reasonable and representative tests as prescribed by the Consumer Product Safety Commission have been performed, which shows that the products, fabrics, or related materials conform to such of the above-mentioned flammability standards as are applicable thereto. Dated, signed, and executed this ----- day of -----, 19----, at ------ (City), -----(State or Territory) (Name under which business is (Impression of corporate seal, if conducted.) corporation.) (If firm is a partnership list partners (Signature of proprietor, partner, or authorized official of corporation.) State of ----, ss: County of -----On this -----, 19----, before me personally appeared the said -----, (Signer of guaranty) proprietor, partner (strike nonapplicable words) -------- (If corporation, give title of signing official) of -----, (Firm name) to me personally known, and acknowledged the execution of the foregoing instrument on behalf of the firm, for the uses and purposes therein stated. [[Page 611]] (Impression of notary seal required Notary Public in and for County of ----- State here.) of ----- My commission expires (c) Any person who has a continuing guaranty on file with the

Page 3 of 5 of such fact by setting forth on the invoice or other paper covering the marketing or handling of the product, fabric, or related material quaranteed the following: Continuing guaranty under the Flammable Fabrics Act filed with the Consumer Product Safety Commission. Provided, however, That such statement may not be used where the quaranty is limited and the invoice or other paper covers any product, fabric, or related material, subject to a flammability standard under the act, which is not covered by the guaranty because of its limited nature. (d) Any person who falsely represents that he has a continuing quaranty on file with the Commission when such is not a fact, or who falsely represents that a limited continuing guaranty he does have on file with the Commission covers any product, fabric, or related material when such is not the case, shall be deemed to have furnished a false quaranty under section 8(b) of the act. (e) Any seller residing in the United States may give a continuing guaranty under section 8 of the act to a buyer applicable to any product, fabric, or related material sold or to be sold to said buyer by seller. All such continuing guaranties shall be fully executed in duplicate and execution of each copy shall be acknowledged before a notary public. To remain in effect, such guaranties must be renewed every 3 years and at such other times as any change occurs in the legal business status of the person giving the guaranty. Representations contained in the prescribed form of continuing guaranty from seller to buyer with respect to reasonable and representative tests may be based upon: (1) A quaranty received and relied upon in good faith by the guarantor, (2) tests performed by or for a guarantor, or (3) class tests, where permitted under these rules. (f) The following is the prescribed form of continuing guaranty from seller to buyer: Continuing Guaranty From Seller to Buyer Under the Flammable Fabrics Act The undersigned, (Corporation, partnership, proprietorship) residing in the United States and having its principal office and place of business at ----------, -------, (Street and number) ------(City), ----- (State or Territory and ZIP code), and being engaged in the marketing or handling of products, fabrics, or related materials subject to the Flammable Fabrics Act, as amended, and Regulations thereunder, Hereby guarantee(s) to ----- (Name and address), buyer, that with regard to all the products, fabrics, or related materials [described as follows: ----- (If guaranty is limited to certain products, fabrics, or related materials, list the general categories here. If guaranty is not so limited, leave these lines blank.) hereafter sold or to be sold to buyer by the undersigned, and for which flammability standards have been issued, amended, or continued in effect under the Flammable Fabrics Act, as amended, reasonable and representative tests as prescribed by the Consumer Product Safety Commission have been performed show that the products,

fabrics, or related materials, at the time of their shipment or delivery by the undersigned, conform to such of the above-mentioned flammability

Dated, signed, and executed this ------ day of ------- 19---, at ----- (State

(Name under which business is

conducted.)

standards as are applicable thereto.

(Impression of corporate seal, if

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or Territory).

corporation.)

Commission may, during the effective period of the guaranty, give notice

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the execution of the foregoing instrument on behalf of the firm, for the uses and purposes therein stated.

(Impression of notary seal required here.)

Notary Public in and for County of ------, State of ------ My commission expires

(Sec. 5 of the Act, 67 Stat. 112, as amended by 81 Stat. 570, 15 U.S.C. 1194: section 8 of the Act 67 Stat. 114, as amended by 81 Stat. 572, 15 U.S.C. 1197)

[40 FR 59887, Dec. 30, 1975, as amended at 52 FR 48810, Dec. 28, 1987]

Sec. 1608.4 Guaranties furnished by nonresidents of the U.S. no bar to prosecution.

A guaranty furnished under section 8 of the act by a person who is not a resident of the United States may not be relied upon as a bar to prosecution under section 7 of the act for a violation of section 3 of the act.

Sec. 1608.5 Salvage operations of common carriers and others.

For the purposes of this act the ordinary course of business of common carriers, contract carriers or freight forwarders, as referred to in section 11 of the act, shall not include the marketing or handling of products, fabrics, or related materials subject to the act in the course of performance of salvage or lien realizing operations.

Sec. 1608.6 Reference to guaranty by Government prohibited.

No representation nor suggestion shall be made in advertising or otherwise marketing or handling products, fabrics or related materials subject to the act that the act, the Government, or any branch thereof, guarantees, in any manner that such product, fabric, or related material conforms to a flammability standard in effect under the act.



BALLOT VOTE SHEET DATE: AUS - \$ 2009 TO: The Commission Todd A. Stevenson, Secretary THROUGH: Cheryl A. Falvey, General Counsel CAF Maruta Budetti, Executive Director MyB FROM: Philip Chao, Assistant General Counsel Hyun S. Kim, Attorney, OGC # ... SUBJECT: Children's Products Containing Lead; Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule AU6 13 2009 **Ballot Vote Due:** Attached is a draft final rule for publication in the Federal Register on determinations regarding certain materials or products that do not exceed the lead content limits under section 101(a) of the Consumer Product Safety Improvement Act (CPSIA) and accompanying staff memoranda. Please indicate your vote on the following options. Approve publication of the draft final rule in the Federal Register without change. (Signature) (Date) Do not approve publication of the draft final rule in the Federal Register. (Signature) (Date) CPSC Hotline: 1-800-638-CPSC(2772) * CPSC's Web Site: http://www.cpsc.gov Note: This document has not been EXCEPTED BY: PETITION
RULEMAKING ADMIN, PRCDG reviewed or accepted by the Commission Initials Date --- WITH PORTIONS REMOVED:

(Signature)	(Date)
Take other action. (Please specify.)	
(Signature)	(Datc)

Attachments:

Draft FR Notice: Children's Product Containing Lead; Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule

Memorandum from Kristina M. Hatlelid and Robert J. Howell, "Consumer Product Safety Improvement Act of 2008 (CPSIA) -- Determination of Lead Content for Certain Products and Materials," August 2009.

Memorandum from Kristina M. Hatlelid to Mary Ann Danello, "Response to Public Comments: Determinations," August 2009.

CPSC Memorandum from Allyson Tenney to Kristina Hatlelid, "Textiles and Apparel Subject to the CPSIA," June 5, 2009.

Memorandum from Mark F. Gill to Kristina M. Hatlelid, "Results of Research on Lead Content in Slate," July 22 2009.

Memorandum from Joel Recht to Kristina Hatlelid, "Lead in Paper," July 2009.

Memorandum from Randy Butturini to Kristina M. Hatlelid, "Lead in Stainless Steel and Titanium Alloys," June 3, 2009.

Memorandum from Robert Franklin to Kristina Hatlelid, "Final regulatory analysis of a rule making determinations that certain materials or products do not have lead contents that exceed the limits established in section 101(a) of the CPSIA," July 2009.

[Billing Code 6335-01]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Children's Products Containing Lead; Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule

SUMMARY: The Consumer Product Safety Commission (Commission) is issuing a final rule on determinations that certain materials do not exceed the lead content limits specified under section 101(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314.

DATE: Effective Date: This regulation becomes effective on [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H.,
Directorate for Health Sciences, Consumer Product Safety Commission, 4330 East West
Highway, Bethesda, Maryland 20814; telephone (301) 504-7254, e-mail
khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Under section 101(a) of CPSIA, consumer products designed or intended primarily for children 12 years old and younger that contain more than 600 ppm of lead (as of February 10, 2009); 300 ppm of lead (as of August 14, 2009); and 100 ppm after

three years (as of August 14, 2011), unless the Commission determines that it is not technologically feasible to have this lower limit, are considered to be banned hazardous substances under the Federal Hazardous Substances Act (FHSA). Products below these lead content limits are not banned; however, in the absence of Commission action, these products and materials used to make children's products remain subject to the lead limits and consequently, the testing requirements of certain provisions of section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA. By this rule, the products and materials determined by Commission to fall under the lead content limits, are no longer subject to section 101(a) of the CPSIA and no testing of these products and materials is required under section 102(a) of the CPSIA.

B. Statutory Authority

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. The Commission has the authority under section 3 of the CPSIA to make determinations that certain commodities or classes of materials or products do not, and, by their nature, will not exceed the lead limits prescribed in section 101(a) of the CPSIA. Accordingly, in this rule, the Commission has determined that certain products or materials inherently do not contain lead or contain lead at levels that do not exceed the lead content limits under section

101(a) of the CPSIA. The effect of such a Commission determination would be to relieve the material or product from the testing requirement of section 102 of the CPSIA for purposes of supporting the required certification. However, if the material or product changes such that it exceeds the lead limits of section 101(a), then the determination is not applicable to that material or product. The changed or altered material or product must then meet the statutory lead level requirements. The Commission intends to obtain and test products in the marketplace to assure that products comply with the CPSIA lead limits and will take appropriate enforcement action if it finds a product to have lead levels exceeding those allowed by law.

C. Notice of Proposed Rulemaking

In the FEDERAL REGISTER of January 15, 2009 (74 FR 2433), the Commission issued a notice of proposed rulemaking on preliminary determinations that certain natural materials do not exceed the lead content limits under section 101(a) of the CPSIA. The preliminary determinations were based on materials that are untreated and unadulterated with respect to the addition of materials or chemicals, including pigments, dyes, coatings, finishes or any other substance, and that did not undergo any processing that could result in the addition of lead into the product or material. These materials included:

- Precious gemstones (diamond, ruby, sapphire, emerald);
- Certain semiprecious gemstones provided that the mineral or material is
 not based on lead or lead compounds and is not associated in nature with
 any mineral that is based on lead or lead compounds (minerals that contain
 lead or are associated in nature with minerals that contain lead include, but

¹ Currently, there is a stay of enforcement of testing and certification requirements of certain provisions of subsection 14(a) of the CPSA, as amended by section 102(a) of the CPSIA until February 10, 2010 (see 74 FR 6936 (February 9, 2009)). The stay does not cover those requirements where testing and certification was required by subsection 14(a) of the CPSA before the CPSIA's enactment, and third party testing and certification requirements for lead paint, full-size and non-full size cribs and pacifiers, small parts, metal components of children's metal jewelry, certifications expressly required by CPSC regulations, certifications required under the Virginia Graeme Baker Pool and Spa Safety Act, certifications of compliance required for All-Terrain Vehicles in section 42(a)(2) of the CPSA, and any voluntary guarantees provided for in the Flammable Fabrics Act.

are not limited to, the following: aragonite, bayldonite, boleite, cerussite, crocoite, linarite, mimetite, phosgenite, vanadinite, and wulfenite);.

- · Natural or cultured pearls;
- Wood;
- · Natural fibers (such as cotton, silk, wool, hemp, flax, linen); and
- Other natural materials including coral, amber, feathers, fur, untreated
 leather.

See 74 FR at 2435.

In addition, in the proposed rule, the Commission preliminarily determined that certain metals and alloys did not exceed the lead content limits under section 101(a) of the CPSIA provided that no lead or lead-containing metal is intentionally added. The metals and alloys considered included surgical steel, precious metals such as gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium. (See 74 FR at 2435). The preliminary determinations did not extend to the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications.

D. Discussion of Comments to the Proposed Rule

The proposed rule generated several hundred comments from a diverse range of interests, including advocacy groups, consumer groups, a State's attorney general's office, and small businesses including crafters. No comment opposed the proposed determinations, and, therefore, the final rule retains those determinations. The proposed rule considered those initial determinations in the context of whether the lead limits of such materials would exceed 600 ppm and 300 ppm.

After reviewing the comments and additional data submitted, the Commission further evaluated those materials in the context of whether these materials would exceed 100 ppm, and finds that, for the reasons discussed in the preamble, that such materials would not exceed 100 ppm. Accordingly, the final rule revises the language in former §§ 1500.91(c) and (d) (renumbered as §§ 1500.91(d) and (e)) to remove references to 600 ppm and 300 ppm, and includes a reference to "lead content limits" to reflect that the determinations made in the final rule also fall below 100 ppm for such materials. Most comments sought to add to the list of materials; accordingly, the preamble to this final rule will focus on those comments suggesting additions to the list and also describe the changes made to the final rule as a result of those comments.

After review of the comments and data comments submitted, the Commission has determined that some materials that fall below the lead content limits may be manufactured or man-made. Accordingly, we have revised proposed § 1500.91(c) (renumbered as § 1500.91(d)) to remove the word "natural" before "materials."

Most comments requested that the Commission add other materials to the list of materials that the Commission determines are not expected to contain lead above the lead limits prescribed under section 101(a) of the CPSIA. However, most comments were not supported by specific data or other information relevant to the determinations of lead content of the materials, and so we did not have a sufficient evidentiary basis to determine whether those materials would not be expected to contain lead above the statutory limits. For determinations on a specific material or product, a party must submit an application that provides the information requested under the rule on procedures and requirements for a Commission determination or exclusion (see 74 FR 10475 (March 11,

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2009)), including objectively reasonable and representative test results and other evidence showing that the product or material does not, and would not, exceed the lead content limits.

In other cases, the comments did provide test data and other information relevant to this proceeding, and those comments are addressed in part D.1 through D.15 of this preamble below.

1. Compliance with section 101(a) of the CPSIA.

Several commenters generally supported the reduction of potentially repetitive and wasteful testing of products and materials that are not expected to contain lead, but they stressed that the Commission should proceed carefully to ensure that the requirements of the law are met. The commenters asserted that the Commission should not only request data from firms, but should test children's products itself, especially those products that have not, to date, been subject to lead content requirements or testing for lead content. One commenter also stated that the final rule should make clear that materials that the Commission determines do not contain excess lead levels must still comply with the statutory lead content standard.

The Commission has already indicated that it intends that all children's products subject to a determination must still comply with the lead limit in its "Statement of Commission Enforcement Policy on Section 101 Lead Limits," dated February 6, 2009 (available on the CPSC's website at http://www.cpsc.gov/about/cpsia/101lead.pdf). However, the Commission agrees with the comments that the final rule should remind interested parties of their obligation to comply with the lead limits even if their products

are the subject of a determination, and so we have amended the final rule to create a new
§ 1500.91(c) (and renumbering the remaining paragraphs accordingly) stating that:

A determination by the Commission under paragraph (b) of this section that a material or product does not contain lead levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable, does not relieve the material or product from complying with the applicable lead limit as provided under paragraph (a) of this section if the product or material is changed or altered so that it exceeds the lead content limits.

In addition, the Commission has in place procedures and requirements for a Commission determination that a specific material or product, contains no lead or a lead level below the applicable statutory limit (see 74 FR 10475). Among other things, any request must be supported by objectively reasonable and representative test results or other evidence showing that the product or materials does not, and would not, exceed the lead limit specified in the request. 74 FR at 10477.

As for compliance with the statutory limits, compliance and enforcement activities, including market testing, have always been and continue to be essential to the Commission's mission. Moreover, even when a particular product or material has been relieved of the testing and certification requirements under section 102 of the CPSIA, manufacturers and importers remain responsible for verifying that the material or product has not been altered or modified, or experienced any change in the processing, facility or supplier conditions that could impart lead into the material or product to ensure that it meets the statutory lead levels at all times.

2. Plant and animal based materials.

Many commenters asserted that there are many natural, plant or animal-based materials that likely do not contain appreciable lead content and should be suitable for use in children's products without testing for lead content. Materials mentioned include plants in general, and specifically bark, leaves, flowers and flower petals, seeds, cones, loofa, rattan, wicker, bamboo, bamboo fiber, plant-based dyes, nut shells, buckwheat hulls, essential plant oils, lavender, witch hazel, jute, kapok, kenaf, ramie, sisal, hemp, agave, coconut, soy, moss, straw, jojoba oil, and tung oil. Animal-based materials that were mentioned included yak, angora, mohair, llama, alpaca, bison, camel, guanaco, cashmere, horse hair, claws, hom, seashells, bone, animal glue, shellac.

Our review showed that plant and animal-based materials generally do not contain lead at levels that exceed the CPSIA lead limits. However, we find that any determinations made regarding plant and animal-based materials must be confined to those materials that are unadulterated by the addition of chemicals and materials (such as paints and similar surface-coating materials, as discussed further in part D.7 of this preamble) since such treatments or additions may not comply with the lead limits without further testing. Although most materials identified in the comments were not specifically included in the proposed rule, the proposed determinations included three categories of natural materials with examples that are similar to many of these items (i.e., wood; natural fibers, including cotton, silk, wool, hemp, flax, and linen; other natural materials including coral, amber, feathers, fur, and untreated leather). Accordingly, the final rule includes other materials, such as plant and animal-based materials that have not been adulterated or modified as a new § 1500.91(d)(8). Specifically, the new provision covers

"other plant-derived and animal-derived materials, including, but not limited to, animal glue, bee's wax, seeds, nut shells, flowers, bone, sea shell, coral, amber, feathers, fur, leather." Leather is discussed further in part D.13(c) of this preamble.

3. Foodstuffs.

Some commenters stated that foodstuffs or materials suitable in food uses may be used in making children's products and should be determined to comply with lead limits given that they are largely natural plant or animal based materials and are considered edible or safe for use by consumers. Some materials mentioned included vegetable and nut oils, medicinal-grade mineral oil, table salt, flax seed, food coloring, food preservatives, cream of tartar, grain flours, dried beans, dried corn, millet, herbs, cherry pits, rice, seeds, milk, honey, bee's wax, candelilla wax, and carnauba wax.

In general, articles that fall within the statutory definition of "food" under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321et seq.) are excluded from the definition of "consumer product" under the Consumer Product Safety Act (CPSA). 15 U.S.C. 2052(a)(5)(I). Section 321(f) of the FFDCA defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Section 402(a)(1) of the FFDCA provides that a food is deemed to be adulterated if it contains any poisonous or deleterious substances, such as chemical contaminants, which may or ordinarily render it harmful to health. Under this provision and other provisions in the FFDCA, the Food and Drug Administration (FDA) oversees the safety of much of the food supply. Accordingly, the Commission will not make determinations on lead content limits for foods used in consumer products. However, to the extent that there are materials available to

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manufacturers, such as bee's wax, that are sometimes sold as food, but that are not always sold in a form intended for consumption, the Commission will treat such products as other natural materials if they are unadulterated and have not been treated with lead-containing material, and new § 1500.91(d)(8) specifically identifies some of those products, such as bee's wax.

4. Cosmetics.

. A few commenters suggested that determinations be made for soaps, lotions and dental floss.

In general, articles that fall within the statutory definition of "cosmetic" or "device" under the FFDCA (21 U.S.C. 321et seq.) are excluded from the definition of "consumer product." 15 U.S.C. 2052(a)(5)(H). Soaps and lotions are considered cosmetics under the FFDCA as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance." 21 U.S.C. 321 (i). Dental floss is considered a "device" under the FFDCA because it is "an instrument, apparatus, implement, machine, contrivance, implant ... intended to affect the structure or any function of the body of man..." or, alternatively, is intended for use in the mitigation or prevention of disease. 21 U.S.C. 321 (h). Products and materials that are not consumer products under the Commission's jurisdiction are not subject to section 101(a) of the CPSIA, and testing of these products and materials are not required under section 102(a) of the CPSIA. Such cosmetics and devices would, instead, be subject to the requirements of the FFDCA.

5. Glues and Adhesives.

A number of commenters sought determinations for glues and adhesives. Certain glues are made entirely from natural materials, such as animal glue. Accordingly, animal glue has been added under new § 1500.91(d)(8). However, we did not receive specific data regarding specific formulations of individual glues and adhesives; therefore we cannot make determination regarding the entire category of glues and adhesives that may be available in the marketplace. However, we believe that in most instances, glues and adhesives will be inaccessible to children.

The Commission has issued a final interpretative rule on inaccessibility (inaccessibility rule) which finds that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities and the aging of the product. This rule is available at http://www.cpsc.gov/about/cpsia/cpsia.html, and will be published in the FEDERAL REGISTER. In the inaccessibility rule, the Commission provided that accessibility probes specified for sharp points or edges at 16 CFR 1500.48 through 1500.49 should be used to determine whether a lead-containing component can be contacted by a child. In addition, the inaccessibility rule provides that the use and abuse tests specified in 16 CFR 1500.50 through 1500.53 should be used to assess the accessibility of lead-component parts during normal and reasonably foresecable use and abuse of a product by a child. However, paint, coatings or electroplating may not be considered a barrier that would render lead in the substrate to be inaccessible to a child.

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Most glues and adhesive are used to affix decorations and ornamentation to products or to secure sections of fabric, leather, wood, paper and other materials. In most instances, the glue or adhesive is usually not physically exposed because the materials covering the glue or adhesive serve as barrier to the underlying glue or adhesive. For instance, a children's book is bound with adhesives, but the adhesive is not accessible because the spine is covered with paper, cloth, leather, or other materials, and would not become physically exposed through reasonably foreseeable use and abuse of the product. As set forth in the inaccessibility rule, manufacturers of children's product should use the Commission accessibility probes specified for sharp points or edges at 16 CFR 1500.48 through 1500.49, and the use and abuse tests specified in 16 CFR 1500.50 through 1500.53 to determine whether glue or adhesives, or other components, would be accessible to children.

6. Composite wood products.

Several commenters stated that wood is not expected to contain lead while other commenters asked us to expand the determination to include related products, such as composite wood constructed of wood, adhesives, and other materials.

The commenters did not provide sufficient test data or other information to enable us to assess whether the lead content of manufactured wood products that contain various non-wood materials would fall under the lead content limits prescribed by the CPSIA. A request for a Commission determination for materials that fall under the lead content limits of the CPSIA must provide data and other information requested under the rule on procedures and requirements for a Commission determination or exclusion (see 74 FR 10475). Accordingly, although the final rule does not include composite wood products,

a request for a specific materials determination may be submitted to the Commission, consistent with those requirements.

7. Certain finishes.

Several commenters requested that water based paints, acrylic paints, water based clear finishes, varnishes, lacquers, and milk paint be determined to comply with the lead content limits.

We decline to revise the rule as suggested by the comments. The Commission has long-standing regulations on paint and similar surface coatings at 16 CFR part 1303. Section 101(f) of the CPSIA imposed an even stricter lead limit for paint and similar surface coatings from 600 ppm total lead by weight to 90 ppm total lead by weight as of August 14, 2009. Because of the well-documented danger to children from contact with lead-containing paints and similar surface coatings and past instances of children's products bearing lead-containing paints or coatings despite regulations prohibiting the practice, such materials must be tested to show their compliance with the regulations, and we have revised proposed § 1500.91(a) to include the following: "Materials used in products intended primarily for children 12 and younger that are treated or coated with paint or similar surface-coating materials that are subject to 16 CFR part 1303, must comply with the requirements for lead paint under section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA."

8. Other metals including titanium, aluminum, pewter, copper.

Some commenters requested that certain other metals, including stainless steel, titanium, aluminum, pewter and copper be added to the list of determinations.

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We agree, in part, with the commenters that stainless steel (with the exception of one stainless steel alloy) and titanium should be added to the list of determinations.

Stainless steel is a generic name for corrosion-resistant steel alloys. Typically, the manufacturing process for stainless steel uses recycled scrap as well as "virgin" (newly refined) steel, yet the manufacturing process heats the steel to temperatures high enough to vaporize any lead and lead oxide present. Once the steel melts, the mix is subjected to a vacuum, and the lead/lead oxide gases are drawn off for condensation and recycling. Consequently, the manufacture of stainless steels results in alloys with lead concentrations less than 100 ppm.

However, we found that one stainless steel alloy, designated as 303Pb, does contain lead. The concentration of lead in 303Pb stainless steel is between 0.12% and 0.30% (1200 to 3000 ppm). The Unified Numbering System designation for 303Pb steel is S30360. Thus, 303Pb stainless steel is excluded from any determination for stainless steel. The Commission has revised proposed § 1500.91(d)(1) (now renumbered as § 1500.91(e)(1)) to add "other stainless steel within the designations of Unified Numbering System, UNS S13800 – S66286, not including the stainless steel designated as 303Pb (UNS S30360)."

Titanium (both α - and β -phase) uses elements such as aluminum, gallium, oxygen, nitrogen, molybdenum, vanadium, tungsten, tantalum, and silicon as alloying materials. Lead is considered an undesired impurity and is not found in titanium alloys. In over 300 titanium alloys examined, we did not find an instance where lead was a constituent. Consequently, the Commission has revised proposed § 1500.91(d)(2) (now

renumbered as § 1500.91(e)(2)) to add "titanium" to the list of determinations on precious metals.

As for other metals and alloys, including aluminum, copper and pewter, such metals and alloys may contain significant amounts of lead and we cannot verify that the specific products containing such metals or alloys comply with the lead content limits without testing. Accordingly, these other metals and alloys continue to be subject to the testing and certification requirements of section 102 of the CPSIA.

9. Other minerals and items found in the earth.

Several commenters stated that, in addition to certain precious and semiprecious gems, other minerals and items found in the earth, such as rocks or fossils, should be determined to contain lead below the lead content limits.

As with the precious gemstones and certain semi-precious stones that the Commission determines do not contain lead at levels that exceed the CPSIA lead content limits, other rocks and stones may comply with lead limits provided that they are not based on lead or lead compounds and are not associated in nature with any mineral that is based on lead or lead compounds. In general, we agree that most minerals do not contain lead.

However, some minerals are known to contain lead or are associated in nature with minerals than contain lead. We have previously identified minerals that can contain lead, such as aragonite, bayldonite, boleite, cerussite, croroite, linarite, mimetite, phosgenite, vanadinite, and wufenite. We have also identified galena, and will add this mineral to the list of lead containing minerals under section 1500.91(d)(2). Accordingly, these minerals are specifically excluded from the determinations regarding minerals

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generally, and would require testing if they are used in any children's products to assess whether they are under the lead content limits.

10. Ceramic glaze and clay.

A few commenters claimed that ceramic glazes and clays comply with lead limits.

We are aware that some products or materials used in ceramics production do not contain lead or use lead-free glazes, but others are known to contain lead at levels that exceed the CPSIA limits for lead content. Lead in ceramic ware typically comes from the varnish or glaze applied to give a shiny finish to the product. In addition, certain colorants used in decoration may contain lead pigments. Without the required testing of ceramic glazes and other materials, compliance with the lead content limits of the CPSIA cannot be verified for the myriad of products that are available. Moreover, in the Joint Conference Report, H.R. Rep. No. 110-787, the conferees stated under the section titled *Special Issues* that they "believe the Commission should take appropriate action with respect to lead included in any ceramic product within its jurisdiction." Conference Report on H.R. 4040, Consumer Product Safety Improvement Act of 2008, 154 Cong. Rec. H7214 (daily ed. July 29, 2008). Accordingly, for children's ceramic ware, until the Commission receives detailed information and test data regarding lead in ceramic ware, the Commission will continue to require the testing and certification requirements under section 102 of the CPSIA.

11. Glass, crystals, and rhinestones.

Several commenters listed glass, glass beads, rhinestones, leaded glass crystals, and porcelain enamel as items that should be exempted from compliance with the CPSIA requirements for lead content or testing.

While not all glass or glass products, crystals, or rhinestones contain lead at levels that exceed the CPSIA lead limits, in the absence of tests or other data on these products, we cannot verify that such products meet the CPSIA's lead content limits. Further, many leaded glass crystals and other glass-based products contain lead at levels exceeding the statutory limits and, therefore, cannot be included in a determination that they do not and would not contain lead. We also note that, on July 17, 2009, the Commission voted 2-1 to deny a request to exclude crystal and glass beads, including rhinestones and cubic zirconium, from the lead content limits. The Commissioners' statements accompanying that decision can be found at: http://www.cpsc.gov/about/cpsia/sect101.html#statements.

12. Pencils, crayons, other materials regulated as art materials.

Some commenters requested that certain art materials be determined to not contain lead at levels that exceed the CPSIA lead limits.

The CPSIA's requirements for lead content are in addition to other statutory and regulatory requirements for children's art materials. Compliance under the Labeling of Hazardous Art Materials Act (LHAMA) (15 U.S.C. 1277) requires the submission of art material product formulations to a toxicologist for review to assess chronic adverse health effects through customary or reasonably foreseeable use. If the toxicologist determines

that the art material has this potential, the producer or repackager must use cautionary labeling on the product in accordance with the requirements set forth at 16 CFR 1400.14(b)(8), and section 2(p) of the FHSA, 15 U.S.C. 1261(p). Any art material intended for children that is or contain a hazardous substance (by reason either of chronic or acute toxicity) would be a banned hazardous substance under section 2(q)(1)(A) of the FHSA, 15 U.S.C. 1261(q)(1)(A). Art supplies that are intended primarily for use by children must also comply with the lead content limits under section 101(a) of the CPSIA. Accordingly, without receiving more information and data regarding the lead content of specific art materials intended primarily for children, we are unable to make any determinations in this proceeding.

13. Fabrics, dyes and similar materials.

Numerous commenters claimed that many fabrics, yarns, batting, fill, and similar materials (such as ribbon), and related materials (such as elastic), including those that are dyed or similarly processed, do not contain lead. In addition, some commenters requested a determination that fabric dyes comply with the lead content limits. The commenters provided data and other information to support their claims. Additionally, during a public meeting held on January 22, 2009, industry representatives, test laboratories, and stakeholders met with CPSC staff and presented materials and test data on lead levels in textile and apparel products. Several hundred test reports and analyses were submitted. The tests analyzed lead levels in various textile and apparel products, including a range of daywear, sleepwear, and outerwear garments. Tests for lead were also conducted on the many functional and decorative components used on apparel items.

These items include adornments (rhinestones and beads), closures snaps, zippers), trims, and fasteners.

Information on the dye industry was also submitted by the Ecologica.

of Dye and Organic Pigment Manufacturers (ETAD). ETAD states that it represe about 80% of worldwide dye manufacturers. According to ETAD, 80% or more of dyes used in commercial processing are organic carbon compounds and do not contain lead. Dyes used for cotton, other cellulosics, and polyester, the most commonly used fibers for apparel, account for 70% of total dye consumption. According to ETAD, these fibers use specific dye classes (e.g., disperse, direct, reactive) that would not contain lead. ETAD also recommends that its member companies follow lead limits of 100 ppm using a sampling and testing procedure that ensures the recommended limits.

a. Textiles

We reviewed the data pertaining to textile products intended for children and the general practices used in the textile industry and the modern production and coloration of textiles and apparel. We conclude that most textile products are manufactured using processes that do not introduce lead or result in an end product that would not exceed the CPSIA's lead limits. Modern textile and apparel production practices are recognized and well-characterized. With a few uncommon exceptions, modern production practices do not involve lead or lead-based chemicals.

In general, textile materials and products do not contain lead and have not undergone any processing or treatment that imparts lead resulting in a total lead content that exceeds the CPSIA total lead limits. Accordingly, new § 1500.91(d) (7) adds "Textiles" to the list of determinations. Additionally, with respect to fibers from natural

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sources, we find that natural fibers are natural materials and do not contain lead, whether they are dyed or undyed. Examples of plant based fibers, from the seed, stem, or leaves of plants, include, but are not limited to, cotton, kapok, flax, linen, jute, ramie, hemp, kenaf, bamboo, coir, and sisal. Animal fibers, or natural protein fibers, include but are not limited to silk, wool (sheep), and hair fibers from alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, and guanaco. The final rule thus adds these natural fibers to § 1500.91(d)(7)(a) (formerly proposed § 1500.91(c)(5)).

We also reviewed information pertaining to fibers that are not obtained from natural sources and are classified as manufactured or man-made. Manufactured fibers are created by technology and are classified as regenerated, inorganic, or synthetic.

Regenerated fibers are made from natural materials that are reformed into usable fibers.

These fibers include, but are not limited to, rayon, azlon, lyocell, acctate, triacetate, and rubber. Synthetic fibers are polymers created through a chemical process and include but are not limited to polyester, olefin, nylon, acrylic, modacrylic, aramid, and spandex. The information we have indicates that manufactured fibers are produced in controlled environments by processes that do not use lead or incorporate lead at any time during their production, whether they are dyed or undyed. Consequently, we have added these manufactured fibers as a new § 1500.91(d)(7)(b); specifically, the new provision refers to "Manufactured fibers (dyed or undyed) including, but not limited to, rayon, axlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex."

b. Dyes

We also examined the dyes used on textiles. Dyes are organic chemicals that can be dissolved and made soluble in water or another carrier so they can penetrate into the fiber. Dyes can be used in solutions or as a paste for printing. Commercial dyes are classified by chemical composition or method of application. Many dyes are fiber specific. For example, disperse dyes are used for dyeing polyester, and direct dyes are used for cellulosic fibers. Dyes can be applied to textiles at the fiber, yarn, fabric, or finished product stage. Dye colorants are not lead based. Although not typical, some dye baths may contain lead. However, even if the dye bath contains lead, the colorant that is retained by the finished textile after the rinsing process would not contain lead above a non-detectable lead level.

In contrast to dyes, pigments are either organic or inorganic. Pigments are insoluble in water, are applied to the surface of textile materials, and are held there by a resinous binder. Binders used with pigments for textiles are non-lead based. Processes that are lead-based are used for some industrial textiles that require a greater level of colorfastness or durability, but are not typically intended for apparel textiles. Although most pigments do not contain lead, there may be some lead based paints and pigments on non-textile materials that may be directly incorporated into textile products or added to the surface of textiles, such as decals, transfers, and screen printing. All such non-textile components must be tested for lead content under section 102 of the CPSIA unless they are made entirely from materials that the Commission has determined would not contain lead in excess of the CPSIA lead limits. Since we are allowing the use of dyes and pigments on textile materials, we have revised proposed § 1500.91(c) (now renumbered as § 1500.91(d)) to remove "or chemicals such as pigments, dyes, coatings, finishes or

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any other substance, nor undergone any processing." However, we have excluded from "Textiles" under new paragraph § 1500.91(d)(7), any textiles that are "after-treatment applications, including screen prints, transfers, decals, or other prints."

c. Leather

Although leather is not made from fibers like most textiles, it may be used to produce apparel and coverings or may be used along with textile products. Leather begins as natural products, but they undergo processing (e.g., tanning) to convert the natural skin into a usable, durable product. Similar to most textile products, leather products are often colored with dyes or pigments during their processing. Many of the same dyes used in the textile industry also are used for dyeing leather. According to information submitted by the Leather Industries of America, many processes used to process and finish leather do not use lead or lead-based chemicals. However, many leather products may be finished with pigment-based coatings, including some that are colored using lead-based pigments. Currently, any children's leather product that has paint or a similar surface-coating material is subject to the lead paint ban at 16 CFR part 1303. Products that are finished with such coatings are subject to the testing and certification for lead paint under section 102 of the CPSIA. Section 1303.2 (Definitions) specifically provides that paint or other similar surface coating includes application on wood, stone, paper, leather, cloth, plastic or other surface. The treatment that could potentially impart lead onto leather is the application of leaded pigment onto the surface of the leather product. We deleted the term "untreated" before the word "leather" from former § 1500.91(c)(6), (now renumbered as § 1500.91(d)(8)) because, as discussed in part D.7 of this preamble, § 1500.91(a) makes explicit that the determinations do not

cover any material in a children's product that has paint or similar surface-coating materials subject to 16 CFR part 1303. Such materials and products must comply with the testing and certification requirements for lead paint under section 102 of the CPSIA.

d. Other comments

Several commenters, including the Organic Trade Association, stated that certifications based on standards such as the Global Organic Textile Standard (GOTS) and Oeko-Tex® should be allowed in place of testing for compliance with the CPSIA lead content requirements.

Because the Commission has determined that textiles fall under the lead content limits, the Commission will not require testing on textiles under section 102 of the CPSIA. However, even when a particular product or material has been relieved of the requirement to undergo testing and certification under section 102 of the CPSIA, manufacturers and importers are responsible for verifying that the material or product has not been altered or modified, or experienced any change in the processing, facility or supplier conditions that could impart lead into the material or product and ensure that the material or product meets the statutory lead levels at all times. With respect to the GOTS and Oeko-Tex® standards, we believe that certifications from GOTS and Oeko-Tex® would serve to provide such verifications for textiles. Both GOTS and Oeko-Tex® standards limit lead content in certain textile products to no more than 100 ppm lead.

14. Book Components

Several commenters, such as associations for the publishing, printing, and paper industries, and libraries, asked us to determine that "ordinary books" are within the CPSIA's lead content limits. The Association of American Publishers (AAP) defined

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"ordinary books" to mean paper-based, printed books that are designed or intended primarily for 12 years and younger. AAP states that it does not intend the term to include so-called "novelty" products such as, for example, plastic-based bath toys or teething products that are made to resemble books in shape and form, or books that have plastic, metal or electronic parts that are not part of the binding and with which children may be expected to interact. According to the commenters, ordinary books generally consist of papers, inks, coatings, adhesives, and bindings. We held two public meetings with representatives of these industries on January 22, 2009 and June 9, 2009 in Bethesda, Maryland.

Under section 101(a) of the CPSIA, the Commission is required to evaluate the lead content limit for any part of a product. Accordingly, we must assess whether each part of a children's book would contain lead over the lead content limits. Therefore, we reviewed comments, data, and other information regarding papers, inks, coatings, adhesives, and bindings to assess whether those components could contain lead over the lead content limits.

a. Pape

Several commenters stated that paper is derived from natural wood, which inherently has a *de minimis* level of total lead content, and that the primary components in the production of paper are wood fiber and water. They stated that lead-based chemicals are not introduced in the major phases of the paper manufacturing process (*i.e.*, wood preparation/pulping; bleaching/refining; running of the paper machine; and finishing processes, including coating).

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After review of the test data and other information submitted by the commenters, we have determined that paper and similar cellulosic materials do not contain lead in excess of the CPSIA's lead content limits. Paper products include paper, paperboard, linerboard and medium, and pulp. Paper is predominantly made from wood, but also may be made with other cellulosic fibers. For tinting and coloring of fibers, dyes are most commonly used. Dyes, especially basic dyes and direct dyes, are relatively inexpensive and widely available and used in easily processed forms which are highly substantive to fiber and produce a uniform color or shade and which can be varied easily to achieve whatever shades are needed. Pigments, particularly inorganic pigments, are comparatively expensive and difficult to use due to their density. Complex chemistry must be added to get the pigments to retain the pigments with the fibers and not have them drain out. The comparative expense and difficulty involved in the use of inorganic pigments for coloration limits their use to highly-specialized grades of paper, such as for laminate counterton and flooring applications where the decorative layer must be lightfast, durable, and be able to withstand the heat and chemical conditions of the resinimpregnation stage to convert layers of paper into a countertop, such as Formica®. Such specialty papers are not expected to be used for ordinary printing and writing purposes. As with the fibers and textiles, paper and similar cellulosic materials, including the dyes and treatments used to make them, are not expected to contain lead above the CPSIA lead limits. Accordingly, we have added paper and similar materials made from wood or other cellulosic fiber, including, but not limited to, paperboard, linerboard, and medium to a new § 1500.91(d)(5).

b. Printing Inks and Coatings

The commenters noted that, in theory, lead pigments can be used in any printing process; however, in practice, lead has been eliminated from all but a few limited applications such as outdoor signage, labels used in harsh environments, or other applications where the product's ability to withstand the weather is a critical factor. The commenters stated that, as a practical matter, lead-based or lead-containing inks are not used in modern printing processes. They explained that the regulations promulgated under the Resource Conservation and Recovery Act of 1976 (RCRA) (40 CFR part 261.24) require that any waste, include printing ink, which contains lead in an amount exceeding five (5) ppm must be treated as hazardous waste. They also pointed to regulations promulgated under the Occupation Safety and Health Act (OSHA) (29 CFR 1910.1025) which requires workplaces in which lead is used to maintain five (5) micrograms/cubic meter or less permissible exposure limits in workplace air environments, as well as the Coalition of Northeastern Governors (CONEG) standard, known as the Model Toxics in Packaging Legislation which has been adopted as packaging regulations by 19 states and the European Union, as factors discouraging the use of lead-based and lead-containing inks in "ordinary" books. Specifically, they stated that the CONEG standard was designed to phase out the use and presence of mercury. lead, cadmium, and hexavalent chromium in packaging and packaging materials and prescribes combined limits for all four of these heavy metals that are lower than the CPSIA's lead content limits. According to the commenters, the CONEG standard has been widely adopted by the children's book publishing industry.

The commenters also stated that lead-based pigments are not compatible with the four-color process. This process, commonly called CMYK, uses transparent eyan (C), magenta (M), and yellow (Y) inks, in addition to black ink, to create a wide range of colors. The comments indicated that lead could be used in "spot colors" and described several lead-based pigments, but claimed that the use of the lead pigments is not current practice because of safety and environmental concerns. The commenters also explained that the types of printing inks that might contain lead, such as for screen-printing and for certain processes for printing on plastic or other non-paper materials, are specifically designed for those purposes and cannot be used for printing children's paper-based books and similar paper-based materials because different printing processes require different ink systems.

We evaluated printing inks, which are distinct from the dyes used to color paper and textiles. Data and information provided in response to the notice of proposed rulemaking, at CPSC public meetings with members of the publishing and printing industries (January 22, 2009; June 9, 2009), and in written materials following those public meetings indicate that the use of lead in printing inks has largely been eliminated, except for certain inks formulated for use in printing on materials such as plastic or fabric, including screen printing. Lead-based pigments are not compatible with the four-color process (and variations of this process, such as those that add colors or diluted colors to the system to improve the quality of images printed using CMYK). Lead would not be found in paper or similar paper-based materials printed using only the CMYK processes. We confirmed that transparent pigments or dyes are used in CMYK process inks and that leaded pigments, which are opaque, are not compatible with "process inks."

Accordingly, we added to the list of determinations printing inks that use the CMYK process under a new § 1500.91(d)(6).

On the other hand, lead-based inks may be used for spot colors, including spot colors used in conjunction with the CMYK process (sometimes referred to as CMYK plus spot). Spot colors are only used when a specific color cannot be reproduced with the CMYK process colors; however, unlike CMYK process colors, spot colors may contain leaded pigments. Accordingly, new § 1500.91(d)(6) specifies that spot colors, other inks that are not used in the CMYK process, and inks that do not become part of the substrate under 16 CFR part 1303 are excluded from the determinations. Inks that do not become part of the substrate are considered to be paints or similar surface-coating material under 16 C.F.R. part 1303 and currently require certification based on third-party testing by an accredited laboratory.

In addition, as discussed in part D.13 of this preamble, we have found that certain after-treatments, including screen printing, may use leaded pigments. Accordingly, inks used in any after-treatments for decals, transfers, and other prints also will be excluded under new § 1500.91(d) (6). Other additional treatments such as or laminators or laminations, including plastic sheet or film, or other coatings, would continue to require testing and certification under section 102 of the CPISA if such products are plastic component parts or a paint or similar surface-coating material under 16 CFR part 1303.

c. Adhesives and Binding Materials

Some commenters stated that the post-press step involves folding, cutting and binding of collated sections into a finished product. According to the commenters, the binding can be done either mechanically or chemically with hot-melt or cold glue

adhesives, sewing them with polyester or cotton threads, saddle stitching them with wire or stapling, or punching holes for use with spiral wires.

As discussed in part D.5 of this preamble, we find that most adhesives in books would not require testing and certification under section 102 of the CPSIA. We have determined that animal glues and threads would not contain lead above the lead content limits. In addition, most adhesives used in children's products, including children's books, would not be accessible under the guidance provided by the Commission in the inaccessibility rule. To the extent that any such adhesive is not covered in the determinations and is accessible, (i.e. not covered by any other material), it, too, would be subject to the testing and certification requirements of section 102 of the CPSIA.

Certain binding materials also may be inaccessible if they are enclosed or encased by material which does not permit physical contact with component part. However, for binding materials that are accessible and contain plastic or metal parts (for which a determination has not been made), the Commission will continue to required testing and certification under section 102 of the CPSIA. Although AAP sought determinations on plastic and metal wire binding, it did not explain why the plastic or metal in those products are distinct or unique from what they describe as "novelty books that have plastic, metal or electronic parts with which children may be expected to interact."

Although the commenters claim that all of their materials are CONEG compliant, the certification of compliance under CONEG is currently based on self-certification by the supplier or manufacturer and not based on a third-party certification by a CPSC accredited laboratory as required under section 102 of the CPSIA. Accordingly, the Commission cannot adopt those certifications in lieu of the certifications required under

the CPSIA. Moreover, the Commission is aware of instances where plastic components have contained lead due to the addition of certain additives or colorants and is aware of instances where metal components have contained lead (such as heavy duty staples). The addition of lead-containing paint on plastic and metal parts in children's products has been and continues to be of great concern. Accordingly, the Commission will continue to require testing and certification on the components parts that have been found to or may contain lead including plastic parts, metal parts, and paints and similar surface-coating materials subject to 16 CFR part 1303.

d. Older Books

Comments were received from the American Library Association (ALA) requesting that books available in libraries not be subject to the CPSIA lead content requirements. In general, ALA claimed that children's books fall outside of the scope of the CPSIA because they are not distributed in interstate commerce. ALA also stated that libraries should not be required to test books that are on the shelf, even new books, given libraries' limited resources.

We disagree with the commenters regarding libraries and the CPSIA. Although ALA requested an exemption from the testing requirements for lead content, ALA may have misinterpreted the testing requirements. Currently, only manufacturers and importers of children's products are required to obtain testing showing compliance with CPSIA lead limits. (See Final Rule on Certificates of Compliance, 74 FR 68328 (November 18, 2008)). A library is neither a manufacturer nor an importer, so it is not required to test products before their sale or distribution.

ALA also argues that library books are not "distributed" in interstate commerce. ALA suggests that because children's library books are not sold, therefore, they are not distributed. As explained in the House Report No. 92-1153 accompanying the Consumer Product Safety Act or 1972, the definition of "consumer product" was not limited to the sale of a product to a consumer. "It is not necessary that a product be actually sold to a consumer, but only that it be produced or distributed for his use. Thus products which are manufactured for lease and products distributed without charge (for promotional purposes or otherwise) are included within the definition and would be subject to regulation under this bill." H.R. 92-1153, 92nd Cong. (2d Sess. 1972). The Commission's authority, therefore, applies to consumer products, including children's products, that are distributed in commerce, whether or not such books are sold or lent, if they are for the use of a child.

According to ALA, library books should not become a "hazardous substance" unless they are "reintroduced" into interstate commerce after the effective dates of the lead limits. Children's products are consumer products that are distributed in interstate commerce regardless of when they are introduced, and the FHSA does not limit the definition of a banned hazardous substance to new products or to the product's first introduction of such a product into interstate commerce. Under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(2)(q)(1), a "banned hazardous substance" is any toy, or other article intend for use by children, which is a banned hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted. Section 4(b) of the FHSA explicitly prohibits "[t]he alteration, mutilation...with respect to, a hazardous substance, if such act

is done while the substance is in interstate commerce, or while the substance is held for sale (whether or not the first sale)..." (emphasis added). In addition, section 4(c) of the FHSA further prohibits "[f]he receipt in interstate commerce of any misbranded hazardous substance or banned hazardous substance and the delivery or proffered delivery thereof for pay or otherwise." (emphasis added.) Under section 101(a) of the CPSIA, Congress has deemed that children's products that do not meet the lead content limits within the specified dates "to be banned hazardous substances." Accordingly, the Commission may not provide relief from the lead content limits except under the specific exclusions provided under section 101(b) of the CPSIA. Absent a finding that all used children's books fall within the scope of an exclusion, the Commission is bound by the statutory language of the CPSIA. Unfortunately, the Commission is unable to make such a determination in this proceeding. Because older books have not been manufactured using modern printing processes, such as the CMYK color process, and have been found, in some circumstances, to contain leaded ink or components, the Commission is unable to make a determination that the components of all older children's books fall under the lead content limits.

For older used children's books that are sold, many of these books may be collector's items that are sold to adults. Such books would not be considered to be intended primarily for children, and accordingly, may continue to be sold to adults. For older used children's books that are lent out, ALA has requested additional guidance regarding the treatment of these products. Accordingly, the Commission intends to issue a separate Statement of Policy addressing the treatment of older children's books.

15. Issues Related to Component Part Testing.

a. Material safety data sheet (MSDS)

Some commenters indicated that the materials they use should not require testing because the material safety data sheets (MSDS) already show that the materials do not contain lead.

As the Commission stated in its rule on procedures and requirements for a determination, material safety data sheets are insufficient for purposes of demonstrating compliance with the lead limits under the CPSIA (74 FR at 10478). Since regulations concerning MSDS require reporting only for chemicals with content levels that exceed 1000 ppm, the MSDS sheets cannot be used to show that a product complies with the lead limits of the CPSIA, which are 600 ppm for products sold after February 10, 2009, 300 ppm for products sold after August 14, 2009, and 100 ppm for products sold after August 14, 2011 (if deemed to be technologically feasible).

b. Metal, Plastic and Painted Components

Many commenters requested a testing exemption for certain metal and plastic items, such as buttons, zippers, snaps, grommets, eyelets, head bands, hair combs and clips, and barrettes. Other commenters mentioned products such as plastic hangers, dolls and doll accessories (such as shoes and eyeglasses), pipe-stem cleaners, brass or other metal bells, beading wire, and certain construction materials such as Plexiglas and aluminum screening. Some commenters listed fasteners, such as nails, screws, or plastic fasteners, as items that should be exempted from compliance with CPSIA requirements. Most commenters did not provide test data or other information about the lead content of these types of products. However, some commenters from the apparel industry

acknowledged that lead has been found sometimes in apparel accessories, such as zippers, buttons, snaps, and grommets.

In general, plastic, metal, and painted materials and products (for which determinations have not been made) have been found, in certain instances, to contain lead at levels that exceed the CPSIA lead limits. Data provided in response to the proposed rule and at the CPSC public meeting with members of the textile industry showed that some items, such as zippers, buttons, and other applied decorations, currently contain lead levels that exceed the CPSIA's lead content levels. In addition, based on the Commission's past experience with other children's products that have been found to contain lead, the Commission cannot make a determination that any component parts made out of plastic or metal (with the exception of metal determinations made in this rule) falls under the lead content limits. Accordingly, these products and materials continue to be subject to the lead content limits of section 101(a) of the CPSIA, as well the testing and certification requirements of section 102 of the CPSIA.

The Commission is aware that there are many questions regarding component part testing and certification for lead content given that any children's product may be made with a number of materials and component parts. The questions regarding testing and certification are significant because not all component parts may need to be tested if they fall under the scope of the exclusions approved by the Commission. For example, component parts would not need to be tested if they: (1) are inaccessible, as set forth under the Commission's regulations at 16 CFR 1500.87; (2) are or contain an electronic device, exempt under the Commission's regulations at 16 CFR 1500.88; or (3) are made of material determined by Commission to fall under lead content limits in this rule (to be

codified as 16 CFR 1500.91(a)-(e)(2). However, all other component parts will need to tested and certified under section 102 of the CPSIA. The Commission intends to address component part testing and the establishment of protocols and standards for ensuring that children's products are tested for compliance with applicable children's products safety rules, as well as products that fall within an exemption, in an upcoming rulemaking.

E. Impact on Small Businesses

A few commenters stated that the new rule would have a significant impact on small businesses. These commenters stated that the CPSIA would have devastating economic consequences for small businesses that cannot afford to test their products.

These commenters have misinterpreted the Regulatory Flexibility Act (RFA) section of the proposed rule. That section did not address the impact of the CPSIA on small businesses; that section addressed what impact the proposed rule on the determinations would have on small businesses. The Commission does not have the authority to change the CPSIA. However, under the general rulemaking authority vested to the Commission under section 3 of the CPSIA, the Commission has the authority to promulgate a rule to determine that certain products or materials would not exceed the lead content limits. When an agency issues a proposed rule, it must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of relieving certain materials or products from the testing

requirements of section 102 of the CPSIA if they were found to be inherently under the lead content limits prescribed. The number of small businesses that will be directly affected by the rule is unknown, but could be considerable. However, the final rule will not result in any increase in the costs of production for any firm. Its only effect on businesses, including small businesses, will be to reduce the costs that would have been associated with testing the materials under section 102 of the CPSIA. Based on the foregoing assessment, the Commission certifies that the rule issued today on procedures and requirements would not have significant impact on a substantial number of small entities.

F. Environmental Considerations

Generally, CPSC rules are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). The determinations rule is not expected to have an adverse impact on the environment, thus, the Commission concludes that no environment assessment or environmental impact statement is required in this proceeding.

G. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this proposal is stated in section 18 of the FHSA. 15 U.S.C. 1261n.

H. Effective Date

The Administrative Procedure Act requires that a substantive rule must be published not less than 30 days before its effective date, unless the rule relieves a restriction. 5 U.S.C. 553(d)(1). Because the final rule provides relief from existing

testing requirements under the CPSIA, the effective date is [date of publication in the Federal Register].

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Toys.

I. Conclusion

For the reasons stated above, the Commission amends title 16 of the Code of Federal Regulations as follows:

PART 1500 - HAZARDOUS SUBSTANCES AND ARTICLES:

ADMINISTRATION AND ENFORCEMENT REGULATIONS

- The authority for part 1500 is amended to read as follows:
 Authority: 15 U.S.C. 1261-1278, 122 Stat. 3016
 - 2. Add a new section 1500.91 to read as follows:

§ 1500,91 Determinations Regarding Lead Content for Certain Materials or Products under Section 101 of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to have this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead

content of a product inaccessible to a child. Materials used in products intended primarily for children 12 and younger that are treated or coated with paint or similar surface-coating materials that are subject to 16 CFR part 1303, must comply with the requirements for lead paint under section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA.

- (b) Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, either on its own initiative or upon the request of any interested person, to make a determination that a material or product does not exceed the lead limits as provided under paragraph (a) of this section.
- (c) A determination by the Commission under paragraph (b) of this section that a material or product does not contain lead levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable, does not relieve the material or product from complying with the applicable lead limit as provided under paragraph (a) of this section if the product or material is changed or altered so that it exceeds the lead content limits.
- (d) The following materials do not exceed the lead content limits under section 101(a) of the CPSIA provided that these materials have neither been treated or adulterated with the addition of materials that could result in the addition of lead into the product or material:
 - (1) Precious gemstones: diamond, ruby, sapphire, emerald
- (2) Semiprecious gemstones and other minerals, provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral based on lead or lead compounds (excluding any mineral that is based on lead or lead compounds including, but not limited to, the following: aragonite, bayldonite,

boleite, cerussite, crocoite, galena, linarite, mimetite, phosgenite, vanadinite, and wulfenite).

- (3) Natural or cultured pearls.
- (4) Wood.
- (5) Paper and similar materials made from wood or other cellulosic fiber, including, but not limited to, paperboard, linerboard and medium.
- (6) Printing inks that use the CMYK process (excluding spot colors, other inks that are not used in CMYK process, inks that do not become part of the substrate under 16 CFR part 1303, and inks used in after-treatment applications, including screen prints, transfers, decals, or other prints).
- (7) Textiles (excluding after-treatment applications, including screen prints, transfers, decals, or other prints) consisting of:
- (a) Natural fibers (dyed or undyed) including, but not limited to, cotton, kapok, flax, linen, jute, ramie, hemp, kenaf, bamboo, coir, sisal, silk, wool (sheep), alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco;
- (b) Manufactured fibers (dyed or undyed) including, but not limited to, rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex.
- (8) Other plant-derived and animal-derived materials including, but not limited to, animal glue, bee's wax, seeds, nut shells, flowers, bone, sea shell, coral, amber, feathers, fur, leather.

- (e) The following metals and alloys do not exceed the lead content limits under section 101(a) of the CPSIA, provided that no lead or lead-containing metal is intentionally added but does not include the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications:
- (1) Surgical steel and other stainless steel within the designations of Unified Numbering System, UNS S13800 - S66286, not including the stainless steel designated as 303Pb (UNS S30360).
 - (2) Precious metals: gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium, titanium.

Dated:

Todd A. Stevenson, Secretary Consumer Product Safety Commission



Memorandum

AUG - 6 2009

TO

The Commission

Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF

Maruta Budetti, Executive Director MyB

: Robert J. Howell, Assistant Executive Director, Office of Hazard Identification

and Reduction AA

Kristina M. Halfelid, Ph.D., M.P.H., Toxicologist, Directorate for Health (#

Sciences

SUBJECT: Consumer Product Safety Improvement Act of 2008 (CPSIA) -- Determination

of Lead Content for Certain Products and Materials

Introduction

Section 101(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) establishes, as of February 10, 2009 (180 days after the enactment of the Act), a limit for lead of 600 parts per million (600 ppm) by weight in any part of a children's product¹. Lead content of any part of a children's product is limited to 300 ppm as of August 14, 2009 (one year after the enactment of the Act), and subsequently to 100 ppm as of August 14, 2011, if technologically feasible.

On January 15, 2009, the Commission published in the Federal Register a notice of proposed rulemaking (74 FR 2433) containing proposed determinations that certain materials do not exceed the lead content limits in CPSIA section 101(a).

Background

The staff identified a number of materials that do not contain lead or that contain lead at levels that do not exceed the CPSIA lead limits, and recommended that the Commission make such a determination through rulemaking. The Commission agreed and a proposed rule was published in January 2009.

The proposed rule specified the following materials or categories of materials that do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA with the provision that the materials have not been treated or adulterated with the addition of materials or chemicals such as pigments, dyes, coatings, finishes or any other substance, nor undergone any processing that could result in the addition of lead into the product or material;

Note: This document has not been reviewed or accepted by the Commission NO MERS/PRVILBERS OR EXCEPTED BY: PETITION

⁴ "Children's product" means a consumer product designed or intended primarily for children 12 years of age or younger as defined in the Consumer Product Safety Act as amended by the CPSIA section 235.

- · Precious gemstones: diamond, ruby, sapphire, emerald.
- Semiprecious gemstones provided that the mineral or material is not based on lead or lead
 compounds and is not associated in nature with any mineral that is based on lead or lead
 compounds (minerals that contain lead or are associated in nature with minerals that
 contain lead include, but are not limited to, the following: aragonite, bayldonite, boleite,
 cerussite, crocoite, linarite, mimetite, phosgenite, vanadinite, and wulfenite).
- Natural or cultured pearls.
- · Wood.
- Natural fibers such as cotton, silk, wool, hemp, flax, linen.
- · Other natural materials including coral, amber, feathers, fur, untreated leather.

Certain metals and alloys were also included in the proposed determinations as not exceeding the 600 ppm or 300 ppm lead content limits with the provision that no lead or lead-containing metal is intentionally added, and that the determination does not include the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications:

- · Surgical steel.
- Precious metals: gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium.

Public comments²

Few of the hundreds of public comments were directed at the proposed determinations published in the notice. No information refuting the Commissions' findings was provided.

Most commenters requested that additional materials be added to the list of materials that the Commission determines are not expected to contain lead at levels that exceed the CPSIA lead limits, but few of these requests included specific data or other information relevant to determinations of lead content of the materials.

Discussion

Based on a review of available information, including data generated by the staff in testing samples of products for lead content, the staff concludes that some of the items and materials mentioned by commenters are known to sometimes contain lead at levels above the prescribed maximum levels in the CPSIA. Since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead.

On the other hand, based on the public comments, public meetings and investigation by the staff, the staff believes that the previously proposed materials, as well as other materials that are substantially similar to the previously proposed materials, do not contain lead at levels that exceed the CPSIA limits for lead content.

Textiles and Apparel

The staff's review³ of the available information indicates that the propose untreated natural fibers is unnecessarily limited and that certain synthetic n. treatments, such as dyes, are also not expected to contain lead at levels that e. lead limits. Therefore, many more types of plant- and animal-derived fibers, s, and the textiles and apparel made from such fibers are not expected to contain le. CPSIA lead limits. The staff cautions that these conclusions apply only to materia include a lead-containing material and have not been processed in a way that would desuit in lead being added to the material.

Although leather and related materials are not made from fibers like most textiles, they may be used to produce apparel and coverings or may be used along with textile products. Leather begins as a natural product, but undergoes processing (e.g., tanning) to convert the natural skin into a usable, durable product. Similar to most textile products, leather products are often colored with dyes or pigments during their processing. Many of the same dyes used in the textile industry are also used for dying leather. According to information submitted by the Leather Industries of America, many of the processes used to process and finish leather do not incorporate lead or lead-based chemicals. However, many leather products may be finished with pigment-based coatings, including some leather products that are colored using lead-based pigments. Therefore, leather could be included among materials that are not expected to contain lead at levels that exceed the CPSIA lead limits, but a children's leather product that incorporates pigment-based coatings, like any children's product that includes paint or a similar surface coating, must conform to the requirements of the lead in paint rule (16 C.F.R. part 1303) and is subject to the third-party testing and certification requirements of section 102 of the CPSIA.

Because products may consist of a number of different materials, some not likely to contain lead, along with some materials that might contain lead at levels that exceed the lead limits, the staff suggests that for purposes of testing and evaluation of a product, distinct parts of products should be considered separately. For example, a garment such as a coat might consist of various threads, fabrics, a liner, buttons, zipper, and rivets. The fabric portions made of one or more of the materials included in a Commission determination, for example, cotton and polyester, would not be expected to contain lead at levels that exceed the CPSIA lead limits. On the other hand, the lead content of the plastic, metal, or painted parts of the coat remains uncertain because of the demonstrated presence of lead in some products. Only the latter materials would require testing to verify that the lead concentration does not exceed the lead limits.

Likewise, a blanket or stuffed doll could be constructed with fabrics, thread, and stuffing or fill made of cotton or polyester or other materials that would not be expected to contain lead at levels that exceed the CPSIA lead limits. Buttons or other non-textile parts of such products would have to be tested for lead content before the product that includes them could be introduced into commerce.

In addition to the non-textile items discussed above, such as buttons and zippers, that may be component parts of products, other non-textile materials may be directly incorporated into textile products or added to the surface of textiles, such as decals, transfers, and screen printing. All such non-textile components should be tested for lead content unless they are made entirely from

² The staff's summary of the public comments and the staff's responses are located in a memorandum from Kristina M. Hutlelid. Ph.D., M.P.H., to Mary Ann Danello, Ph.D., "Response to Public Comments; Determinations," August 2009.

³ CPSC Memorandum from Allyson Tenney to Kristina Hatlelid, "Textiles and Apparel Subject to the CPSIA," June 5, 2009.

materials that the Commission has determined would not contain lead in excess of the CPSIA lead limits.

Other Natural Materials

As with the natural fibers, the staff's review indicates that many products and materials, including foodstuffs and plant- and animal-derived materials could fall under the general category of natural materials, which, as proposed, included coral, amber, feathers, fur, and untreated leather. The staff has found no data that indicates that other natural materials, both plant-based and animal-derived, are expected to have lead content exceeding the CPSIA lead limits. Therefore, some additional materials may be considered as not containing lead above the CPSIA lead limits, including, for example, bee's wax, dried flowers, plant-based oits, bone and state⁴. As stated above, leather that has not been treated with a pigment-containing paint or surface coating could also be included among materials that are not expected to contain lead at levels that exceed the CPSIA lead limits.

Paper, Printing Ink, and Books and Similar Printed Materials

Paper⁵ is predominantly made from wood, but may also be made with other cellulosic fibers. As with the fibers, textiles, and apparel discussed above, paper and similar materials, such as paperboard, including the dyes and treatments used to make them, are not expected to contain lead above the CPSIA lead limits. Data and information⁶ submitted to CPSC by the American Forest & Paper Association support the staff's conclusion.

The staff also reviewed printing inks, which are distinct from the dyes used to color paper and textiles. Data and information provided in response to the notice of proposed rulemaking, at CPSC staff public meetings with members of the publishing and printing industries (January 22, 2009; June 9, 2009), and in written materials following those public meetings indicates that the use of lead in printing inks has largely been eliminated, except for certain inks formulated for use in printing on materials such as plastic or fabric, including screen-printing. In their July 1, 2009 letter, industry members explained that lead-based pigments are not compatible with the fourcolor process. This process, commonly called CMYK, uses transparent cyan (C), magenta (M), and yellow (Y) inks, in addition to black ink, in combination to create a wide range of colors. The letter indicated that lead could be used in "spot colors" and described several lead-based pigments, but claimed that the use of the lead pigments is not current practice because of safety and environmental concerns. The Printing Industries of America followed the July 1, 2009 letter with correspondence⁷ providing additional information about four-color process printing to support the previous assertion that lead-based pigments are not compatible with this process. The staff has independently confirmed that lead-based pigments cannot be used in the four-color process, but, while it may not be the current practice, could be used in spot colors.3

The industry members' July 1, 2009 letter also explained that the types of printing inks that might contain lead, such as for screen-printing and for certain processes for printing on plastic or

other non-paper materials, are specifically designed for those purposes and cannot be used for printing children's paper-based books and similar paper-based materials because different printing processes require different ink systems.

The staff's review shows that lead-based pigments are not compatible with the four-color process (and variations of this process, such as those that add colors or diluted colors to the system to improve the quality of images printed using CMYK) and, therefore, that excess lead would not be found in books or similar paper-based materials printed using only CMYK processes. On the other hand, lead-based inks may be used for spot colors, including spot colors used in conjunction with CMYK processes. Further, printing inks for use on plastic or in screen printing could use lead-containing pigments. Accordingly, the staff recommends that testing continue to be required for inks used in screen printing, inks that are not directly part of a CMYK system, and inks that are used to print on materials other than paper, including plastic and metal. The staff also notes that inks that do not become part of the substrate, such as those applied to plastic and metal surfaces may be regulated as paints or similar surface coatings under 16 C.F.R. part 1303.

As discussed above with respect to apparel, products may consist of a number of different materials, some not likely to contain lead, along with some materials that might contain lead at levels that exceed the lead limits. The staff suggests that for purposes of testing and evaluation of a product, distinct parts of products should be considered separately. For books and similar printed materials, the paper, paperboard and similar materials made with cellulosic fibers, printing using four-color process ink systems, and certain other materials that are included in a Commission determination would not be expected to contain lead at levels that exceed the CPSIA lead limits. On the other hand, the lead content of printed spot colors, printing not based on CMYK processes, including screen printing, plastic or metal parts, and paint or printing on non-paper parts of a product remains uncertain because of the demonstrated presence of lead in some products. The latter materials would require testing to verify that the lead concentration does not exceed the lead limits.

Metals and Alloys

The Commission has previously indicated that surgical steel and certain precious metals are not expected to contain lead above the CPSIA lead limits. Surgical steel is a type of stainless steel. Further review of these alloys indicates that most stainless steels do not contain lead at levels above the CPSIA lead limits. These steels have Unified Numbering System (UNS) designations \$13800 - \$66286. The exception to this conclusion is 303Pb stainless steel (UNS \$30360), which contains lead at levels from 1200 ppm to 3000 ppm. In addition, staff believes that titanium and titanium alloys do not contain lead.

Regulatory Analysis

Staff prepared the regulatory analysis ¹⁰ required for Commission regulatory proceedings, including an assessment of the impact on small businesses and an environmental assessment.

⁴ CPSC Memorandum from Mark F. Gill to Kristina M. Hatlelid, "Results of Research on Lead Content in Slate," July 22 2009.

⁵ CPSC Memorandum from Joel Recht to Kristina Hatlefid, "Lead in Paper," July 15, 2009.

^{*} Paul Noe, American Forest & Paper Association, letter to Consumer Product Safety Commission, July 28, 2009.

⁷ Julie Bushee Riccio, Printing Industries of America, E-mail correspondence, July 29, 2009.

Scott A. Williams, Ph.D., Rochester Institute of Technology, Personal communication, July 27, 2009.

OPSC Memorandum from Randy Butturini to Kristina M. Hatlelid, "Lead in Stainless Steel and Titanium Alloys," June 3, 2009.

¹⁰ CPSC Memorandom from Robert Franklin to Kristina Hatlelid, "Final regulatory analysis of a rule making determinations that certain materials or products do not have lend contents that exceed the limits established in section 101(a) of the CPSIA." July 17, 2009.

Because the effect of the rule would be to relieve manufacturers and importers of certain products and materials from the testing and certification requirements of section 102 of the CPSIA, the potential costs of the rule consist of the risk that some hazardous exposures to lead could occur that would have been prevented had the materials or products been tested for lead content. However, because the materials and products for which the determinations are being made are those which the staff has concluded inherently do not contain lead in excess of the statutory limits, they are unlikely to pose a risk of injury due to the absorption of lead. Therefore, the costs of the rule, if any, would be negligible. The potential benefits of the rule consist of a reduction in the testing costs that would have been incurred by firms to test materials that inherently do not contain lead in excess of the statutory requirements but would otherwise have to be tested under the requirements of the CPSIA. Given the large number of products or product components that would not need to be tested under this rule, these benefits may be considerable. Because the reduced testing costs represent the benefits of the rule and the costs of the rule (in terms of increased risk of lead absorption) are negligible, the benefits of the rule would exceed the costs.

The number of small businesses that will be directly affected by the rule is unknown but could be considerable. However, because the effect of the rule would be to relieve the manufacturers and importers of the specified materials from the testing and certification requirements the CPSIA, it will not result in any increase in the costs of production for any firm. Its only effect on businesses, including small businesses, will be to reduce the costs that would have been associated with testing the specified materials.

Finally, the staff concludes that this rule does not fall into one of the categories of actions described in the CPSC environmental review regulations as having the potential to the produce environmental effects (16 CFR 1021.5) and is in fact highly unlikely to produce an environmental effect.

Recommendations

The staff recommends that the Commission issue a final rule determining that certain materials and classes of materials do not exceed the lead content limits in CPSIA section 101(a). The recommendation includes all of the materials included in the proposed rule; additional fibers and textiles; additional plant- and animal-derived materials; and additional metals and alloys.

Other items and materials mentioned by commenters are known to sometimes contain lead at levels above the prescribed maximum levels in the CPSIA. Therefore, the staff believes that it would not be appropriate for the Commission to determine at this time that such products do not exceed the lead limits, and, since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead. The staff also notes that products often are made of many different materials and components that should be considered separately for testing purposes. Thus, some parts of a product would be subject to the testing requirements, but other components, if part of the Commission's determination that the material would not contain lead in excess of the CPSIA lead limits, would not require testing for lead content.

The Commission has in place a procedure and requirements for a Commission determination that the lead content of a specific material or product does not exceed the CPSIA section 101 limits. 16 C.F.R. § 1500.90. Through this procedure, interested people could provide data and other

information supporting a request for additional materials and products to be considered by the Commission.

CPSC staff recommends that the final rule include the following materials or categories of materials that the staff believes do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA, provided that the materials have not been treated or adulterated with the addition of materials or chemicals nor undergone any processing that could result in the addition of lead into the product or material:

- · Precious gemstones: diamond, ruby, sapphire, emerald.
- · Semiprecious gemstones, and other minerals,
 - o provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral that is based on lead or lead compounds (minerals that contain lead or are associated in nature with minerals that contain lead include, but are not limited to, the following: aragonite, bayldonite, boleite, cerussite, crocoite, galena, linarite, mimetite, phosgenite, vanadinite, and wulfenite).
- Natural or cultured pearls.
- Wood
- Paper and similar materials made from wood or other cellulosic fiber, including paperboard, linerboard and medium.
- Printing inks in CMYK processes (cyan, magenta, yellow, and black inks used in combination to create a wide range of color).
- Natural fibers including, but not limited to, cotton, kapok, flax, jute, ramie, hemp, kenaf, bamboo, coir, sisal, silk, wool (sheep), alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco, and the threads, yarns, fabrics, and other textiles made from such fibers, whether dyed or undyed.
- Synthetic fibers including, but not limited to, rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex, and the threads, yarns, fabrics, and other textiles made form such fibers, whether dyed or undyed.
- Other plant-derived and animal-derived materials including, but not limited to, bee's wax, seeds, nut shells, flowers, animal glue, bone, sea shell, coral, amber, feathers, fur, and leather.

The following metals and alloys do not exceed the 600 ppm or 300 ppm lead content limits provided that no lead or lead-containing metal is intentionally added, but this conclusion does not include the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications:

- Surgical steel and other stainless steels within the designations of the Unified Numbering System, UNS S13800 – S66286, not including the stainless steel designated as 303Pb (UNS S30360).
- Precious metals: gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium; titanium.

6



Memorandum

TO

Date: AUS - 6 2009

: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health

Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for]

Health Sciences

FROM : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health

Sciences

SUBJECT: Response to Public Comments: Determination of Lead Content for Certain

Products and Materials

Introduction

On January 15, 2009, the Commission published in the Federal Register a notice of proposed rulemaking (74 FR 2433) containing proposed determinations that certain materials do not exceed the lead content limits in section 101(a) of the Consumer Products Safety Improvement Act of 2008 (CPSIA). This memorandum summarizes the comments received from the public in response to this notice, and provides the staff's responses to the comments. The index of public comments is in Appendix A.

The Commission received more than 244 comments in response to the notice. Few comments were directed at the proposed determinations published in the notice. Most commenters requested additional materials be added to the list of materials that the Commission determines are not expected to contain lead at levels that exceed the CPSIA lead limits. Few of these requests included specific data or other information relevant to determinations of lead content of the materials.

Discussion

Comment: Determinations process and data requirements.

Comments from advocacy and consumer groups (American Academy of Pediatrics and others, comment no. 221), (Consumers Union and others, comment no. 226), and the State of California Attorney General's office (comment no. 227) indicate support for reducing potentially repetitive and wasteful testing of products and materials that are not expected to contain lead. However, these commenters stressed that the Commission must proceed carefully to ensure that the requirements of the law are met and that children do not face harm from lead content of children's products. The commenters cautioned that the Commission should not only request data from firms, but should also conduct its own testing of children's products, especially products that have not, to date, been subject to lead content requirements or testing for lead content. The California Attorney General's office also stated that the final rule should make clear that materials that the Commission

determines do not contain excess lead levels must still comply with the statutory lead content standard.

CPSC Staff Response:

The Commission has already indicated that all children's products subject to a determination must comply with the lead limit in its Statement of Commission Enforcement Policy on Section 1011.ead Limits, dated February 6, 2009. Further, the Commission's procedures and requirements for a Commission determination that the lead content of a specific material or product does not exceed the CPSIA section 101 limits provides that a request for a Commission determination must be supported by objectively reasonable and representative test results or other scientific evidence showing that the product or materials does not, and would not, exceed the lead limit specified in the request. 16 C.F.R. § 1500.90. Compliance and enforcement activities, including market testing, have always been, and continue to be, essential to the Commission's mission. Moreover, if a particular product or material has been relieved of the requirement to undergo testing and certification under section 102 of the CPSIA, manufacturers and importers continue to be responsible for verifying that the material or product has not been altered or modified, or experienced any change in the processing, facility or supplier conditions that could import lead into the material or product to ensure that it meets the statutory lead levels at all times.

Comment: Fabrics and similar materials, whether processed or dyed.

Numerous commenters claimed that many fabrics, yarus, batting, fill, and similar materials, such as ribbon, and related materials, such as clastic, including those that are dyed or similarly processed, do not contain lead. Results of laboratory testing for lead in textiles and products, as well as other information, were provided in support of such claims by the American Apparel and Footwear Association and affiliated firms and associations.

CPSC Staff Response:

Based on the data provided in response to the notice of proposed rulemaking and at a CPSC staff public meeting with members of the textiles and apparel industries (January 22, 2009), as well as the staff's knowledge and testing of products, staff agrees that common textiles and similar products, such as ribbon, and other materials used to make apparel, such as elastic, are not expected to contain lead at levels that exceed the CPSIA lead limits.

However, non-textile materials that may be added to textile products and apparel, such as decals, transfers, and screen printing, have not been shown to be materials that cannot contain lead. In fact, screen printing inks sometimes do contain lead. Therefore, since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead.

Comment: Products certified as compliant with the Global Organic Textile Standard (GOTS) or Ocko-Tex® should be excluded from testing for lead.

Commenters, including the Organic Trade Association (comment no. 216), stated that certifications such as the Global Organic Textile Standard (GOTS)¹ and Oeko-Tex®² should be allowed in place of testing for compliance with the CPSIA lead content requirements. Both GOTS and Oeko-Tex®³

Available at www.global-standard.org.

²Available at www.nekntex.com.

standards limit lead content in certain textile and textile-based products to no more than 100 ppm lead.

CPSC Staff Response:

The staff believes that textiles and textile-based products do not contain lead at levels that exceed the CPSIA section 101 limits for lead content, and therefore, should be included in a Commission determination. However, while such products may not be subject to required testing and certification, all children's products subject to a Commission determination must comply with the lead limit of section 101(a) of the CPSIA. Further, manufacturers and importers continue to be responsible for verifying that a material or product has not been altered or modified, or experienced any change in the processing, facility or supplier conditions that could impart lead into the material or product to ensure that it meets the statutory lead levels at all times. The staff believes that certifications from GOTS or Ocko-Tex® could serve to provide such verifications, given that these standards also have testing and compliance requirements.

Comment: Certain components for apparel or other products.

Many commenters requested a testing exemption for certain metal and plastic items, such as buttons, zippers, snaps, grommets, cyclets, head bands, hair combs and clips, and barrettes.

CPSC Staff Response

Data provided in response to the notice of proposed rulemaking and at a CPSC staff public meeting with members of the textiles and apparel industries (January 22, 2009) showed that some items, such as zippers, buttons, and other applied decorations currently contain lead at levels that exceed the CPSIA section 101 lead limits. In acknowledging this, industry members agreed that testing such parts is necessary, and urged the Commission to consider component level testing or supplier certification acceptable for demonstrating compliance with statutory lead content requirements.

Based on the available data, the staff believes that metal and plastic materials and products sometimes contain significant lead content, such that the lead levels may exceed the maximum levels set by the CPSIA. Therefore, it would not be appropriate for the Commission to determine that such products do not exceed the lead limits, and, since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead. The Commission will address certification requirements for component part testing and the establishment of protocols and standards for ensuring that children's products are tested for compliance with applicable children's products safety rules, as well as products that fall within an exemption, in an upcoming rulemaking.

Comment: Leather.

Some commenters claimed that leather and similar products should be determined to comply with the lead limits. A comment from the Leather Industries of America (comment no. 213) provided a detailed discussion of the leather treatments and products that do not add lead to the leather, as well as applications that might include lead. This comment indicated that only pigment-based paints, coatings or certain applied decorations might contain lead; all other leather treatments would not.

CPSC Staff Response:

Leather from hide or skin is based on natural products, but must undergo processing (e.g., tanning) to convert the natural skin into a usable, durable product. Similar to most textile products, leather products are often colored with dyes or pigments during their processing. Many of the same dyes

used in the textile industry are also used for dying leather. According to information submitted by the Leather Industries of America, most processes used to finish leather do not include lead-based chemicals. However, many leather products may be finished with pigment-based coatings, including some that are colored using lead-based pigments. Accordingly, a children's leather product that incorporates pigment-based coatings, like any children's product that includes paint or a similar surface coating, must conform to the requirements of the lead in paint rule (16 C.F.R. part 1303) and are subject to the third-party testing and certification requirements of section 102 of the CPSIA

Comment: Plant and animal based materials.

Many commenters indicated that there are a number of natural, plant or animal-based materials that likely do not contain appreciable lead content and should be suitable for use in children's products without testing for lead content. Materials mentioned include plants in general, and specifically bark, leaves, flowers and flower petals, seeds, cones, loofa, rattan, wicker, bamboo, bamboo fiber, plant-based dyes, nut shells, buckwheat hulls, essential plant oils, lavender, witch hazel, jute, kapok, kenaf, ramic, sisal, hemp, agave, coconut, soy, moss, straw, jojoba oil, and tung oil. Animal-based materials included yak, angora, mohair, llama, alpaca, bison, camel, guanaco, cashmere, horse hair, claws, horn, seashells, bone, hide glue, and shellac.

CPSC Staff Response:

The staff agrees that plant and animal-based materials generally do not contain lead at levels that exceed the CPSIA lead limits. However, this conclusion applies only to such materials that are unadulterated by the addition of chemicals and materials such as pigments, paints and similar surface coatings, and metal or plastic materials since such treatments or additions cannot be known to comply with the lead limits without testing. Although most of these materials were not specifically included in the proposed rule, the proposed determinations included three categories of natural materials with examples that are similar to many of these items (i.e., wood: natural fibers, including cotton, silk, wool, hemp, flax, and linen; other natural materials including coral, amber, feathers, fur, and untreated leather). The staff believes that these three natural materials categories could reasonably encompass the natural items suggested by commenters.

Comment: Foodstuffs.

Some commenters also stated that foodstuffs or materials suitable in food uses may be used in making children's products and should be determined to comply with lead limits given that they are largely natural plant or animal based materials and are considered edible or safe for use by consumers. Some of the materials mentioned include vegetable and nut oils, medicinal-grade mineral oil, table salt, flax seed, food coloring, food preservatives, cream of tartar, grain flours, dried beans, dried corn, millet, herbs, cherry pits, rice, seeds, milk, honey, bee's wax, candelilla wax, and carnauba wax.

CPSC Staff Response:

Foods are under the jurisdiction of the US Food and Drug Administration (FDA), and are therefore not subject to the CPSIA requirements, even when used as components of consumer products. However, there may be materials available to manufacturers, such as bee's wax, that are sometimes foods, but that are not always sold in a form intended for consumption or that complies with FDA regulations. To the extent that such materials are also natural materials that have not been

adulterated or treated with a lead-containing material, the staff believes that the proposed determination for some natural materials could reasonably encompass additional substances.

Comment: Some wood products.

Several commenters confirmed that wood is not expected to contain lead, and also requested that the determination be expanded to include related products, such as composite wood constructed of wood, adhesives, and other materials (comment no. 228).

CPSC Staff Response:

The commenters did not provide test data or other information to enable the staff to properly assess whether the lead content of manufactured wood products that contain various non-wood materials would fall under the lead content limits prescribed by the CPSIA. A request for a Commission determination must provide data and other information requested under the Commission's rule on procedures and requirements for a determination. 16 C.F.R. § 1500.90. Accordingly, a request for a specific materials determination may be submitted to the Commission by an interested person. consistent with those requirements.

Comment: Some paper products.

Several commenters, including the American Forest & Paper Association (comment no. 230), requested that the determination include paper, paperboard, linerboard and medium, and specific paper products, such as cardboard, scrapbooking and embroiderable papers.

CPSC Staff Response:

The staff agrees that manufactured paper products do not necessarily contain lead at levels that exceed the CPSIA lead limits, especially those that contain no other materials (i.e., do not include lead-based paints or similar surface coatings, lead-based pigments, or metal or plastic parts).

Comment: Fabrie dyes

Commenters requested that fabric dyes be determined to comply with the CPSIA lead limits.

CPSC Staff Response:

Based on information and data provided in response to the notice of proposed rulemaking and at a CPSC staff public meeting with members of the textiles and apparel industries (January 22, 2009), the staff believes that dyes used in fabrics do not contain lead at levels that exceed the CPSIA lead limits.

Comment: Printing inks

Commenters requested that printing inks be determined to comply with the CPSIA lead limits.

CPSC Staff Response:

Data and information provided in response to the notice of proposed rulemaking, at CPSC staff public meeting with members of the publishing and printing industries (January 22, 2009; June 9, 2009), and in written materials following those public meetings indicates that the use of lead in printing inks has largely been eliminated, but that inks formulated for use in printing on substrates such as plastic or fabric, including screen-printing, may contain lead. In their July 1, 2009 letter, industry members explained that lead-based pigments are not compatible with the four-color process. This process, commonly called CMYK, uses transparent cyan (C), magenta (M), and yellow (Y) inks, in addition to black ink, in combination to create a wide range of colors. The letter

indicated that lead could be used in "spot colors" and described several lead-based pigments, but claimed that the use of the lead pigments is not current practice because of safety and environmental concerns. The staff has independently confirmed that lead-based pigments cannot be used in the four-color process, but, while it may not be the current practice, could be used in spot colors.\(^1\) The industry members' letter also explained that the types of printing inks that might contain lead, such as for screen-printing and for certain processes for printing on plastic or other non-paper materials, are specifically designed for those purposes and cannot be used for printing children's paper-based books and similar paper-based materials because different printing processes require different ink systems.

The staff's review shows that lead-based pigments are not compatible with the four-color process (and variations of this process, such as those that add colors or diluted colors to the system to improve the quality of images printed using CMYK) and, therefore, that excess lead would not be found in books or similar paper-based materials printed using only CMYK processes. On the other hand, lead-based inks may be used for spot colors, including spot colors used in conjunction with CMYK processes. Further, printing inks for use on plastic or in screen printing could use lead-containing pigments. Therefore, these materials or the products made with them cannot be known to comply with the lead limits without testing.

Comment: Metals such as titanium, aluminum, pewter, copper.

Some commenters referenced the proposed determination for lead content for surgical steel and certain precious metals and requested other metals, including other stainless steels (Specialty Steel Industry of North America, comment no. 214) be added to the list.

CPSC Staff Response:

Based on staff review of available information, the staff agrees that, like surgical steel, other common stainless steels do not contain excess lead levels. One type of stainless steel, designated as 303Pb steel or S30360, has lead content that exceeds the CPSIA lead limits.

The staff has not found that titanium would contain lead at levels that exceed the CPSIA lead limits. On the other hand, other metals and alloys, including aluminum, copper and pewter may contain significant amounts of lead, and specific products containing such metals or alloys cannot be known to comply with the lead limits without testing.

Comment: Stones, rocks, and earth.

C.M. Paula Company (comment no. 220) and other commenters stated that, in addition to certain precious and semiprecious gems, other minerals and items found in the earth, such as fossils. should be determined as not containing lead above the CPSIA lead limits.

CPSC Staff Response:

As is the case with the precious gemstones and certain semi-precious stones that the Commission proposed do not contain lead at levels that exceed the CPSIA lead limits, other rocks and stones could be considered to comply with lead limits provided that the mineral or material is not based on lead or lead compounds, and is also not associated in nature with any mineral that is based on lead or lead compounds. Staff has researched some materials, and has concluded, for example, that slate would not be expected to exceed the CPSIA lead limits. Although no commenter submitted data on

¹ Scott A. Williams, Ph.D., Rochester Institute of Technology, Personal communication, July 27, 2009.

the numerous minerals and other materials that commenters claimed would be likely to comply with CPSIA lead limits, in general, the staff agrees that many minerals do not contain lead. The staff has previously identified a number of minerals, including semi-precious gemstones, that contain lead. Another important lead-containing mineral is galena.

Comment: Adhesives.

Several commenters requested a determination that glues and adhesives do not contain lead.

CPSC Staff Response:

The staff currently does not have data or other information about the wide range of formulations of glues and adhesives or the lead content of such products. However, animal glues are animal-based materials that the staff does not expect to contain excess lead. Further, the staff believes that in many applications and finished products, adhesives will not be accessible to a child; component parts of products that are not accessible to a child do not need to comply with the lead limits and testing for lead is not required.

Comment: Certain finishes.

Several comments suggested that water based paints, acrylic paints, water based clear finishes, varnishes, lacquers, and milk paint should all be determined to comply with lead limits.

CPSC Staff Response:

The Commission has long-standing regulations on paint and similar surface coatings at 16 CFR part 1303. Section 101(f) of the CPSIA imposed an even stricter lead limit for paint and similar surface coatings from 600 ppm total lead by weight to 90 ppm total lead by weight as of August 14, 2009. Because of the well-documented danger to children from contact with lead-containing paints and surface coatings, and past instances of children's products bearing lead-containing paints or coatings despite regulations forbidding the practice, such materials must be tested to show their compliance with the regulations. Currently, paint and surface coatings require third-party testing by an accredited lab under section 14(a) of the CPSA.

Comment: Ceramic glaze and clay.

A few commenters claimed that ceramic glazes and clays comply with lead limits.

CPSC Staff Response:

While it may be the case that some products or materials used in ceramics production do not contain lead, many products within this product type are known to contain lead at levels that exceed the CPSIA limits for lead content. Without testing of ceramic glazes and other materials, compliance with the lead content limits of the CPSIA cannot be shown.

Comment: Giass.

Several commenters listed glass, glass beads, rhinestones, leaded glass crystals, and porcelain enamel (The Enamelist Society, comment no. 209) as items that should be exempted from compliance with the CPSIA requirements for lead content or testing.

CPSC Staff Response:

The staff recognizes that not all glass or glass products contain lead at levels that exceed the CPSIA lead limits. However, without testing the glass, compliance with the lead content limits of the CPSIA cannot be shown. Further, leaded glass crystals and other glass-based products that contain

lead clearly exceed the lead content limits and cannot be considered in the Commission's rulemaking to determine that certain materials do not contain lead.

Comment: Nails, screws, and other fasteners.

Some commenters listed metal or plastic fasteners as items they use to make children's products and that should be exempted from compliance with CPSIA requirements.

CPSC Staff Response:

Because products such as nails, screws and other fasteners may contain lead at levels that exceed the lead content limits, the staff has concluded that they cannot be considered as products that do not contain lead at levels the exceed the CPSIA section 101 lead limits.

Comment: Pencils, erayons, other materials regulated as art materials and subject to the voluntary standard ASTM D4236.

Commenters requested that certain art materials be determined to not contain lead at levels that exceed the CPSIA lead limits.

CPSC Staff Response:

The CPSIA requirements for lead content are in addition to other statutory and regulatory requirements for children's art materials. Because these other requirements do not necessarily limit lead content of products, testing of art materials is required to demonstrate compliance with the lead content limits. Compliance under the Labeling of Hazardous Art Materials Act (LHAMA) requires the submission of art material product formulations to a toxicologist for review to assess chronic adverse health effects; the CPSIA requires further testing of children's art materials to assess the total lead content by weight for any part of the product.

Comment: Other items.

Commenters listed many other products and materials that they use in children's products, that they would like exempted from testing requirements. Some of the products mentioned include plastic hangers, dolls and doll accessories such as shoes and eyeglasses, pipe-stem cleaners, brass or other metal bells, beading wire, and certain construction materials such as Plexiglas® and aluminum screening.

CPSC Staff Response:

The staff currently does not have data or other information about the lead content of these many types of products. Because some plastic and metal materials or products contain lead at levels that exceed the CPSIA lead limits, the variety of products mentioned by the commenters cannot be known to comply with the lead limits without testing. A request for a Commission determination must provide the data and other information requested under the Commission's rule on procedures and requirements for a determination. 16 C.F.R. § 1500.90.

Comment: Previously tested items or items with a material safety data sheet (MSDS),

Some commenters indicated that the materials they used should not require testing because they have already been tested. Some commenters refer to material safety data sheets to show that the materials do not contain lead.

CPSC Staff Response:

Previous testing of product components and materials ("component testing") refers to testing by suppliers of components and materials prior to sale to the ultimate manufacturer of the children's product. The Commission will address more specifically testing and certification requirements for children's products in an upcoming rulemaking.

Material safety data sheets may also relate to component testing, but there is an additional issue. Federal regulations concerning material safety data sheets generally require reporting of chemical content of products or materials for chemicals with content levels that exceed 1000 ppm, although smaller concentrations may have to be reported in certain instances. Because material safety data sheets do not necessarily report all chemicals present at any concentration, these sheets cannot be used to show that a product complies with the lead limits of the CPSIA, which are 600 ppm for products sold after February 10, 2009, 300 ppm for products sold after August 14, 2009, and 100 ppm for products sold after August 14, 2011 (if technologically feasible).

Comment: Books, including library books.

A number of comments, including the Association of American Publishers, Inc. (comment no. 210), Scholastic, Inc. (comment no. 219), and many printers (collectively comment no. 240) addressed whether children's books contain lead at levels that exceed the CPSIA section 101 limits and requested that ordinary books and other printed materials be excluded from testing requirements.

Some commenters, including the American Library Association (comment no. 169), requested that books available in libraries should not be subject to the CPSIA requirements, or should be determined to not contain lead the exceeds the CPSIA limits, and should not be required to be tested.

CPSC Staff Response:

Based on data and information provided in response to the notice of proposed rulemaking and at CPSC staff public meetings with members of the publishing and printing industries (January 22, 2009; June 9, 2009), the staff believes that some components of books, such as paper and similar materials, are not expected to contain excess levels of lead. Further, some parts of books would be inaccessible to a child, and therefore not subject to the lead content requirements (see the Commission's accessibility guidance rule published in the Federal Register). Other parts of books do not necessarily contain lead, but materials such as plastic and metal may contain lead at levels that exceed the CPSIA lead content limits.

With respect to whether libraries must test books in their collections, only manufacturers and importers of children's products are required to obtain testing showing compliance with CPSIA lead limits. A library is neither a manufacturer nor an importer, and just like a seller of used products, is not required to obtain testing of products prior to sale or distribution.

Children's ordinary books and similar products may be addressed in a separate Commission proceeding to provide specific guidance for these products.

APPENDIX A

AFFILIATION

joppich.heidi@gmail.com

buster.sugar@vahoo.com

jsandkgaffney@hotmail.com

www.DillyBopDesigns.com Fresh & Funky Loungewear

sgantiques@earthlink.net

MJKetner119@aol.com

carolkroll@vahoo.com

CJ's Fine Designs

For Little Ones!

United States Consumer Product Safety Commission
4330 EAST WEST HIGHWAY BETHESDA, MARYLAND 20814

Memorandum

Date: JUL 13 2009

TO : The Commission

: Todd A. Stevenson, Director, FROM

Office of the Secretary

SUBJECT: Children's Products Containing Lead; Proposed Determination Regarding

Lead Content Limits on Certain Materials or Products; NPR:

Published in the Federal Register January 15, 2009

Comments due by February 17, 2009

	Comments	due by rebruary 17, 2009		16	1/09/09	Ann Whisler	www.creativeworksbyann.com
COMMENT	DATE	SIGNED BY	<u>AFFILIATION</u>	17	1/09/09	Hilda Scire	Pembroke, ME
1	12/28/08	Joanne M. Arthur	Happy-Girl-Lucky	18	1/09/09	Liz Fraijo	Sugarplum Creations
		Proprietor		19	1/09/09	Laurie Williams	Crawler Covers & More
2	1/03/09	The Handmade Toy Alliance	(144 toy stores)	20	1/09/09	Lindsey Hignite	lhignite@nc.rr.com
3	no date	Pam Crowson Stay at home mom	crowsnest5@Surry.net	21	1/09/09	Judy Elizabeth Reid	reidsranch@3riversdbs.net Box 6, Babb. MT 59411
4	12/28/08	Pam Crowson	se 44	22	1/09/09	Bridget Ann Parsell	Charbridge Knits & Gifts
5	1/05/09	Laura E. Jones Executive Director	United States Association of Importers of Textiles and			· ·	6490 Chabot Rd. Lachine, MI 49753
			Apparel 1140 Connecticut Ave., NW Washington, DC 20036	23	1/09/09	Stefanie Rehbein	Hip Kids Tye Dye Madison, WI 53719
6	1/08/09	Cynthia Jamin Owner/Designer	TwirlyGirl Girl's Clothing Company	24	1/09/09	Suzi Lang	Starbright Baby Giraffes! www.starbrightbaby.ctsy.com
			(USA)	25	1/09/09	Christine Harling	bluemoose@cableone.net
7	1/09/09	Jennifer Goldston	pumpkinesque725@hotmail.com	. 26	1/09/09	Laura Farrell	lefarrell@gmail.com

COMMENT DATE

1/09/09

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SIGNED BY

Heidi Joppich

Sara Sacks

Carol Kroll

Janie Gaffney

Cindy Jordan

Sharon Griffin

Marilyn Ketner

Michele Williams

CPSC Hotiline: 1-800-638-CPSC (2772) * CPSC's Web Site: http://www.cpsc.gov

COMMENT	DATE	SIGNED BY	AFFILIATION	COMMENT	DATE	SIGNED BY	<u>AFFILIATION</u>
27	1/09/09	Stefanie Rehbein	HipKids Tye Dye	44	1/09/09	Tammara Alwaked	Garland, TX
		(additional clarification)	Madison, WI 53719	45	1/09/09	William L. Martin III	Downs Rachin Martin PLLC
28	1/09/09	Brenda Lovejoy	PO Box 506 Wittmann, AZ 85361	46	1/09/09	Jenn	jlsouth2@insightbb.com
29	1/09/09	Jesi Joston	www.HipViolet.Etsy.com	47	1/09/09	Clint and Katie Nelson	cknelsen@iowatelecom.net
30	1/09/09	Brenda Lovejoy	PO Box 506	48	1/09/09	Allison Ruhman-Rood	iciclechic@aol.com
			Wittmann, AZ 85361	49	1/09/09	Heather	heather.watling@verizon.net
31	1/09/09	Neeka Norbury	nnorbury@gmail.com	50	1/09/09	Cheri Ita	krita@danvilletelco.net
32	1/09/09	Sue Cogan	coganscreations@yahoo.com	51	1/09/09	Teresa S. Ruhman	t.ruhman@sbcglobal.net
33	1/09/09	Nicky O'Reilly	ncoreilly@comcast.net	52	1/09/09	Shelley Rae Ruhman	Alain Pinel Realtors
34	1/09/09	Allyson	Timeless Puzzles sales@timelesspuzzles.com			•	2 Theatre Square, Suite 215 Orinda, CA 94563
35	1/09/09	Debbie Suess	Lillifee Boutique	53	1//09/09	Darlene LeBrock	dmlebrock@earthlink.net
36	1/09/09	Rachel Zylstra	Hop Scotch Children's Store	54	1/09/09	Linda Kessler	lkcreation@yahoo.com
		Owner	962 Lake Dr. SE Grand Rapids, MI 49506	55	1/09/09	Amy Nance	www.barenecessities.etsy.com
37	1/09/09	Susan Deady	Susie Dee's	56	1/09/09	Caroline Baird	palmtreessun@hotmail.com
38	1/09/09	Melissa Dunnaway	she-elf-1@hotmail.com	57	1/10/09	Linda Kessler	lkcreation@yahoo.com
39	1/09/09	Shaylind Standing	rww.constantdreamer.etsy.com	58	1/10/09	Candice Mangum	13180 Taylor Wells Rd. Chardon, OH 44024
40	1/09/09	Elaine Bard	Elaine_Bard@umit.maine.edu	59	1/10/09	Jennifer Young	youngjenn76@aim.com
41	1/09/09	Kelly	kstuffings@comeast.net	60	1/10/09	Sarah B. Natividad	Curious Workmanship
42	1/09/09	Nick & Sandy	nicks42@frontiernet.net	61	1/10/09	Rose Jagt	prairieroses@gmail.com
43	1/09/09	Denise Handwerker	www.crastwerker.etsy.com	62	1/10/09	Joyce Tipton	Winchester, KY
				63	1/10/09		eativekiddo@consolidated.net
•		,		64	1/10/09	Erin Oeser	erinoeser@yahoo.com

COMMI	ENT DATE	SIGNED BY	<u>AFFILIATION</u>
65	1/10/09	Beth Rippen	thwapped@thwapped.com
66	1/10/09	Michelle Gibas	eyeletsewing@sbcglobal.net
67	1/10/09	Melisa Parker	melisa@prettypiggysboutique.com
68	1/10/09	Jessica Bailey	Bow Maker and Stay at home Mom
69	1/10/09	Pamela J. Todd	3313 E. Rhorer Road Bloomington, IN 47401
70	1/10/09	May Nunes	Kids~Cottage~Boutique
71	1/10/09	Delena Wright	del_wri@yahoo.com
72	1/10/09	William B. Morris	3205 Cottonwood Ln Temple, TX 76502-1703
73	1/10/09	Tammy Nichols	625 SE Bugle Ct. Blue Springs, MO 64014
74	1/10/09	Carrie Bigbie	Dressin' Cutie cjv97@yahoo.com
75	1/10/09	Lee Williams	Puzzles N Things puzzlesnthings@att.net
76	1/10/09	June Ballou	garyballou@sbcglobal.net
77	1/10/09	Laura Singer	Lil' Munchkin Boutique
78	1/10/09	Patricia Henning	Stitchin' Tricia Embroidery Works
79	1/10/09	Sherryl Mascarinas	sherrylmascarinas@gmail.com
80	1/10/09	Shirley	even-if@earthlink.net
81	1/10/09	April Eaton	aprileaton04@yahoo.com
82	1/10/09	Shannon M. Brott	shannonmargetbrott@gmail.com
83	1/10/09	Jen Winckler	wincklers@thewincklers.com

COMMENT	DATE	SIGNED BY	AFFILIATION
84	1/10/09	Vicky	caseyhanrahan@sbcglobal.net
85	1/10/09	Betty Hilyer	betsysbows@earthlink.net
86	1/10/09	Valerie Oldemeyer	2115 W. 6 th St. Port Angeles, WA 98363
87	1/10/09	Marizel Muniz	marizelb@yahoo.com
88	1/10/09	Michelle Ware	Gracie Belle Bows
89	1/10/09	Bretta Gonsalez Owner	Grace Bowtique
90	1/10/09	Elizabeth Lopez	dlizious04@yahoo.com
91	1/10/09	Keri Buck	kerioke13@yahoo.com
92	1/10/09	Kristin Cranmer	Kristin@vloutextiles.com
93	1/10/09	Heather McDonald	javandheather@yahoo.com
94	1/10/09	Candice Bannan	candicenicole19@yahoo.com
95	1/10/09	Missy Milne	missyswanberg@yahoo.com
96	1/11/09	Lois Jarvis	Madison, WI
97	1/11/09	Robert Carriveau	rovel2@centurytel.net
98	1/11/09	Shawn Foy	shawnmu97@yahoo.com
99	1/11/09	Tracy Erger	PBandJ*Creations
100	1/11/09	Lori Jozwiak	lorijoz@netzero.net
101	1/11/09	Sue Lappan Creator and Designer	Ecoleeko
102	1/11/09	Renee Eggleston	candy stick lane@yahoo.com
103	1/11/09	Jacquie Barker	barkerebay@yahoo.com

COMMEN	T DATE	SIGNED BY	AFFILIATION	COMME	NT DATE	SIGNED BY	<u>AFFILIATION</u>
104	1/11/09	Cindy	cmyflowers@aol.com	120	1/13/09	Suzsh	suzsh@yahoo.com
105	1/11/09	Robin Beal	1104 SW 19 th St. Blue Springs, MO 64015	121	1/13/09	Robin Riggs	Ella Jean Baby Gifts www.ellajeangifts.etsv.com
106	1/11/09	Melinda Tabacco	mtabaccoll@yahoo.com	122	1/13/09	Melanie Tommey	MCC Enterprises AkaMel's Country Crafts
107	1/11/09	Stephanie Mains	ablushingbride@yahoo.com				www.melscountrycrafts.com 1004 N Lincoln
108	1/11/09	Kalli Inman	www.KalQuilts,biz Custom Embroidery				Sand Springs, OK 74063
109	1/11/09	Francisbel Boutique	francisbelboutique@hotmail.com	123	1/13/09	Karen Blum Boateng	Little Gems
110	1/11/09	Mary Lou Huelsman	Princess Purses	124	1/13/09	Deborah Lundgren	DebAviary@aol.com
111	1/11/09	Heather Akers	Creative Kiddos	125	1/13/09	Allison Kelly, M.D. Owner/Designer	Little Miss Blooms
112	1/12/09	Jennifer van Vorst	Turtle Park Tots	126	1/13/09	Sarah Kronland	Mairzey Dotes www.mairzeydotes.com
113	1/12/09	Joanne Levine	Jodi Levine, Wild Child Tie-Dyes www.wildchildtiedyes.com 33 Amherst Road	127	1/13/09	Hilary Lane	TOT Warehouse
			Pelham, MA 01002	128	1/13/09	Brenda Lovejoy	Lovejoy Fabrication
114	1/12/09	Sarah Lee	sarah@sarahssilks.com	129	1/13/09	Lisa A. Rooney	crescentmoonschool@gmail.com
115	1/12/09	Wendy Platt Owner	Ruby RedShoes Baby, Inc.	. 130	1/14/09	Kathy Anderson	bumpkinpatch@hotmail.com
116	1/12/09	Holli Grubb	Hair Sprouts Bowtique	131	1/14/09	The Crowson Family	crowsnest@surry.net
117	1/13/09	Louise Genowitz	lgenowitz@hotmail.com	132	1/14/09	Marsha Stoops Vifquain Vice President	Edeo, Inc.
118	1/13/09	Claudia Garcia-Bouchacourt	Le Petit Boutique Handmade Blythe Clothing 3800 North Mesa Street Suite A2 #219	133	1/14/09	Jaminda Springer	Nato Bello Beautiful Baby Slings For the Artful Mother
119	1/12/09	Gavin & Laura Smith	El Paso, TX 79902 Baby Boss	134 (same text	1/14/09 as 131)	The Crowson Family	crowsnest5@surry.net
117	1/12/07	Curm & Lana Onnui	9625 Monticello Drive Granbury, TX 76049	135	1/14/09	Paula Mair	Paula_sews@comcast.net

COMMENT	DATE	SIGNED BY	AFFILIATION	COMMENT	DATE	SIGNED BY	<u>AFFILIATION</u>
136	1/14/09	Sherry E. Baber	7704 Lampworth Terrace Richmond, VA 23231	153	1/21/09	Susan J. Moore	Moore Teddy Bears 617 Fieldstone Circle W Chelsea, MI 48118
137	1/14/09	Michelle Fei	Hip Girl Boutique	154	1/21/09	Lawerence H. Kloess, III	917 Jones Parkway
138	1/15/09	Craft Yarn Council of Americ Caron International	a				Brentwood, TN 37027
		Coats & Clark Lion Brand Yarn Co.		155	1/21/09	Rachel Shaw	rachelkshaw@gmail.com
		Spinrite, Inc. TMA Yam		156	1/21/09	Tammy	tammyt1957@aoi.com
139	1/15/09	Christine Ewald	Taxewald@aol.com	157	1/21/09	Anja Wray	8235 Stafford Mills Rd. Oak Ridge, NC 27310
140	1/15/09	Lori Wahl	Mister Judy, LLC	158	1/21/09	Shelly Meintzer <u>lii</u>	l-ladvbugs@mi-connection.com
		Partner/Owner		159	1/22/09	Laura Mellberg	162 Ash Street
141	1/15/09	Diana Havier	dhawkeyette@yahoo.com				Denver, CO 80220
142	1/15/09	Carol Garrett	<u>cr@bjwe.com</u>	160	No Date	Laura Mameesh	Oakland, CA
143	1/15/09	Camille Workman Owner/Designer/Seamstress	Camille@framehuggers.com	161	1/23/09	Cheryl Kelly	821 East State Street Salem, Oh 44460-2298
144	1/16/09	Willy Lin SBS JP Vice Chairman	Textile Council of Hong Kong	162	1/23/09	Rose Kos	roksyworld@yahoo.com
145	1/16/09	Valerie Hall	lariha53@bellsouth.net	163	1/24/09	Jeanne Stock Knitter	6571 Loud, Dr. Oscode, MI 48750
146	1/17/09	Rae LynnGlispin	kidzcomfort@vahoo.com	164	1/25/09	David L. Tucker Linda S. Lagace	6042 Lone Star Lane Riverbank, CA 95367
147	1/18/09	Mindy Harris	mindyharris@yahoo.com	165	1/25/09	Ivy Tomosawa	ivy@mysweetiebean.com
148	1/19/09	Sue Zoedak	zoedak@sbcglobal.net	166	1/25/09	Robert F. Johnessee	Bunker Hill Public Library
149	1/19/09	Joe Williams	AirbrushGvpsy@aol.com	100		President	PO Box P Bunker Hill, IL 62014
150	1/20/09	The Real Diaper Industry Asso	ciation	167	3/23/09	Wang Nini	China WTO/TBY National
151		April Todd y Designer and Mom	www.littlemissprincesstutu.com	10,	3,23,03	Director General	Notification & Enquiry Ctr No. 9 Ma Dian Dong Lu, Hai Dian District, Beijing
152	1/20/09	Julie S	userhc2001@gmail.com	168	1/26/09	Phillip Wakelyn PhD	National Cotton Council

COMMEN	T DATE	SIGNED BY	AFFILIATION	COMMENT	DATE	SIGNED BY	<u>AFFILIATION</u>
169	1/26/09	Nathan A. Brown On behalf of American Library Association	Ropes & Gray LLP One Metro Center 700 12th Street, Ste 900	186	1/23/09	Sara Saxton Youth Services Librarian	Tuzzy Consortium Library Barrow, AK
		•	Washington, DC 20005-3948	187	1/23/09	Delane R. James Library Director	Buckham Memorial Library 11 Division Street East
170	1/26/09	Mindy Harris	mindyharris@yahoo.com				Faribault, MN 55021
171	1/26/09	Marilyn Chalais	mchalais@earthlink.net	188	1/24/09	Katie Gatten Children's Librarian	Mansfield/Richland County Mansfield, OH
172	1/26/09	Julie O'Connor	Heavenly Hues Wool Studio			Madison Branch	
173	1/27/09	Stacey Kitchen	spacewurx@gmail.com	189	1/28/09	Karen C. Neville	P.O. Box 913 Berlin, MD 21811
174	1/27/09	Beverly Dye	gramps@dye2.myrf.net	190	1/28/09	Meredith Kivi	2411 Weston Avenue
175	1/27/09	Judy	judyahope@comcast.net	190	1/28/09	Meredith Kivi	Schofield, WI 54476
176	1/27/09	Tracey Dowker	tracey@hollandhospital.org	191	1/30/09	Deborah Poillon Library Director	Cape May County Library 4 Moore Road, DN2030
177	1/27/09	Donna Albertson	donnasquiltcreations@charter.nct				30 West Mechanic Street Cape May Court House, NJ
178	1/28/09	Allyson van Ginneken	greenthumb_ally@hotmail.com				08210
179	1/28/09	Susan Weir	Weir Crafts	192	1/29/09	Robert Carona Membership Chairman	Jax Woodworkers Club
180	1/28/09	Ellie Peck	1680 NE 8 th Ave Oak Harbor, WA 98277	193	1/29/09	Susanna DeFazio Owner	Papa Don's Toys 87805 Walker Creek Road
181	1/28/09	Kathy Anderson	bumpkinpatch@hotmail.com			,	Walton, OR 97490
182	1/28/09	Ann Marie Rodgerson	amrodgerson@gmail.com	194	1/29/09	Angela Plagge Assistant Library Director	Cape May County Library 4 Moore Road, DN2030
183	1/28/09	Joyce Deutsch	turtlerejoicing@yahoo.com			1 District District District	30 West Mechanic Street Cape May Court House, NJ
184	1/28/09	Richard A. Stewart Mayor	City Hall 14177 Frederick Street PO Box 88005	195	1/29/09	Alison Orr	08210 Palos Verdes Library District
	1 100 /00	note all need	Moreno Valley, CA 92552			Young Adult Assistant Manager	701 Silver Spur Rd. Rolling Hills Estates, CA 90274
185	1/29/09	Robert E. Reed Board of Directors	Tallassee (Alabama) Community Library 88838 Tallassee Highway Tallassee, AL 36078	196	1/29/09	Nancy Gold President	Tough Traveler 1012 State Street Schenectady, NY 12307

COMMEN	T DATE	SIGNED BY	AFFILIATION	COMMENT	<u> DATE</u>	SIGNED BY	AFFILIATION
197	1/29/09	Sandrine Droumenq Lolligo Managing Partner	Lolligo LLC 39 Ely Brook Road East Hampton, NY 11937	209	2/11/09	Cullen L. Hacker Managing Director	The Enamelist Society PO Box 920220 Norcross, GA 30010
198	1/29/09	Tina Hill	Kidzsack PO Box 492 West Newbury, MA 01985	210	2/12/09	Allan Adler Vice President for Legal & Government Affairs	Association of American Publishers 50 F Street, NW Washington, DC 20001
199	1/29/09	Julie Rebboah President	Lightning Bug Learning Corp	211	2/12/09	Jim Schollaert Executive Director	Made in USA Strategies 2256 N. Upton St.
200	1/29/09	Marion Scott Owner	Close2Me				Arlington, VA 22207
201	1/30/09	Mary Campbell Director of R&D	Environments, Inc. 501 Carteret Street PO Box 1348 Beaufort, SC 29901-1348	212	2/12/09	Cecelia L. Gardner President, CEO and General Counsel	Jewelers Vigilance Committee 25 West 45 th Street Suite 1406 New York, NY 10036
202	1/30/09	Kathleen Geiger	messnerk001@hawaii.п.com	213	2/13/09	John L. Wittenborn Joseph J. Green	Kelley Drye & Warren LLP Washington Harbour, Ste 400
203	1/30/09	Stephen Lamar Executive Vice President	American Apparel & Footwear Association 1601 N. Kent Street, 12 th FL			Counsel to the Leather Industries of America	3050 K Street, NW Washington, DC 20007
			Arlington, VA 22209	214	2/13/09	Joseph J. Green Wayne D'Angelo	Kelley Drye & Warren LLP Washington Harbour, Ste 400
204	2/02/09	Barry Evans COO	Covenant Communications, Inc.			Counsel to the Specialty Steel Industry of North America	3050 K Street, NW Washington, DC 20007
205	2/02/09	Alan Bell Managing Director	The Bell Group / Rio Grande	215	2/16/09	Laura E. Jones Executive Director Submitted by John B.	United States Association of Importers of Textiles and Apparel
206	2/04/09	J. Michael Smith, Esq. President	HSLDA Advocates for Homeschooling Purcellville, VA 20134			Pellegrini Counsel for	13 East 16 th Street, 6 th Floor New York, NY 10003
207	2/06/09	Charlotte MacDonald	Wheeel Everyday Play Gear	216	2/17/09	Tom Hutcheson Regulatory and Policy Manager	Organic Trade Association PO Box 547 Greenfield, MA 01302
208	2/09/09	Shan Aithal, Ph.D. Director of Technology	Stuller, Inc. 302 Rue Louis XIV Lafayette, LA 70508	217	2/18/09	Becky Maggard	Freelance Children's Clothing Design Monogram & Embroidery

COMMENT DAT	CE SIGN	ED BY	AFFILIATION	COMMENT	DATE	SIGNED BY	<u>AFFILIATION</u>
218 2/17/	Ned S	itted by tteiner er@strtrade.com	The Hosiery Association Acme-McCrary Corporation Crescent Inc. Hanesbrands Inc. Kayser-Roth Corporation	222	2/17/09	Ryan Trainer Executive Vice President & General Counsel	International Sleep Products Association 501 Wythe Street Alexandria, VA 22314-1917
			Knit-Rite Inc. Renfro Corporation	223	2/17/09	Sheila A. Millar On behalf of Fashion Jewelry Trade	Keller and Heckman LLP 1001 G Street, NW Suite 500 West
219 2/17/		ew Hedden . & General Counsel	Scholastic Inc. 557 Broadway			Association	Washington, DC 20001
			New York, NY 10012	224	2/17/09	Kevin M. Burke President & CEO	American Apparel & Footwear Association
	V.P	ine Colaneri - Manufacturing and y Chain				Trestant & ODO	1601 North Kent Street Suite 1200 Arlington, VA 22209
220 2/17/		ent and CEO	C.M. Paula Company 6049 Hi-Tek Court Mason, OH 45040	225	2/17/09	Steve Lamar Submitted on behalf of coalition of 30 trade associations	American Apparel & Footwear Association
		m Creager tive VP / CFO		226	2/17/09	Donald L. Mays Senior Director, Product Safety & Technical Public Policy	Consumers Union
221 2/17/	/09 David Preside	T. Tayloe, Jr., MD, FAAP ent	American Academy of Pediatrics			Janell Mayo Duncan Senior Counsel	Consumer Union
			Consumer Federation of				
		or of Product Safety enior Counsel	America			Rachel Weintraub Director of Product Safety and Senior Counsel	Consumer Federation of America
		Director, Product and Technical Public	Consumers Union/ Consumer Reports			Nancy A. Cowles Executive Director	Kids in Danger
	Nancy		Kids in Danger			Diana Zuckerman President	National Center for Women & Families
		Zuckerman, Ph.D.	National Research Center for Women & Families			David Arkush Director	Public Citizen's Congress Watch
	Elizabe	eth Hitchcock	U.S. Public Interest Research Group			Ed Mierzwinski Federal Consumer Program Director	U.S. Public Interest Research Group

COMMEN	<u> DATE</u>	SIGNED BY	<u>AFFILIATION</u>
226 cont'd.	2/17/09	Elizabeth Hitchcock Public Health Advocate	U.S. Public Interest Research Group
	2/17/0 9	Harrison M. Pollak Deputy Attorney General	Edmund G. Brown Jr. Attorney General State of California Department of Justice 1515 Clay Street, 20 th FL Oakland, CA 94612
228	2/17/09	John Bradfield Director Environmental Affairs	Composite Panel Association 19465 Deerfield Avenue Suite 306 Leesburg, VA 20176
229	2/17/09	Georgia C. Ravitz	Arent Fox LLP Washington, DC
		Scott A. Cohn	Arent Fox LLP New York, NY
230	2/17/09	Paul Noe Vice President, Public Policy	American Forest & Paper Association 1111 Nineteenth Street, NW Suite 800 Washington, DC 20036
. 231	2/17/09	Keith A. Jenkins Submitted on behalf Gildan Activewear	Sorini, Samet & Associates, LLC Ten G Street, NE, Suite 710 Washington, DC 20002
232	2/17/09	Ryan Trainer Executive Vice President & General Counsel	International Sleep Products Association 501 Wythe Street Alexandria, VA 22314-1917
233	2/18/09	Peter T. Mangione	Footwear Distributors and Retailers of America 1319 F Street, NW, Suite 700 Washington, DC 20004

COMMENT DATE	SIGNED BY	<u>AFFILIATION</u>
234 2/20/09	Emily Sheketoff	American Library Association 1615 New Hampshire Avenue, NW Washington, DC 20009
235 1/12/09	Amber Widlake-Herring	adwidlakeherring@yahoo.com
236 1/12/09	Becky McMullen	mypewteriscewter@comcast.net
237 3/17/09	Amy Schulz	Happy Magpie LLC
238	form letters (5)	natural and other textile and apparel materials
239	form letters (7)	natural products
240	form letters (57)	book printers
241	form letters (85)	hair ribbon and bows, etc.
242	form letters (29)	ribbon, etc.
243	form letters (24)	Project Linus
244 2/25/09 CONFIDENTIAL	Michael S. DeFranks Director of Engineering	Simmons Company



Memorandum

Date:

June 5, 2009

TO

: Kristina Hatlelid, Ph.D., M.P.H., Project Manager

Directorate for Health Sciences

THROUGH: Hugh M. McLaurin, Associate Executive Director

Directorate for Engineering Sciences Patricia K. Adair, Division Director Combustion and Fire Sciences

FROM

: Allyson Tenney, M.S., Textile Technologist

Directorate for Engineering Sciences

SUBJECT: Textiles and Apparel Subject to the CPSIA

Introduction

Section 101 of the Consumer Product Safety Improvement Act (CPSIA) sets new limits on lead content in any children's product as defined in the Act. Under the Act, by February 10, 2009 products designed or intended primarily for children 12 years of age and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. The limit will be reduced to 100 ppm in 2011 unless the Commission determines that it is not technologically feasible.

Apparel and textile products intended for children are subject to the prescribed lead limits under the Act. This memorandum summarizes the general practices used in the textile industry and in the modern production and coloration of textiles and apparel. Most textile products are manufactured using processes that do not introduce lead or result in an end product that would exceed the lead limits prescribed in the Act.

Segments of the Textile Industry

Textile products are manufactured for a variety of uses including toys and children's products, apparel, home/decorative furnishings, and industrial/technical applications. The major production stages of the textile industry are fibers, yarns (and threads), fabrics, finishing, and coloration (dyeing and printing).

Textile Fibers Fiber production is one major segment of the textile industry. Fibers are the basic element of textile structures and are either natural or manufactured (man-made). Natural fibers are obtained from either plants or animals. Examples of plant based fibers, from the seed, stem, or leaves

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of plants, include but are not limited to cotton, kapok, flax, jute, ramie, hemp, kenaf, bamboo, coir, and sisal. Animal fibers, or natural protein fibers, include but are not limited to silk, wool (sheep), and hair fibers from alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut. and guanaco. Natural fibers are natural materials and do not contain lead.

Fibers that are not obtained from natural sources are classified as manufactured or man-made. Manufactured fibers are created by technology and are classified as regenerated, inorganic, or synthetic. Regenerated fibers are made from natural materials that are reformed into usable fibers. These fibers include but are not limited to rayon, azlon, lyocell, acetate, triacetate, and rubber. Synthetic fibers are polymers created through a chemical process and include but are not limited to polyester, olefin, nylon, acrylic, modacrylic, aramid, and spandex. Manufactured fibers are produced in controlled environments by processes that do not use lead or incorporate lead at any time during their production.

Yarns and Fabric Two other segments of the industry include the production of yarns (and threads) and fabric (textile) formation. Yarns and threads are produced with fibers2 that are grouped and twisted together in a spinning mill. Yarns and threads are then used to produce fabrics and textile products. Fabrics can broadly mean any woven, knitted, braided, knotted, or non-woven textile structure made of fibers or yarns. Most textile fabrics are made from yarns, although some fabrics are created from solution or fibers, as in the case of non-wovens. Textile fabrics are produced in a wide range of weights, thicknesses, and sizes and are used to produce many types of products. In addition to forming the base fabrics for apparel, textile fabrics used for apparel include underlinings, fillings, interlinings, ribbons, trims (lace, edgings, tapes), clastic, and some closures and findings.

Textile fiber content, yarn construction, and type of fabric are selected based on cost factors, end use, and desired performance of the product. Most apparel products are made from cotton and polyester. These fibers are the two most used fibers for apparel; the industry estimates that they account for about 80% of the fiber used to produce apparel. Fabric for children's products and apparel is selected for its cost, durability, comfort, and case of care. For these reasons, some materials are rarely used for children's products. For example, silk, metallic threads, specialty fibers, and glass fibers are seldom used for children's products and apparel.

Textile Finishing The finishing segment of the industry includes a number of treatments that are used to aid processing, enhance appearance, improve performance, or achieve a desired surface effect. Finishing processes can be done to fibers, yarns, or fabrics and can be described as either dry or wet finishing. Some examples of finishing treatments may include scouring, bleaching, heat setting, calendaring, embossing, and pressing. Finishing also includes the application of chemical finishes that are applied to enhance performance. Examples include softening, soil release, and durable press finishes Most wet finishes use inorganic chlorine, peroxide compounds, and organic compounds that would not be expected to introduce lead into the process. Some processes are done before coloration while others are done after coloration.

Textile Coloration Another segment of the industry involves coloration which includes dyeing and printing. Coloration of textile products is achieved by the addition of colorants (dyestuffs) that are either dyes or pigments.

Textiles and Apparel

¹ Natural fibers are also obtained from mineral sources.

² Yams may also be produced from extruded polymer films for slit film yarns and polyester and nylon foils. These yarns may have a metallic appearance, but do not contain lead, lead based materials, or other metals,

Dyes are organic chemicals that can be dissolved and made soluble in water or another carrier so they can penetrate into the fiber. Dyes can be used in solutions or as a paste for printing. Commercial dyes are classified by chemical composition or method of application. Many dyes are fiber specific. For example, disperse dyes are used for dyeing polyester and direct dyes are used for cellulosic fibers. Dyes can be applied to textiles at the fiber, yarn, fabric, or finished product stage. Dye colorants are not lead based. Although not typical, some dye baths may contain lead. However, even if the dye bath contained lead, the colorant that is retained by the finished textile after the rinsing process would not contain lead above the non-detect lead level.

In contrast to dyes, pigments are either organic or inorganic. Pigments are insoluble in water and are applied to the surface of textile materials and are held there by a resinous binder. Most pigments do not contain lead, but there are some lead based paints and pigments that could be used for textile printing, such as a transfer or decal type print. The type of colorant, either pigment or dye, is selected based on fiber type, desired color, coloration process, and required colorfastness. Most commercial coloration processes do not use lead-based processes. Processes that are lead-based are used for some industrial textiles that require a greater level of colorfastness or durability, but are not typically intended for apparel textiles.

Industry Data

During a public meeting held on January 22, 2009, industry representatives, test laboratories, and stakeholders met with CPSC staff and presented materials and test data⁴ on lead levels in textile and apparel products. Several hundred test reports and analyses were submitted. The tests analyzed lead levels in various textile and apparel products, including a range of daywear, sleepwear, and outerwear garments. Tests for lead were also conducted on the many functional and decorative components used on apparel items. These items include adornments (rhinestones and bends), closures and findings (buttons, snaps, zippers), trims, and fasteners. The data were reviewed by CPSC staff and showed that many textile and apparel products do not contain lead that would exceed the limits established by the CPSIA.

Information on the dye industry was submitted by the Ecological Association of Dye and Organic Pigment Manufacturers (ETAD). ETAD represents about 80% of worldwide dye manufacturers. According to ETAD, 80% or more of dyes used in commercial processing are organic carbon compounds and do not contain lead. Dyes used for cotton, other cellulosics, and polyester, the most commonly used fibers for apparel, account for 70% of total dye consumption. These fibers use specific dye classes (e.g., disperse, direct, reactive) that do not typically contain lead. ETAD recommends that ETAD member companies follow lead limits of 100 ppm using a sampling and testing procedure that ensures the recommended limits. Any lead levels in excess of 100 ppm are reported in a Materials Safety Data Sheet (MSDS).

Textiles and Apparel

Other Products

Although leather and fur are not made from fibers like most textiles, they may be used to produce apparel and coverings or may be used along with textile products. Fur and leather begin with natural products, but they must undergo processing (e.g., tanning) to convert the natural skin into a usable, durable product. Similar to most textile products, fur and leather products are often colored with dyes or pigments during their processing. Many of the same dyes used in the textile industry are also used for dying leather. According to information submitted by the Leather Industries of America, many of the processes used to process and finish leather do not incorporate lead or lead-based chemicals. However, some leather products may be colored using lead-based pigments.

Conclusion

Apparel and textile products intended for children are subject to the prescribed lead limits under the Consumer Product Safety Improvement Act (CPSIA). Modern textile and apparel production established practices that are recognized and well-characterized. With a few uncommon exceptions, the modern production practices do not involve lead or lead-based chemicals. There is no indication that any of the production practices introduce lead amounts into textile products and apparel that would exceed the lead limits established by the CPSIA. Textile materials and products that do not contain lead and have not undergone any processing or treatment that imparts lead resulting in a total lead content that exceeds the CPSIA total lead limits could be included in the exemptions. Appendix A lists some of the possible exemptions.

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³ Binders used with pigments for textiles are non-lead based.

Available from the U.S. CPSC Office of the Secretary.

⁵ Available from the U.S. CPSC Office of the Secretary,

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Appendix A: Possible Textiles and Apparel Product Exemptions

Exemptions include materials and products that do not contain lead and have not undergone any processing or treatment that imparts lead resulting in a total lead content that exceeds the CPSIA total lead limits.

Included in the exemptions:

Non-metallic, dyed, undyed (and/or finished) fibers, threads, yarns, fabrics (woven, knit, or non-woven) (base fabrics, underlining fabrics, and fillings), ribbons, trims (lace, edgings, and tapes), closures, and other findings and fasteners (e.g., clastics, hook and loop tape) consisting of:

Natural fibers:

Plant-based seed, bast, and leaf fibers including but not limited to cotton, kapok, flax, jute. ramic, hemp, kenaf, bamboo, coir, sisal

Animal-based fibers including but not limited to silk, wool (sheep), and hair fibers from alpaca. Ilama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco

Man-made fibers

Modified/regenerated and natural polymers including but not limited to rayon, azion, lyocell, acetate, triacetate, rubber

Synthetic polymers including but not limited to polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex

Other:

Leather

Fur

Feathers and down

- With or without dyes or other finishing treatments, provided that added substances will not result
 in lead content that exceeds the CPSIA lead limits
- Non-metallic, includes slit film yarns or yarns from extruded polymer films (e.g., polyester and nylon foils)

Not included in the exemptions:

Items that contain lead or have undergone further treatment or processing that may impart lead:

- Plastic or metal fasteners, such as zippers, buttons, grommets, or snaps, with possible lead content
- · Transfers, decals, prints, or after-treatments that use lead-based paints or pigments
- Yarns that contain metal cores
- · Labels that contain metal components or metallic threads or yarns
- Metallic, plastic, painted, coated components, ornaments, or objects, such as rhinestones, due to lead content of some materials shown to exceed CPSIA lead limits
- Polyvinyl chloride (also called PVC and vinyl), due to use of lead in PVC formulations or coloring additives
- · Leather that is finished or colored with lead-based chemicals or pigments

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Memorandum

Date: July 22, 2009

TO

Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health

FROM

THROUGH: Hugh M. McLaurin, Associate Executive Director, Directorate for Engineering

Andrew M. Trotta, Director, Division of Electrical Engineering Sciences

Mark F. Gill, P.E., Electrical Engineer, Division of Electrical Engineering,

Directorate for Engineering Sciences

SUBJECT: Results of Research on Lead Content in Slate

Introduction

This memorandum provides the Directorate for Engineering Sciences (ES) response to the request by the Directorate for Health Sciences to determine the compliance of slate with the lead (Pb) limits established by the Consumer Product Safety Improvement Act (CPSIA). The primary uses of slate in children's products, as defined in the CPSIA, are chalkboards. To answer the question, ES staff attempted to define lead content typically found in slate by researching its geological origins. The response was prepared after consultation with geologists from the US Geological Survey (USGS), the agency in the Department of the Interior which has the scientific staff and expertise on the earth and its composition.

Slate is classified as a dimension stone, which is defined by the USGS as "natural rock material quarried for the purpose of obtaining blocks or slabs that meet specifications as to size (width, length, and thickness) and shape. Color, grain texture and pattern, and surface finish of the stone are normal requirements. Durability (essentially based on mineral composition and hardness and past performance), strength, and the ability of the stone to take a polish are other important selection criteria." The principal rock types are granite, limestone, marble, sandstone, and state.

Assessment

The question of the lead content of slate was directed to Mr. Bill Langer, Research Geologist with the USGS based in Denver, Colorado. Mr. Langer cited a research paper2, "Distribution of the Elements in Some Major Units on the Earth's Crust," that indicated that the concentration of lead in an average or typical shale rock was 20 parts per million (ppm) by weight. Through the

geological process of metamorphism, shale (a sedimentary rock) is transformed into slate (a metamorphic rock) by heat and pressure. Mr. Langer commented, "Slate is much less permeable than shale, and lead mobilization is apt to be even less," indicating that it would be highly unlikely for lead to migrate into slate rock formations after the geological genesis of the slate.

Mr. Langer indicated that in extremely rare instances, metallic ore bodies (containing lead, zinc, copper, gold, etc.) may be created adjacent to bodies of slate through geological processes, as well as any other type of dimension stone. The process of metallic ore body genesis could raise the levels of lead in any adjacent dimension stone bodies (granite, limestone, marble, sandstone, slate) beyond 600 ppm. However, to re-emphasize, ore bodies are considered to be extremely rare geological structures.

Conclusions

It is the opinion of the Directorate for Engineering Sciences staff, with input from the USGS, that the typical dimension stone known as "slate" has a lead content far less than 100 ppm by weight, The typical slate is therefore compliant with the lead content requirements stated by the CPSIA.

¹ United States Geological Survey website, http://minerals.usgs.gov/minerals/pubs/commodity/stone_dimension/

² Turckian, K.K., and Wedepohl, K.H., 1961, "Distribution of the elements in some major units on the Earth's enist: Geological Society of America Bulletin, v. 72, no. 2, pp. 175-192



Memorandum

Date:

July 15, 2009

TO

: Kristina Hatlelid, Ph.D., M.P.H., Project Manager

THROUGH: Andrew G. Stadnik, Associate Executive Director (Music Husbaul), 1.6Directorate for Laboratory Sciences

FROM: Joel Recht, Ph.D., Division Director, Chemistry Division (March Directorate for Laboratory Sciences)

SUBJECT : Lead in Paper

Paper is a generic word for many different products, primarily made from wood pulp or other cellulosic fibers, wet-formed, pressed and dried into thin sheets or rolls (webs) and commonly used in thin sheets for printing, writing, packaging and decorative purposes. Many specialty types of paper exist as well, such as roofing paper, friction paper, abrasive paper, insulation, laminate countertop and flooring, and more. Additionally, synthetic products such as polymer sheets and spun-bonded polyoletins (such as Tyvek®), are sometimes referred to as paper. Given the diverse range of paper products existing, and the vast array of specialty additives necessary to produce some specialty papers, the scope of this memorandum is limited to printing, writing and book papers, along with cover stock, newsprint and other similar cellulosic-based papers, such as cardstock, envelope paper, and folder stock. Examples of these paper types include all of the non-synthetic paper grades listed in the Government Paper Specification Standards² published by the Government Printing Office. (The only two synthetic grades in the Government Paper Specification Standards are O-90 and V90.)

Even given the limited scope of this memorandum, paper contains many components. Uncoated papers typically consist of cellulosic fiber and potentially other plant matter, fillers, process and functional chemical additives, colorants, and recycled materials of the same varieties. Coated papers are made by applying one or more layers of pigments, binders, colorants, and additives to one or both sides of an uncoated base paper. Papermaking generally consists of the following steps: Cellulosic fiber is obtained through mechanical and/or chemical means from wood or other plants. The fibers are dispersed in water to the point of being a suspension of individual fibers in a furnish (the sturry of water, paper, fillers and additives used to make paper). Fillers, process chemicals and functional chemicals are also added to the papermaking furnish to produce a well-mixed stock that is typically about 99% water. This papermaking furnish is

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pumped out through a wide slot onto a porous conveyer belt, known as a "Fourdrenier wire" or simply the "wire", at the so-called "wet-end" of the paper machine. The furnish settles on the "wire" with water draining through, and at this point in the process most of the water is removed through gravity and with vacuum. The fibers settle onto the wire into a mat, which is transferred to a series of presses to remove more water and increase the bonding of the fibers which attract each other through hydrogen bonding as the water is removed. The web of paper is then run through heat-dryers, typically in direct contact with heated rolls, to remove most of the remaining water as the paper web progresses to the so-called dry-end of the paper machine. Additional steps in some grades of paper can include application of surface treatments such as sizing, where the paper is run through a size-press to impart starch and other surface treatments. as well as coating to produce papers such as those used in high quality magazine covers. calendars, etc. Each of the papermaking steps will be considered for the possibility of lead introduction into paper.

Cellulosic Fiber

The major component of most paper is cellulosic fiber. The overwhelming majority of paper is made from wood pulp, but a small amount of specialty paper is made with cotton, jute, kenaf, bamboo, and other natural cellulosic fibers. All these natural plant-fibers are inherently free of excessive lead, and would be expected to be well below 100 parts per million lead, regardless of the growing conditions.

There are several significant ways in which wood and other plants are converted into papermaking pulp. Pulp can be classified as chemical pulp, most commonly, through the sulfate (or Kraft) process, where chemical treatments are applied to wood chips to fully remove lignin and other non-cellulose materials, to produce a "wood-free" paper; mechanical or thermomechanical pulp, where mechanical grinding forces alone are used to convert nearly 100% of wood chips into a useable, but less durable material, such as the "groundwood" pulp used for newsprint and other less durable products; and semi-chemical pulp, such as chemi-thermomechanical pulp, where chemical impregnation of the wood chips precedes the grinding to produce a product with less lignin and properties approaching those of fully chemical pulps. Each of these types of pulps can be bleached by a variety of means. Typical bleaching treatments involve the use of chlorinated compounds, such as chlorine or chlorine dioxide. oxygenated compounds such as ozone, oxygen and hydrogen peroxide, and commonly combinations of the above, along with extractions, washes and other chemical treatments to brighten and whiten pulp and remove impurities that adversely affect durability. Neither bleaching, nor pulping imparts lead to the pulp, so bleached and unbleached mechanical, chemical and semi-chemical pulp are all expected to be below 100 parts per million lead.

The other major source of pulp fiber is reclaimed fiber from pre- and post-consumer recycling as well as in-plant reprocessing. Printed papers are commonly deinked and/or washed prior to introduction into the papermaking process. Evidence presented by the printing industry at a public meeting with CPSC staff and in comments indicates that it is highly unusual for leaded pigments to be present in printing inks. If leaded pigments are present, they are much denser than cellulosic fibers, and their removal during washing and de-inking would be expected to be

¹ Dr. Recht worked as a Senior Research Engineer, specializing in papermaking chemistry including fillers, process additives and functional additives to paper for a major pulp, paper and packaging company prior to working for the Government Printing Office as Chief of Testing and Technical Services until he joined the Consumer Product Safety

² Government Paper Specification Standards, No. 11, February 1999, http://www.gpo.gov/customers/vol.11.htm

³ http://www.rrd.com/wwwCPSIA/home.asp.

nearly complete. Thus, it is not expected that recycled papers, even 100% recycled papers, would contain in excess of 100 parts per million lead.

Filler

Many materials are added to paper both for functional and economic purposes. The primary fillers used in papermaking are kaolin clay and calcium carbonate – two inexpensive (relative to bleached chemical wood pulp), white, easily processed pigments which are either mined and processed to purify, whiten and otherwise improve processing, or made by synthetic production, such as precipitated calcium carbonate. The next most common filler used is fitanium dioxide, a bright white pigment with excellent hiding power used to increase both the brightness and the opacity of paper. Titanium dioxide is typically more expensive than the fibers that it replaces, but its superior opacity allows for the use of lighter weight papers and provides value. Other, less common fillers include tale, alumina, and silica. These fillers are manufactured and sold as purified materials intended to impart brightness and uniformity to paper, and none of these natural materials or synthetic pigments is expected to impart lead into paper.

Process and functional chemical additives

A range of chemical additives are combined with paper, including colloidal additives such as alum, quaternary amines, and charged polymers to assist in the removal of water and the retention of fine particles and fillers in the forming of paper, dry- and wet-strength additives such as starch and epichlorohydrin cross-linking resins, and chemicals to impart water-resistance to paper, such as rosin and alkyl ketene dimers. None of these process chemicals are expected to contain or impart any lead to the papermaking process.

Colorants

Dyes and pigments are also added to paper, including "white" paper which is shaded to various tints based on order specifications. While the use of pigments for coloring of paper is possible, their use is limited, and the use of inorganic pigments is even more limited than organic pigments due to a number of factors. For tinting and coloring of fibers at the wet-end, dyes are most commonly used. Dyes, especially basic dyes and direct dyes are relatively inexpensive and widely available and used in easily processed forms which are highly substantive to fiber and produce a uniform color or shade and which can be varied easily to achieve whatever shades are needed. Pigments are comparatively expensive and difficult to use, particularly inorganic pigments, which due to their density tend to produce a pronounced two-sidedness as the pigment will tend to settle in the forming paper mat on the paper machine at a different rate than the fiber and filler suspension. Complex chemistry must be added to get the pigments to retain the pigments with the fibers and not have them drain out through the Fourdrenier wire.

The comparative expense and difficulty involved in the use of inorganic pigments for coloration at the wet-end limits their use to highly-specialized grades of paper, such as for laminate countertop and flooring applications where the decorative layer must be lightfast, durable and be able to withstand the heat and chemical conditions of the resin-impregnation stage to convert

layers of paper into a countertop, such as Formica. Such specialty papers are not expected to be used for ordinary printing and writing purposes.

Size-press coloring is occasionally added as a means of affecting surface properties, and could be done with pigments, but it is unlikely in this case as well to find lead introduction as lead pigments are an unlikely choice for a size-press color. Most size-press applications of color are applications of white pigments for improved surface properties and the same white pigments used as fillers are the ones used in size-press applications. Additives applied at the size press are typically prepared in batches rather than continuous addition as is the case for wet-end dyes so color tinting is generally preferable to control at the wet-end where there is minimal lag time in changing the paper tint upon finding a need to adjust.

Coating

Paper coatings are applied either directly on a paper machine with an integrated coater, or offmachine on a separate coater. In either case, a coating similar to latex house-paint is applied by a
rod or blade to the web of fully formed, dried paper, excess coating is doctored off and the
coated paper is dried, typically by hot air, and/or by passing over heated drums. The coatings
consist of typically the same range of pigments used in wet-end fillers, plus plastic pigments,
binders such as starch and/or latex, colorants and viscosity modifiers. Again, the only case
where lead might be introduced would be the use of leaded pigments for coloring. Again, this is
not done in practice for "ordinary" grades of paper such as those discussed in this memo and
would typically be reserved for specialty grades where there was a specific need. A member of
the American Forest and Paper Association (AF&PA) related at a public meeting with the CPSC
that no lead was found in any paper tested, and that all member companies have stated that they
do not use lead additives.

Summary

Lead is inherently not expected in cellulosic pulp. Other additives to paper include filler, colorants, process chemicals, surface-sizing and coating. While lead pigment colorants are certainly known and used in some industries, such as paint and anti-corrosion coatings, hone of these lead pigments are expected to be used in papermaking for the types of paper used for printing writing and ordinary packaging as described in this memo. Paper of these types is not expected to have greater than 100ppm lead.

⁴ Buxbaum, Gunter. (1998), Industrial Inorganic Pigments, Second Edition. New York; Wiley-VCH.



Memorandum

Date:

3 June 2009

TO

Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health

THROUGH:

Robert J. Howell, Assistant Executive Director, Office of Hazard Identification

and Reduction

FROM

: Randy Butturini, PE, Program Area Team Leader, Office of Hazard

Identification and Reduction

SUBJECT: Lead in Stainless Steel and Titanium Alloys

Stainless steel is a generic name for corrosion-resistant steel alloys. Typically, the manufacturing process for stainless steel uses recycled scrap as well as "virgin" (newly refined) steel. However, the stainless steel manufacturing processes (such as Argon Oxygen Decarburization) heat the steel to temperatures high enough to vaporize any lead and lead oxide present. Once the steel melts, the mix is subjected to a vacuum, and the lead/lead oxide gases are drawn off for condensation and recycling. Consequently, the manufacture of stainless steels results in alloys with lead concentrations less than 100 parts-per-million (ppm).

CPSC staff has searched for stainless steel alloy chemical compositions, both in printed literature (Key to Steel, Verlag Stahlschlüssel, Wegst GmbH, D7142 Marbach, Germany, 1992), and on the internet (e.g., Google, Matweb, ASTM.org). Only one stainless steel alloy, 303Pb, was found to contain lead. The concentration of lead in 303Pb steel is between 0.12% and 0.30% (1200 to 3000 ppm). The Unified Numbering System designation for 303Pb steel is S30360.

Similarly, titanium (both α - and β -phase) uses elements such as aluminum, gallium, oxygen, nitrogen, molybdenum, vanadium, tungsten, tantalum, and silicon as alloying materials. Lead is considered an undesired impurity and is not found in titanium alloys. In over 300 titanium alloys examined. CPSC staff was unable to find an instance where lead was a constituent.

Therefore, the following materials can be considered not to contain lead in concentrations above 100 ppm. Using the Unified Numbering System (UNS):

- 1) Stainless steel currently manufactured of the following types:
 - a. UNS S13800 S66286.
 - b. Exception, UNS \$30360 (303Pb stainless steel) contains lead in excess of the CPSIA limits for children's products.
- 2) Titanium alloys, UNS R5xxxx

CPSC Hotline: 1-800-638-CPSC (2772) *CPSC's Web Site: http://www.cpsc.gov



Memorandum

Date:

17 July 2009

TO

Kristina Hatlelid, Ph.D., Project Manager

Directorate for Health Sciences

THROUGH:

Gregory B. Rodgers, Ph.D.

Associate Executive Director

Directorate for Economic Analysis

Deborah V. Aiken, Ph.D. Senior Staff Coordinator

Directorate for Economic Analysis

FROM

Robert Franklin

Economist

Directorate for Economic Analysis

SUBJECT: Final regulatory analysis of a rule making determinations that certain materials or products do not have lead contents that exceed the limits established in

section 101(a) of the CPSIA

Introduction

On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. Subsection 101(a) of the Act establishes, as of February 10, 2009, a lead limit of 600 parts per million (ppm) by weight for any part of a children's product. Lead content is thereafter limited to 300 ppm as of August 14, 2009, and 100 ppm as of August 14, 2011, if technologically feasible.

On January 15, 2009, the Commission published a notice of proposed rulemaking (NPR) under Section 3 of the CPSIA that made preliminary determinations that certain materials or products inherently do not contain lead in excess of the limits established in subsection 101(a) of the CPSIA. The effect of the determinations would be to relieve manufacturers and importers from the third-party testing and certification requirements established in section 102 of the CPSIA.

The proposed determinations in the NPR were limited to some specific metals or alloys (e.g., surgical steel and precious metals) and some natural materials, including some natural fibers, provided that they had not "been treated or adulterated with the addition of materials or chemicals such as pigments, dyes, coatings, finishings or any other substance, nor undergone any

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ACC's 2009 Annual Meeting

processing that could result in the addition of lead into the product or material." Based on information supplied during the comment period and additional research by the staff, the CPSC staff is confident that the list of materials for which determinations that the materials do not contain lead in excess of the statutory limits can be expanded. Among the materials for which the staff believes determinations are merited include most fabrics (including dyed fabrics), foodgrade materials, paper (including dyed paper), titanium, and slate. In addition the staff believes that a determination can be made that all but one grade of stainless steel do not contain lead in excess of the statutory limits. The final rule contains the full list of materials for which determinations are being made.

Regulatory Analysis

Because the effect of the rule would be to relieve manufacturers and importers of the materials from the testing and certification requirements of Section 102 of the CPSIA, the potential costs of the rule consist of the risk that some hazardous exposures to lead could occur that would have been prevented had the materials or products been tested and certified. However, because the materials and products for which the determinations are being made are those which the staff has concluded inherently do not contain lead in excess of the statutory standards, they are unlikely to pose a risk of injury due to the absorption of lead. Therefore, the costs of the rule, if any, should be negligible.

The potential benefits of the rule consist of the reduced testing costs that would have been incurred by firms to test materials that inherently do not contain lead in excess of the statutory requirements but would have had to be tested anyway under the requirements of the CPSIA. These benefits have not been quantified but are likely to be high. Third-party testing for lead reportedly costs between \$50 and \$100 per substrate tested. Therefore, the Commission's determination that the lead content of these materials do not exceed the statutory requirements could reduce the cost of obtaining third-party testing of a children's product that contains these materials by at least \$50, and possibly more than \$100, depending upon the number of materials used in the product. Since most manufacturers or importers of children's products can be expected to offer at least several different items, this determination could reduce the testing cost for each manufacturer or importer of children's products in which these materials are used by at least several hundred dollars. Because the reduced testing costs represent the benefits of the rule and the costs of the rule (in terms of increased risk of lead absorption) are negligible, the benefits of the rule would exceed the costs.

Impact on Small Businesses

Section 605 of the Regulatory Flexibility Act (RFA) requires the Commission to consider the impact of the rule on small businesses. The number of small businesses that will be directly affected by the rule is unknown but could be considerable. However, because the effect of the proposed rule would be to relieve the manufacturers and importers of the specified materials from the testing and certification requirements the CPSIA, it will not result in any increase in the costs of production for any firm. Its only effect on businesses, including small businesses, will be to reduce the costs that would have been associated with testing the specified materials.

For small manufacturers the reduction in costs provided by the rule could be significant. Small manufacturers typically have small production runs and so the cost of testing each component for lead increases the cost per unit of the final product by more than it does for a large manufacturer.

A few public comments were received that reflected a misunderstanding of the discussion in the NPR of the impact of the rule on small businesses. The commenters mistakenly assumed that the conclusion that the rule would not have a significant impact on a substantial number of small entities referred to the impact on small businesses of the testing required by the CPSIA. However, this analysis covers only the impact of the rulemaking before the Commission - the determination that some materials inherently do not contain lead and, therefore, do not need to be tested

Environmental Assessment

The National Environmental Policy Act requires that the Commission consider the impact of its actions on the environment. The determinations that are the subject of the rulemaking would only relieve manufacturers and importers of certain materials and products that inherently do not contain lead in excess of the CPSIA limits from testing the materials and products for lead content. This rule does not fall into one of the categories of actions described in the CPSC environmental review regulations as having the potential to the produce environmental effects (16 CFR 1021.5) and is in fact highly unlikely to produce an environmental effect.

-2

Product Safety – The CEO's Duty to Report "Defects Immediately" to the Government – Managing the Recall that May Follow

COURSE MATERIALS FOR JOSEPH M. BECK

- SUPPLEMENT Product Safety The CEO's Duty to Report "Defects Immediately" to the Government – Managing the Recall that May Follow
- 16 CFR Part 1115
- 16 CFR Part 1116
- CPSC Interim Final Rule and Withdrawal

SUPPLEMENT

Product Safety – The CEO's Duty to Report "Defects Immediately" to the Government – Managing the Recall that May Follow

— Joseph M. Beck Partner

Overview of the Consumer Product Safety Act (the "CPSA")¹ and the Consumer Product Safety Improvement Act (the "CPSIA") as They Apply to the Duty to Notify the CPSC and Conduct Recalls

Although the CPSC may adopt and impose specific safety standards for the manufacture of products, it more commonly attempts to persuade and sometimes "jaw bone" firms to adhere to (and sometimes upgrade) voluntary industry safety standards.

The Commission may mandate recalls, including the repair or replacement of defective products and the refund of the purchase price; however, the Commission more typically supervises recalls "voluntarily" initiated by affected firms – an ingenious regulatory approach that relies, for its success, upon the "notification" mandate of 15 U.S.C. 2064 (b).

The Duty to Notify Under Section 15 of the CPSA

One of the most important sections of the CPSA requires manufacturers, distributors, importers and retailers to report "immediately" any "product defect" or violation of a CPSC "rule" which "creates a substantial risk of injury to the public." See 15 U.S.C. 2064

¹ In addition to the CPSA, the Commission enforces the Flammable Fabrics Act, including the Standard for Flammability of Clothing Textiles and the more stringent Children's Sleepwear Standard; the Federal Hazardous Substances Act (regulating products ranging from toys to explosives); the Poison Prevention Packaging Act (packaging for a variety of items including common household medications) and the Refrigerator Safety Act. Food, drugs, cosmetics and medical devices are regulated by the FDA pursuant to the Federal Food, Drug and Cosmetic Act; automobiles and other vehicles by the National Highway Transportation Safety Act.

Moreover, § 37 of the CPSA requires manufacturers of consumer products to report information about settled or adjudicated lawsuits if a particular model is the subject of at least three civil actions within specified two-year periods; the lawsuits involve death or grievous bodily injury; and the manufacturer of the product, having notice of the action, is involved in discharging any obligation owed to the plaintiff as a result of the settlement or judgment.

In summary, the CPSA requires companies to report product defects which cause or could cause death or serious injury or which create a substantial risk of doing so.² A failure to report (or to report "immediately") can result not only in fines; it also can complicate defense of product liability suits and generate damaging publicity.

On the other hand, a decision to report to the CPSC will also set in motion a potentially costly chain of events. A firm that reports a defect usually must at the same time describe to the CPSC a proposed "corrective action plan" – typically, the steps the company is taking or soon will take to notify customers and consumers of the risk and of the fact that the company will repair or replace the product or refund the purchase price.

In our experience, it is often advisable to lay out as detailed and effective a corrective action plan as possible and to have begun implementation even before reporting to the CPSC.

The Commission is a small agency, and although its staff is dedicated, it cannot plan and administer the hundreds of recalls that occur each year.

Again in our experience, the CPSC will permit companies that report promptly and undertake a reasonably effective corrective action plan to manage the recall without excessive government control.

An incorrect decision not to report to the CPSC can result in very serious consequences; a decision to report may result in unanticipated costs. Therefore, it is important to consider the question of the duty to report in more detail.

Evaluating the Duty to Report

It is the view of the CPSC that Congress intended to encourage widespread reporting of potential product hazards. Accordingly, the CPSC takes the position that companies must report if the product **could** "create a substantial risk of injury to the public." See generally 16 CFR Part 1115.

While it is possible to argue that a particular product "defect" does not necessarily present a "substantial risk" of injury, it sometimes is wise to "voluntarily"

² As noted, companies also must immediately report any failure of a regulated product to comply with "an applicable Consumer Product Safety Rule" if the failure "creates a substantial risk of injury to the public."

report and in the same report disclaim any obligation to do so. This is because of the CPSC's aggressive notification policy and the serious consequences that flow from guessing incorrectly about the need to report.

The CPSC takes a broad view of the term "defect". Regulations suggest that a "defect" could result from a manufacturing or production error; from a design deficiency or the materials used in a product; or could occur in a product's contents, construction, finish, packaging, warnings and/or instructions. 16 CFR § 1115.4. Assuming that a product contains a "defect," a company must next consider whether the defect may be serious enough to create a substantial risk of injury.

Section 15 lists the following criteria for evaluating this issue:

"Pattern of defect" -- CPSC guidance as to the meaning of this phrase is not very helpful, merely repeating that the defect may stem from the design, composition, content, construction, finish or packaging of a product or from warnings and/or instructions accompanying it.

"The number of defective products distributed in commerce" -- The CPSC states that "even one defective product" can give rise to a reporting obligation where there is a risk of serious injury. 16 CFR 1115.12(g)(1)(ii).

"Severity of the risk" -- The more serious the risk, the greater the likelihood there will be a duty to report it.

"Likelihood of injury"

The Imputation of Knowledge to the Chief Executive Officer

The CPSC will deem a company to have obtained reportable information when the information has been received by an employee who "may reasonably be expected to be capable of appreciating the significance of the information." 16 CFR 1115.14(b).

The regulation continues:

"Under ordinary circumstances, five days should be the maximum reasonable time for information to reach the Chief Executive Officer The Commission will impute knowledge possessed by the Chief Executive Officer . . . simultaneously to the subject firm."

When the Obligation to Report Arises

The obligation to report arises "immediately" under § 15 of the CPSA. The CPSC recognizes that a firm may require some time to investigate and evaluate; however:

"This investigation and evaluation should not exceed ten days unless a firm can demonstrate that a longer period is reasonable.

The Commission will deem that, at the end of ten days, a subject firm has received and considered all information which would have been available to it had a reasonable, expeditious and diligent investigation been undertaken."

16 CFR 1115.14(d).

To summarize then, a report may be due in as little as 16 days: 5 days for information to reach the CEO (or other person designated to make a § 15 report); 10 days to investigate and evaluate; and 1 day (24 hours) to make the report.

The CPSC warns that "a subject firm should not await complete or accurate risk estimates before reporting under § 15(b) of the CPSA." 16 CFR 1115.14(c).

Consequences of Failing to Report or to Report in Timely Manner

A failure to inform the CPSC "immediately and adequately" as required under the Act is deemed to be a "prohibited act" within § 19(a)(4) of the CPSA. The CPSIA authorizes the CPSC to seek fines of millions of dollars for "knowing" violations. The CPSC has been aggressive in this area.

Information Available to the CPSC

The CPSC receives information from a wide variety of sources, including electronic data from hospital emergency rooms and other healthcare sources. Plaintiffs' lawyers and consumers themselves frequently notify the CPSC of concerns. In addition, the CPSC conducts its own investigations.

For example, the Commission fined a national retailer as a result of an investigation that began when CPSC staff collected from a store in Pennsylvania samples of a consumer product that violated a regulation.

Delegation of Authority to Report

The regulations provide that the Chief Executive Officer of the subject firm should sign any written reports to the Commission under § 15(b) unless this responsibility has been delegated by filing a written delegation of authority with the Commission's Office of Compliance and Enforcement, Division of Corrective Actions.

In view of all the burdens placed on many CEO's (not to mention the risk that a CEO will be traveling or otherwise unavailable during the critical time period), we often recommend that CEO's execute in advance an appropriate form of delegation.

Planning for the Recall of a Consumer Product

Should it become necessary to institute a recall, a number of departments within a company may become involved, including quality control, shipping, inventory, risk management, engineering, design and public relations. Because of the legal issues involved and the need to facilitate accurate and candid communication through use of the attorney-client and work product privileges, the legal department, assisted by outside counsel with experience in this area of the law, should be involved in all aspects of a recall.

Planning for a Recall

As noted, the decision to institute a recall must be made under extreme time pressure. For companies accustomed to moving product efficiently and expeditiously into the hands of customers and consumers, a recall can be the equivalent of suddenly going from overdrive to reverse. Much of the disruption can be minimized by advance planning.

Product Liability Review -- A product liability review conducted by counsel will not only facilitate a recall, should one become necessary; it can also reduce, if not eliminate, the risk of ever having to face a recall. Briefly put, a product safety review would involve examination by counsel of various decision points about products from the point of view of safety.

Decision points would include design issues; choice of merchandise (for example, to sell or not sell comparatively "risky" products); finished and component parts and agreements with suppliers (including overseas suppliers) of them; manufacturing techniques; overseas and domestic quality control; warnings; and distribution issues.

A company's claims and litigation recordkeeping practices (including record creation) should be reviewed; recommendations - subject to the attorney-client privilege – should be provided.

Designating a Recall Coordinator -- We recommend designating a Recall Coordinator to lead the recall team should it become necessary to recall a product. The Recall Coordinator should have the following qualifications and duties:

- 1. Knowledge of the CPSA, CPSIA and other acts enforced by the CPSC
- 2. Ability and authority to function as the central coordinator within the company for receiving and processing information regarding a recall and the safety of the company's products (<u>e.g.</u>, quality control records, engineering analyses, test results, consumer complaints, warranty returns or claims, lawsuits, and insurance claims).

- 3. Responsibility for keeping the company's Chief Executive Officer and its General Counsel informed about safety problems or potential problems that could lead to product recalls;
- 4. Authority to involve appropriate departments of the company in implementing a product recall.

Facilitating Identification of Recalled Products -- The company should evaluate its product identification system (e.g., date of manufacture codes). If a product recall is necessary, this system could allow the company to identify more easily all affected products without undertaking a costly recall of the entire production.

Similarly, once a specific product has been recalled and corrected, a new model number or other means of identification used on new corrected products allows distributors, retailers, and consumers to distinguish products subject to recall from the new items.

Delegation of Authority from the CEO -- The CPSA and regulations require that notifications to the CPSC under §§ 15 and 37 be made by the Chief Executive Officer of the company or his authorized designee.

In view of the extremely short amount of time in which to reach a decision and to notify the CPSC and the pressures (including travel) on CEO's, it may be prudent to execute in advance an appropriate delegation of authority.

The Recall Plan: A Checklist of Actions to Consider in Recalling a Product

While many decisions regarding a recall must be made within the context of the particular recall (including the product and the risk involved), as a general rule the following actions will be required.

Inventory -- Products which are the subject of a recall and are in the company's inventory as of the time the decision to recall is made should be <u>immediately</u> identified, segregated from other products and retained in a secure location.

To the extent some but not all of a line, model or batch of products are considered to pose a risk, all products within the risk category should be quarantined until an inspection can be performed and authorization is given by management to resume shipments.

Shipment and sale of defective inventory after a recall of it has been announced can lead to punitive damage claims and harsh CPSC measures and can jeopardize insurance coverage.

Communications with Customers and Consumers -- Once a recall is directed, it will become necessary to notify customers and consumers. The notice must explain the

defect in a manner that truthfully informs the recipient of the risk without unnecessarily jeopardizing appropriate legal defenses, insurance coverage and goodwill.

It will be important for defensive purposes to maintain adequate records of such notifications. Depending upon the nature of the risk and other circumstances, notification may be by telephone, e-mail, fax and/or ordinary mail.

The CPSC often requires a press release, in-store warning posters and a toll free telephone line to facilitate and encourage communications from customers.

Training of Company Personnel in Implementing a Recall -- It is necessary to train personnel who can respond to questions of customers and consumers, explain procedures for refunds and document communications regarding risks.

Consumers who claim that there has been an injury to person or property should be referred to a designated and specifically trained member of the recall team. "Scripts" should be prepared for use by personnel who will be speaking with customers, distributors and consumers.

Unusual Problems and "Difficult" Customers/Consumers -- A member of the recall team should be assigned to handle customers and consumers presenting unusual or difficult issues, including resistance to returning products; demands for inappropriate compensation; and "threats." Customers or consumers who retain counsel should be referred to the designated member of the recall team (ideally, to in-house or outside counsel).

Notification of Insurance Carriers -- Risk management personnel, in consultation with the legal department, may need to inform insurance carriers "promptly" of any injuries or claims and of the decision to recall a product, in order to satisfy "conditions" of coverage.

Coordination of Private Litigation Involving Recalled Products -- Litigation regarding a recalled product may be brought before a recall is ordered, during the course of it or upon its completion.

It bears repeating: Care must be taken to insure that publicity about a recall accomplishes its goal of protecting the public and complying with the demands of the CPSC without unnecessarily prejudicing the defense of lawsuits or jeopardizing insurance coverages.

In this regard, it is not unusual for plaintiffs' attorneys (or competitors) to submit "Freedom of Information Act" requests to the CPSC upon the announcement of a recall, seeking all recall documents in the CPSC's possession.

The company should receive notice from the CPSC of any such FOIA requests and they should be delivered immediately to the Recall Coordinator and to legal counsel experienced in evaluating and, where appropriate, resisting such FOIA requests.

Receipt and Handling of Recalled Products -- A member of the recall team should be designated by the Recall Coordinator to supervise the receipt and quarantining of recalled products in a secure location.

Records identifying the source of the recalled product (customer, consumer, distributor or other including dates, name and address) must be kept in such manner as will enable their use as "business records" under the hearsay exception.

Products which are returned should be inspected and counted. Customer or consumer abuse or shipping or other damage should be noted.

No recalled products should be reintroduced into commerce or exported without express written authorization of the CPSC. Persons handling recalled products should exercise care to avoid altering or damaging the products or any instructional or warning materials.

Legal counsel in consultation with appropriate quality control and engineering personnel should consider retaining an independent testing firm to evaluate returned products. Any such independent testing firm should be asked to execute a confidentiality agreement with the company.

Counsel should take all appropriate measures to utilize appropriately the attorney-client and work-product privileges in order to facilitate truthful and candid communications and to prevent misuse of legal advice by third parties.

Assessing the Effect of a Decision to Recall a Product on the Safety of Related Products -- A decision to recall a particular product or line of products may suggest the need to give additional attention to related company products.

Accordingly, a member of the recall team should be designated to examine other lines of merchandise as they may be impacted by knowledge gained from the decision to recall the subject product.

Locating Products Subject to the Recall – In the case of products sold through distributors and retailers and not directly to consumers, it may be necessary, depending on the severity of the risk to consumers, to secure cooperation from a company's customers, including placement of "point of sale" posters in stores and review of consumer credit (e.g., Visa/Mastercharge) documents for the purpose of identifying consumers.

Obviously it is easier to recall a product in the possession of a customer than it is to recall products which have been acquired by consumers; therefore, every effort

should be made to persuade customers to immediately remove products subject to a recall from their shelves and to return them promptly to the company.

Replacements -- A member of the recall team should be responsible for identifying and shipping replacement units to distributors and customers in order to minimize disruptions and damage to company good will. Care should be taken to ensure that the replacements are safe and in compliance with all laws, and are kept separate from recalled products.

Records Maintenance -- Documentation of a recall is very important. Appropriate forms should be created no later than the time the decision to recall is made for the purpose of documenting communications with customers, distributors and consumers and the return, retention, evaluation, assessment and disposition of all returned products.

Forms for use by company personnel involved in telephone communications also will be required and should be created so as to facilitate the report of accurate information while minimizing exaggeration, improper disparagement or other unnecessarily harmful remarks.

All such documents will be sought and used (and sometimes misused) by plaintiffs' counsel, to the extent not privileged.

Because many such documents also may be used defensively by the company, they should be maintained so as to satisfy the business records exception of the hearsay rule.

In most CPSC notifications and recalls with which we have been involved (and these have ranged from notifications involving no injuries to as many as 11 deaths) we have found it to be advantageous, at the time of notification, to present the CPSC with a proposed recall/corrective action plan, including a suggested joint press release, proposed point of sale posters, letters to distributors, etc.

The CPSC has the authority to require these measures, but typically reacts favorably when a company "takes the bull by the horns" and identifies a solution and not merely a problem.

The "fast track" program, which implicitly endorses our traditional approach to recalls, offers the potential additional bonus that the staff will not make a preliminary determination that a product contains a "defect which creates a substantial product hazard," and this "non-finding" can be useful in defending parallel private litigation.

Just as a decision to notify the CPSC will often mean the need to develop a corrective action plan, so, in most cases, a decision to recall a consumer product will require notification to the CPSC.

Indeed, in view of the civil and criminal penalties that may be imposed for failure to notify, a decision to recall for safety reasons without notifying and coordinating with the CPSC should be made only on advice of counsel.

That being said, notification to the CPSC, in our experience, does not require turning over to the government important decisions about how to locate and remove dangerous merchandise from the market.

On the contrary, companies which we have represented that have reported to the CPSC, and that at the same time have proposed comprehensive recall plans, have been allowed to proceed with little, if any, government intervention.

Title 16: Commercial Practices

PART 1115—SUBSTANTIAL PRODUCT HAZARD REPORTS

Section Contents

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- § 1115.2 Scope and finding.
- § 1115.3 Definitions.
- § 1115.4 Defect.
- § 1115.5 Reporting of failures to comply with a voluntary consumer product safety standard relied upon
- by the Commission under section 9 of the CPSA.
- § 1115.6 Reporting of unreasonable risk of serious injury or death.
- § 1115.7 Relation to other provisions.
- § 1115.8 Compliance with product safety standards.
- § 1115.9 [Reserved]
- § 1115.10 Persons who must report and where to report.
- § 1115.11 Imputed knowledge.
- § 1115.12 Information which should be reported; evaluating substantial product hazard.
- § 1115.13 Content and form of reports; delegations of authority.
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Subpart B—Remedial Actions and Sanctions

- § 1115.20 Voluntary remedial actions.
- § 1115.21 Compulsory remedial actions.
- § 1115.22 Prohibited acts and sanctions.

Appendix to Part 1115—Voluntary Standards on Which the Commission Has Relied Under Section 9 of the Consumer Product Safety Act

Authority: 15 U.S.C. 2061, 2064, 2065, 2066(a), 2068, 2069, 2070, 2071, 2073, 2076, 2079 and 2084.

Source: 43 FR 34998, Aug. 7, 1978, unless otherwise noted.

Subpart A—General Interpretation

§ 1115.1 Purpose.

The purpose of this part 1115 is to set forth the Consumer Product Safety Commission's (Commission's) interpretation of the reporting requirements imposed on manufacturers (including importers), distributors, and retailers by section 15(b) of the Consumer Product Safety Act, as amended (CPSA) (15 U.S.C. 2064(b)) and to indicate the actions and sanctions which the Commission may require or impose to protect the public from substantial product hazards, as that term is defined in section 15(a) of the CPSA.

§ 1115.2 Scope and finding.

- (a) Section 15(a) of the CPSA (15 U.S.C. 2064(a)) defines substantial product hazard as either:
- (1) A failure to comply with an applicable consumer product safety rule, which failure creates a substantial risk of injury to the public,

- (2) A product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.
- (b) Section 15(b) of the CPSA requires every manufacturer (including an importer), distributor, and retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that the product fails to comply with an applicable consumer product safety rule, fails to comply with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, contains a defect which could create a substantial product hazard described in subsection 15(a)(2) of the CPSA, or creates an unreasonable risk of serious injury or death, immediately to inform the Commission, unless the manufacturer (including an importer), distributor or retailer has actual knowledge that the Commission has been adequately informed of such failure to comply, defect, or risk. This provision indicates that a broad spectrum of safety related information should be reported under section 15(b) of the CPSA.
- (c) Sections 15 (c) and (d) of the CPSA, (15 U.S.C. 2064(c) and (d)), empower the Commission to order a manufacturer (including an importer), distributor, or retailer of a consumer product distributed in commerce that presents a substantial product hazard to give various forms of notice to the public of the defect or the failure to comply and/or to order the subject firm to elect either to repair, to replace, or to refund the purchase price of such product. However, information which should be reported under section 15(b) of the CPSA does not automatically indicate the presence of a substantial product hazard, because what must be reported under section 15(b) are failures to comply with consumer product safety rules or voluntary standards upon which the Commission has relied under section 9, defects that could create a substantial product hazard, and products which create an unreasonable risk of serious injury or death. (See §1115.12.)
- (d) The provisions of this part 1115 deal with all consumer products (including imports) subject to regulation under the Consumer Product Safety Act, as amended (15 U.S.C. 2051–2081) (CPSA), and the Refrigerator Safety Act (15 U.S.C. 1211–1214) (RSA). In addition, the Commission has found that risks of injury to the public from consumer products subject to regulation under the Flammable Fabrics Act (15 U.S.C. 1191–1204) (FFA), the Federal Hazardous Substances Act (15 U.S.C. 1261–1274) (FHSA), and the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471–1476) (PPPA) cannot be eliminated or reduced to a sufficient extent in a timely fashion under those acts. Therefore, pursuant to section 30(d) of the CPSA (15 U.S.C. 2079(d)), manufacturers (including importers), distributors, and retailers of consumer products which are subject to regulation under provisions of the FFA, FHSA, and PPPA must comply with the reporting requirements of section 15(b).

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34227, Aug. 4, 1992]

§ 1115.3 Definitions.

In addition to the definitions given in section 3 of the CPSA (15 U.S.C. 2052), the following definitions apply:

- (a) Adequately informed under section 15(b) of the CPSA means that the Commission staff has received the information requested under §§1115.12 and/or 1115.13 of this part insofar as it is reasonably available and applicable or that the staff has informed the subject firm that the staff is adequately informed.
- (b) Commission meeting means the joint deliberations of at least a majority of the Commission where such deliberations determine or result in the conduct or disposition of official Commission business. This term is synonymous with "Commission meeting" as defined in the Commission's regulation issued under the Government in the Sunshine Act, 16 CFR part 1012.
- (c) Noncompliance means the failure of a consumer product to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA.
- (d) A person means a corporation, company, association, firm, partnership, society, joint stock company, or individual.
- (e) Staff means the staff of the Consumer Product Safety Commission unless otherwise stated.
- (f) Subject firm means any manufacturer (including an importer), distributor, or retailer of a consumer product.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34227, Aug. 4, 1992]

§ 1115.4 Defect.

Section 15(b)(2) of the CPSA requires every manufacturer (including an importer), distributor, and retailer of a consumer product who obtains information which reasonably supports the conclusion that the product contains a defect which could create a substantial product hazard to inform the Commission of such defect. Thus, whether the information available reasonably suggests a defect is the first determination which a subject firm must make in deciding whether it has obtained information which must be

reported to the Commission. In determining whether it has obtained information which reasonably supports the conclusion that its consumer product contains a defect, a subject firm may be guided by the criteria the Commission and staff use in determining whether a defect exists. At a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect, for example, may be the result of a manufacturing or production error; that is, the consumer product as manufactured is not in the form intended by, or fails to perform in accordance with, its design. In addition, the design of and the materials used in a consumer product may also result in a defect. Thus, a product may contain a defect even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public. A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended. A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury. To assist subject firms in understanding the concept of defect as used in the CPSA, the following examples are offered:

- (a) An electric appliance presents a shock hazard because, through a manufacturing error, its casing can be electrically charged by full-line voltage. This product contains a defect as a result of manufacturing or production error.
- (b) Shoes labeled and marketed for long-distance running are so designed that they might cause or contribute to the causing of muscle or tendon injury if used for long-distance running. The shoes are defective due to the labeling and marketing.
- (c) A kite made of electrically conductive material presents a risk of electrocution if it is long enough to become entangled in power lines and be within reach from the ground. The electrically conductive material contributes both to the beauty of the kite and the hazard it presents. The kite contains a design defect.
- (d) A power tool is not accompanied by adequate instructions and safety warnings. Reasonably foreseeable consumer use or misuse, based in part on the lack of adequate instructions and safety warnings, could result in injury. Although there are no reports of injury, the product contains a defect because of the inadequate warnings and instructions.
- (e) An exhaust fan for home garages is advertised as activating when carbon monoxide fumes reach a dangerous level but does not exhaust when fumes have reached the dangerous level. Although the cause of the failure to exhaust is not known, the exhaust fan is defective because users rely on the fan to remove the fumes and the fan does not do so.

However, not all products which present a risk of injury are defective. For example, a knife has a sharp blade and is capable of seriously injuring someone. This very sharpness, how- ever, is necessary if the knife is to function adequately. The knife does not contain a defect insofar as the sharpness of its blade is concerned, despite its potential for causing injury, because the risk of injury is outweighed by the usefulness of the product which is made possible by the same aspect which presents the risk of injury. In determining whether the risk of injury associated with a product is the type of risk which will render the product defective, the Commission and staff will consider, as appropriate: The utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and other factors relevant to the determination. If the information available to a subject firm does not reasonably support the conclusion that a defect exists, the subject firm need not report. However, if the information does reasonably support the conclusion that a defect exists, the subject firm must then consider whether that defect could create a substantial product hazard. (See §1115.12(f) for factors to be assessed in determining whether a substantial product hazard could exist.) If the subject firm determines that the defect could create a substantial product hazard, the subject firm must report to the Commission. Most defects could present a substantial product hazard if the public is exposed to significant numbers of defective products or if the possible injury is serious or is likely to occur. Since the extent of public exposure and/or the likelihood or seriousness of injury are ordinarily not known at the time a defect first manifests itself, subject firms are urged to report if in doubt as to whether a defect could present a substantial product hazard. On a case-by-case basis the Commission and the staff will determine whether a defect within the meaning of section 15 of the CPSA does, in fact, exist and whether that defect presents a substantial product hazard. Since a consumer product may be defective even if it is designed, manufactured, and marketed exactly as intended by a subject firm, subject firms should report if in doubt as to whether a defect exists. Defect, as discussed in this section and as used by the Commission and staff, pertains only to interpreting and enforcing the Consumer Product Safety Act. The criteria and discussion in this section are not intended to apply to any other area of the law.

[43 FR 34998, Aug. 7, 1978, as amended at 71 FR 42030, July 25, 2006]

§ 1115.5 Reporting of failures to comply with a voluntary consumer product safety standard relied upon by the Commission under section 9 of the CPSA.

(a) General provision. Under the CPSA, the Commission may rely on voluntary standards in lieu of developing mandatory ones. In recognition of the role of voluntary standards under the CPSA, section 15(b)(1) requires reports if a product fails to comply with a voluntary standard "upon which the Commission has relied under section 9" of the CPSA. The Commission has relied upon a

voluntary consumer product safety standard under section 9 of the CPSA if, since August 13, 1981 it has terminated a rulemaking proceeding or withdrawn an existing consumer product safety rule because it explicitly determined that an existing voluntary standard, or portion(s) thereof, is likely to result in an adequate reduction of the risk of injury and it is likely there will be substantial compliance with that voluntary standard. (See appendix to this part 1115 for a list of such voluntary standards.) This provision applies only when the Commission relies upon a voluntary standard in a rulemaking proceeding under section 9 of the CPSA. In evaluating whether or not to rely upon an existing voluntary standard, the Commission shall adhere to all the procedural safeguards currently required under the provisions of the CPSA, including publication in theFederal Registerof the Commission's intent to rely upon a voluntary standard in order to provide the public with a fair opportunity to comment upon such proposed action.

(b) Reporting requirement. A firm must report under this section if it has distributed in commerce, subsequent to the effective date of the Consumer Product Safety Improvement Act of 1990 (November 16, 1990), a product that does not conform to a voluntary standard or portion(s) of a voluntary standard relied upon by the Commission since August 13, 1981. If the Commission relied upon only a portion(s) of a voluntary standard, a firm must report under this section only nonconformance with the portion(s) of the voluntary standard relied upon by the Commission. Pursuant to section 7(b)(2) of the CPSA, the Commission shall monitor any modifications of a voluntary standard upon which it has relied and determine, as a matter of policy, at the time any substantive safety related modification is adopted, whether it shall continue to rely upon the former standard or whether it shall rely, subsequently, upon the modified standard. The Commission shall publish such decisions in theFederal Register.Until the Commission makes such a decision, subject firms need not report under this provision a product which complies with either the original version of the voluntary standard relied upon by the Commission or the new version of the standard. A firm must continue to evaluate whether deviations from other portions of a voluntary standard, or other voluntary standards not relied upon by the Commission, either constitute a defect which could create a substantial product hazard or create an unreasonable risk of serious injury or death.

[57 FR 34228, Aug. 4, 1992; 57 FR 39597, Sept. 1, 1992]

§ 1115.6 Reporting of unreasonable risk of serious injury or death.

- (a) General provision. Every manufacturer, distributor, and retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that its product creates an unreasonable risk of serious injury or death is required to notify the Commission immediately. 15 U.S.C. 2064(b)(3). The requirement that notification occur when a responsible party "obtains information which reasonably supports the conclusion that" its product creates an unreasonable risk of serious injury or death is intended to require firms to report even when no final determination of the risk is possible. Firms must carefully analyze the information they obtain to determine whether such information "reasonably supports" a determination that the product creates an unreasonable risk of serious injury or death. (See §1115.12(f) for a discussion of the kinds of information that firms must study and evaluate to determine whether they have an obligation to report.) Firms that obtain information indicating that their products present an unreasonable risk of serious injury or death should not wait for such serious injury or death to actually occur before reporting. Such information can include reports from experts, test reports, product liability lawsuits or claims, consumer or customer complaints, quality control data, scientific or epidemiological studies, reports of injury, information from other firms or governmental entities, and other relevant information. While such information shall not trigger a per se reporting requirement, in its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA, the Commission shall attach considerable significance if such firm learns that a court or jury has determined that one of its products has caused a serious injury or death and a reasonable person could conclude based on the lawsuit and other information obtained by the firm that the product creates an unreasonable risk of serious injury or death.
- (b) Unreasonable risk. The use of the term "unreasonable risk" suggests that the risk of injury presented by a product should be evaluated to determine if that risk is a reasonable one. In determining whether a product presents an unreasonable risk, the firm should examine the utility of the product, or the utility of the aspect of the product that causes the risk, the level of exposure of consumers to the risk, the nature and severity of the hazard presented, and the likelihood of resulting serious injury or death. In its analysis, the firm should also evaluate the state of the manufacturing or scientific art, the availability of alternative designs or products, and the feasibility of eliminating the risk. The Commission expects firms to report if a reasonable person could conclude given the information available that a product creates an unreasonable risk of serious injury or death. In its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA the Commission shall, as a practical matter, attach considerable significance if such firm obtains information which reasonably supports the conclusion that its product violates a standard or ban promulgated under the FHSA, FFA, PPPA or RSA and the violation could result in serious injury or death.
- (c) Serious injury or death. The term "serious injury" is not defined in the CPSA. The Commission believes that the term includes not only the concept of "grievous bodily injury," defined at §1115.12(d), but also any other significant injury. Injuries necessitating hospitalization which require actual medical or surgical treatment, fractures, lacerations requiring sutures, concussions, injuries to the eye, ear, or internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day are examples of situations in which the Commission shall presume that such a serious injury has occurred. To determine whether an unreasonable risk of serious injury or death exists, the firm should evaluate chronic or long term health effects as well as immediate injuries.

[57 FR 34228, Aug. 4, 1992]

§ 1115.7 Relation to other provisions.

The reporting requirements of section 37 of the CPSA (15 U.S.C. 2084) are in addition to the requirement in section 15 of the CPSA. Section 37 requires a product manufacturer to report certain kinds of lawsuit information. It is intended as a supplement to, not a substitute for, the requirements of section 15(b) of the CPSA. Whether or not a firm has an obligation to provide information under section 37, it must consider whether it has obtained information which reasonably supports the conclusion that its product violates a consumer product safety rule, does not comply with a voluntary safety standard upon which the Commission has relied under section 9, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death. If a firm has obtained such information, it must report under section 15(b) of the CPSA, whether or not it is required to report under section 37. Further, in many cases the Commission would expect to receive reports under section 15(b) long before the obligation to report under section 37 arises since firms have frequently obtained reportable information before settlements or judgments in their product liability lawsuits.

[57 FR 34229, Aug. 4, 1992]

§ 1115.8 Compliance with product safety standards.

(a) Voluntary standards. The CPSA and other federal statutes administered by the Commission generally encourage the private sector development of, and compliance with voluntary consumer product safety standards to help protect the public from unreasonable risks of injury associated with consumer products. To support the development of such consensus standards, Commission staff participates in many voluntary standards committees and other activities. The Commission also strongly encourages all firms to comply with voluntary consumer product safety standards and considers, where appropriate, compliance or non-compliance with such standards in exercising its authorities under the CPSA and other federal statutes, including when making determinations under section 15 of the CPSA. Thus, for example, whether a product is in compliance with applicable voluntary safety standards may be relevant to the Commission staff's preliminary determination of whether that product presents a substantial product hazard under section 15 of the CPSA.

(b) Mandatory standards. The CPSA requires that firms comply with all applicable mandatory consumer product safety standards and to report to the Commission any products which do not comply with either mandatory standards or voluntary standards upon which the Commission has relied. As is the case with voluntary consumer product safety standards, compliance or non-compliance with applicable mandatory safety standards may be considered by the Commission and staff in making relevant determinations and exercising relevant authorities under the CPSA and other federal statutes. Thus, for example, while compliance with a relevant mandatory product safety standard does not, of itself, relieve a firm from the need to report to the Commission a product defect that creates a substantial product hazard under section 15 of the CPSA, it will be considered by staff in making the determination of whether and what type of corrective action may be required.

[71 FR 42030, July 25, 2006]

§ 1115.9 [Reserved]

§ 1115.10 Persons who must report and where to report.

(a) Every manufacturer (including importer), distributor, or retailer of a consumer product that has been distributed in commerce who obtains information that such consumer product contains a defect which could create a substantial risk of injury to the public shall immediately notify the Office of Compliance, Division of Corrective Actions, Consumer Product Safety Commission, Washington, DC 20207 (telephone: 301–504–0608), or such other persons as may be designated. Manufacturers (including importers), distributors, and retailers of consumer products subject to regulation by the Commission under provisions of the FFA, FHSA, PPPA, as well as consumer products subject to regulation under the CPSA and RSA, must comply with this requirement.

(b) Every manufacturer (including importer), distributor, or retailer of a consumer product that has been distributed in commerce who obtains information that such consumer product fails to comply with an applicable consumer product safety standard or ban issued under the CPSA shall immediately notify the Commission's Office of Compliance and Enforcement, Division of Corrective Actions or such other persons as may be designated. A subject firm need not report a failure to comply with a standard or regulation issued under the provisions of the RSA, FFA, FHSA, or PPPA unless it can be reasonably concluded that the failure to comply results in a defect which could create a substantial product hazard. (See paragraph (a) of this section.)

(c) Every manufacturer (including importer), distributor, and retailer of a consumer product that has been distributed in commerce who obtains information that such consumer product fails to comply with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, shall immediately notify the Commission's Office of Compliance and Enforcement, Division of Corrective Actions or such other persons as may be designated.

- (d) Every manufacturer (including importer), distributor, and retailer of a consumer product that has been distributed in commerce who obtains information that such consumer product creates an unreasonable risk of serious injury or death shall immediately notify the Commission's Office of Compliance and Enforcement, Division of Corrective Actions or such other persons as may be designated. This obligation applies to manufacturers, distributors and retailers of consumer products subject to regulation by the Commission under the Flammable Fabrics Act, Federal Hazardous Substances Act, Poison Prevention Packaging Act, and Refrigerator Safety Act as well as products subject to regulation under the CPSA.
- (e) A distributor or retailer of a consumer product (who is neither a manufacturer nor an importer of that product) is subject to the reporting requirements of section 15(b) of the CPSA but may satisfy them by following the procedure detailed in §1115.13(b).
- (f) A manufacturer (including an importer), distributor, or retailer need not inform the Commission under section 15(b) of the CPSA if that person has actual knowledge that the Commission has been adequately informed of the defect or failure to comply. (See section 15(b) of the CPSA.)

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34229, Aug. 4, 1992; 62 FR 46667, Sept. 4, 1997]

§ 1115.11 Imputed knowledge.

- (a) In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information. (See §1115.14(b).)
- (b) In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to know what a reasonable person acting in the circumstances in which the firm finds itself would know. Thus, the subject firm shall be deemed to know what it would have known if it had exercised due care to ascertain the truth of complaints or other representations. This includes the knowledge a firm would have if it conducted a reasonably expeditious investigation in order to evaluate the reportability of a death or grievous bodily injury or other information. (See §1115.14.)

§ 1115.12 Information which should be reported; evaluating substantial product hazard.

- (a) General. Subject firms should not delay reporting in order to determine to a certainty the existence of a reportable noncompliance, defect or unreasonable risk. The obligation to report arises upon receipt of information from which one could reasonably conclude the existence of a reportable noncompliance, defect which could create a substantial product hazard, or unreasonable risk of serious injury or death. Thus, an obligation to report may arise when a subject firm received the first information regarding a potential hazard, noncompliance or risk. (See §1115.14(c).) A subject firm in its report to the Commission need not admit, or may specifically deny, that the information it submits reasonably supports the conclusion that its consumer product is noncomplying, contains a defect which could create a substantial product hazard within the meaning of section 15(b) of the CPSA, or creates an unreasonable risk of serious injury or death. After receiving the report, the staff may conduct further investigation and will preliminarily determine whether the product reported upon presents a substantial product hazard. This determination can be based on information supplied by a subject firm or from any other source. If the matter is adjudicated, the Commission will ultimately make the decision as to substantial product hazard or will seek to have a court make the decision as to imminent product hazard.
- (b) Failure to comply. A subject firm must report information indicating that a consumer product which it has distributed in commerce does not comply with an applicable consumer product safety standard or ban issued under the CPSA, or a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA.
- (c) Unreasonable risk of serious injury or death. A subject firm must report when it obtains information indicating that a consumer product which it has distributed in commerce creates an unreasonable risk of serious injury or death.
- (d) Death or grievous bodily injury. Information indicating that a noncompliance or a defect in a consumer product has caused, may have caused, or contributed to the causing, or could cause or contribute to the causing of a death or grievous bodily injury (e.g., mutilation, amputation/dismemberment, disfigurement, loss of important bodily functions, debilitating internal disorders, severe burns, severe electrical shocks, and injuries likely to require extended hospitalization) must be reported, unless the subject firm has investigated and determined that the information is not reportable.
- (e) Other information indicating a defect or noncompliance. Even if there are no reports of a potential for or an actual death or grievous bodily injury, other information may indicate a reportable defect or noncompliance. In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to know what a reasonable and prudent manufacturer (including an importer), distributor, or retailer would know. (See §1115.11.)

- (f) Information which should be studied and evaluated. Paragraphs (f)(1) through (7) of this section are examples of information which a subject firm should study and evaluate in order to determine whether it is obligated to report under section 15(b) of the CPSA. Such information may include information that a firm has obtained, or reasonably should have obtained in accordance with §1115.11, about product use, experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States. All information should be evaluated to determine whether it suggests the existence of a noncompliance, a defect, or an unreasonable risk of serious injury or death:
- (1) Information about engineering, quality control, or production data.
- (2) Information about safety-related production or design change(s).
- (3) Product liability suits and/or claims for personal injury or damage.
- (4) Information from an independent testing laboratory.
- (5) Complaints from a consumer or consumer group.
- (6) Information received from the Commission or other governmental agency.
- (7) Information received from other firms, including requests to return a product or for replacement or credit. This includes both requests made by distributors and retailers to the manufacturer and requests from the manufacturer that products be returned.
- (g) Evaluating substantial risk of injury. Information which should be or has been reported under section 15(b) of the CPSA does not automatically indicate the presence of a substantial product hazard. On a case-by-case basis the Commission and the staff will determine whether a defect or noncompliance exists and whether it results in a substantial risk of injury to the public. In deciding whether to report, subject firms may be guided by the following criteria the staff and the Commission use in determining whether a substantial product hazard exists:
- (1) Hazard created by defect. Section 15(a)(2) of the CPSA lists factors to be considered in determining whether a defect creates a substantial risk of injury. These factors are set forth in the disjunctive. Therefore, the exist- ence of any one of the factors could create a substantial product hazard. The Commission and the staff will consider some or all of the following factors, as appropriate, in determining the substantiality of a hazard created by a product defect:
- (i) Pattern of defect. The Commission and the staff will consider whether the defect arises from the design, composition, contents, construction, finish, packaging, warnings, or instructions of the product or from some other cause and will consider the conditions under which the defect manifests itself.
- (ii) Number of defective products distributed in commerce. Even one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination under section 15 of the CPSA if the injury which might occur is serious and/or if the injury is likely to occur. However, a few defective products with no potential for causing serious injury and little likelihood of injuring even in a minor way will not ordinarily provide a proper basis for a substantial product hazard determination. The Commission also recognizes that the number of products remaining with consumers is a relevant consideration.
- (iii) Severity of the risk. A risk is severe if the injury which might occur is serious and/or if the injury is likely to occur. In considering the likelihood of any injury the Commission and the staff will consider the number of injuries reported to have occurred, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the product (e.g., children, elderly, handicapped).
- (iv) Other considerations. The Commission and the staff will consider all other relevant factors.
- (2) Hazard presented by noncompliance. Section 15(a)(1) of the CPSA states that a substantial product hazard exists when a failure to comply with an applicable consumer product safety rule creates a substantial risk of injury to the public. Therefore, the Commission and staff will consider whether the noncompliance is likely to result in injury when determining whether the noncompliance creates a substantial product hazard. As appropriate, the Commission and staff may consider some or all of the factors set forth in paragraph (f)(1) of this section in reaching the substantial product hazard determination.
- [43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34229, Aug. 4, 1992; 66 FR 54925, Oct. 31, 2001; 71 FR 42031, July 25, 2006]

§ 1115.13 Content and form of reports; delegations of authority.

(a) Written reports. The chief executive officer of the subject firm should sign any written reports to the Commission under section 15(b) of the CPSA unless this responsibility has been delegated by filing a written delegation of authority with the Commission's Office of Compliance and Enforcement, Division of Corrective Actions. Delegations of authority filed with the Commission under §1115.9 of the previous regulations interpreting section 15 of the CPSA will remain in effect until revoked by the chief executive officer of the subject firm. The delegation may be in the following form:

Delegation of Authority
(Name of company)
I hereby certify that I am Chief Executive Officer of the above-named company and that as such I am authorized to sign documents and to certify on behalf of said company the accuracy and completeness of information in such documents.
Pursuant to the power vested in me, I hereby delegate all or, to the extent indicated below, a portion of that authority to the person listed below.
This delegation is effective until revoked in writing. Authority delegated to:
(Name)(Address)(Title)
Extent of authority:
Signed:
(Name)(Address)(Title)
(b) Distributors and retailers. A distributor or retailer of a product (who is neither a manufacturer nor an importer of that product) satisfies the initial reporting requirements either by telephoning or writing the Office of Compliance and Enforcement, Division of Corrective Actions, Consumer Product Safety Commission, Washington, DC 20207, phone 301–504–0608; by sending a letter describing the noncompliance, defect or risk of injury to the manufacturer (or importer) of the product and sending a copy of the letter to the Commission's Division of Corrective Actions; or by forwarding to the Commission's Division of Corrective Actions reportable information received from another firm. A distributor or retailer who receives reportable information from a manufacturer (or importer) shall report to the Commission unless the manufacturer (or importer) informs the distributor or retailer that a report habeen made to the Commission. A report under this paragraph should contain the information detailed in paragraph (c) of this section insofar as it is known to the distributor or retailer. Unless further information is requested by the staff, this action will constitute a sufficient report insofar as the distributor or retailer is concerned.
(c) Initial report. Immediately after a subject firm has obtained information which reasonably supports the conclusion that a product fails to comply with an applicable consumer product safety rule or a voluntary standard, contains a defecat which could create a substantial risk of serious injury or death, the subject firm should provide the Division of Corrective Actions, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207 (telephone: 301–504–0608), with an initial report containing the information listed in paragraphs (c) (1) through (6) of this section. This initial report may be made by any means, but if it is not in writing, it should be confirmed in writing within 48 hours of the initial report. (See §1115.14 for time computations.) The initial repors should contain, insofar as is reasonably available and/or applicable:
(1) An identification and description of the product.
(2) The name and address of the manufacturer (or importer) or, if the manufacturer or importer is not known, the names and addresses of all known distributors and retailers of the product.
(3) The nature and extent of the possible defect, the failure to comply, or the risk.

- (4) The nature and extent of the injury or risk of injury associated with the product.
- (5) The name and address of the person informing the Commission.
- (6) To the extent such information is then reasonably available, the data specified in §1115.13(d).
- (d) Full report. Subject firms which file initial reports are required to file full reports in accordance with this paragraph. Retailers and distributors may satisfy their reporting obligations in accordance with §1115.13(b). At any time after an initial report, the staff may modify the requirements detailed in this section with respect to any subject firm. If the staff preliminarily determines that there is no substantial product hazard, it may inform the firm that its reporting obligation has been fulfilled. However, a subject firm would be required to report if it later became aware of new information indicating a reportable defect, noncompliance, or risk, whether the new information related to the same or another consumer product. Unless modified by staff action, the following information, to the extent that it is reasonably available and/or applicable, constitutes a "full report," must be submitted to the staff, and must be supplemented or corrected as new or different information becomes known:
- (1) The name, address, and title of the person submitting the "full report" to the Commission.
- (2) The name and address of the manufacturer (or importer) of the product and the addresses of the manufacturing plants for that product.
- (3) An identification and description of the product(s). Give retail prices, model numbers, serial numbers, and date codes. Describe any identifying marks and their location on the product. Provide a picture or a sample of the product.
- (4) A description of the nature of the defect, failure to comply, or risk. If technical drawings, test results, schematics, diagrams, blueprints, or other graphic depictions are available, attach copies.
- (5) The nature of the injury or the possible injury associated with the product defect, failure to comply, or risk.
- (6) The manner in which and the date when the information about the defect, noncompliance, or risk (e.g., complaints, reported injuries, quality control testing) was obtained. If any complaints related to the safety of the product or any allegations or reports of injuries associated with the product have been received, copies of such complaints or reports (or a summary thereof) shall be attached. Give a chronological account of facts or events leading to the report under section 15(b) of the CPSA, beginning with receipt of the first information which ultimately led to the report. Also included may be an analysis of these facts or events.
- (7) The total number of products and units involved.
- (8) The dates when products and units were manufactured, imported, distributed, and sold at retail.
- (9) The number of products and units in each of the following: in the possession of the manufacturer or importer, in the possession of private labelers, in the possession of distributors, in the possession of retailers, and in the possession of consumers.
- (10) An explanation of any changes (e.g., designs, adjustments, and additional parts, quality control, testing) that have been or will be effected to correct the defect, failure to comply, or risk and of the steps that have been or will be taken to prevent similar occurrences in the future together with the timetable for implementing such changes and steps.
- (11) Information that has been or will be given to purchasers, including consumers, about the defect, noncompliance, or risk with a description of how this information has been or will be communicated. This shall include copies or drafts of any letters, press releases, warning labels, or other written information that has been or will be given to purchasers, including consumers.
- (12) The details of and schedule for any contemplated refund, replacement, or repair actions, including plans for disposing of returned products (e.g., repair, destroy, return to foreign manufacturer).
- (13) A detailed explanation and description of the marketing and distribution of the product from the manufacturer (including importer) to the consumer (e.g., use of sales representatives, independent contractors, and/or jobbers; installation of the product, if any, and by whom).
- (14) Upon request, the names and addresses of all distributors, retailers, and purchasers, including consumers.
- (15) Such further information necessary or appropriate to the functions of the Commission as is requested by the staff.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34229, Aug. 4, 1992]

§ 1115.14 Time computations.

- (a) General. Weekends and holidays are excluded from the computation of the time periods in this part.
- (b) Imputing knowledge. In evaluating whether or when a firm should have reported, the Commission shall impute to the subject firm knowledge of product safety related information received by an official or employee of a subject firm capable of appreciating the significance of the information. Under ordinary circumstances, 5 days should be the maximum reasonable time for information to reach the Chief Executive Officer or the official or employee responsible for complying with the reporting requirements of section 15(b) of the CPSA. The Commission will impute knowledge possessed by the Chief Executive Officer or by the official or employee responsible for complying with the reporting requirements of section 15(b) of the CPSA simultaneously to the subject firm.
- (c) Time when obligation to report arises. The obligation to report under section 15(b) of the CPSA may arise upon receipt by a subject firm of the first information regarding a noncompliance, or a potential hazard presented by a product defect, or an unreasonable risk. Information giving rise to a reporting obligation may include, but is not limited to, complaints, injury reports, quality control and engineering data. A subject firm should not await complete or accurate risk estimates before reporting under section 15(b) of CPSA. However, if information is not clearly reportable, a subject firm may spend a reasonable time for investigation and evaluation. (See §1115.14(d).)
- (d) Time for investigation and evaluation. A subject firm may conduct a reasonably expeditious investigation in order to evaluate the reportability of a death or grievous bodily injury or other information. This investigation and evaluation should not exceed 10 days unless a firm can demonstrate that a longer period is reasonable. The Commission will deem that, at the end of 10 days, a subject firm has received and considered all information which would have been available to it had a reasonable, expeditious, and diligent investigation been undertaken.
- (e) *Time to report*. Immediately, that is, within 24 hours, after a subject firm has obtained information which reasonably supports the conclusion that its consumer product fails to comply with an applicable consumer product safety rule or voluntary consumer product safety standard, contains a defect which could create a substantial risk of injury to the public, or creates an unreasonable risk of serious injury or death, the firm should report. (See §1115.13.) If a firm elects to conduct an investigation in order to evaluate the existence of reportable information, the 24-hour period begins when the firm has information which reasonably supports the conclusion that its consumer product fails to comply with an applicable consumer product safety rule or voluntary consumer product safety standard upon which the Commission has relied under section 9, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death. Thus, a firm could report to the Commission before the conclusion of a reasonably expeditious investigation and evaluation if the reportable information becomes known during the course of the investigation. In lieu of the investigation, the firm may report the information immediately.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34230, Aug. 4, 1992]

§ 1115.15 Confidentiality and disclosure of data.

- (a) General. The Commission does not routinely make reports available to the public until the staff has made a preliminary hazard determination. Copies of reports will not be available to the public in the Commission's public reading room, and information contained in reports will not ordinarily be disclosed to the public in the absence of a formal request.
- (b) Freedom of Information Act. Any person who submits information to the Commission who believes that any portion of the information is entitled to exemption from public disclosure under the provisions of the Freedom of Information Act, as amended (15 U.S.C. 552(b)), of the CPSA, as amended, or of another Federal statute must accompany the submission with a written request that the information be considered exempt from disclosure or indicate that a written request will be submitted within 10 working days of the submission. The request shall (1) identify the portions of the information for which exemption is claimed, which may include the identity of the reporting firm and the fact that it is making a report, and (2) state the facts and reasons which support the claimed exemption. After the staff has made its preliminary hazard determination, and regardless of whether or not the staff preliminarily determines that a product presents a substantial product hazard, the Commission will no longer honor requests for exempt status for the identity of the reporting firm, the identity of the consumer product, and the nature of the reported alleged defect or noncompliance. This information, together with the staff's preliminary hazard determination, will be made available to the public in the Commission's public reading room. Information for which exempt status is claimed (such as alleged trade secrets, confidential commercial or financial information, or information the disclosure of which would constitute an unwarranted invasion of personal privacy) shall not be released to the public except in accordance with the applicable statute or the Commission's Freedom of Information Act regulations (16 CFR part 1015).
- (c) Section 6(b) of the CPSA. The Commission believes that the first two sentences in section 6(b)(1) of the CPSA (15 U.S.C. 2055(b)(1)) apply to affirmative dissemination of information by the Commission (such as press releases or fact sheets distributed to the public) from which the public may ascertain readily the identity of the product's manufacturer and/or private labeler.

Manufacturers and private labelers will ordinarily be given 30 days' notice before the Commission makes such affirmative disseminations. However, this 30-day notice will not apply if the Commission finds that a lesser notice period is required in the interest of public health and safety.

Subpart B—Remedial Actions and Sanctions

§ 1115.20 Voluntary remedial actions.

As appropriate, the Commission will attempt to protect the public from substantial product hazards by seeking one or more of the following voluntary remedies:

- (a) Corrective action plans. A corrective action plan is a document, signed by a subject firm, which sets forth the remedial action which the firm will voluntarily undertake to protect the public, but which has no legally binding effect. The Commission reserves the right to seek broader corrective action if it becomes aware of new facts or if the corrective action plan does not sufficiently protect the public.
- (1) Corrective action plans shall include, as appropriate:
- (i) A statement of the nature of the alleged hazard associated with the product, including the nature of the alleged defect or noncompliance and type(s) of injury or potential injury presented.
- (ii) A detailed statement of the means to be employed to notify the public of the alleged product hazard (e.g., letter, press release, advertising), including an identification of the classes of persons who will receive such notice and a copy or copies of the notice or notices to be used.
- (iii) A specification of model number and/or other appropriate descriptions of the product.
- (iv) Any necessary instructions regarding use or handling of the product pending correction.
- (v) An explanation of the specific cause of the alleged substantial product hazard, if known.
- (vi) A statement of the corrective action which will be or has been taken to eliminate the alleged substantial product hazard. The firm should indicate whether it is repairing or replacing the product or refunding its purchase price. If products are to be returned to a subject firm, the corrective action plan should indicate their disposition (e.g., reworked, destroyed, returned to foreign manufacturer). Samples of replacement products and relevant drawings and test data for repairs or replacements should be available.
- (vii) A statement of the steps that will be, or have been, taken to reasonably prevent recurrence of the alleged substantial product hazard in the future.
- (viii) A statement of the action which will be undertaken to correct product units in the distribution chain, including a timetable and specific information about the number and location of such units.
- (ix) The signatures of representatives of the subject firm.
- (x) An acknowledgment by the subject firm that the Commission may monitor the corrective action and that the firm will furnish necessary information, including customer lists.
- (xi) An agreement that the Commission may publicize the terms of the plan to the extent necessary to inform the public of the nature and extent of the alleged substantial product hazard and of the actions being undertaken to correct the alleged hazard presented.
- (xii) Additional points of agreement, as appropriate.
- (xiii) If desired by the subject firm, the following statement or its equivalent: "The submission of this corrective action plan does not constitute an admission by (the subject firm) that either reportable information or a substantial product hazard exists."
- (xiv) An acknowledgment that the corrective action plan becomes effective only upon its final acceptance by the Commission.
- (2) In determining whether to recommend to the Commission acceptance of a corrective action plan, the staff shall consider favorably both the promptness of the subject firm's reporting and any remedial actions taken by the subject firm in the interest of

public safety. The staff also shall consider, insofar as possible, prior involvement by the subject firm in corrective action plans and Commission orders if such involvement bears on the likelihood that the firm will comply fully with the terms of the corrective action plan.

- (3) Upon receipt of a corrective action plan and staff recommendation, the Commission may:
- (i) Approve the plan;
- (ii) Reject the plan and issue a complaint (in which case an administrative and/or judicial proceeding will be commenced); or
- (iii) Take any other action necessary to insure that the plan is adequate.
- (4) When time permits and where practicable in the interest of protecting the public, a summary of the plan shall be published in the Commission's Public Calendar. Those portions of the plan that are not restricted will be made available to the public in the Commission's public reading room as much in advance of the Commission meeting as practicable. Any interested person wishing to comment on the plan must file a Notice of Intent to Comment at least forty-eight (48) hours prior to the commencement of the Commission meeting during which the plan will be discussed. If no notices of intent are received, the Commission may take final action on the plan. If such notice is received within the time limits detailed above, the plan will, if practicable, be docketed for the following week's agenda. All comments must be in writing, and final written comments must be submitted at least forty-eight (48) hours before that session.
- (b) Consent order agreements under section 15 of CPSA. The consent order agreement (agreement) is a document executed by a subject firm (Consenting Party) and a Commission staff representative which incorporates both a proposed complaint setting forth the staff's charges and a proposed order by which such charges are resolved.
- (1) Consent order agreements shall include, as appropriate:
- (i) An admission of all jurisdictional facts by the Consenting Party.
- (ii) A waiver of any rights to an administrative or judicial hearing and of any other procedural steps, including any rights to seek judicial review or otherwise challenge or contest the validity of the Commission's Order.
- (iii) A statement that the agreement is in settlement of the staff's charges.
- (iv) A statement that the Commission's Order is issued under section 15 of the CPSA (15 U.S.C. 2064) and that a violation is a prohibited act within the meaning of section 19(a)(5) of the CPSA (15 U.S.C. 2068(a)(5)) and may subject a violator to civil and/or criminal penalties under sections 20 and 21 of the CPSA (15 U.S.C. 2069 and 2070).
- (v) An acknowledgment that the Commission reserves its right to seek sanctions for any violations of the reporting obligations of section 15(b) of CPSA (15 U.S.C. 2064(b)) and its right to take other appropriate legal action.
- (vi) An acknowledgment that the agreement becomes effective only upon its final acceptance by the Commission and its service upon the Consenting Party.
- (vii) An acknowledgment that the Commission may disclose terms of the consent order agreement to the public.
- (viii) A listing of the acts or practices from which the Consenting Party will refrain.
- (ix) A statement that the Consenting Party shall perform certain acts and practices pursuant to the agreement.
- (x) An acknowledgment that any interested person may bring an action pursuant to section 24 of the CPSA (15 U.S.C. 2073) in any U.S. district court for the district in which the Consenting Party is found or transacts business to enforce the order and to obtain appropriate injunctive relief.
- (xi) A description of the alleged substantial product hazard.
- (xii) If desired by the Consenting Party, the following statement or its equivalent: "The signing of this consent order agreement does not constitute an admission by (the Consenting Party) that either reportable information or a substantial product hazard exists."
- (xiii) The elements of a corrective action plan as set forth in §1115.20(a).

- (2) At any time in the course of an investigation, the staff may propose to a subject firm which is being investigated that some or all of the allegations be resolved by a consent order agreement. Additionally, such a proposal may be made to the staff by a subject firm
- (3) Upon receiving an executed agreement, the Commission may:
- (i) Provisionally accept it;
- (ii) Reject it and issue a complaint (in which case an administrative and/or judicial proceeding will be commenced); or
- (iii) Take such other action as it may deem appropriate.
- (4) If the consent order agreement is provisionally accepted, the Commission shall place the agreement on the public record and shall announce provisional acceptance of the agreement in the Commission's public calendar and in theFederal Register. Any interested person may request the Commission not to accept the agreement by filing a written request in the Office of the Secretary. Such written request must be received in the Office of the Secretary no later than the close of business of the fifteenth (15th) calendar day following the date of announcement in theFederal Register.
- (5) If the Commission does not receive any requests not to accept the agreement within the time period specified above, the consent order agreement shall be deemed finally accepted by the Commission on the twentieth (20th) calendar day after the date of announcement in theFederal Register,unless the Commission determines otherwise. However, if the Commission does receive a request not to accept the consent order agreement, then it will consider such request and vote on the acceptability of such agreement or the desirability of further action. After the consent order agreement is finally accepted, the Commission may then issue its complaint and order in such form as the circumstances may require. The order is a final order in disposition of the proceeding and is effective immediately upon its service upon the Consenting Party pursuant to the Commission's Rules of Practice for Adjudicative Proceedings (16 CFR part 1025). The Consenting Party shall thereafter be bound by and take immediate action in accordance with such final order.
- (6) If the Commission does not accept the consent order agreement on a final basis, it shall so notify the Consenting Party. Such notification constitutes withdrawal of the Commission's provisional acceptance unless the Commission orders otherwise. The Commission then may:
- (i) Issue a complaint, in which case an administrative and/or judicial proceeding will be commenced;
- (ii) Order further investigation; or
- (iii) Take such other action as it may deem appropriate.

§ 1115.21 Compulsory remedial actions.

As appropriate, the Commission will attempt to protect the public from hazards presented by consumer products by seeking one or more of the following:

- (a) Adjudicated Commission Order. An adjudicated Commission Order under section 15 (c) or (d) of the CPSA may be issued after parties and interested persons have had an opportunity for a hearing in accordance with section 554 of title 5, United States Code, and with section 15(f) of the CPSA. This hearing is governed by the Commission's Rules of Practice for Adjudicative Proceedings (16 CFR part 1025).
- (b) Injunctive relief. The Commission may apply to a U.S. district court in accordance with the provisions of section 15(g) of the CPSA for a preliminary injunction to restrain the distribution in commerce of a product it has reason to believe presents a substantial product hazard. The Commission may seek enforcement of its orders issued under sections 15 (c) and (d) of the CPSA in accordance with provisions of sections 22 and 27(b)(7) of the CPSA (15 U.S.C. 2071 and 2076(b)(7)).
- (c) Judicial determination of imminent hazard. The Commission may file a complaint in a U.S. district court in accordance with the provisions of section 12 of the CPSA (15 U.S.C. 2061).
- (d) Orders of the Secretary of the Treasury. The Commission staff may inform the Secretary of the Treasury that a consumer product offered for importation into the customs territory of the United States fails to comply with an applicable consumer product safety rule and/or has a product defect which constitutes a substantial product hazard. The Commission may request the Secretary of the Treasury under section 17 of the CPSA (15 U.S.C. 2066) to refuse admission to any such consumer product.

§ 1115.22 Prohibited acts and sanctions.

- (a) Statements generally. Whoever knowingly and willfully falsifies, or conceals a material fact in a report under the CPSA and rules thereunder, is subject to criminal penalties under 18 U.S.C. 1001.
- (b) *Timeliness and adequacy of reporting.* A failure to inform the Commission immediately and adequately, as required by section 15(b) of the CPSA, is a prohibited act within section 19(a)(4) of the CPSA (15 U.S.C. 2068(a)(4)).
- (c) Failure to make reports. The failure or refusal to make reports or provide information as required under the CPSA is a prohibited act within the meaning of section 19(a)(3) of the CPSA (15 U.S.C. 2068(a)(3)).
- (d) Noncomplying products. The manufacture for sale, offering for sale, distribution in commerce, and/or importation into the United States of a consumer product which is not in conformity with an applicable consumer product safety rule under CPSA is a prohibited act within the meaning of sections 19 (a)(1) and (a)(2) of the CPSA (15 U.S.C. 2068 (a)(1) and (a)(2)).
- (e) Orders issued under section 15 (c) and/or (d). The failure to comply with an order issued under section 15 (c) and/or (d) of the CPSA is a prohibited act within the meaning of section 19(a)(5) of the CPSA (15 U.S.C. 2068(a)(5)).
- (f) Consequences of engaging in prohibited acts. A knowing violation of section 19(a) of the CPSA subjects the violator to a civil penalty in accordance with section 20 of the CPSA (15 U.S.C. 2069). "Knowing," as defined in section 20(c) of the CPSA (15 U.S.C. 2069(c)), means the having of actual knowledge or the pressumed having of knowledge deemed to be possessed by a reasonable person who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. A knowing and willful violation of section 19(a), after the violator has received notice of noncompliance, subjects the violator to criminal penalties in accordance with section 21 of the CPSA (15 U.S.C. 2070).

Appendix to Part 1115—Voluntary Standards on Which the Commission Has Relied Under Section 9 of the Consumer Product Safety Act

The following are the voluntary standards on which the Commission has relied under section 9 of the Consumer Product Safety Act:

- 1. American National Standard for Power Tools—Gasoline-Powered Chain Saws—Safety Regulations, ANSI B175.1–1985 sections 4.9.4, 4.12, 4.15, 7 and 8, or the current version: ANSI B175.1–1991 sections 5.9.4, 5.12, 5.15, 8 and 9.
- 2. American National Standard for Gas-Fired Room Heaters, Volume II, Unvented Room Heaters, ANSI Z21.11.2–1989 and addenda ANSI Z21.11.2 a and b- 1991), sections 1.8, 1.20.9, and 2.9.

[57 FR 34230, Aug. 4, 1992]

Title 16: Commercial Practices

PART 1116—REPORTS SUBMITTED PURSUANT TO SECTION 37 OF THE CONSUMER PRODUCT SAFETY ACT

Section Contents

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Authority: 15 U.S.C. 2055(e), 2084.

Source: 57 FR 34239, Aug. 4, 1992, unless otherwise noted.

§ 1116.1 Purpose.

The purpose of this part 1116 is to establish procedures for filing with the Consumer Product Safety Commission ("the Commission") reports required by section 37 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2084) and to set forth the Commission's interpretation of the provisions of section 37.

§ 1116.2 Definitions.

- (a) A 24-month period(s) means the 24-month period beginning on January 1, 1991, and each subsequent 24-month period beginning on January 1 of the calendar year that is two years following the beginning of the previous 24-month period. The first statutory two year period ends on December 31, 1992. The second begins on January 1, 1993 and ends on December 31, 1994, and so forth.
- (b) Grievous bodily injury includes, but is not limited to, any of the following categories of injury:
- (1) Mutilation or disfigurement. Disfigurement includes permanent facial disfigurement or non-facial scarring that results in permanent restriction of motion;
- (2) Dismemberment or amputation, including the removal of a limb or other appendage of the body;
- (3) The loss of important bodily functions or debilitating internal disorder. These terms include:

- (i) Permanent injury to a vital organ, in any degree;
- (ii) The total loss or loss of use of any internal organ,
- (iii) Injury, temporary or permanent, to more than one internal organ;
- (iv) Permanent brain injury to any degree or with any residual disorder (e.g. epilepsy), and brain or brain stem injury including coma and spinal cord injuries;
- (v) Paraplegia, quadriplegia, or permanent paralysis or paresis, to any degree;
- (vi) Blindness or permanent loss, to any degree, of vision, hearing, or sense of smell, touch, or taste;
- (vii) Any back or neck injury requiring surgery, or any injury requiring joint replacement or any form of prosthesis, or;
- (viii) Compound fracture of any long bone, or multiple fractures that result in permanent or significant temporary loss of the function of an important part of the body;
- (4) Injuries likely to require extended hospitalization, including any injury requiring 30 or more consecutive days of in-patient care in an acute care facility, or 60 or more consecutive days of in-patient care in a rehabilitation facility;
- (5) Severe burns, including any third degree burn over ten percent of the body or more, or any second degree burn over thirty percent of the body or more;
- (6) Severe electric shock, including ventricular fibrillation, neurological damage, or thermal damage to internal tissue caused by electric shock.
- (7) Other grievous injuries, including any allegation of traumatically induced disease.

Manufacturers may wish to consult with the Commission staff to determine whether injuries not included in the examples above are regarded as grievous bodily injury.

- (c) A particular model of a consumer product is one that is distinctive in functional design, construction, warnings or instructions related to safety, function, user population, or other characteristics which could affect the product's safety related performance. (15 U.S.C. 2084(e)(2))
- (1) The *functional design* of a product refers to those design features that directly affect the ability of the product to perform its intended use or purpose.
- (2) The *construction* of a product refers to its finished assembly or fabrication, its materials, and its components.
- (3) Warnings or instructions related to safety include statements of the principal hazards associated with a product, and statements of precautionary or affirmative measures to take during the use, handling, or storage of a product, to the extent that a reasonable person would

understand such statements to be related to the safety of the product. Warnings or instructions may be written or graphically depicted and may be attached to the product or appear on the product itself, in operating manuals, or in other literature that accompanies or describes the product.

- (4) The *function* of a product refers to its intended use or purpose.
- (5) *User population* refers to the group or class of people by whom a product is principally used. While the manufacturer's stated intent may be relevant to an inquiry concerning the nature of the user population, the method of distribution, the availability of the product to the public and to specific groups, and the identity of purchasers or users of the product should be considered.
- (6) Other characteristics which could affect a product's safety related performance include safety features incorporated into the product to protect against foreseeable risks that might arise during the use, handling, or storage of a product.
- (d) The term *manufacturer* means any person who manufactures or imports a consumer product. (15 U.S.C. 2052(a)(4)).

[57 FR 34239, Aug. 4, 1992, as amended at 58 FR 16121, Mar. 25, 1993]

§ 1116.3 Persons who must report under section 37.

A manufacturer of a consumer product must report if:

- (a) A particular model of the product is the subject of at least 3 civil actions filed in Federal or State Court;
- (b) Each suit alleges the involvement of that particular model in death or grievous bodily injury;
- (c) The manufacturer is-
- (1) A party to, or
- (2) Is involved in the defense of or has notice of each action prior to entry of a final order, and is involved in the discharge of any obligation owed to plaintiff under the settlement of or in satisfaction of the judgment after adjudication in each of the suits; and
- (d) During one of the 24-month periods defined in §1116.2(a), each of the three actions results in either a final settlement involving the manufacturer or in a court judgment in favor of the plaintiff.

For reporting purposes, a multiple plaintiff suit for death or grievous bodily injury is reportable if the suit involves three or more separate incidents of injury. The reporting obligation arises when at least three plaintiffs have settled their claims or when a combination of settled claims and adjudications favorable to plaintiffs reaches three. Multiple lawsuits arising from one incident involving the same product only count as one lawsuit for the purposes of section 37.

§ 1116.4 Where to report.

Reports must be sent in writing to the Commission's Office of Compliance and Enforcement, Division of Corrective Actions, Washington, DC 20207, telephone (301) 504–0608).

§ 1116.5 When must a report be made.

- (a) A manufacturer must report to the Commission within 30 days after the final settlement or court judgment in the last of the three civil actions referenced in §1116.3.
- (b) If a manufacturer has filed a section 37 report within one of the 24-month periods defined in §1116.2(a), the manufacturer must also report the information required by section 37(c)(1) for any subsequent settlement or judgment in a civil action that alleges that the same particular model of the product was involved in death or grievous bodily injury and that takes place during the same 24-month period. Each such supplemental report must be filed within 30 days of the settlement or final judgment in the reportable civil action.

§ 1116.6 Contents of section 37 reports.

- (a) Required information. With respect to each of the civil actions that is the subject of a report under section 37, the report must contain the following information:
- (1) The name and address of the manufacturer of the product that was the subject of each civil action;
- (2) The model and model number or designation of the consumer product subject to each action;
- (3) A statement as to whether the civil action alleged death or grievous bodily injury, and, in the case of an allegation of grievous bodily injury, a statement of the category of such injury;
- (4) A statement as to whether the civil action resulted in a final settlement or a judgment in favor of the plaintiff; and
- (5) In the case of a judgment in favor of the plaintiff, the name of the civil action, the number assigned to the civil action, and the court in which the civil action was filed.
- (b) Optional information. A manufacturer furnishing a report may include:
- (1) A statement as to whether any judgment in favor of the plaintiff is under appeal or is expected to be appealed (section 15 U.S.C. 2084(c)(2)(A));
- (2) Any other information that the manufacturer chooses to provide (15 U.S.C. 2084(c)(2)(B)), including the dates on which final orders were entered in the reported lawsuits, and, where appropriate, an explanation why the manufacturer has not previously filed a report under section 15(b) of the CPSA covering the same particular product model that is the subject of the section 37 report; and

- (3) A specific denial that the information it submits reasonably supports the conclusion that its consumer product caused a death or grievous bodily injury.
- (c) Statement of amount not required. A manufacturer submitting a section 37 report is not required by section 37 or any other provision of the Consumer Product Safety Act to provide a statement of any amount paid in final settlement of any civil action that is the subject of the report.
- (d) Admission of liability not required. A manufacturer reporting to the Commission under section 37 need not admit that the information it reports supports the conclusion that its consumer product caused a death or grievous bodily injury.

§ 1116.7 Scope of section 37 and its relationship to section 15(b) of the CPSA.

- (a) According to the legislative history of the Consumer Product Safety Improvement Act of 1990, the purpose of section 37 is to increase the reporting of information to the Commission that will assist it in carrying out its responsibilities.
- (b) Section 37(c)(1) requires a manufacturer or importer (hereinafter "manufacturer") to include in a section 37 report a statement as to whether a civil action that is the subject of the report alleged death or grievous bodily injury. Furthermore, under section 37(c)(2), a manufacturer may specifically deny that the information it submits pursuant to section 37 reasonably supports the conclusion that its consumer product caused a death or grievous bodily injury, and may also include any additional information that it chooses to provide. In view of the foregoing, the reporting obligation is not limited to those cases in which a product has been adjudicated as the cause of death or grievous injury or to those settled or adjudicated cases in which the manufacturer has satisfied itself that the product was the cause of such trauma. Rather, when the specific injury alleged by the plaintiff meets the definition of "grievous bodily injury" contained in §1116.2(b) of this part, the lawsuit falls within the scope of section 37 after settlement or adjudication. The manufacturer's opinion as to the validity of the allegation is irrelevant for reporting purposes. The category of injury alleged may be clear from the face of an original or amended complaint in a case or may reasonably be determined during pre-complaint investigation, post-complaint discovery, or informal settlement negotiation. Conclusory language in a complaint that the plaintiff suffered grievous bodily injury without further elaboration raises a presumption that the injury falls within one of the statutory categories, but is insufficient in itself to bring the suit within the ambit of the statute, unless the defendant manufacturer elects to settle such a matter without any investigation of the underlying facts. A case alleging the occurrence of grievous bodily injury in which a litigated verdict contains express findings that the injury suffered by the plaintiff did not meet the statutory criteria is also not reportable. Should a manufacturer believe that its product is wrongly implicated in an action, the statute expressly incorporates the mechanism for the manufacturer to communicate that belief to the Commission by denying in the report the involvement of the product or that the injury in fact suffered by the plaintiff was not grievous bodily injury, despite the plaintiff's allegations to the contrary. In addition, the statute imposes stringent confidentiality requirements on the disclosure by the Commission or the Department of Justice of information submitted pursuant to sections 37(c)(1) and 37(c)(2)(A). Moreover, it specifies that the reporting of a civil action shall not constitute an admission of liability under any statute or common law or under the relevant provisions of the Consumer Product Safety Act. In view of these safeguards, the reporting of lawsuits alleging the occurrence of death or grievous injury should have little adverse effect on manufacturers.

- (c) Section 37 applies to judgments and "final settlements". Accordingly, the date on which a civil action is filed or the date on which the product that is the subject of such an action was manufactured is irrelevant to the obligation to report. A settlement is final upon the entry by a court of an order disposing of a civil action with respect to the manufacturer of the product that is the subject of the action, even through the case may continue with respect to other defendants.
- (d) A judgment becomes reportable upon the entry of a final order by the trial court disposing of the matter in favor of the plaintiff and from which an appeal lies. Because section 37(c)(2) specifies that a reporting manufacturer may include a statement that a judgment in favor of a plaintiff is under appeal or is expected to be appealed, Congress clearly intended section 37 to apply prior to the exhaustion of or even the initiation of action to seek appellate remedies.
- (e) No language in section 37 limits the reporting obligation to those litigated cases in which the plaintiff prevails completely. Therefore, if a court enters a partial judgment in favor of the plaintiff, the judgment is reportable, unless it is unrelated to the product that is the subject of the suit. For example, if a manufacturer's product is exonerated during a suit, but liability is assessed against another defendant, the manufacturer need not report under section 37.
- (f)(1) Section 37 applies to civil actions that allege the involvement of a particular model of a consumer product in death or grievous bodily injury. Section 3(a) of the Consumer Product Safety Act (15 U.S.C. 2052(a)) defines a "consumer product" as any article, or component part thereof, produced or distributed for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or for the personal use, consumption, or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise. The term "consumer product" does not include any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer.
- (2) Since section 37 focuses on consumer products, it is the responsibility of the manufacturer of a product implicated in a civil action to determine whether the production or distribution of the product satisfies the statutory criteria of section 3(a). If it does, the action falls within the ambit of section 37. True industrial products are beyond the scope of section 37. However, if a lawsuit is based on an allegation of injury involving a consumer product, that suit falls within the scope of section 37, even though the injury may have occurred during the use of the product in employment. By the same token, occupational injuries arising during the fabrication of a consumer product are not reportable if the entity involved in the injury is not a consumer product at the time the injury occurs. In determining whether a product meets the statutory definition, manufacturers may wish to consult the relevant case law and the advisory opinions issued by the Commission's Office of the General Counsel. The unique circumstances surrounding litigation involving asbestos-containing products warrant one exception to this analysis. The Commission, as a matter of agency discretion, will require manufacturers of such products to report under section 37 only those lawsuits that allege the occurrence of death or grievous bodily injury as the result of exposure to asbestos from a particular model of a consumer product purchased by a consumer for personal use. Such lawsuits would include not only injury to the purchaser, but also to other consumers including family, subsequent property owners, and visitors. The Commission may consider granting similar relief to manufacturers of other products that present a risk of chronic injury similar to that presented by asbestos. Any such request must contain documented evidence demonstrating that compliance with the reporting

requirements will be unduly burdensome and will be unlikely to produce information that will assist the Commission in carrying out its obligations under the statutes it administers.

- (g) The definition of "consumer product" also encompasses a variety of products that are subject to regulation under the Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*), the Poison Prevention Packaging Act (15 U.S.C. 1471 *et seq.*), the Flammable Fabrics Act (15 U.S.C. 1191 *et seq.*), and the Refrigerator Safety Act (15 U.S.C. 1211 *et seq.*). Lawsuits involving such products are also subject to section 37, notwithstanding the fact that the products may be regulated or subject to regulation under one of the other statutes.
- (h) Relationship of Section 37 to Section 15 of the CPSA. (1) Section 37 plays a complementary role to the reporting requirements of section 15(b) of the CPSA (15 U.S.C. 2064(b)). Section 15(b) establishes a substantial obligation for firms to review information as it becomes available to determine whether an obligation to report exists. Accordingly, the responsibility to report under section 15(b) may arise long before enough lawsuits involving a product are resolved to create the obligation to report under section 37. The enactment of section 15(b)(3) in the Consumer Product Safety Improvement Act of 1990 reinforces this expectation. Under this amendment, manufacturers must report to the Commission when they obtain information that reasonably supports the conclusion that a product creates an unreasonable risk of serious injury or death. Previously, the reporting obligation for unregulated products only arose when available information indicated that the product in question was defective and created a substantial product hazard because of the pattern of the defect, the severity of the risk of injury, the number of products distributed in commerce, etc. The effect of the 1990 amendment is discussed in detail in the Commission's interpretative rule relating to the reporting of substantial product hazards at 16 CFR part 1115.
- (2) The new substantive reporting requirements of section 15(b)(3) support the conclusion that Congress intended section 37 to capture product-related accident information that has not been reported under section 15(b). Between the time a firm learns of an incident or problem involving a product that raises safety-related concerns and the time that a lawsuit involving that product is resolved by settlement or adjudication, the firm generally has numerous opportunities to evaluate whether a section 15 report is appropriate. Such evaluation might be appropriate, for example, after an analysis of product returns, the receipt of an insurance investigator's report, a physical examination of the product, the interview or deposition of an injured party or an eyewitness to the event that gave rise to the lawsuit, or even preparation of the firm's responses to plaintiff's discovery requests. Even if a manufacturer does not believe that a report is required prior to the resolution of a single lawsuit, an obligation to investigate whether a report is appropriate may arise if, for example, a verdict in favor of the plaintiff raises the issue of whether the product in question creates an unreasonable risk of death or serious injury.
- (3) In contrast, the application of section 37 does not involve the discretionary judgment and subjective analyses of hazard and causation associated with section 15 reports. Once the statutory criteria of three settled or adjudicated civil actions alleging grievous injury or death in a two year period are met, the obligation to report under section 37 is automatic. For this reason, the Commission regards section 37 as a "safety net" to surface product hazards that remain unreported either intentionally or by inadvertence. The provisions in the law limiting such reports to cases in which three or more lawsuits alleging grievous injury or death are settled or adjudicated in favor of plaintiffs during a two year period provide assurance that the product involved presents a sufficiently grave risk of injury to warrant consideration by the Commission. Indeed, once the obligation to report under section 37 arises, the obligation to file a section 15

report concurrently may exist if the information available to the manufacturer meets the criteria established in section 15(b) for reporting.

(4) Section 37 contains no specific record keeping requirements. However, to track and catalog lawsuits to determine whether they are reportable, prudent manufacturers will develop and maintain information systems to index and retain lawsuit data. In the absence of a prior section 15 report, once such systems are in place, such manufacturers will be in a position to perform a two-fold analysis to determine whether the information contained in such systems is reportable under either section 15(b) or 37. A manufacturer might conclude, for example, that the differences between products that are the subject of different lawsuits make them different models or that the type of injury alleged in one or more of the suits is not grievous bodily injury. Based on this analysis, the manufacturer might also conclude that the suits are thus not reportable under section 37. However, a reporting obligation under section 15 may exist in any event if the same information reasonably supports the conclusion that the product(s) contain a defect which could create a substantial product hazard or create an unreasonable risk of serious injury or death.

§ 1116.8 Determination of particular model.

- (a) The obligation rests with the manufacturer of a product to determine whether a reasonable basis exists to conclude that a product that is the subject of a settled or adjudicated lawsuit is sufficiently different from other similar products to be regarded as a "particular model" under section 37 because it is "distinctive." To determine whether a product is "distinctive", the proper inquiry should be directed toward the degree to which a product differs from other comparable products in one or more of the characteristics enumerated in section 37(e)(2) and §1116.2(c) of this part. A product is "distinctive" if, after an analysis of information relating to one or more of the statutory characteristics, a manufacturer, acting in accordance with the customs and practices of the trade of which it is a member, could reasonably conclude that the difference between that product and other items of the same product class manufactured or imported by the same manufacturer is substantial and material. Information relevant to the determination of whether a product is a "particular model" includes:
- (1) The description of the features and uses of the products in question in written material such as instruction manuals, description brochures, marketing or promotional programs, reports of certification of products, specification sheets, and product drawings.
- (2) The differences or similarities between products in their observable physical characteristics and in components or features that are not readily observable and that are incorporated in those products for safety-related purposes;
- (3) The customs and practices of the trade of which the manufacturer is a member in marketing, designating, or evaluating similar products.
- (4) Information on how consumers use the products and on consumer need or demand for different products, such as products of different size. In analyzing whether products are different models, differences in size or calibration afford the basis for distinguishing between products only if those differences make the products distinctive in functional design or function.
- (5) The history of the manufacturer's model identification and marketing of the products in question;

- (6) Whether variations between products relate solely to appearance, ornamentation, color, or other cosmetic features; such variations are not ordinarily sufficient to differentiate between models.
- (7) Whether component parts used in a product are interchangeable with or perform substantially the same function as comparable components in other units; if they are, the use of such components does not afford a basis for distinguishing between models.
- (8) Retail price. Substantial variations in price arising directly from the characteristics enumerated in section 37(e)(2) for evaluating product models may be evidence that products are different models because their differences are distinctive. Price variations imposed to accommodate different markets or vendors are not sufficient to draw such a distinction.
- (9) Manufacturer's designation, model number, or private label designation. These factors are not controlling in identifying "particular models".
- (10) Expert evaluation of the characteristics of the products in question, and surveys of consumer users or a manufacturer's retail customers.
- (b) The definition of "consumer product" expressly applies to components of consumer products. Should a component manufacturer be joined in a civil action against a manufacturer of a consumer product, the section 37 reporting requirements may apply to that manufacturer after a combination of three judgments or settlements involving the same component model during a two year period, even though the manufacturer of the finished product is exempt from such reporting because the lawsuits do not involve the same particular model of the finished consumer product. The same proposition holds true for common components used in different consumer products. If the manufacturer of such a component is a defendant in three suits and the requisite statutory criteria are met, the reporting obligations apply.
- (c) Section 37 expressly defines the reporting obligation in terms of the particular model of a product rather than the manner in which a product was involved in an accident. Accordingly, even if the characteristic of a product that caused or resulted in the deaths of grievous injuries alleged in three or more civil actions is the same in all of the suits, the requirement to report under section 37 would arise only if the same particular model was involved in at least three of the suits. However, the existence of such a pattern would strongly suggest that the obligation to file a report under section 15(b) (2) or (3) (15 U.S.C. 2064(b) (2) or (3)) exists because the information reasonably supports the conclusion that the product contains a defect that could present a substantial risk of injury to the public or creates an unreasonable risk of serious injury or death.
- (d) Section 37 does not require that the same category of injury be involved in multiple lawsuits for the reporting obligation to arise. As long as a particular model of a consumer product is the subject of at least three civil actions that are settled or adjudicated in favor of the plaintiff in one of the statutory two year periods, the manufacturer must report, even though the alleged category of injury and the alleged causal relationship of the product to the injury in each suit may differ.

§ 1116.9 Confidentiality of reports.

- (a) Pursuant to section 6(e) of the Consumer Product Safety Act (15 U.S.C. 2055(e)) no member of the Commission, no officer or employee of the Commission, and no officer or employee of the Department of Justice may publicly disclose information furnished to the Commission under section 37(c)(1) and section 37(c)(2)(A) of the Act, except that:
- (1) An authenticated copy of a section 37 report furnished to the Commission by or on behalf of a manufacturer may, upon written request, be furnished to the manufacturer or its authorized agent after payment of the actual or estimated cost of searching the records and furnishing such copies; or
- (2) Any information furnished to the Commission under section 37 shall, upon written request of the Chairman or Ranking Minority Member of the Committee on Commerce, Science, and Transportation of the Senate or the Committee on Energy and Commerce of the House of Representatives or any subcommittee of such committee, be provided to the Chairman or Ranking Minority Member for purposes that are related to the jurisdiction of such committee or subcommittee.
- (b) The prohibition contained in section 6(e) (15 U.S.C. 2055(e)) against the disclosure of information submitted pursuant to section 37 only applies to the specific items of information that a manufacturer is required to submit under section 37(c)(1) and to statements under section 37(c)(2)(A) relating to the possibility or existence of an appeal of a reported judgment adverse to a manufacturer. Section 6(e)(1) does not, by its terms, apply to information that the manufacturer voluntarily chooses to submit pursuant to section 37(c)(2)(B). Thus, disclosure of such information is governed by the other provisions of section 6 of the CPSA (15 U.S.C. 2055) and by the interpretative rules issued by the Commission (16 CFR parts 1101 and 1015). For example, if a manufacturer includes information otherwise reportable under section 15 as part of a section 37 report, the Commission will treat the information reported pursuant to section 15 as "additional information" submitted pursuant to section 37(c)(2)(B). Generally, any issue of the public disclosure of that information will be controlled by the relevant provisions of section 6(b), including section 6(b)(5) relating to the disclosure of substantial product hazard reports, and section 6(a) relating to the disclosure of confidential or trade secret information. However, to the extent the section 15 report reiterates or references information reported under section 37, the confidentiality provisions of section 6(e) still apply to the reiteration or reference. In addition, interpretative regulations issued under section 6(b) of the Act establish that disclosure of certain information may be barred if the disclosure would not be fair in the circumstances. 16 CFR 1101.33. Accordingly, issues of releasing additional information submitted pursuant to section 37 will also be evaluated under the fairness provisions of section 6(b). Should the Commission receive a request for such information or contemplate disclosure on its own initiative, the manufacturer will be given an opportunity to present arguments to the Commission why the information should not be disclosed, including, if appropriate, why disclosure of the information would be unfair in the circumstances. Among the factors the Commission will consider in evaluating the fairness of releasing the information are the nature of the information, the fact that it is an adjunct to a Congressional protected report, and whether the information in question supports the conclusion that a section 37 or 15(b), CPSA, report should have been filed earlier.
- (c) Section 6(e) imposes no confidentiality requirements on information obtained by the Commission independently of a report pursuant to section 37. The provisions of section 6(b) govern the disclosure of such information.

§ 1116.10 Restrictions on use of reports.

No member of the Commission, no officer or employee of the Commission, and no officer or employee of the Department of Justice may use information provided to the Commission under section 37 for any purpose other than to carry out the responsibilities of the Commission.

§ 1116.11 Reports of civil actions under section 37 not admissions.

Pursuant to section 37(d), 15 U.S.C. 2084(d), the reporting of a civil action under section 37 shall not constitute an admission of—

- (a) An unreasonable risk of injury;
- (b) A defect in the consumer product which was the subject of the civil action;
- (c) A substantial product hazard;
- (d) An imminent hazard; or
- (e) Any other liability under any statute or any common law.

§ 1116.12 Commission response to section 37 reports.

Upon receipt of a section 37 report, the Commission will evaluate the information contained in the report and any relevant information contained in its files or data bases to determine what, if any, follow-up or remedial action by the Commission is appropriate. If the Commission requires additional information, it will notify the manufacturer in writing of the specific information to provide. In addition, the Commission will routinely review section 37 reports to determine whether the reporting manufacturers have fulfilled their obligations under both sections 37 and 15(b) in a timely manner. Such a review may also engender a request for additional information, including the dates on which final orders were entered in each of the lawsuits reported under section 37. The Commission will treat any subsequent submission of information by the manufacturer as a submission under section 37(c)(2)(B) subject to the restrictions on public disclosure contained in sections 6(a) and (b) of the Consumer Product Safety Act.



BALLOT VOTE SHEET

DATE: AUG - 7 2009

TO:

The Commission

Todd A. Stevenson, Secretary

THROUGH: Maruta Budetti, Executive Director M 45

Cheryl A. Falvey, General Counsel (AF

Phillip L. Chao, Assistant General Counsel

FROM:

Melissa V. Hampshire, GCEL WH Harleigh Ewell, Attorney, GCRA

SUBJECT:

1. Interim Final Rule Interpreting Factors To Be Considered When Seeking Civil

Penalties

2. Withdrawal of Previous Proposed Interpretive Rule On Civil Penalty Factors

AUG 1 3 2009 **Ballot Vote Due:**

Attached for the Commission's consideration are two draft Federal Register notices. The first notice would issue an interim final rule to comply with the requirement of section 217(b)(2) of the Consumer Product Safety Improvement Act of 2008 that "the Commission shall issue a final regulation providing its interpretation of the penalty factors described in section 20(b) of the Consumer Product Safety Act (15 U.S.C. 2069(b)), section 5(c)(3) of the Federal Hazardous Substances Act (15U.S.C. 1264(c)(3)), and section 5(e)(2) of the Flammable Fabrics Act, (15 U.S.C. 1194(e)(2))." The second notice would withdraw the proposed interpretive rule on civil penalty factors that the Commission published on July 12, 2006 (71 Fed. Reg. 39248). The Office of the General Counsel is providing its legal analysis concerning these actions in a separate (restricted) memorandum.

Note: This document has not been reviewed or accepted by the Commission. Date 8-7-09

Page 1 of 4

PRODUCTS IDENTIFIE EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG WITH PORTIONS REMOVED:

ne C	Please indicate your vote on the attached drommission's interpretation concerning civil p	aft notice to issue an interim final rule to provide enalty factors.	
A.	Approve publication of the draft notice in the Federal Register without change.		
	(Signature)	(Date)	
B.	Do not approve publication of the draft notice in the Federal Register.		
	(Signature)	(Date)	
·.	Publish the draft notice in the Federal Regist	ter with changes (please specify).	
	(Signature)	(Date)	

D.	Other (please specify).		
	(Signature)	(Date)	
II. inter	Please indicate your vote on the attached draft no pretation concerning civil penalty factors.	otice to withdraw the previously proposed	
A.	Approve publication of the draft notice in the Federal Register without change.		
	(Signature)	(Date)	
В.	Do not approve publication of the draft notice in the Federal Register.		
	(Signature)	(Date)	

(Signature)	(Date)
Other (please specify).	
Other (piease specify).	

Attachments: Draft *Federal Register* Notices: (1) Civil Penalty Factors; (2) Civil Penalty Factors: Withdrawal of Proposed Rule

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1. Interim Final Rule Interpreting Factors To Be Considered When Seeking Civil Penalties

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1119

Civil Penalty Factors

AGENCY: Consumer Product Safety Commission.

ACTION: Interim final interpretative rule.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 ("CPSIA"), Public Law 110-314, 122 Stat. 3016, requires the Consumer Product Safety Commission ("Commission") to issue a final rule providing its interpretation of the civil penalty factors found in section 20(b) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. 2069(b), section 5(c)(3) of the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. 1264 (c)(3) and section 5(e)(2) of the Flammable Fabrics Act ("FFA"), 15 U.S.C. 1194(e)(2), as amended by section 217 of the CPSIA. These statutory provisions require the Commission to consider certain factors in determining the amount of any civil penalty. The Commission is issuing its interpretation of the statutory factors.

DATES: This rule is effective upon publication in Federal
Register]. Comments must be received [insert date that is
30 days after publication in the Federal Register].
ADDRESSES: You may submit comments, identified by Docket
No. [insert CPSC docket number], 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 www.regulations.gov.

Written Submissions

Submit written comments 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 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 rule. 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 electronically. 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: Melissa V. Hampshire,
Attorney, Division of Enforcement and Information, Office
of the General Counsel at 301-504-7631, mhampshire@cpsc.gov
SUPPLEMENTARY INFORMATION:

A. Background

The CPSIA specifies that the Commission, by August 14, 2009, must issue a final regulation providing its interpretation of civil penalty factors in section 20(b) of the CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA. This rule interprets the factors in section 20(b) of the CPSA, section 5(c)(3) of the FHSA and section 5(e)(2) of the FFA, and describes other factors the Commission may consider in evaluating the amount of a civil penalty to be sought for knowing violations of the prohibited acts found in section 19 of the CPSA, section 4 of the FHSA, and section 5 of the FFA. The statutory

factors the Commission is required to consider in determining the amount of a civil penalty to seek are: the nature, circumstances, extent and gravity of the violation, including the nature of the product defect, the severity of the risk of injury, the occurrence or absence of injury, the number of defective products distributed, the appropriateness of the penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses, and such other factors as appropriate.

The statutory factors the Commission is required to consider in determining the amount of a civil penalty to seek are the same factors identified in section 20(c) of the CPSA, section 5(c)(4) of the FHSA, and section 5(e)(3) of the FFA for determining whether a civil penalty may be compromised by the Commission. These statutory provisions instruct the Commission to consider the following factors in determining the amount of a compromised penalty and whether it should be remitted or mitigated by the Commission: the nature, circumstances, extent and gravity of the violation, including the nature of the product

defect, the severity of the risk of injury, the occurrence or absence of injury, the number of defective products distributed, the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses and such other factors as appropriate. The Commission will apply its interpretation to these statutory terms in determining whether and in what amounts any penalties may be compromised.

As set forth in section 217(a)(4) of the CPSIA, new penalty amounts specified in section 217(a) of the CPSIA take effect on the date that is the earlier of the date on which a final rule providing the Commission's interpretation of penalty factors is issued or on August 14, 2009 (one year after the date of enactment of the CPSIA). Under the amendments, the maximum penalty amounts increase from \$8,000 to \$100,000 for each knowing violation under the CPSA, FHSA, and FFA. Maximum penalty amounts for any related series of violations increase from \$1,825,000 to \$15,000,000.

B. Prior Proposal on Civil Penalty Factors

This factor applies only to the CPSA. The FHSA factor is "the nature of the substance." The FFA has no comparable separate factor apart from the nature, circumstances extent and gravity of the violation.

On July 12, 2006, the Commission published a proposed interpretative rule (71 FR 39248) that identified additional factors to be considered in assessing and compromising civil penalties under sections 20(b) and (c) of the CPSA. The factors identified in the proposed rule were in addition to those already required to be considered under section 20(b) and (c) of the CPSA in evaluating the appropriateness and amount of a civil penalty. Commission invited comment on whether the Commission and staff should consider, as appropriate, one or more of the following factors in determining the appropriateness and amount of a civil penalty: (1) a firm's previous record of compliance with CPSA requirements; (2) timeliness of a firm's response to relevant information; (3) safety and compliance monitoring; (4) cooperation and good faith; (5) economic gain from any delay or noncompliance with CPSC safety or reporting requirements; (6) a product's failure rate; and (7) any other pertinent factors. The comment period closed August 11, 2006. The Commission received four comments.

C. CPSIA Requirements

The enactment of the CPSIA superseded the proposed rule by requiring that the Commission provide its interpretation of the enumerated statutory factors under

section 20(b) of the CPSA, section 5(c)(3) of the FHSA and section 5(e)(2) of the FFA. The CPSIA also expanded the statutory factors under the CPSA, FHSA and FFA for the Commission to consider in determining an appropriate penalty amount by explaining that consideration of existing statutory factors should include the nature, circumstances, extent, and gravity of the violation. The CPSIA modified the factor of appropriateness of the penalty in relation to the size of the business of the person charged by requiring that this factor include a consideration of how to mitigate undue adverse economic impacts on small business. This small business analysis element was added to the CPSA and FHSA but not added to the FFA factor. The Commission will consider the small business analysis element as another appropriate factor under the FFA. The CPSIA also added to the CPSA, FHSA, and FFA a new catch-all statutory factor "other factors as appropriate" for consideration. effect of the CPSIA amendments was noted in the Fall 2008 Current Regulatory Plan and the Unified Agenda (RIN: 3041-AC40) by stating that the proposed rule would be withdrawn. By a separate notice in this issue of the Federal Register the Commission is withdrawing the July 12, 2006 notice of proposed rulemaking (71 FR 39248).

On November 18, 2008 the Commission staff posted a notice on the Commission website inviting comment on information the Commission should address in considering the amended statutory factors under the CPSA, FHSA, and FFA as outlined below:

CPSA (15 U.S.C. 2069(b))	FHSA (15 U.S.C. 1264 (c)(3))	FFA (15 U.S.C. 1194 (e)(2))
The nature, circumstances, extent, and gravity of the violation, including	The nature, circumstances, extent, and gravity of the violation, including	The nature, circumstances, extent, and gravity of the violations,
the nature of the product defect,	the nature of the substance,	
the severity of the risk of injury,	the severity of the risk of injury,	the severity of the risk of injury,
the occurrence or absence of injury,	the occurrence or absence of injury,	the occurrence or absence of injury,
the number of defective products distributed,	the amount of substance distributed,	
the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses,	the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses,	the appropriateness of such penalty in relation to the size of the business of the person charged,
and such other factors as appropriate	and such other factors as appropriate	and such other factors as appropriate

The Commission staff also invited comment on what other factors are appropriate to consider in penalty determinations including: (1) a previous record of

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compliance; (2) timeliness of response; (3) safety and compliance monitoring; (4) cooperation and good faith; (5) economic gain from noncompliance; (6) product failure rate; and (7) what information the Commission should consider in determining how to mitigate the adverse economic impact of a particular penalty on a small business. The Commission staff also invited comment on whether it should develop a formula or matrix for weighing any or all of the various factors and what criteria it should use in any weighting formula or matrix. The Commission received 16 comments in response to the 2008 website notice.

D. Discussion

1. What are the Requirements for Imposition of Civil Penalties?

Implementation of a scheme for assessment of civil penalties should allow for maximum flexibility within an identified framework to determine the amount of any civil penalty to seek and/or compromise. The CPSIA requirement for the Commission to interpret the civil penalty factors gives transparency to the regulated community about the framework the Commission will use to guide its penalty calculations in the enforcement process and may provide incentives for greater compliance. The changes made by various CPSIA provisions to the CPSA, FHSA and FFA,

including those to the CPSA prohibited acts and the addition of new prohibited acts, present the regulated community with many new compliance challenges.

Any proposed civil penalty determination is based first on a violation of a prohibited act under the CPSA, FHSA or FFA. Civil penalties may then be sought against any person who "knowingly violates" section 19 of the CPSA, section 4 of the FHSA or a regulation or standard under section 4 of the FFA. The term "knowingly" is defined in section 20(d) of the CPSA, 15 U.S.C. 2069(d), section 5(c)(5) of the FHSA, 15 U.S.C. 1264(c)(5), and section 5(e)(1) of the FFA, 15 U.S.C. 1194(e)(1) to mean the having of actual knowledge or the presumed having of knowledge deemed to be possessed by a reasonable man who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Since its enactment in 1973, the CPSA always contained a civil penalty provision; however, until 1990, the FHSA and FFA did not contain comparable provisions for civil penalties. Under the FFA, the Commission had to seek civil penalties under the Federal Trade Commission Act, using the authorities under that provision. The FHSA had no civil penalty provision. The Consumer Product Safety Improvement Act of 1990, Public Law

101-608, 104 Stat. 3110, November 16, 1990, amended section 5 of the FHSA and section 5 of the FFA giving the Commission authority to seek civil penalties for knowing violations of the prohibited acts under those Acts. If a penalty cannot be compromised by the Commission, the Commission will seek to commence an action in Federal Court to obtain a penalty. See, Advance Machine Co. v. Consumer Product Safety Commission, 666 F.2d 1166 (8th Cir. 1981); Athlone Industries, Inc. v. Consumer Product Safety Commission (D.C. Cir. 1983).

2. How do the CPSIA Amendments to the CPSA's Prohibited Acts Affect Civil Penalties?

In the past, the majority of civil penalties for prohibited acts were imposed for: a knowing failure to furnish information required by section 15(b) of the CPSA, or for regulatory violations under the CPSA, FHSA or FFA. The regulatory violations included violations of mandatory standards or bans or violations of statutory notification requirements relating to notifying the Commission, prior to exportation, of products that fail to comply with consumer product safety rules or are banned or misbranded hazardous substances under the FHSA. The CPSIA amended these three statutes to strengthen the Commission's enforcement ability and allow for more uniform enforcement under the CPSA,

where applicable.

The new amendments expand the acts prohibited under the CPSA and give the Commission the ability to enforce violations of FHSA and FFA as prohibited acts under the CPSA. Thus, the amended CPSA now prohibits the sale, offer for sale, distribution in commerce, or importation into the United States of any consumer product, or other product or substance that is regulated under the CPSA or any other Act enforced by the Commission, that is not in conformity with an applicable consumer product safety rule under the CPSA, or any similar rule, regulation, standard, or ban under any other Act enforced by the Commission. 15 U.S.C. 2068(a)(1).

The CPSA, as amended, adds a new prohibited act for the sale, manufacture, distribution, or importation of products subject to a voluntary recall taken by a manufacturer and publicly announced by the Commission or if the seller, distributor, or manufacturer knew or should have known of such voluntary corrective action. 15 U.S.C. 2068(a)(2)(B).

The CPSA, as amended, broadens the prohibited act for the sale, offer for sale, manufacture for sale, or distribution or importation of any consumer product or other product or substance subject to a section 15 mandatory recall order to include products subject to a

section 12 order. A section 15 order is imposed in an adjudicative proceeding to declare a product a "substantial product hazard" under section 15 of the CPSA, 15 U.S.C. 2064. A section 12 order, which may include a mandatory order requiring notification to purchasers and repair, replacement or refund is one imposed by a District Court after an "imminent hazard" proceeding under section 12 of the CPSA, 15 U.S.C. 2061.

The amended prohibited acts section of the statute is also broadened to include the sale, offer for sale manufacture for sale, distribution in commerce or importation into the United States of a banned hazardous substance under the FHSA as an act prohibited under the CPSA. 15 U.S.C. 2068(a)(2)(D).

The CPSA prohibited act in section 19(a)(6) of the CPSA relating to certification under section 14 of the CPSA is newly expanded to make the failure to furnish a certificate required by any other Act enforced by the Commission, a prohibited act under the CPSA. This prohibited act now also references a new tracking label requirement of section 103 of the CPSIA by specifying that the failure to comply with any requirement of section 14 includes the failure to comply with the requirement for tracking labels or any rule or regulation promulgated under

section 14.

The CPSA statutory language has also been expanded to include a new prohibited act for the sale, offer for sale, distribution in commerce or importation into the United States of any consumer product containing an unauthorized third party certification mark. 15 U.S.C. 2068(a)(12).

Misrepresentations to Commission officers or employees about the scope of consumer products subject to recall or material misrepresentations in the course of an investigation under any act enforced by the Commission also is a new prohibited act under the CPSA. 15 U.S.C.

In addition, the CPSA adds as a new prohibited act, the exercise or attempt to exercise undue influence on a third party conformity assessment body that tests products for compliance under laws administered by the Commission.

15 U.S.C. 2068(a)(14).

The CPSIA adds to the Commission's export prohibition authority Section 19(a)(15) of the CPSA that makes it illegal to export for purposes of sale from the United States any consumer product or other product or substance (other than the export of a product or substance permitted by the Secretary of the Treasury under section 17(e) of the CPSA) that is subject to Court- or Commission-ordered

recall or that is banned under the FHSA or subject to voluntary recall announced by the Commission. 15 U.S.C. 2068(a)(15).

The CPSIA also adds a new prohibited act that makes it illegal to violate a Commission order issued under new section 18(c) of the CPSA, which allows the Commission to prohibit export for sale of any consumer product not in conformity with an applicable consumer product safety rule. 15 U.S.C. 2068(a)(16).

3. Should Penalties be Sought for Violations that do not Involve Evidence of "Bad Intentions" or "Ill Will?"

Some commenters stated that the Commission should reserve seeking penalties only for the most egregious and dangerous situations and that most violations do not involve bad intentions or ill will.

The CPSA defines "knowingly" as actual knowledge or presumed knowledge based on knowledge attributed to a reasonable person acting in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representation. Since the knowledge requirements in the CPSA, FHSA, and FFA include presumed knowledge, as well as actual knowledge, the Commission declines to follow the commenters' suggestion to seek a penalty only where there is evidence of bad intentions or

ill will. To follow the commenters' position to impose penalties only where there is knowing and willful conduct would read the "presumed knowledge" element out of the "knowing" definition in the statute.

4. Should the Commission Implement a Matrix or Formula for Computing Penalty Amounts?

All but two commenters rejected the concept of a penalty matrix or formula for use in the assessment of civil penalties. Commenters opposed to such a matrix or formula highlighted the difficulty of applying any formula in a particular circumstance as too rigid an approach that would not take into consideration information that might be important to consider in one instance of a penalty but not in another. One commenter suggested that if the Commission reduced its penalty formulation to a matrix it would encourage regulated parties to calculate the cost and risk of prohibited conduct and not to follow the statutory requirements.

The Commission declines to follow a formulaic or matrix approach to penalty assessment or to otherwise state in the regulation any specific circumstances that will warrant a certain penalty amount but has instead provided guidance about what factors may influence the Commission's determination under the various statutory and other

enumerated factors. Importantly, in an individual case, the Commission would review the facts and circumstances surrounding the violations and the proposed assessment of penalties in light of the factors and framework described in the rule. Therefore, the rule does not contain a matrix or formula for assigning specified amounts to the various factors in this notice. Specific considerations under each factor are discussed below.

- 5. How Does the New Rule Interpret the Civil Penalty Factors?
 - A. § 1119.1 Purpose.

Section 1119.1 describes the purpose of new Part 1119
"Civil Penalty Factors," explaining that it is the

Commission's interpretation of the statutory civil penalty
factors set forth in the Consumer Product Safety Act (15

U.S.C. 2051-2089), Federal Hazardous Substances Act (15

U.S.C. 1261-1278), and the Flammable Fabrics Act (15 U.S.C.
1191-1204).

B. § 1119.2 - Applicability.

Section 1119.2 explains that the part applies to all civil penalty determinations that the Commission proposes to seek or compromise for knowing violations of the prohibited acts under the CPSA, the FHSA, or the FFA.

C. § 1119.3 - Definitions.

Section 1119.3 defines certain terms used in the rule. For example, the term "product defect" is broadly defined to cover a product or substance associated with a prohibited act under the CPSA, FHSA or FFA as well as to include the meaning of defect as referenced in the CPSA and the Commission definition of defect at 16 CFR 1115.4. The term "violator" would define any legally responsible party who committed a knowing violation of a prohibited act under the CPSA, FHSA or FFA. The rule explains that the definitions apply for purposes of this rule.

D. § 1119.4(a)(1) - Nature, circumstances, extent, and gravity of the violation.

One commenter observed that Congress amended the CPSIA adding this general factor in addition to the enumerated statutory factors to clarify its intention that the Commission adopt a holistic assessment of all relevant information for penalty determinations rather than place undue emphasis on one or more specific factors.

The Commission agrees that this language allows the Commission to consider the totality of the circumstances surrounding a violation while recognizing that depending upon the case, the significance and importance of each factor may vary. The Commission also believes that this particular factor allows for the consideration of the

seriousness and extent of a particular violation that may not otherwise be considered with respect to the other enumerated statutory factors. Therefore, in each case, the Commission will continue to look at the enumerated statutory factors, as all of well as other factors (described in paragraph J below) that the Commission may determine are appropriate, and consider the factors in determining the civil penalty amount.

E. § 1119.4(a)(2) - Nature of the product defect.

The Commission will consider, under this provision, where appropriate and applicable in each particular case, the nature of the hazard presented by the product for which a penalty is sought. The Commission considers this factor broadly as applying to products or substances that may in fact contain a defect which could create a substantial product hazard (as defined and explained in 16 CFR 1115.4), to products which present a hazard because of a violation of a rule, regulation, standard or ban under the CPSA, FHSA and FFA, as well as any other violation of a prohibited act and how the nature of those violations relate to the underlying products or substances. Therefore, with respect to this factor, a proposed penalty could involve a prohibited act violation, such as a reporting failure under section 15(b) of the CPSA or a failure to comply with any

consumer product safety rule under the CPSA, or any similar rule, regulation, standard or ban under any other act enforced by the Commission. A penalty also could involve any other prohibited act, and the Commission may examine its relation to the underlying product or substance and the prohibited act. Under this factor, the Commission could consider, as appropriate and where the business has reported in a timely fashion under section 15, information about the complexity of identifying a particular product hazard.

Two commenters suggested that the Commission should evaluate violations of regulatory standards by distinguishing those that do not involve actual risk of harm, but rather the potential risk of harm, differently than those that do involve real potential for significant injury.

The Commission declines to accept the suggestion that it distinguish any violations of regulatory standards, rule, or bans in this manner. The promulgation of a mandatory regulation by the Commission, or by Congress when they enact statutory bans and standards, carries with it a corresponding determination that the standard is necessary to address an unreasonable risk of injury presented by the product included within its scope. Violation of such a

statutory provision or Commission regulation presents a risk to consumers that has previously been determined to be addressed by compliance with the statute or regulation. If the commenters' suggestion were followed, the Commission would be classifying certain mandatory standards as more important than others. In addition, the comment does not account for the fact that the Commission can seek penalties for other prohibited act violations (in addition to knowing violations of mandatory rules, standards or bans).

F. § 1119.4(a)(3) - Severity of the risk of injury.

The Commission is to be guided by its discussion of the severity of the risk at 16 CFR 1115.12, as appropriate, in evaluating a particular penalty.

One commenter noted that penalties should not be assessed for risks of minor or moderate injury.

The Commission declines to follow this suggestion.

However, the rule indicates that the Commission may, in addition to considering information about injury potential and the seriousness of the potential injuries, consider the likelihood of injury occurring. In assessing the severity of the risk, the Commission may also consider the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the risk (e.g. children, elderly, handicapped.)

G. § 1119.4(a)(4) - The occurrence or absence of injury.

The Commission received several comments suggesting that it should not seek a penalty where the information the Commission evaluates reveals that the violation involved no injury or only minor injuries have occurred.

The Commission declines to follow this suggestion because a product may present a serious risk to consumers due to a failure to comply with a mandatory standard or other prohibited act even though no actual injuries have occurred. Therefore, the Commission states in the rule that it may consider under this factor whether injuries have or have not occurred, and indicate that if any information is available about injuries, such information may also be considered by the Commission. Under this factor, the rule would direct review, as appropriate, of the injuries that have occurred, or lack thereof, in connection with consideration of the particular violation.

H. § 1119.4(a)(5) - The number of defective products distributed.

Under this provision, the Commission is required to consider the actual number of defective products distributed in commerce. The Commission recognizes, as some commenters pointed out, that the actual number of

defective products in consumers' hands may be different than the number of defective products distributed.

However, the statutory language makes no distinction between those defective products that consumers receive and those defective products distributed in commerce.

Therefore, the Commission chooses not to make any such distinction in any evaluation of information under this factor. The rule reflects this consideration.

I. § 1119.4(a)(6) - The appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses.

The Commission is required to consider the size of a business in relation to the amount of the proposed penalty. This factor reflects the relationship between the size of the business of the person charged and the deterrent effect of civil penalties. In considering business "size," the Commission may look to several factors including the firm's number of employees, net worth, and annual sales. The Commission may be guided, where appropriate, by any relevant financial factors to help determine a violator's ability to pay a proposed penalty including:

- (i) liquidity factors--factors that help measure a violator's ability to pay its short-term obligations;
- (ii) solvency factors--factors that help measure a violator's ability to pay its long-term obligations; and
- (iii) profitability factors-- factors that measure a violator's level of return on investment

The Commission is aware that penalties may have adverse economic consequences on violators, including small business violators. The statute requires the Commission to consider how to mitigate the adverse economic consequences on small business violators only if those consequences would be "undue." What the Commission considers to be "undue" will vary based upon the violator's business size and financial condition as well as the nature, circumstances, extent and gravity of the violation(s). When considering how to mitigate undue adverse economic consequences, the Commission may also follow its Small Business Enforcement Policy set forth at 16 CFR § 1020.5. In determining a small business violator's ability to pay a proposed penalty, the Commission may be guided, where appropriate, by the financial factors set forth above in subsections (i)-(iii).

J. § 1119.4(b) -- Other factors as appropriate.

Congress clarified in the CPSIA that the Commission does have the ability to consider factors in addition to

the ones enumerated in the Act in individual cases, as appropriate. Both the Commission and the violator are free to raise any other factors they believe are relevant in determining an appropriate civil penalty amount.

Additional factors which may be considered in an individual

Additional factors which may be considered in an individual case include, but are not limited to, the following:

- (i) Safety/Compliance Program and/or System: The
 Commission may consider whether a violator has a
 reasonable program/or system for collecting and
 analyzing information related to safety issues,
 including incident reports, lawsuits, warranty
 claims, and safety-related issues related to
 repairs or returns; and whether a violator
 conducted adequate and relevant premarket testing
 of the product(s) at issue.
- (ii) Compliance History: The Commission may consider if the violator has a history of compliance or noncompliance with the CPSC and whether a higher penalty should be assessed for repeated noncompliance.
- (iii) Economic Gain from Noncompliance: The Commission may consider whether a firm benefitted economically from a delay in complying with statutory and regulatory requirements.

Which, if any, additional factors the Commission considers in determining an appropriate penalty amount will be unique to each case. In all civil penalty matters, any additional factors beyond those enumerated in the statute that the Commission takes into consideration for purposes of determining an appropriate civil penalty amount will be made known to and discussed with the violator.

M. § 1119.5 - Notification.

Section 1119.5 of the rule sets forth a notification provision that has been informally followed by the Commission in determining the amount and appropriateness of a civil penalty to seek or compromise for knowing violations of the prohibited acts.

E. Immediate Effective Date

The Commission must issue a final rule, in accordance with the procedures set forth at 5 U.S.C. 553 of the Administrative Procedure Act, by August 14, 2009, providing its interpretation of the penalty factors in section 20(b) of the CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA. Maximum civil penalty amounts are increasing on August 14, 2009. Therefore, the Commission proposes that any final rule resulting from this rulemaking become effective upon publication. The rule is interpretative and does not impose obligations on regulated

parties beyond those imposed by the CPSA, FHSA, and FFA.

Therefore, there is no need to provide a delayed effective date in order to allow for regulated parties to prepare for the rule.

F. Regulatory Flexibility Certification

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612, directs agencies to consider the potential impact of regulations on small business and other small entities.

However, the RFA does not apply to rulemaking that is not subject to notice and comment requirement of the Administrative Procedure Act, 5 U.S.C. 553. Interpretative rules, such as the one issued by this notice, are not subject to the notice and comment requirement. Accordingly, neither an initial nor a final regulatory flexibility analysis is required for this rule.

G. Paperwork Reduction Act

The rule does not impose any information collection requirements. Rather it describes the statutory civil penalty factors and how the Commission interprets those factors. Accordingly, it is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501-3520.

H. Environmental Considerations

The Commission's regulations at 16 CFR 1021.5(a) provide that there are no CPSC actions that ordinarily

produce significant environmental effects. The rule does not fall within the categories in 16 CFR 1021.5(b) of CPSC actions that have the potential for producing environmental effects. The rule does not have any potential for adversely affecting the quality of the human environment. Council of Environmental Quality regulations at 40 CFR 1508.18(a) provide that agency actions subject to environmental review "do not include bringing judicial or administrative enforcement actions." Therefore, no environmental assessment or environmental impact state is required.

List of Subjects in 16 CFR PART 1119

Administrative practice and procedure, Business and Industry, Consumer protection, Reporting and recordkeeping requirements.

Accordingly, the Commission proposes to amend title 16 of the Code of Federal Regulations by adding a new Part 1119 to read as follows:

PART 1119 CIVIL PENALTY FACTORS

Sec.

- § 1119.1 Purpose.
- § 1119.2 Applicability.
- § 1119.3 Definitions.
- § 1119.4 Factors Considered In Determining

Civil Penalties.

§ 1119.5 Enforcement Notification.

AUTHORITY: 15 U.S.C. 2058, 2063, 2064, 2067(b), 2068, 2069, 2076(e), 2084, 1261, 1263, 1264, 1270, 1273, 1278, 1191, 1192, 1193, 1194, 1195, 1196.

§ 1119.1 Purpose.

This part sets forth the Consumer Product Safety

Commmission's (Commission) interpretation of the statutory

factors considered in determining the amount of civil

penalties the Commission may seek or compromise.

§ 1119.2 Applicability.

Application. This part applies to all civil penalty determinations the Commission may seek or compromise under the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051-2089), the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261-1278), and the Flammable Fabrics Act (FFA) (15 U.S.C. 1191-1204). Any person who knowingly violates a prohibited act set forth in section 19 of the CPSA, section 4 of the FHSA, or section 5(e) of the FFA is subject to a civil penalty.

§ 1119.3 Definitions.

For purposes of this rule the following definitions apply:

(a) Product defect means a product or substance that is associated with a prohibited act under the CPSA, FHSA or FFA, including the meaning of defect as referenced in the

CPSA and defined in Commission regulations at 16 CFR 1115.4.

- (b) Violation means a knowing violation, as defined in the CPSA, FHSA or FFA of any prohibited act found in section 19 of the CPSA, section 4 of the FHSA, or section 5 of the FFA.
- (c) Violator means any manufacturer, importer, distributor or retailer or any other legally responsible party who committed a knowing violation of a prohibited act under the CPSA, FHSA or FFA and is thus subject to penalties.

§ 1119.4 Factors considered in determining civil penalties.

(a) Statutory Factors. Section 20(b) of the CPSA, section 5(c)(3) of the FHSA and section 5(e)(2) of the FFA specify factors considered by the Commission in determining the amount of a civil penalty to be sought upon commencing an action for knowing violations of the prohibited acts section of each act. These factors are:

CPSA (15 U.S.C. 2069(b))	FHSA (15 U.S.C. 1264 (c)(3))	FFA (15 U.S.C. 1194 (e)(2))
The nature, circumstances, extent, and gravity of the violation, including	The nature, circumstances, extent, and gravity of the violation, including	The nature, circumstances, extent, and gravity of the violations,
the nature of the product defect,	the nature of the substance,	
the severity of the risk of injury,	severity of the risk of injury,	the severity of the risk of injury,
the occurrence or absence of injury,	the occurrence or absence of injury,	the occurrence or absence of injury,
the number of defective products distributed,	the amount of substance distributed,	
the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses,	the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses,	the appropriateness of such penalty in relation to the size of the business of the person charged,
and such other factors as appropriate	and such other factors as appropriate	and such other factors as appropriate

(1) The nature, circumstances, extent and gravity of the violation. Under this factor, the Commission will

consider the totality of the circumstances surrounding a violation, including how many provisions of law were violated. The Commission will continue to look at the enumerated statutory factors, as well as other factors (as described in subsection (b) below) that the Commission may determine are appropriate, and consider all of the factors in determining the civil penalty amount.

- (2) Nature of the product defect. The Commission will consider the nature of the product hazard/substance for which a penalty is sought. A product defect under this factor includes violations for products that contain defects which present substantial product hazards as referenced in the CPSA and defined and explained in 16 CFR 1115.4; regulatory violations of a rule, regulation, standard or ban; or product hazards presented by any other violation of the prohibited acts of section 19 of the CPSA.
- (3) Severity of the risk of injury. Consistent with its discussion of severity of the risk at 16 CFR 1115.12, the Commission will consider, among other factors, the potential for serious injury or death (and whether any injury required actual medical treatment including hospitalization or surgery; the likelihood of injury; the intended or reasonably foreseeable use or misuse of the product; and the population at risk (including vulnerable

populations such as children, the elderly, or those with disabilities).

- (4) The occurrence or absence of injury. The Commission will consider whether injuries have or have not occurred with respect to any product associated with the violation.
- (5) The number of defective products distributed. The Commission will consider the number of products imported and the number of products placed in the stream of commerce to distributors, retailers, and consumers.
- (6) The appropriateness of such penalty in relation to the size of the business of the person charged including how to mitigate undue adverse economic consequences on small business. The Commission is required to consider the size of a business in relation to the amount of the proposed penalty. This factor reflects the relationship between the size of business of the person charged and the deterrent effect of civil penalties. In considering business "size," the Commission may look to several factors including the firm's number of employees, net worth, and annual sales. The Commission may be guided, where appropriate, by any relevant financial factors to help determine a violator's ability to pay a proposed penalty

including: liquidity factors; solvency factors; and profitability factors.

The statute requires the Commission to consider how to mitigate the adverse economic consequences on small business violators only if those consequences would be "undue." What the Commission considers to be "undue" will vary based upon the violator's business size and financial condition as well as the nature, circumstances, extent and gravity of the violation(s). When considering how to mitigate undue adverse economic consequences, the Commission may also follow its Small Business Enforcement Policy set forth at 16 CFR §1020.5.

- (b) Other factors as appropriate. In determining the amount of any civil penalty to be pursued when a knowing violation of the prohibited acts section of the CPSA, FHSA, or FFA has occurred, the Commission may consider, where appropriate, other factors in addition to those listed in the statutes. These factors may be presented either by the violator or by the Commission and may act to either mitigate or aggravate the amount of any penalty.

 Additional factors which may be considered in an individual case include, but are not limited to, the following:
 - (i) Safety/Compliance Program and/or System:

 The Commission may consider whether a

violator has a reasonable program/or system for collecting and analyzing information related to safety issues, including incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns; and whether a violator conducted adequate and relevant premarket testing of the product(s) at issue.

- (ii) Compliance History: The Commission may consider if the violator has a history of compliance or noncompliance with the CPSC and whether a higher penalty should be assessed for repeated noncompliance.
- (iii) Economic Gain from Noncompliance: The
 Commission may consider whether a firm
 benefitted economically from a delay in
 complying with statutory and regulatory
 requirements.

Which, if any, additional factors the Commission considers in determining an appropriate penalty amount will be unique to each case. In all civil penalty matters, any additional factors beyond those enumerated in the statute that the Commission takes into consideration for purposes of

determining an appropriate civil penalty amount will be made known to and discussed with the violator.

§ 1119.5 Enforcement Notification.

A potential violator will be informed in writing that the Commission believes it is subject to a possible civil penalty. The basis of such determination will be outlined in the notification. The violator will be able to submit evidence and arguments to an identified CPSC employee that it is not subject to such a penalty.

Dated:		 	
	 	 -	

Todd A. Stevenson, Secretary

Consumer Product Safety Commission

2. Withdrawal of Previous Proposed Interpretive Rule On Civil Penalty Factors

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1119

Civil Penalty Factors; Withdrawal of Proposed Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Withdrawal of proposed rule.

SUMMARY: In the FEDERAL REGISTER of July 12, 2006, the Consumer Product Safety Commission ("CPSC" or "Commission") issued a proposed rule that would identify and explain related factors, other than those specified by statute, which the Commission may consider in evaluating the appropriateness and amount of a civil penalty under the Consumer Product Safety Act ("CPSA"). The Consumer Product Safety Improvement Act of 2008 ("CPSIA"), Public Law 110-314, 122 Stat. 3016, supersedes the proposed rule by amending the CPSA, the Federal Hazardous Substances Act ("FHSA"), and the Flammable Fabrics Act ("FFA") to require the Commission to consider additional factors and to issue a rule providing its interpretation of all statutory factors pertaining to civil penalties. Consequently, the Commission is withdrawing the July 12, 2006 proposed rule.

DATES: The proposed rule is withdrawn as of [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Melissa V. Hampshire, Office of the General Counsel, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504–7631, e-mail mhampshire@cpsc.gov.

SUPPLEMENTARY INFORMATION:

In the FEDERAL REGISTER of July 12, 2006 (71 FR 39248), the CPSC proposed to amend its regulations to add a new part, 16 CFR 1119, titled "Civil Penalty Factors." The proposed rule would describe the factors the Commission may consider in determining the appropriateness and amount of a civil penalty for violations of section 19(a) of the CPSA, which includes the failure to furnish information required by section 15(b) of the CPSA.

The proposal was intended to provide further clarity and transparency in how the CPSC determines civil penalty amounts. The Commission believed that the proposed rule would result in a better understanding by the public of the Commission's approach to determining the appropriateness and amount of a civil penalty.

The Commission received four comments in response to the proposed rule. The CPSIA was subsequently enacted, and section 217 of the CPSIA revised certain sections of the CPSA, the FHSA, and the Flammable Fabrics Act. In general, section 217 of the CPSIA increased the maximum civil penalty amounts, described new factors for the CPSC to consider when determining civil penalty amounts, and instructed the CPSC to issue a final rule to interpret the "penalty factors described in section 20(b) of the [CPSA] section 5(c)(3) of the [FHSA] and section 5(e)(2) of the [FFA] as amended by subsection(a) [of the CPSIA]."

Section 217 of the CPSIA, therefore, effectively superseded the July 12, 2006 proposed rule by adding new factors for consideration and directing the Commission to issue a final rule providing its interpretation all the factors in section 20(b) of CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA. Consequently, the Commission, through this notice, is withdrawing the July 12, 2006 proposal.

Elsewhere in this issue of the FEDERAL REGISTER, the Commission is issuing
new interim final rule to interpret the penalty factors pursuant to section 217 of the
PSIA.
ated:
Todd A. Stevenson, Secretary, Consumer Product Safety

Commission.

The Consumer Product Safety Improvement Act – How You Are Affected – It's More than Children's Products

COURSE MATERIALS FOR ALAN H. SCHOEM

- Consumer Product Safety Improvement Act of 2008
- CPSC Phthalate Component Policy
- CPSC Tracking Label Policy
- CPSC Tracking Label FAQs Children's Products Section 103
- CPSC Guidelines for Mandatory Recall Notices
- CPSC Whistleblower Protections Section 219
- CPSC Notice of Stay of Enforcement of Testing & Certification
 Requirements

CONSUMER PRODUCT SAFETY IMPROVEMENT ACT OF 2008

PUBLIC LAW 110-314-AUG. 14, 2008

Public Law 110-314 110th Congress

An Act

Aug. 14, 2008 [H.R. 4040]

To establish consumer product safety standards and other safety requirements for children's products and to reauthorize and modernize the Consumer Product Safety Commission.

Consumer Product Safety Improvement Act of 2008. Commerce and trade. 15 USC 2051

note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE: TABLE OF CONTENTS.

- (a) Short Title.—This Act may be cited as the "Consumer Product Safety Improvement Act of 2008".
- (b) Table of Contents.—The table of contents for this Act is as follows:
- Sec. 1. Short title; table of contents.
- Sec. 2. References.
 Sec. 3. Authority to issue implementing regulations.

TITLE I—CHILDREN'S PRODUCT SAFETY

- Sec. 101. Children's products containing lead; lead paint rule.
- Sec. 102. Mandatory third party testing for certain children's products. Sec. 103. Tracking labels for children's products.
- Sec. 104. Standards and consumer registration of durable nursery products.
- Sec. 105. Labeling requirement for advertising toys and games.
- Sec. 106. Mandatory toy safety standards.
- Sec. 107. Study of preventable injuries and deaths in minority children related to consumer products.
- Sec. 108. Prohibition on sale of certain products containing specified phthalates.

TITLE II—CONSUMER PRODUCT SAFETY COMMISSION REFORM

Subtitle A—Administrative Improvements

- Sec. 201. Reauthorization of the Commission.
- Sec. 202. Full Commission requirement; interim quorum; personnel.
- Sec. 203. Submission of copy of certain documents to Congress.

- Sec. 204. Expedited rulemaking.
 Sec. 205. Inspector general audits and reports.
 Sec. 206. Industry-sponsored travel ban.
 Sec. 207. Sharing of information with Federal, State, local, and foreign government agencies.
- Sec. 208. Employee training exchanges. Sec. 209. Annual reporting requirement.

Subtitle B-Enhanced Enforcement Authority

- Sec. 211. Public disclosure of information.
- Sec. 212. Establishment of a public consumer product safety database. Sec. 213. Prohibition on stockpiling under other Commission-enforced statutes.

- Sec. 214. Enhanced recall authority and corrective action plans.
 Sec. 215. Inspection of firewalled conformity assessment bodies; identification of supply chain.

- Sec. 216. Prohibited acts.
 Sec. 217. Penalties.
 Sec. 218. Enforcement by State attorneys general.
- Sec. 219. Whistleblower protections.

122 STAT. 3017

Subtitle C—Specific Import-Export Provisions

Sec. 221. Export of recalled and non-conforming products.

Sec. 222. Import safety management and interagency cooperation. Sec. 223. Substantial product hazard list and destruction of noncompliant imported

products.

Sec. 224. Financial responsibility.

Sec. 225. Study and report on effectiveness of authorities relating to safety of imported consumer products.

Subtitle D-Miscellaneous Provisions and Conforming Amendments

Sec. 231. Preemption. Sec. 232. All-terrain v

Sec. 232. All-terrain vehicle standard. Sec. 233. Cost-benefit analysis under the Poison Prevention Packaging Act of 1970. Sec. 234. Study on use of formaldehyde in manufacturing of textile and apparel ar-

Sec. 235. Technical and conforming changes.

Sec. 236. Expedited judicial review.
Sec. 237. Repeal.
Sec. 238. Pool and Spa Safety Act technical amendments.
Sec. 239. Effective dates and Severability.

SEC. 2. REFERENCES.

15 USC 2051

(a) Defined Terms.—As used in this Act—
(1) the term "appropriate Congressional committees" means the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate; and

(2) the term "Commission" means the Consumer Product

Safety Commission.

(b) CONSUMER PRODUCT SAFETY ACT.—Except as otherwise expressly provided, whenever in this Act an amendment is expressed as an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Consumer Product Safety Act (15 U.S.C. 2051

SEC. 3. AUTHORITY TO ISSUE IMPLEMENTING REGULATIONS.

15 USC 2051

The Commission may issue regulations, as necessary, to implement this Act and the amendments made by this Act.

TITLE I—CHILDREN'S PRODUCT SAFETY

SEC. 101. CHILDREN'S PRODUCTS CONTAINING LEAD; LEAD PAINT 15 USC 1278a. RULE.

(a) GENERAL LEAD BAN.—

(1) Treatment as a banned hazardous substance.— Except as expressly provided in subsection (b) beginning on the dates provided in paragraph (2), any children's product (as defined in section 3(a)(16) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(16))) that contains more lead than the limit established by paragraph (2) shall be treated as a banned hazardous substance under the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.).

(2) LEAD LIMIT.

Effective dates.

(A) 600 PARTS PER MILLION.—Except as provided in subparagraphs (B), (C), (D), and (E), beginning 180 days after the date of enactment of this Act, the lead limit referred to in paragraph (1) is 600 parts per million total lead content by weight for any part of the product.

(B) 300 PARTS PER MILLION.—Except as provided by subparagraphs (C), (D), and (E), beginning on the date

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that is 1 year after the date of enactment of this Act, the lead limit referred to in paragraph (1) is 300 parts per million total lead content by weight for any part of the product.

Applicability.

- (C) 100 Parts Per Million.—Except as provided in subparagraphs (D) and (E), beginning on the date that is 3 years after the date of enactment of this Act, subparagraph (B) shall be applied by substituting "100 parts per million" for "300 parts per million" unless the Commission determines that a limit of 100 parts per million is not technologically feasible for a product or product category. The Commission may make such a determination only after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products.
- (D) ALTERNATE REDUCTION OF LIMIT.—If the Commission determines under subparagraph (C) that the 100 parts per million limit is not technologically feasible for a product or product category, the Commission shall, by regulation, establish an amount that is the lowest amount of lead, lower than 300 parts per million, the Commission determines to be technologically feasible to achieve for that product or product category. The amount of lead established by the Commission under the preceding sentence shall be substituted for the 300 parts per million limit under subparagraph (B) beginning on the date that is 3 years after the date of enactment of this Act.
- (E) Periodic review and further reductions.—The Commission shall, based on the best available scientific and technical information, periodically review and revise downward the limit set forth in this subsection, no less frequently than every 5 years after promulgation of the limit under subparagraph (C) or (D) to require the lowest amount of lead that the Commission determines is technologically feasible to achieve. The amount of lead established by the Commission under the preceding sentence shall be substituted for the lead limit in effect immediately before such revision.
- (b) EXCLUSION OF CERTAIN MATERIALS OR PRODUCTS AND INACCESSIBLE COMPONENT PARTS.—
 - (1) CERTAIN PRODUCTS OR MATERIALS.—The Commission may, by regulation, exclude a specific product or material from the prohibition in subsection (a) if the Commission, after notice and a hearing, determines on the basis of the best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither—
 - (A) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor
 - (B) have any other adverse impact on public health or safety.
 - (2) EXCEPTION FOR INACCESSIBLE COMPONENT PARTS.—
 - (A) IN GENERAL.—The limits established under subsection (a) shall not apply to any component part of a children's product that is not accessible to a child through

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normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. A component part is not accessible under this subparagraph if such component part is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product. Reasonably foreseeable use and abuse shall include to, swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

(B) INACCESSIBILITY PROCEEDING.—Within 1 year after the date of enactment of this Act, the Commission shall promulgate a rule providing guidance with respect to what product components, or classes of components, will be considered to be inaccessible for purposes of subparagraph

(C) APPLICATION PENDING CPSC GUIDANCE.—Until the Commission promulgates a rule pursuant to subparagraph (B), the determination of whether a product component is inaccessible to a child shall be made in accordance with the requirements laid out in subparagraph (A) for considering a component to be inaccessible to a child.

(3) CERTAIN BARRIERS DISQUALIFIED.—For purposes of this subsection, paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate inaccessible to a child, or to prevent absorption of any lead into the human body, through normal and reasonably foresee-

able use and abuse of the product.

(4) CERTAIN ELECTRONIC DEVICES.—If the Commission determines that it is not technologically feasible for certain electronic devices, including devices containing batteries, to comply with subsection (a), the Commission, by regulation, shall-

(A) issue requirements to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices, which may include requirements that such electronic devices be equipped with a child-resistant cover or casing that prevents exposure to and accessibility of the parts of the product containing lead; and

(B) establish a schedule by which such electronic devices shall be in full compliance with the limits in subsection (a), unless the Commission determines that full compliance will not be technologically feasible for such

devices within a schedule set by the Commission.

(5) Periodic review.—The Commission shall, based on the best available scientific and technical information, periodically review and revise the regulations promulgated pursuant to this subsection no less frequently than every 5 years after the first promulgation of a regulation under this subsection to make them more stringent and to require the lowest amount of lead the Commission determines is technologically feasible to achieve.

(c) APPLICATION WITH ASTM F963.—To the extent that any regulation promulgated by the Commission under this section (or any section of the Consumer Product Safety Act or any other Act enforced by the Commission, as such Acts are affected by this section) is inconsistent with the ASTM F963 standard, such

Requirements.

Deadline.

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promulgated regulation shall supersede the ASTM F963 standard to the extent of the inconsistency.

- (d) TECHNOLOGICAL FEASIBILITY DEFINED.—For purposes of this section, a 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.
- (e) Pending Rulemaking Proceedings To Have No Effect.—The pendency of a rulemaking proceeding to consider—
 - (1) a delay in the effective date of a limit or an alternate limit under this section related to technological feasibility.
 - (2) an exception for certain products or materials or inacces-
 - sibility guidance under subsection (b) of this section, or
 - (3) any other request for modification of or exemption from any regulation, rule, standard, or ban under this Act or any other Act enforced by the Commission,

shall not delay the effect of any provision or limit under this section nor shall it stay general enforcement of the requirements of this section.

(f) More Stringent Lead Paint Ban.—

etive data (1) IN

(1) IN GENERAL.—Effective on the date that is 1 year after the date of enactment of this Act, the Commission shall modify section 1303.1 of its regulations (16 C.F.R. 1301.1) by substituting "0.009 percent" for "0.06 percent" in subsection (a) of that section.

(2) Periodic review and reduction.—The Commission shall, no less frequently than every 5 years after the date on which the Commission modifies the regulations pursuant to paragraph (1), review the limit for lead in paint set forth in section 1303.1 of title 16, Code of Federal Regulations (as revised by paragraph (1)), and shall by regulation revise downward the limit to require the lowest amount of lead that the Commission determines is technologically feasible to achieve.

(3) METHODS FOR SCREENING LEAD IN SMALL PAINTED AREAS.—In order to provide for effective and efficient enforcement of the limit set forth in section 1303.1 of title 16, Code of Federal Regulations, the Commission may rely on x-ray fluorescence technology or other alternative methods for measuring lead in paint or other surface coatings on products subject to such section where the total weight of such paint or surface coating is no greater than 10 milligrams or where such paint or surface coating covers no more than 1 square centimeter of the surface area of such products. Such alternative methods for measurement shall not permit more than 2 micrograms of lead in a total weight of 10 milligrams or less of paint or other surface coating or in a surface area of 1 square centimeter or less.

Effective date.

Deadline.

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- (4) ALTERNATIVE METHODS OF MEASURING LEAD IN PAINT GENERALLY.-
 - (A) STUDY.—Not later than 1 year after the date of Deadline. enactment of this Act, the Commission shall complete a study to evaluate the effectiveness, precision, and reliability of x-ray fluorescence technology and other alternative methods for measuring lead in paint or other surface coatings when used on a children's product or furniture article in order to determine compliance with part 1303 of title 16, Code of Federal Regulations, as modified pursuant to this subsection.
 - (B) RULEMAKING.—If the Commission determines, based on the study in subparagraph (A), that x-ray fluorescence technology or other alternative methods for measuring lead in paint are as effective, precise, and reliable as the methodology used by the Commission for compliance determinations prior to the date of enactment of this Act, the Commission may promulgate regulations governing the use of such methods in determining the compliance of products with part 1303 of title 16, Code of Federal Regulations, as modified pursuant to this subsection. Any regulations promulgated by the Commission shall ensure that such alternative methods are no less effective, precise, and reliable than the methodology used by the Commission prior to the date of enactment of this Act.

(5) Periodic review.—The Commission shall, no less frequently than every 5 years after the Commission completes the study required by paragraph (4)(A), review and revise any methods for measurement utilized by the Commission pursuant to paragraph (3) or pursuant to any regulations promulgated under paragraph (4) to ensure that such methods are the most effective methods available to protect children's health. The Commission shall conduct an ongoing effort to study and encourage the further development of alternative methods for measuring lead in paint and other surface coating that can effectively, precisely, and reliably detect lead levels at or below the level set forth in part 1303 of title 16, Code of Federal Regulations, or any lower level established by regulation.

(6) NO EFFECT ON LEGAL LIMIT.—Nothing in paragraph (3), nor reliance by the Commission on any alternative method of measurement pursuant to such paragraph, nor any rule prescribed pursuant to paragraph (4), nor any method established pursuant to paragraph (5) shall be construed to alter the limit set forth in section 1303 of title 16, Code of Federal Regulations, as modified pursuant to this subsection, or provide any exemption from such limit.

(7) CONSTRUCTION.—Nothing in this subsection shall be construed to affect the authority of the Commission or any other person to use alternative methods for detecting lead as a screening method to determine whether further testing or action is needed.

(g) Treatment as a Regulation Under the FHSA.—Any ban imposed by subsection (a) or rule promulgated under subsection (a) or (b) of this section, and section 1303.1 of title 16, Code of Federal Regulations (as modified pursuant to subsection (f)(1) or (2)), or any successor regulation, shall be considered a regulation of the Commission promulgated under or for the enforcement of

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section 2(q) of the Federal Hazardous Substances Act (15 U.S.C. 1261(q)).

SEC. 102. MANDATORY THIRD PARTY TESTING FOR CERTAIN CHIL-DREN'S PRODUCTS.

(a) MANDATORY AND THIRD PARTY TESTING.—

(1) General conformity certification.—

(A) AMENDMENT.—Paragraph (1) of section 14(a) (15

U.S.C. 2063(a)) is amended to read as follows:

"(1) General conformity certification.—Except as provided in paragraphs (2) and (3), every manufacturer of a product which is subject to a consumer product safety rule under this Act or similar rule, ban, standard, or regulation under any other Act enforced by the Commission and which is imported for consumption or warehousing or distributed in commerce (and the private labeler of such product if such product bears a private label) shall issue a certificate which-

"(A) 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 this Act or any other Act

enforced by the Commission; and

"(B) shall specify each such rule, ban, standard, or

regulation applicable to the product.".

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall take effect 90 days after the date of enactment of this Act.

(2) Third party testing requirement.—Section 14(2) (15 U.S.C. 2063(2)) is further amended by redesignating paragraph (2) as paragraph (4) and inserting after paragraph (1) the

following:

"(2) THIRD PARTY TESTING REQUIREMENT.—Effective on the dates provided in paragraph (3), before importing for consumption or warehousing or distributing in commerce any children's product that is subject to a children's product safety rule, every manufacturer of such children's product (and the private labeler of such children's product if such children's product bears a private label) shall-

'(A) 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 under paragraph (3) to be tested for compliance

with such children's product safety rule; and

"(B) based on such testing, 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 conduct such tests.

A manufacturer or private labeler shall issue either a separate certificate for each children's product safety rule applicable to a product or a combined certificate that certifies compliance with all applicable children's product safety rules, in which case each such rule shall be specified.

"(3) Schedule for implementation of third party TESTING.

"(A) GENERAL APPLICATION.—Except as provided under subparagraph (F), the requirements of paragraph (2) shall

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Certification.

Notice.

apply to any children's product manufactured more than 90 days after the Commission has established and published notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which such children's product is subject.

"(B) TIME LINE FOR ACCREDITATION.—

"(i) LEAD PAINT.—Not later than 30 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall publish notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with part 1303 of title 16, Code of Federal Regulations.

"(ii) FULL-SIZE CRIBS; NON FULL-SIZE CRIBS; PAC-IFIERS.—Not later than 60 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall publish notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with

parts 1508, 1509, and 1511 of such title.

"(iii) SMALL PARTS.—Not later than 90 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall publish notice of the requirements for accreditation of third party conformity assessment bodies to assess con-

formity with part 1501 of such title.

"(iv) CHILDREN'S METAL JEWELRY.—Not later than 120 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall publish notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with the requirements of section 101(a)(2) of such Act with respect to children's metal jewelry.

"(v) Baby Bouncers, Walkers, and Jumpers.— Not later than 210 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall publish notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with

parts 1500.18(a)(6) and 1500.86(a) of such title.

"(vi) ALL OTHER CHILDREN'S PRODUCT SAFETY RULES.—The Commission shall publish notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with other children's product safety rules at the earliest practicable date, but in no case later than 10 months after the date of enactment of the Consumer Product Safety Improvement Act of 2008, or, in the case of children's product safety rules established or revised 1 year or more after such date of enactment, not later than 90 days before such rules or revisions take effect.

"(C) Accreditation of third party conformity assessment bodies pursuant to the requirements established under subparagraph (B) may be conducted

Deadlines.

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either by the Commission or by an independent accredita-

tion organization designated by the Commission.

"(D) Periodic Review.—The Commission shall periodically review and revise the accreditation requirements established under subparagraph (B) to ensure that the requirements assure the highest conformity assessment body quality that is feasible.

"(E) Publication of accredited entities.—The Commission shall maintain on its Internet website an upto-date list of entities that have been accredited to assess conformity with children's product safety rules in accordance with the requirements published by the Commission under this paragraph.

"(F) EXTENSION.—If the Commission determines that an insufficient number of third party conformity assessment bodies have been accredited to permit certification for a children's product safety rule under the accelerated schedule required by this paragraph, the Commission may extend the deadline for certification to such rule by not more than 60 days.

"(G) RULEMAKING.—Until the date that is 3 years after the Consumer Product Safety Improvement Act of 2008, Commission proceedings under this paragraph shall be exempt from the requirements of sections 553 and 601 through 612 of title 5, United States Code."

(3) Conforming amendments.—Section 14(a)(4) (15 U.S.C. 2063(a)(4)), as redesignated by paragraph (2) of this subsection, is amended—

(A) by striking "required by paragraph (1) of this subsection" and inserting "required under paragraph (1), (2), or (3)"; and

(B) by striking "requirement under paragraph (1)" and inserting "requirement under paragraph (1), (2), or (3)".
(b) ADDITIONAL REQUIREMENTS; DEFINITIONS.—Section 14 (15 U.S.C. 2063) is further amended by adding at the end the following: "(d) ADDITIONAL REGULATIONS FOR THIRD PARTY TESTING.—

"(1) AUDIT.—Not later than 10 months after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall by regulation establish requirements for the periodic audit of third party conformity assessment bodies as a condition for the continuing accreditation of such conformity assessment bodies under subsection (a)(3)(C).

"(2) COMPLIANCE; CONTINUING TESTING.—Not later than 15 months after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall by regulation—

"(A) initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of subsection (a); and

"(B) establish protocols and standards—
"(i) for ensuring that a children's product tested for compliance with an applicable 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 sourcing of component parts;

Web site. Records.

Termination date.

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"(ii) for the testing of random samples to ensure continued compliance;

"(iii) for verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules; and

"(iv) for safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

"(e) WITHDRAWAL OF ACCREDITATION.—

"(1) IN GENERAL.—The Commission may withdraw its accreditation or its acceptance of the accreditation of a third party conformity assessment body accredited under this section if the Commission finds, after notice and investigation, that—

"(A) a manufacturer, private labeler, or governmental entity has exerted undue influence on such conformity assessment body or otherwise interfered with or compromised the integrity of the testing process with respect to the certification of a children's product under this section; or

"(B) such conformity assessment body failed to comply with an applicable protocol, standard, or requirement established by the Commission under subsection (d).

"(2) PROCEDURE.—In any proceeding to withdraw the accreditation of a conformity assessment body, the Commission—

"(A) shall consider the gravity of the conformity assessment body's action or failure to act, including—

"(i) whether the action or failure to act resulted

in injury, death, or the risk of injury or death;

"(ii) whether the action or failure to act constitutes an isolated incident or represents a pattern or practice; and

"(iii) whether and when the conformity assessment body initiated remedial action; and "(B) may— $\,$

"(i) withdraw its acceptance of the accreditation of the conformity assessment body on a permanent or temporary basis; and

"(ii) establish requirements for reaccreditation of

the conformity assessment body.

"(3) FAILURE TO COOPERATE.—The Commission may suspend the accreditation of a conformity assessment body if it fails to cooperate with the Commission in an investigation under this section.

"(f) Definitions.—In this section:

"(1) CHILDREN'S PRODUCT SAFETY RULE.—The term 'children's product safety rule' means a consumer product safety rule under this Act 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.

"(2) THIRD PARTY CONFORMITY ASSESSMENT BODY.—

"(A) IN GENERAL.—The term 'third party conformity assessment body' means a conformity assessment body that, except as provided in subparagraph (D), is not owned, managed, or controlled by the manufacturer or private

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labeler of a product assessed by such conformity assessment

body.

"(B) GOVERNMENTAL PARTICIPATION.—Such term may include an entity that is owned or controlled in whole or in part by a government if-

"(i) 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;

"(ii) the entity's testing results are not subject to undue influence by any other person, including

another governmental entity;
"(iii) the entity is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited under this section;

"(iv) the entity's testing results are accorded no greater weight by other governmental authorities than those of other third party conformity assessment bodies accredited under this section; and

"(v) the entity 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 entity's conformity assess-

"(C) TESTING AND CERTIFICATION OF ART MATERIALS AND PRODUCTS.—A certifying organization (as defined in appendix A to section 1500.14(b)(8) of title 16, Code of Federal Regulations (or any successor regulation or ruling)) meets the requirements of subparagraph (A) with respect to the certification of art material and art products required under this section or by regulations prescribed under the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.).

"(D) FIREWALLED CONFORMITY ASSESSMENT BODIES.— Upon request, the Commission may accredit a conformity assessment body that is owned, managed, or controlled by a manufacturer or private labeler as a third party conformity assessment body if the Commission by order finds that-

"(i) accreditation of the conformity assessment body would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body; and

"(ii) the conformity assessment body has established procedures to ensure that—

"(I) its test results are protected from undue influence by the manufacturer, private labeler or other interested party;

"(II) the Commission is notified immediately of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results; and

"(III) allegations of undue influence may be reported confidentially to the Commission.

"(g) REQUIREMENTS FOR CERTIFICATES.—

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- "(1) IDENTIFICATION OF ISSUER AND CONFORMITY ASSESS-MENT BODY.—Every certificate required under this section shall identify the manufacturer or private labeler issuing the certificate and any third party conformity assessment body on whose testing the certificate depends. The certificate shall include, at a minimum, the date and place of manufacture, the date and place where the product was tested, each party's name, full mailing address, telephone number, and contact information for the individual responsible for maintaining records of test results.
- "(2) ENGLISH LANGUAGE.—Every certificate required under this section shall be legible and all content required by this section shall be in the English language. A certificate may also contain the same content in any other language.
- "(3) AVAILABILITY OF CERTIFICATES.—Every certificate required under this section 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. Upon request, the manufacturer or private labeler issuing the certificate shall furnish a copy of the certificate to the Commission.

"(4) ELECTRONIC FILING OF CERTIFICATES FOR IMPORTED PRODUCTS.—In consultation with the Commissioner of Customs, the Commission may, by rule, provide for the electronic filing of certificates under this section up to 24 hours before arrival of an imported product. Upon request, the manufacturer or private labeler issuing the certificate shall furnish a copy to the Commission and to the Commissioner of Customs.

"(h) RULE OF CONSTRUCTION.—Compliance of any children's product with third party testing and certification or general conformity certification requirements under this section shall not be construed to exempt such children's product from any requirement that such product actually be in conformity with all applicable rules, regulation, standards, or ban under any Act enforced by the Commission.".

(c) CPSC Consideration of Existing Requirements.—In establishing standards for accreditation of a third party conformity assessment body under section 14(a)(3) of the Consumer Product Safety Act, as added by subsection (a), the Commission may consider standards and protocols for accreditation of such conformity assessment bodies by independent accreditation organizations that are in effect on the date of enactment of this Act, but shall ensure that the protocols, standards, and requirements prescribed under such section 14(a)(3) incorporate, as the standard for accreditation, the most current scientific and technological standards and techniques available.

(d) CONFORMING AMENDMENTS.—Section 14(b) (15 U.S.C. 2063(b)) is amended—

(1) by striking "consumer products which are subject to consumer product safety standards under this Act" and inserting "any product which is subject to a consumer product safety rule under this Act, or a similar rule, regulation, standard, or ban under any other Act enforced by the Commission,"; and

(2) by striking "or testing programs." and inserting ", unless the Commission, by rule, requires testing by an independent Records

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third party for a particular rule, regulation, standard, or ban, or for a particular class of products.".

SEC. 103. TRACKING LABELS FOR CHILDREN'S PRODUCTS.

(a) IN GENERAL.—Section 14(a) (15 U.S.C. 2063(a)), as amended by section 102 of this Act, is further amended by adding at the end the following:

end the following:

Effective date.

- "(5) Effective 1 year after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the manufacturer of a children's product shall place permanent, distinguishing marks on the product and its packaging, to the extent practicable, that will enable—
 - "(A) the manufacturer to ascertain the location and date of production of the product, cohort information (including the batch, run number, or other identifying characteristic), and any other information determined by the manufacturer to facilitate ascertaining the specific source of the product by reference to those marks; and
 - "(B) the ultimate purchaser to ascertain the manufacturer or private labeler, location and date of production of the product, and cohort information (including the batch, run number, or other identifying characteristic).".

 (b) LABEL INFORMATION.—Section 14(c) (15 U.S.C. 2063(c)) is
- (b) Label Information.—Section 14(c) (15 U.S.C. 2063(c)) is amended by redesignating paragraphs (2) and (3) as paragraphs (3) and (4) and by inserting after paragraph (1) the following:

"(2) The cohort information (including the batch, run number, or other identifying characteristic) of the product.".

- (c) ADVERTISING, LABELING, AND PACKAGING REPRESENTATION.—Section 14 (15 U.S.C. 2063) is further amended by adding at the end the following:
- "(d) REQUIREMENT FOR ADVERTISEMENTS.—No advertisement for a consumer product or label or packaging of such product may contain a reference to a consumer product safety rule or a voluntary consumer product safety standard unless such product conforms with the applicable safety requirements of such rule or standard.".

SEC. 104. STANDARDS AND CONSUMER REGISTRATION OF DURABLE NURSERY PRODUCTS.

(a) SHORT TITLE.—This section may be cited as the "Danny Keysar Child Product Safety Notification Act".

(b) SAFETY STANDARDS.—

- (1) IN GENERAL.—The Commission shall—
- (A) in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products; and
- (B) in accordance with section 553 of title 5, United States Code, promulgate consumer product safety standards that—
 - (i) are substantially the same as such voluntary standards; or
 - (ii) are more stringent than such voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products.

(2) TIMETABLE FOR RULEMAKING.—Not later than 1 year after the date of enactment of this Act, the Commission shall

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commence the rulemaking required under paragraph (1) and shall promulgate standards for no fewer than 2 categories of durable infant or toddler products every 6 months thereafter, beginning with the product categories that the Commission determines to be of highest priority, until the Commission has promulgated standards for all such product categories. Thereafter, the Commission shall periodically review and revise the standards set forth under this subsection to ensure that such standards provide the highest level of safety for such products that is feasible.

- (3) JUDICIAL REVIEW.—Any person adversely affected by such standards may file a petition for review under the procedures set forth in section 11(g) of the Consumer Product Safety Act (15 U.S.C. 2060(g)), as added by section 236 of this Act. (c) Cribs.-
- (1) IN GENERAL.—It shall be a violation of section 19(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2068(a)(1)) for any person to which this subsection applies to manufacture, sell, contract to sell or resell, lease, sublet, offer, provide for use, or otherwise place in the stream of commerce a crib that is not in compliance with a standard promulgated under subsection (b).
- (2) Persons to which subsection applies.—This subsection applies to any person that-

(A) manufactures, distributes in commerce, or contracts to sell cribs;

(B) based on the person's occupation, holds itself out as having knowledge or skill peculiar to cribs, including child care facilities and family child care homes;

(C) is in the business of contracting to sell or resell, lease, sublet, or otherwise place cribs in the stream of

- (D) owns or operates a place of public accommodation affecting commerce (as defined in section 4 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2203) applied without regard to the phrase "not owned by the Federal Government").
- (3) Crib defined.—In this subsection, the term "crib" includes-

(A) new and used cribs;

(B) full-sized or nonfull-sized cribs; and

(C) portable cribs and crib-pens.

(d) Consumer Registration Requirement.-

(1) RULEMAKING.—Notwithstanding any provision of chapter 6 of title 5, United States Code, or the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.), not later than provision of Deadline. 1 year after the date of enactment of this Act, the Commission shall, pursuant to its authority under section 16(b) of the Consumer Product Safety Act (15 U.S.C. 2065(b)), promulgate a final consumer product safety rule to require each manufacturer of a durable infant or toddler product-

(A) to provide consumers with a postage-paid consumer

registration form with each such product;

(B) to maintain a record of the names, addresses, email addresses, and other contact information of consumers who register their ownership of such products with the

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manufacturer in order to improve the effectiveness of manufacturer campaigns to recall such products; and

- (C) to permanently place the manufacturer name and contact information, model name and number, and the date of manufacture on each durable infant or toddler product.
- (2) REQUIREMENTS FOR REGISTRATION FORM.—The registration form required to be provided to consumers under paragraph (1) shall—
 - (A) include spaces for a consumer to provide the consumer's name, address, telephone number, and e-mail address;
 - (B) include space sufficiently large to permit easy, legible recording of all desired information;
 - (C) be attached to the surface of each durable infant or toddler product so that, as a practical matter, the consumer must notice and handle the form after purchasing the product;
 - (D) include the manufacturer's name, model name and number for the product, and the date of manufacture;
 - (E) include a message explaining the purpose of the registration and designed to encourage consumers to complete the registration;
 - (F) include an option for consumers to register through the Internet; and
 - (G) include a statement that information provided by the consumer shall not be used for any purpose other than to facilitate a recall of or safety alert regarding that product.

In issuing regulations under this section, the Commission may prescribe the exact text and format of the required registration form.

- (3) RECORD KEEPING AND NOTIFICATION REQUIREMENTS.— The rules required under this section shall require each manufacturer of a durable infant or toddler product to maintain a record of registrants for each product manufactured that includes all of the information provided by each consumer registered, and to use such information to notify such consumers in the event of a voluntary or involuntary recall of or safety alert regarding such product. Each manufacturer shall maintain such a record for a period of not less than 6 years after the date of manufacture of the product. Consumer information collected by a manufacturer under this Act may not be used by the manufacturer, nor disseminated by such manufacturer to any other party, for any purpose other than notification to such consumer in the event of a product recall or safety alert.
- (4) STUDY.—The Commission shall conduct a study at such time as it considers appropriate on the effectiveness of the consumer registration forms required by this section in facilitating product recalls and whether such registration forms should be required for other children's products. Not later than 4 years after the date of enactment of this Act, the Commission shall report its findings to the appropriate Congressional committees.
- (e) Use of Alternative Recall Notification Technology.—

Deadline. Reports.

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Effective date.

- (1) Technology assessment and report.—The Commission shall—
 - (A) beginning 2 years after a rule is promulgated under subsection (d), regularly review recall notification technology and assess the effectiveness of such technology in facilitating recalls of durable infant or toddler products; and

(B) not later than 3 years after the date of enactment of this Act and periodically thereafter as the Commission considers appropriate, transmit a report on such assessments to the appropriate Congressional committees.

- ments to the appropriate Congressional committees.

 (2) Determination.—If, based on the assessment required by paragraph (1), the Commission determines by rule that a recall notification technology is likely to be as effective or more effective in facilitating recalls of durable infant or toddler products as the registration forms required by subsection (d), the Commission—
 - (A) shall submit to the appropriate Congressional committees a report on such determination; and
 - (B) shall permit a manufacturer of durable infant or toddler products to use such technology in lieu of such registration forms to facilitate recalls of durable infant or toddler products.
- (f) DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT.—As used in this section, the term "durable infant or toddler product"—
 - (1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and
 - (2) includes—
 - (A) full-size cribs and nonfull-size cribs;
 - (B) toddler beds;
 - (C) high chairs, booster chairs, and hook-on chairs;
 - (D) bath seats;
 - (E) gates and other enclosures for confining a child;
 - (F) play yards;
 - (G) stationary activity centers;
 - (H) infant carriers;
 - (I) strollers;
 - (J) walkers;
 - (K) swings; and
 - (L) bassinets and cradles.

SEC. 105. LABELING REQUIREMENT FOR ADVERTISING TOYS AND GAMES.

Section 24 of the Federal Hazardous Substances Act (15 U.S.C. 1278) is amended—

- (1) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and
 - (2) by inserting after subsection (b) the following:
- "(c) ADVERTISING.—
 - "(1) REQUIREMENT.—
 - "(A) CAUTIONARY STATEMENT.—Any advertisement by a retailer, manufacturer, importer, distributor, or private labeler (including advertisements on Internet websites or in catalogues or other printed materials) that provides a direct means for the purchase or order of a product

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for which a cautionary statement is required under subsection (a) or (b) shall include the appropriate cautionary statement displayed on or immediately adjacent to that advertisement, as modified by regulations issued under paragraph (3).

(B) APPLICATION TO RETAILERS.—

"(i) REQUIREMENT TO INFORM.—A manufacturer, importer, distributor, or private labeler that provides such a product to a retailer shall inform the retailer of any cautionary statement requirement applicable

to the product.

- "(ii) Retailer's requirement to inquire.—A retailer is not in violation of subparagraph (A) if the retailer requested information from the manufacturer, importer, distributor, or private labeler as to whether the cautionary statement required by subparagraph (A) applies to the product that is the subject of the advertisement and the manufacturer, importer, distributor, or private labeler provided false information
- or did not provide such information.

 "(C) DISPLAY.—The cautionary statement required by subparagraph (A) shall be prominently displayed—

 "(i) in the primary language used in the advertise-

ment;

"(ii) in conspicuous and legible type in contrast by typography, layout, or color with other material printed or displayed in such advertisement; and

"(iii) in a manner consistent with part 1500 of title 16, Code of Federal Regulations.

- "(D) DEFINITIONS.—In this subsection:

 "(i) The terms 'manufacturer', 'distributor', and 'private labeler' have the meaning given those terms in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052).
- "(ii) The term 'retailer' has the meaning given that term in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052), but does not include an individual whose selling activity is intermittent and does not
- constitute a trade or business.
 "(2) Effective date.—The requirement in paragraph (1) shall take effect-
 - "(A) with respect to advertisements on Internet websites, 120 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008; and

"(B) with respect to catalogues and other printed mate-

rials, 180 days after such date of enactment.

"(3) RULEMAKING.—Notwithstanding any provision of chapter 6 of title 5, United States Code, or the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.), the Commission shall, not later than 90 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, promulgate regulations to effectuate this section with respect to catalogues and other printed material. The Commission may, under such regulations, provide a grace period of no more than 180 days for catalogues and other printed material printed prior to the effective date of paragraph (1) during which time distribution of such catalogues and other printed material shall

Deadlines.

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not be considered a violation of such paragraph. The Commission may promulgate regulations concerning the size and placement of the cautionary statement required by paragraph (1) of this subsection as appropriate relative to the size and placement of the advertisements in such catalogues and other printed material. The Commission shall promulgate regulations that clarify the applicability of these requirements to catalogues and other printed material distributed solely between businesses and not to individual consumers.

"(4) Enforcement.—The requirements in paragraph (1) shall be treated as a consumer product safety standard promulgated under section 9 of the Consumer Product Safety Act (15 U.S.C. 2056). The publication or distribution of any advertisement that is not in compliance with paragraph (1) shall be treated as a prohibited act under section 19(a)(1) of such Act (15 U.S.C. 2068).".

SEC. 106. MANDATORY TOY SAFETY STANDARDS.

(a) IN GENERAL.—Beginning 180 days after the date of enactment of this Act, the provisions of ASTM International Standard F963-07 Consumer Safety Specifications for Toy Safety (ASTM F963), as it exists on the date of enactment of this Act (except for section 4.2 and Annex 4 or any provision that restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute) shall be considered to be consumer product safety standards issued by the Commission under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058).

(b) RULEMAKING FOR SPECIFIC TOYS, COMPONENTS AND RISKS.—

(1) EVALUATION.—Not later than 1 year after the date of enactment of this Act, the Commission, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, shall examine and assess the effectiveness of ASTM F963 or its successor standard (except for section 4.2 and Annex 4), as it relates to safety requirements, safety labeling requirements, and test methods related to—

(A) internal harm or injury hazards caused by the ingestion or inhalation of magnets in children's products;

(B) toxic substances;

- (C) toys with spherical ends;
- (D) hemispheric-shaped objects:
- (E) cords, straps, and elastics; and

(F) battery-operated toys.

(2) RULEMAKING.—Within 1 year after the completion of Deadline. the assessment required by paragraph (1), the Commission shall promulgate rules in accordance with section 553 of title 5, United States Code, that-

(A) take into account other children's product safety rules; and

(B) are more stringent than such standards, if the Commission determines that more stringent standards would further reduce the risk of injury of such toys.

(c) Periodic Review.—The Commission shall periodically review and revise the rules set forth under this section to ensure that such rules provide the highest level of safety for such products that is feasible.

Effective date. 15 USC 2056b.

Deadline.

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- (d) Consideration of Remaining ASTM Standards.—After promulgating the rules required by subsection (b), the Commission shall—
 - (1) in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, examine and assess the effectiveness of ASTM F963 (and alternative health protective requirements to prevent or minimize flammability of children's products) or its successor standard, and shall assess the adequacy of such standards in protecting children from safety hazards; and

(2) in accordance with section 553 of title 5, United States

Code, promulgate consumer product safety rules that-

(A) take into account other children's product safety rules; and

(B) are more stringent than such standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with such toys

such toys.

(e) PRIORITIZATION.—The Commission shall promulgate rules beginning with the product categories that the Commission determines to be of highest priority, until the Commission has promulgated standards for all such product categories.

(f) Treatment as Consumer Product Safety Standards.—Rules issued under this section shall be considered consumer product safety standards issued by the Commission under section

9 of the Consumer Product Safety Act (15 U.S.C. 2058).

(g) REVISIONS.—If ASTM International (or its successor entity) proposes to revise ASTM F963–07, or a successor standard, it shall notify the Commission of the proposed revision. The Commission shall incorporate the revision or a section of the revision into the consumer product safety rule. The revised standard shall be considered to be a consumer product safety standard issued by the Consumer Product Safety Commission under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058), effective 180 days after the date on which ASTM International notifies the Commission of the revision unless, within 90 days after receiving that notice, the Commission notifies ASTM International that it has determined that the proposed revision does not improve the safety of the consumer product covered by the standard. If the Commission so notifies ASTM International with respect to a proposed revision of the standard, the existing standard shall continue to be considered to be a consumer product safety rule without regard to the proposed revision.

(h) RULEMAKING TO CONSIDER EXEMPTION FROM PREEMPTION.—

(1) EXEMPTION OF STATE LAW FROM PREEMPTION.—Upon application of a State or political subdivision of a State, the Commission shall, after notice and opportunity for oral presentation of views, consider a rulemaking to exempt from the provisions of section 26(a) of the Consumer Product Safety Act (under such conditions as it may impose in the rule) any proposed safety standard or regulation which is described in such application and which is designed to protect against a risk of injury associated with a children's product subject to the consumer product safety standards described in subsection (a) or any rule promulgated under this section. The Commission shall grant such an exemption if the State or political subdivision standard or regulation—

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(A) provides a significantly higher degree of protection from such risk of injury than the consumer product safety standard or rule under this section; and

(B) does not unduly burden interstate commerce. In determining the burden, if any, of a State or political subdivision standard or regulation on interstate commerce, the Commission shall consider and make appropriate (as determined by the Commission in its discretion) findings on the technological and economic feasibility of complying with such standard or regulation, the cost of complying with such standard or regulation, the geographic distribution of the consumer product to which the standard or regulation would apply, the probability of other States or political subdivisions applying for an exemption under this subsection for a similar standard or regulation, and the need for a national, uniform standard under this Act for such consumer product.

(2) Effect of standards on established state laws.— Nothing in this section or in section 26 of the Consumer Product Safety Act (15 U.S.C. 2075) shall prevent a State or political subdivision of a State from continuing in effect a safety requirement applicable to a toy or other children's product that is designed to deal with the same risk of injury as the consumer product safety standards established by this section and that is in effect on the day before the date of enactment of this Act, if such State or political subdivision has filed such requirement with the Commission within 90 days after the date of enactment of this Act, in such form and in such manner as the Commission may require.

(i) JUDICIAL REVIEW.—The issuance of any rule under this section is subject to judicial review as provided in section 11(g) of the Consumer Product Safety Act (15 U.S.C. 2060(g)), as added

by section 236 of this Act.

SEC. 107. STUDY OF PREVENTABLE INJURIES AND DEATHS IN MINORITY CHILDREN RELATED TO CONSUMER PRODUCTS.

(a) IN GENERAL.—Not later than 90 days after the date of Deadline. enactment of this Act, the Comptroller General shall initiate a study, by the Government Accountability Office or by contract through an independent entity, to assess disparities in the risks and incidence of preventable injuries and deaths among children of minority populations, including Black, Hispanic, American Indian, Alaska Native, Native Hawaiian, and Asian/Pacific Islander children in the United States. The Comptroller General shall consult with the Commission as necessary.

(b) REQUIREMENTS.—The study shall examine the racial disparities of the rates of preventable injuries and deaths related to suffocation, poisonings, and drownings, including those associated with the use of cribs, mattresses and bedding materials, swimming pools and spas, and toys and other products intended for use by

children.

- (c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General shall report the findings to the appropriate Congressional committees. The report shall include-
 - (1) the Comptroller General's findings on the incidence of preventable risks of injuries and deaths among children

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of minority populations and recommendations for minimizing such risks;

- (2) recommendations for public outreach, awareness, and prevention campaigns specifically aimed at racial minority populations; and
- (3) recommendations for education initiatives that may reduce statistical disparities.

15 USC 2057c.

SEC. 108. PROHIBITION ON SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES.

Effective date.

- (a) PROHIBITION ON THE SALE OF CERTAIN PRODUCTS CONTAINING PHTHALATES.—Beginning on the date that is 180 days after the date of enactment of this Act, it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP).
- (b) Prohibition on the Sale of Additional Products Containing Certain Phthalates.—

Effective date.

(1) INTERIM PROHIBITION.—Beginning on the date that is 180 days after the date of enactment of this Act and until a final rule is promulgated under paragraph (3), it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP).

Deadlines.

- (2) CHRONIC HAZARD ADVISORY PANEL.—
- (A) APPOINTMENT.—Not earlier than 180 days after the date of enactment of this Act, the Commission shall begin the process of appointing a Chronic Hazard Advisory Panel pursuant to the procedures of section 28 of the Consumer Product Safety Act (15 U.S.C. 2077) to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles.
- (B) EXAMINATION.—The panel shall, within 18 months after its appointment under subparagraph (A), complete an examination of the full range of phthalates that are used in products for children and shall—
 - (i) examine all of the potential health effects (including endocrine disrupting effects) of the full range of phthalates;
 - (ii) consider the potential health effects of each of these phthalates both in isolation and in combination with other phthalates;
 - (iii) examine the likely levels of children's, pregnant women's, and others' exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of such products;
 - (iv) consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources, such as personal care products;
 - (v) review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies

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of these phthalates and phthalate alternatives that employ objective data collection practices or employ other objective methods;

(vi) consider the health effects of phthalates not only from ingestion but also as a result of dermal,

hand-to-mouth, or other exposure;

(vii) consider the level at which there is a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals and their offspring, considering the best available science, and using sufficient safety factors to account for uncertainties regarding exposure and susceptibility of children, pregnant women, and other potentially susceptible individuals; and

(viii) consider possible similar health effects of phthalate alternatives used in children's toys and child

care articles.

The panel's examinations pursuant to this paragraph shall be conducted de novo. The findings and conclusions of any previous Chronic Hazard Advisory Panel on this issue and other studies conducted by the Commission shall be reviewed by the panel but shall not be considered determinative.

- (C) REPORT.—Not later than 180 days after completing its examination, the panel appointed under subparagraph (A) shall report to the Commission the results of the examination conducted under this section and shall make recommendations to the Commission regarding any phthalates (or combinations of phthalates) in addition to those identified in subsection (a) or phthalate alternatives that the panel determines should be declared banned hazardous substances.
- (3) PERMANENT PROHIBITION BY RULE.—Not later than 180 days after receiving the report of the panel under paragraph (2)(C), the Commission shall, pursuant to section 553 of title 5, United States Code, promulgate a final rule to-

(A) determine, based on such report, whether to continue in effect the prohibition under paragraph (1), in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an

adequate margin of safety; and

(B) evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children.

(c) Treatment of Violation.—A violation of subsection (a) or (b)(1) or any rule promulgated by the Commission under subsection (b)(3) shall be treated as a violation of section 19(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2068(a)(1)).

(d) Treatment as Consumer Product Safety Standards; EFFECT ON STATE LAWS.—Subsections (a) and (b)(1) and any rule promulgated under subsection (b)(3) shall be considered consumer product safety standards under the Consumer Product Safety Act. Nothing in this section or the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) shall be construed to preempt or otherwise Deadline.

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affect any State requirement with respect to any phthalate alternative not specifically regulated in a consumer product safety standard under the Consumer Product Safety Act.

(e) Definitions.—

(1) DEFINED TERMS.—As used in this section:

(A) The term "phthalate alternative" means any common substitute to a phthalate, alternative material to a phthalate, or alternative plasticizer.

(B) The term "children's toy" means a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child

when the child plays.

(C) The term "child care article" means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

(D) The term "consumer product" has the meaning given such term in section 3(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(1)).

(2) DETERMINATION GUIDELINES.—

- (A) AGE.—In determining whether products described in paragraph (1) are designed or intended for use by a child of the ages specified, the following factors shall be
 - (i) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.

(ii) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate

for use by children of the ages specified.

(iii) Whether the product is commonly recognized by consumers as being intended for use by a child of the ages specified.

(iv) The Age Determination guidelines issued by the Commission staff in September 2002 and any suc-

cessor to such guidelines.

(B) TOY THAT CAN BE PLACED IN A CHILD'S MOUTH.— For purposes of this section a toy can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children's product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.

TITLE II—CONSUMER PRODUCT SAFETY COMMISSION REFORM

Subtitle A—Administrative Improvements

SEC. 201. REAUTHORIZATION OF THE COMMISSION.

(a) AUTHORIZATION OF APPROPRIATIONS.—Subsection (a) of section 32 (15 U.S.C. 2081) is amended to read as follows:

"(a) GENERAL AUTHORIZATION OF APPROPRIATIONS.-

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"(1) IN GENERAL.—There are authorized to be appropriated to the Commission for the purpose of carrying out the provisions of this Act and any other provision of law the Commission is authorized or directed to carry out—

"(A) \$118,200,000 for fiscal year 2010;

"(B) \$115,640,000 for fiscal year 2011;

"(C) \$123,994,000 for fiscal year 2012;

"(D) \$131,783,000 for fiscal year 2013; and

"(E) \$136,409,000 for fiscal year 2014.

- "(2) Travel allowance.—From amounts appropriated pursuant to paragraph (1), there shall be made available \$1,200,000 for fiscal year 2010, \$1,248,000 for fiscal year 2011, \$1,297,000 for fiscal year 2012, \$1,350,000 for fiscal year 2013, and \$1,403,000 for fiscal year 2014, for travel, subsistence, and related expenses incurred in furtherance of the official duties of Commissioners and employees with respect to attendance at meetings or similar functions, which shall be used by the Commission for such purposes in lieu of acceptance of payment or reimbursement for such expenses from any person—
 - "(A) seeking official action from, doing business with, or conducting activities regulated by, the Commission; or "(B) whose interests may be substantially affected by the performance or nonperformance of the Commissioner's or employee's official duties."
- (b) REPORT.—Not later than 180 days after the date of enactment of this Act, the Commission shall transmit to the appropriate Congressional committees a report of its plans to allocate the funding authorized by subsection (a). Such report shall include—

(1) the number of full-time investigators and other full-

time equivalents the Commission intends to employ;

(2) efforts by the Commission to develop standards for training product safety inspectors and technical staff employed by the Commission;

(3) efforts and policies of the Commission to encourage Commission scientific staff to seek appropriate publishing opportunities in peer-reviewed journals and other media; and

- (4) the efforts of the Commission to reach and educate retailers of second-hand products and informal sellers, such as thrift shops and yard sales, concerning consumer product safety rules and product recalls, especially those relating to durable nursery products, in order to prevent the resale of any products that have been recalled, including the development of educational materials for distribution not later than 1 year after the date of enactment of this Act.
- (c) Conforming Amendments.—Section 32 (15 U.S.C. 2081) is further amended by striking subsection (b) and redesignating subsection (c) as subsection (b) and inserting after such subsection designation the following: "LIMITATION.—".

SEC. 202. FULL COMMISSION REQUIREMENT; INTERIM QUORUM; PERSONNEL.

15 USC 2053 note.

(a) TEMPORARY QUORUM.—Notwithstanding section 4(d) of the Consumer Product Safety Act (15 U.S.C. 2053(d)), 2 members of the Commission, if they are not affiliated with the same political party, shall constitute a quorum for the transaction of business

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for the 1 year period beginning on the date of enactment of this Act.

(b) REPEAL OF QUORUM LIMITATION.—

- (1) REPEAL.—Title III of Public Law 102–389 is amended by striking the first proviso in the item captioned "Consumer PRODUCT SAFETY COMMISSION, SALARIES AND EXPENSES" (15 U.S.C. 2053 note).
- (2) Effective date.—The amendment made by paragraph (1) shall take effect 1 year after the date of enactment of this Act.

(c) Personnel.—

Deadline.

15 USC 2053

- (1) Professional Staff.—The Commission shall increase the number of full-time personnel employed by the Commission to at least 500 by October 1, 2013, subject to the availability of appropriations.
- (2) PORTS OF ENTRY; OVERSEAS INSPECTORS.—As part of the 500 full-time employees required by paragraph (1), the Commission shall hire personnel to be assigned to duty stations at United States ports of entry, or to inspect overseas manufacturing facilities, subject to the availability of appropriations.

SEC. 203. SUBMISSION OF COPY OF CERTAIN DOCUMENTS TO CON-

15 USC 2076 note.

- (a) In General.—Notwithstanding any rule, regulation, or order to the contrary, the Commission shall comply with the requirements of section 27(k) of the Consumer Product Safety Act (15 U.S.C. 2076(k)) with respect to budget recommendations, legislative recommendations, testimony, and comments on legislation submitted by the Commission to the President or the Office of Management and Budget after the date of enactment of this Act.
- (b) REINSTATEMENT OF REQUIREMENT.—Section 3003(d) of Public Law 104–66 (31 U.S.C. 1113 note) is amended—
 - (1) by striking "or" after the semicolon in paragraph (31);
 - (2) by redesignating paragraph (32) as (33); and
 - (3) by inserting after paragraph (31) the following:
 - "(32) section 27(k) of the Consumer Product Safety Act (15 U.S.C. 2076(k)); or".

SEC. 204. EXPEDITED RULEMAKING.

- (a) ANPR REQUIREMENT.—
 - (1) IN GENERAL.—Section 9 (15 U.S.C. 2058) is amended—
 - (A) by striking "shall be commenced" in subsection
 (a) and inserting "may be commenced";
 (B) by striking "in the notice" in subsection (b) and

 - inserting "in a notice"; (C) by striking "unless, not less than 60 days after publication of the notice required in subsection (a), the"
 - in subsection (c) and inserting "unless the"; (D) by striking "an advance notice of proposed rulemaking under subsection (a) relating to the product involved," in the third sentence of subsection (c) and inserting "the notice,"; and

 (E) by striking "Register." in the matter following para-

graph (4) of subsection (c) and inserting "Register. Nothing in this subsection shall preclude any person from submitting an existing standard or portion of a standard as a

proposed consumer product safety standard.".

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(2) Conforming amendment.—Section 5(a)(3) (15 U.S.C. 2054(a)(3)) is amended by striking "an advance notice of proposed rulemaking or".

(b) Rulemaking Under Federal Hazardous Substances ACT.-

(1) IN GENERAL.—Section 3(a) of the Federal Hazardous Substances Act (15 U.S.C. 1262(a)) is amended to read as follows:

"(a) RULEMAKING.—

- "(1) In General.—Whenever in the judgment of the Commission such action will promote the objectives of this Act by avoiding or resolving uncertainty as to its application, the Commission may by regulation declare to be a hazardous substance, for the purposes of this Act, any substance or mixture of substances, which it finds meets the requirements of section 2(f)(1)(A).
- "(2) PROCEDURE.—Proceedings for the issuance, amendment, or repeal of regulations under this subsection and the admissibility of the record of such proceedings in other proceedings, shall be governed by the provisions of subsections

- (f) through (i) of this section.".

 (2) PROCEDURE.—Section 2(q)(2) of the Federal Hazardous Substances Act (15 U.S.C. 1261(q)(2)) is amended by striking "Proceedings for the issuance, amendment, or repeal of regulations pursuant to clause (B) of subparagraph (1) of this paragraph shall be governed by the provisions of sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act: Provided, That if" and inserting "Proceedings for the issuance, amendment, or repeal of regulations pursuant to clause (B) of subparagraph (1) of this paragraph shall be governed by the provisions of subsections (f) through (i) of section 3 of this Act, except that if".
- (3) ANPR REQUIREMENT.—Section 3 of the Federal Hazardous Substances Act (15 U.S.C. 1262) is amended—

(A) by striking "shall be commenced" in subsection (f) and inserting "may be commenced";

(B) by striking "in the notice" in subsection (g)(1) and

inserting "in a notice";

(C) by striking "unless, not less than 60 days after "active required in subsection (f), the"

- publication of the notice required in subsection (f), the" in subsection (h) and inserting "unless the"; and

 (D) by striking "Committee on Commerce" and all that follows through "Representatives." in subsection (h), and inserting "appropriate Congressional committees. Nothing in this subsection shall preclude any person from submitting an existing standard or portion of a standard as a proposed regulation."
- (4) OTHER CONFORMING AMENDMENTS.—The Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) is amended—
 - (A) by striking paragraphs (c) and (d) of section 2 and inserting the following:
- "(c) The term 'Commission' means the Consumer Product Safety Commission."
 - (B) by striking "Secretary" each place it appears and inserting "Commission" except-
 - (i) in section 10(b) (15 U.S.C. 1269(b));
 - (ii) in section 14 (15 U.S.C. 1273); and

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15 USC 1263, 1270, 1272.

15 USC 1261.

1262, 1273.

15 USC 1263

et~al.

(iii) in section 21(a) (15 U.S.C. 1276(a)); (C) by striking "Department" each place it appears, except in sections 5(c)(6)(D)(i) and 14(b) (15 U.S.C. 1264(c)(6)(D)(i) and 1273(b)), and inserting "Commission"; (D) by striking "he" and "his" each place they appear

in reference to the Secretary and inserting "it" and "its",

(E) by striking "Secretary of Health, Education, and

Welfare" each place it appears in section 10(b) (15 U.S.C. 1269(b)) and inserting "Commission";

(F) by striking "Secretary of Health, Education, and Welfare" each place it appears in section 14 (15 U.S.C. 1273) and inserting "Commission";

(G) by striking "Department of Health, Education, and Welfare" in section 14 (b) (15 U.S.C. 1272(b)) and inserting

Welfare" in section 14(b) (15 U.S.C. 1273(b)) and inserting "Commission":

(H) by striking "Consumer Product Safety Commission"

each place it appears and inserting "Commission";

(Î) by striking "(hereinafter in this section referred to as the 'Commission')" in section 14(d) (15 U.S.C. 1273(d)) and section 20(a)(1) (15 U.S.C. 1275(a)(1)); and (J) by striking paragraph (5) of section 18(b) (15 U.S.C.

1261 note).

(c) RULEMAKING UNDER FLAMMABLE FABRICS ACT.-

(1) IN GENERAL.—Section 4 of the Flammable Fabrics Act (15 U.S.C. 1193) is amended-

(A) by striking "shall be commenced" in subsection (g) and inserting "may be commenced by a notice of pro-

posed rulemaking or";

(B) by striking "unless, not less than 60 days after publication of the notice required in subsection (g), the"

in subsection (i) and inserting "unless the"; and
(C) by striking "Committee on Commerce" and all that
follows through "Representatives." in subsection (i), and inserting "appropriate Congressional committees. Nothing in this subsection shall preclude any person from submitting an existing standard or portion of a standard as a proposed regulation."

(2) OTHER CONFORMING AMENDMENTS.—The Flammable Fabrics Act (15 U.S.C. 1193) is amended—

(A) by striking paragraph (i) of section 2 (15 U.S.C.

1191(i)) and inserting the following:
"(i) The term 'Commission' means the Consumer Product Safety

Commission." 15 USC 1193,

1201. 15 USC 1193, 1204.

15 USC 1193.

15 USC 1202.

(B) by striking "Secretary of Commerce" each place it appears and inserting "Commission";

(C) by striking "Secretary" each place it appears and inserting "Commission", except in sections 9 and 14 (15 U.S.C. 1198 and 1201);

(D) by striking "he" and "his" each place either such word appears in reference to the Secretary and inserting "it" and "its", respectively;

(E) by striking paragraph (5) of section 4(e) (15 U.S.C. 1193(e)) and redesignating paragraph (6) as paragraph (5);

(F) by striking "Consumer Product Safety Commission (hereinafter in this section referred to as the 'Commission') in section 15 (15 U.S.C. 1202)" and inserting "Commission";

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(G) by amending subsection (d) of section 16 (15 U.S.C. 1203) to read as follows:

"(d) In this section, a reference to a flammability standard or other regulation for a fabric, related material, or product in effect under this Act includes a standard of flammability continued in effect by section 11 of the Act of December 14, 1967 (Public Law 90–189)."; and

(H) by striking "Consumer Product Safety Commission" in section 17 (15 U.S.C. 1204) and inserting "Commission".

SEC. 205. INSPECTOR GENERAL AUDITS AND REPORTS.

15 USC 2076b.

Reviews.

(a) IMPROVEMENTS BY THE COMMISSION.—The Inspector General of the Commission shall conduct reviews and audits to assess—

- (1) the Commission's capital improvement efforts, including improvements and upgrades of the Commission's information technology architecture and systems and the development of the database of publicly available information on incidents involving injury or death required under section 6A of the Consumer Product Safety Act, as added by section 212 of this Act; and
- (2) the adequacy of procedures for accrediting conformity assessment bodies as authorized by section 14(a)(3) of the Consumer Product Safety Act (15 U.S.C. 2063(a)(3)), as amended by this Act, and overseeing the third party testing required by such section.
- (b) EMPLOYEE COMPLAINTS.—Within 1 year after the date of enactment of this Act, the Inspector General shall conduct a review of—

Deadline. Reviews.

- (1) complaints received by the Inspector General from employees of the Commission about failures of other employees to enforce the rules or regulations of the Consumer Product Safety Act or any other Act enforced by the Commission or otherwise carry out their responsibilities under such Acts if such alleged failures raise issues of conflicts of interest, ethical violations, or the absence of good faith; and
- (2) actions taken by the Commission to address such failures and complaints, including an assessment of the timeliness and effectiveness of such actions.
- (c) Public Internet Website Links.—Not later than 30 days after the date of enactment of this Act, the Commission shall establish and maintain—

(1) a direct link on the homepage of its Internet website to the Internet webpage of the Commission's Office of Inspector General: and

(2) a mechanism on the webpage of the Commission's Office of Inspector General by which individuals may anonymously report cases of waste, fraud, or abuse with respect to the Commission.

(d) Reports.—

(1) ACTIVITIES AND NEEDS OF INSPECTOR GENERAL.—Not later than 60 days after the date of enactment of this Act, the Inspector General of the Commission shall transmit a report to the appropriate Congressional committees on the activities of the Inspector General, any structural barriers which prevent the Inspector General from providing robust oversight of the activities of the Commission, and any additional authority or resources that would facilitate more effective oversight.

Deadline.

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Effective date.

(2) REVIEWS OF IMPROVEMENTS AND EMPLOYEE COMPLAINTS.—Beginning for fiscal year 2010, the Inspector General of the Commission shall include in an annual report to the appropriate Congressional committees the Inspector General's findings, conclusions, and recommendations from the reviews and audits under subsections (a) and (b).

SEC, 206. INDUSTRY-SPONSORED TRAVEL BAN.

(a) IN GENERAL.—The Act (15 U.S.C. 1251 et seq.) is amended by adding at the end the following new section:

15 USC 2086.

"SEC. 39. PROHIBITION ON INDUSTRY-SPONSORED TRAVEL.

"Notwithstanding section 1353 of title 31, United States Code, and section 27(b)(6) of this Act, no Commissioner or employee of the Commission shall accept travel, subsistence, or related expenses with respect to attendance by a Commissioner or employee at any meeting or similar function relating to official duties of a Commissioner or an employee, from a person—

"(1) seeking official action from, doing business with, or

conducting activities regulated by, the Commission; or

"(2) whose interests may be substantially affected by the performance or nonperformance of the Commissioner's or employee's official duties."

(b) CLERICAL AMENDMENT.—The table of contents in section 1 (15 U.S.C. 2051 note) is amended by inserting at the end the following:

"Sec. 39. Prohibition on industry-sponsored travel.".

SEC. 207. SHARING OF INFORMATION WITH FEDERAL, STATE, LOCAL, AND FOREIGN GOVERNMENT AGENCIES.

Section 29 (15 U.S.C. 2078) is amended by adding at the end the following:

"(f) Sharing of Information With Federal, State, Local, and Foreign Government Agencies.—

"(1) AGREEMENTS AND CONDITIONS.—Notwithstanding the requirements of subsections (a)(3) and (b) of section 6, relating to public disclosure of information, the Commission may make information obtained by the Commission available to any Federal, State, local, or foreign government agency upon the prior certification of an appropriate official of any such agency, either by a prior agreement or memorandum of understanding with the Commission or by other written certification, that such material will be maintained in confidence and will be used only for official law enforcement or consumer protection purposes, if—

"(A) the agency has set forth a bona fide legal basis for its authority to maintain the material in confidence;

"(B) the materials are to be used for purposes of investigating, or engaging in enforcement proceedings related to, possible violations of—

"(i) laws regulating the manufacture, importation, distribution, or sale of defective or unsafe consumer products, or other practices substantially similar to practices prohibited by any law administered by the Commission;

"(ii) a law administered by the Commission, if disclosure of the material would further a Commission investigation or enforcement proceeding; or

"(iii) with respect to a foreign law enforcement agency, with the approval of the Attorney General, other foreign criminal laws, if such foreign criminal laws are offenses defined in or covered by a criminal mutual legal assistance treaty in force between the government of the United States and the foreign law enforcement agency's government; and

"(C) in the case of a foreign government agency, such agency is not from a foreign state that the Secretary of State has determined, in accordance with section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), has repeatedly provided support for acts of international terrorism, unless and until such determination is rescinded pursuant to section 6(j)(4) of that Act (50 U.S.C. App. 2405(j)(4)).

"(2) ABROGATION OF AGREEMENTS.—The Commission may abrogate any agreement or memorandum of understanding with another agency if the Commission determines that the other agency has failed to maintain in confidence any information provided under such agreement or memorandum of understanding, or has used any such information for purposes other than those set forth in such agreement or memorandum of understanding.

"(3) ADDITIONAL RULES AGAINST DISCLOSURE.—Except as provided in paragraph (4), the Commission shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law—

"(A) any material obtained from a foreign government agency, if the foreign government agency has requested confidential treatment, or has precluded such disclosure under other use limitations, as a condition of providing the material;

"(B) any material reflecting a consumer complaint obtained from any other foreign source, if that foreign source supplying the material has requested confidential treatment as a condition of providing the material; or

"(C) any material reflecting a consumer complaint submitted to a Commission reporting mechanism sponsored in part by foreign government agencies.

"(4) LIMITATION.—Nothing in this subsection authorizes the Commission to withhold information from the Congress or prevent the Commission from complying with an order of a court of the United States in an action commenced by the United States or the Commission.

"(5) Definition.—In this subsection, the term 'foreign government agency' means—

"(A) any agency or judicial authority of a foreign government, including a foreign state, a political subdivision of a foreign state, or a multinational organization constituted by and comprised of foreign states, that is vested with law enforcement or investigative authority in civil, criminal, or administrative matters; and

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"(B) any multinational organization, to the extent that it is acting on behalf of an entity described in subparagraph

"(g) NOTIFICATION TO STATE HEALTH DEPARTMENTS.—Whenever the Commission is notified of any voluntary corrective action taken by a manufacturer (or a retailer in the case of a retailer selling a product under its own label) in consultation with the Commission, or issues an order under section 15(c) or (d) with respect to any product, the Commission shall notify each State's health department (or other agency designated by the State) of such voluntary corrective action or order.".

15 USC 2053a.

SEC. 208. EMPLOYEE TRAINING EXCHANGES.

(a) IN GENERAL.—The Commission may—

(1) retain or employ officers or employees of foreign government agencies on a temporary basis pursuant to section 4 of the Consumer Product Safety Act (15 U.S.C. 2053) or section 3101 or 3109 of title 5, United States Code; and

(2) detail officers or employees of the Commission to work on a temporary basis for appropriate foreign government agen-

cies for the purpose of providing or receiving training.

(b) RECIPROCITY AND REIMBURSEMENT.—The Commission may execute the authority contained in subsection (a) with or without reimbursement in money or in kind, and with or without reciprocal arrangements by or on behalf of the foreign government agency involved. Any amounts received as reimbursement for expenses incurred by the Commission under this section shall be credited to the appropriations account from which such expenses were paid.

(c) STANDARDS OF CONDUCT.—An individual retained or employed under subsection (a)(1) shall be considered to be a Federal employee while so retained or employed, only for purposes of—

(1) injury compensation as provided in chapter 81 of title 5, United States Code, and tort claims liability under chapter 171 of title 28, United States Code;

(2) the Éthics in Government Act (5 U.S.C. App.) and the provisions of chapter 11 of title 18, United States Code;

(3) any other statute or regulation governing the conduct of Federal employees.

SEC. 209. ANNUAL REPORTING REQUIREMENT.

(a) IN GENERAL.—Section 27(j) (15 U.S.C. 2076(j)) is amended—

(1) in the matter preceding paragraph (1), by striking "The Commission" and inserting "Notwithstanding section 3003 of the Federal Reports Elimination and Sunset Act of 1995 (31 U.S.C. 1113 note), the Commission"; and

(2) by redesignating paragraphs (5) through (11) as paragraphs (7) through (13), respectively, and inserting after para-

graph (4) the following:

"(5) the number and a summary of recall orders issued under section 12 or 15 during such year and a summary of voluntary corrective actions taken by manufacturers in consultation with the Commission of which the Commission has notified the public, and an assessment of such orders and

"(6) beginning not later than 1 year after the date of enactment of the Consumer Product Safety Improvement Act

of 2008-

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"(A) progress reports and incident updates with respect to action plans implemented under section 15(d);

"(B) statistics with respect to injuries and deaths associated with products that the Commission determines present a substantial product hazard under section 15(c);

"(C) the number and type of communication from consumers to the Commission with respect to each product with respect to which the Commission takes action under section 15(d);".

(b) Effective Date.—The amendments made by this section shall apply with respect to reports submitted for fiscal year 2009 and thereafter.

15 USC 2076

Subtitle B—Enhanced Enforcement Authority

SEC. 211. PUBLIC DISCLOSURE OF INFORMATION.

Section 6 (15 U.S.C. 2055) is amended—

(1) by inserting "A manufacturer or private labeler shall Deadline. submit any such mark within 15 calendar days after the date on which it receives the Commission's offer." after "paragraph (2)." in subsection (a)(3);

(2) by striking "30 days" in subsection (b)(1) and inserting

"15 days";

(3) by striking "finds that the public" in subsection (b)(1) and inserting "publishes a finding that the public";

- (4) by striking "notice and publishes such a finding in the Federal Register)," in subsection (b)(1) and inserting "notice),"
- (5) by striking "10 days" in subsection (b)(2) and inserting "5 days'
 - (6) by striking "finds that the public" in subsection (b)(2)

- and inserting "publishes a finding that the public";

 (7) by striking "notice and publishes such finding in the Federal Register." in subsection (b)(2) and inserting "notice."; (8) in subsection (b)—
 - (A) by striking "(3)" and inserting "(3)(A)"; and (B) by adding at the end thereof the following:
 - "(B) If the Commission determines that the public health and safety requires expedited consideration of an action brought under subparagraph (A), the Commission may file a request with the District Court for such expedited consideration. If the Commission files such a request, the District Court shall-
 - "(i) assign the matter for hearing at the earliest possible date:
 - "(ii) give precedence to the matter, to the greatest extent practicable, over all other matters pending on the docket of the court at the time;

"(iii) expedite consideration of the matter to the

greatest extent practicable; and

"(iv) grant or deny the requested injunction within Deadline. 30 days after the date on which the Commission's request was filed with the court.";

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(9) by striking "section 19 (related to prohibited acts);" in subsection (b)(4) and inserting "any consumer product safety rule or provision of this Act or similar rule or provision of any other Act enforced by the Commission;"

(10) by striking "or" after the semicolon in subsection

(11) by striking "disclosure." in subsection (b)(5)(C) and inserting "disclosure; or";
(12) by inserting in subsection (b)(5) after subparagraph

(C) the following:

"(D) the Commission publishes a finding that the public health and safety requires public disclosure with a lesser period of notice than is required under paragraph (1).";

(13) in the matter following subparagraph (D) of subsection (b)(5) (as added by paragraph (12) of this section), by striking "section 19(a)," and inserting "any consumer product safety rule or provision under this Act or similar rule or provision of any other Act enforced by the Commission,".

SEC. 212. ESTABLISHMENT OF A PUBLIC CONSUMER PRODUCT SAFETY DATABASE.

(a) IN GENERAL.—The Act is amended by inserting after section 6 (15 U.S.C. 2055) the following:

15 USC 2055a.

"SEC. 6A. PUBLICLY AVAILABLE CONSUMER PRODUCT SAFETY INFORMATION DATABASE.

"(a) Database Required.-

"(1) IN GENERAL.—Subject to the availability of appropriations, the Commission shall, in accordance with the requirements of this section, establish and maintain a database on the safety of consumer products, and other products or substances regulated by the Commission, that is-"(A) publicly available;

"(B) searchable; and

"(C) accessible through the Internet website of the Commission.

Web site.

Deadline.

"(2) Submission of detailed implementation plan to CONGRESS.—Not later than 180 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall transmit to the appropriate Congressional committees a detailed plan for establishing and maintaining the database required by paragraph (1), including plans for the operation, content, maintenance, and functionality of the database. The plan shall detail the integration of the database into the Commission's overall information technology improvement objectives and plans. The plan submitted under this subsection shall include a detailed implementation schedule for the database, and plans for a public awareness campaign to be conducted by the Commission to increase consumer awareness of the database.

Deadline.

"(3) Date of initial availability.—Not later than 18 months after the date on which the Commission submits the plan required by paragraph (2), the Commission shall establish the database required by paragraph (1).

"(b) CONTENT AND ORGANIZATION.

(1) CONTENTS.—Except as provided in subsection (c)(4), the database shall include the following:

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"(A) Reports of harm relating to the use of consumer products, and other products or substances regulated by the Commission, that are received by the Commission from-

"(i) consumers;

"(ii) local, State, or Federal government agencies:

"(iii) health care professionals; "(iv) child service providers; and

"(v) public safety entities.

"(B) Information derived by the Commission from notice under section 15(c) or any notice to the public relating to a voluntary corrective action taken by a manufacturer, in consultation with the Commission, of which action the Commission has notified the public.

"(C) The comments received by the Commission under subsection (c)(2)(A) to the extent requested under subsection (c)(2)(B).

"(2) SUBMISSION OF INFORMATION.—In implementing the database, the Commission shall establish the following:

(A) Electronic, telephonic, and paper-based means of submitting, for inclusion in the database, reports described in paragraph (1)(A) of this subsection.

"(B) A requirement that any report described in paragraph (1)(A) submitted for inclusion in such database

include, at a minimum-

- "(i) a description of the consumer product (or other product or substance regulated by the Commission)
- '(ii) identification of the manufacturer or private labeler of the consumer product (or other product or
- substance regulated by the Commission);
 "(iii) a description of the harm relating to the use of the consumer product (or other product or substance regulated by the Commission);

"(iv) contact information for the person submitting

the report; and

- "(v) a verification by the person submitting the information that the information submitted is true and accurate to the best of the person's knowledge and that the person consents that such information be included in the database.
- "(3) ADDITIONAL INFORMATION.—In addition to the reports received under paragraph (1), the Commission shall include in the database, consistent with the requirements of section 6(a) and (b), any additional information it determines to be in the public interest.
- "(4) Organization of database.—The Commission shall categorize the information available on the database in a manner consistent with the public interest and in such manner as it determines to facilitate easy use by consumers and shall ensure, to the extent practicable, that the database is sortable and accessible by

"(A) the date on which information is submitted for inclusion in the database:

"(B) the name of the consumer product (or other product or substance regulated by the Commission);

"(C) the model name;

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"(D) the manufacturer's or private labeler's name; and "(E) such other elements as the Commission considers in the public interest.

"(5) NOTICE REQUIREMENTS.—The Commission shall provide clear and conspicuous notice to users of the database that the Commission does not guarantee the accuracy, complete-

ness, or adequacy of the contents of the database.

- "(6) AVAILABILITY OF CONTACT INFORMATION.—The Commission may not disclose, under this section, the name, address, or other contact information of any individual or entity that submits to the Commission a report described in paragraph (1)(A), except that the Commission may provide such information to the manufacturer or private labeler of the product with the express written consent of the person submitting the information. Consumer information provided to a manufacturer or private labeler under this section may not be used or disseminated to any other party for any purpose other than verifying a report submitted under paragraph (1)(A). "(c) PROCEDURAL REQUIREMENTS.—
- "(1) Transmission of reports to manufacturers and private labelers.—Not later than 5 business days after the Commission receives a report described in subsection (b)(1)(A) which includes the information required by subsection (b)(2)(B), the Commission shall to the extent practicable transmit the report, subject to subsection (b)(6), to the manufacturer or private labeler identified in the report.

"(2) Opportunity to comment.—

- "(A) IN GENERAL.—If the Commission transmits a report under paragraph (1) to a manufacturer or private labeler, the Commission shall provide such manufacturer or private labeler an opportunity to submit comments to the Commission on the information contained in such report.
- "(B) REQUEST FOR INCLUSION IN DATABASE.—A manufacturer or private labeler may request the Commission

to include its comments in the database.

"(C) CONFIDENTIAL MATTER.—

"(i) IN GENERAL.—If the Commission transmits a report received under paragraph (1) to a manufacturer or private labeler, the manufacturer or private labeler may review the report for confidential information and request that portions of the report identified as confidential be so designated.

"(ii) REDACTION.—If the Commission determines that the designated information contains, or relates to, a trade secret or other matter referred to in section 1905 of title 18, United States Code, or that is subject to section 552(b)(4) of title 5, United States Code, the Commission shall redact the designated information in the report before it is placed in the database.

"(iii) Review.—If the Commission determines that the designated information is not confidential under clause (ii), the Commission shall notify the manufacturer or private labeler and include the information in the database. The manufacturer or private labeler may bring an action in the district court of the United States in the district in which the complainant resides,

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or has its principal place of business, or in the United States District Court for the District of Columbia, to seek removal of the information from the database.

"(3) PUBLICATION OF REPORTS AND COMMENTS.—

"(A) REPORTS.—Except as provided in paragraph (4)(A), if the Commission receives a report described in subsection (b)(1)(A), the Commission shall make the report available in the database not later than the 10th business day after the date on which the Commission transmits the report under paragraph (1) of this subsection.

"(B) COMMENTS.—Except as provided in paragraph (4)(A), if the Commission receives a comment under paragraph (2)(A) with respect to a report described in subsection (b)(1)(A) and a request with respect to such comment under paragraph (2)(B) of this subsection, the Commission shall make such comment available in the database at the same time as such report or as soon as practicable thereafter. "(4) INACCURATE INFORMATION.—

"(A) INACCURATE INFORMATION IN REPORTS AND COM-MENTS RECEIVED.—If, prior to making a report described in subsection (b)(1)(A) or a comment described in paragraph (2) of this subsection available in the database, the Commission determines that the information in such report or comment is materially inaccurate, the Commission shall—

"(i) decline to add the materially inaccurate information to the database;

"(ii) correct the materially inaccurate information in the report or comment and add the report or comment to the database; or

"(iii) add information to correct inaccurate information in the database.

"(B) INACCURATE INFORMATION IN DATABASE.—If the Commission determines, after investigation, that information previously made available in the database is materially inaccurate or duplicative of information in the database, the Commission shall, not later than 7 business days after such determination—

"(i) remove such information from the database;

"(ii) correct such information; or

"(iii) add information to correct inaccurate information in the database.

"(d) ANNUAL REPORT.—The Commission shall submit to the appropriate Congressional committees an annual report on the database, including—

"(1) the operation, content, maintenance, functionality, and cost of the database for the reporting year; and

"(2) the number of reports and comments for the year—"(A) received by the Commission under this section;

"(B) posted on the database; and

"(C) corrected on or removed from the database.

"(e) GAO STUDY.—Within 2 years after the date on which the Commission establishes the database under this section, the Comptroller General shall submit a report to the appropriate Congressional committees containing—

"(1) an analysis of the general utility of the database, including—

Deadline.

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- "(A) an assessment of the extent of use of the database by consumers, including whether the database is accessed by a broad range of the public and whether consumers find the database to be useful; and
 - "(B) efforts by the Commission to inform the public

about the database; and "(2) recommendations for

- "(2) recommendations for measures to increase use of the database by consumers and to ensure use by a broad range of the public.
- "(f) APPLICATION OF CERTAIN NOTICE AND DISCLOSURE REQUIREMENTS.—
 - "(1) IN GENERAL.—The provisions of section 6(a) and (b) shall not apply to the disclosure under this section of a report described in subsection (b)(1)(A) of this section.
 - "(2) CONSTRUCTION.—Paragraph (1) shall not be construed to exempt from the requirements of section 6(a) and (b) information received by the Commission under—

"(A) section 15(b); or

- "(B) any other mandatory or voluntary reporting program established between a retailer, manufacturer, or private labeler and the Commission.
- "(g) HARM DEFINED.—In this section, the term 'harm' means—"(1) injury, illness, or death; or
- "(2) risk of injury, illness, or death, as determined by the Commission.".
- (b) Upgrade of Commission Information Technology Systems.—The Commission shall expedite efforts to upgrade and improve the information technology systems in use by the Commission on the date of enactment of this Act.
- (c) CLERICAL AMENDMENT.—The table of contents in section 1 (15 U.S.C. 2051 note), as amended by section 206, is amended by inserting after the item relating to section 6 the following new item:

"Sec. 6A. Publicly available consumer product safety information database.".

SEC. 213. PROHIBITION ON STOCKPILING UNDER OTHER COMMISSION-ENFORCED STATUTES.

Section 9(g)(2) (15 U.S.C. 2058(g)(2)) is amended—

- (1) by inserting "or to which a rule under this Act or similar rule, regulation, standard, or ban under any other Act enforced by the Commission applies," after "applies,"; and
- enforced by the Commission applies," after "applies,"; and
 (2) by striking "consumer product safety rule" the second, third, and fourth places it appears, and inserting "rule, regulation, standard, or ban".

SEC. 214. ENHANCED RECALL AUTHORITY AND CORRECTIVE ACTION PLANS.

- (a) Enhanced Recall Authority.—Section 15 (15 U.S.C. 2064) is amended—
 - (1) in subsection (a)(1), by inserting "under this Act or a similar rule, regulation, standard, or ban under any other Act enforced by the Commission" after "consumer product safety rule":

(2) in subsection (b)—

(A) by striking "consumer product distributed in commerce," and inserting "consumer product, or other product or substance over which the Commission has jurisdiction

15 USC 2053 note.

122 STAT. 3053

under any other Act enforced by the Commission (other than motor vehicle equipment as defined in section 30102(a)(7) of title 49, United States Code), distributed in commerce,"

(B) by redesignating paragraphs (2) and (3) as para-

graphs (3) and (4), respectively;

(C) by inserting after paragraph (1) the following:

"(2) fails to comply with any other rule, regulation, standard, or ban under this Act or any other Act enforced

by the Commission;"; and

- (D) by adding at the end the following: "A report provided under paragraph (2) may not be used as the basis for criminal prosecution of the reporting person under section 5 of the Federal Hazardous Substances Act (15 U.S.C. 1264), except for offenses which require a showing of intent to defraud or mislead.".
- (3) in subsection (c)-

(A) by inserting "(1)" after the subsection designation; (B) by inserting "or if the Commission, after notifying

the manufacturer, determines a product to be an imminently hazardous consumer product and has filed an action under section 12," after "from such substantial product hazard,";

(C) by redesignating paragraphs (1) through (3) as

subparagraphs (D) through (F), respectively;

(D) by inserting after "the following actions:" the following:

"(A) To cease distribution of the product.

"(B) To notify all persons that transport, store, distribute, or otherwise handle the product, or to which the product has been transported, sold, distributed, or otherwise handled, to cease immediately distribution of the product.

"(C) To notify appropriate State and local public health

officials.":

(E) by striking "comply." in subparagraph (D), as redesignated, and inserting "comply, including posting clear and conspicuous notice on its Internet website, providing notice to any third party Internet website on which such manufacturer, retailer, distributor, or licensor has placed the product for sale, and announcements in languages other than English and on radio and television where the Commission determines that a substantial number of consumers to whom the recall is directed may not be reached by other notice."; and

(F) by adding at the end the following:

"(2) The Commission may require a notice described in paragraph (1) to be distributed in a language other than English if the Commission determines that doing so is necessary to adequately

protect the public.

"(3) If a district court determines, in an action filed under section 12, that the product that is the subject of such action is not an imminently hazardous consumer product, the Commission shall rescind any order issued under this subsection with respect to such product."

(4) in subsection (f)—

(A) by striking "An order" and inserting "(1) Except as provided in paragraph (2), an order"; and

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(B) by inserting at the end the following:

- "(2) The requirement for a hearing in paragraph (1) shall not apply to an order issued under subsection (c) or (d) relating to an imminently hazardous consumer product with regard to which the Commission has filed an action under section 12."
- (b) Corrective Action Plans.—Section 15(d) (15 U.S.C. 2064(d)) is amended-

(1) by inserting "(1)" after the subsection designation;

(2) by inserting "to provide the notice required by subsection (c) and" after "such product" the first place it appears;
(3) by striking "whichever of the following actions the per-

son to whom the order is directed elects:" and inserting "any one or more of the following actions it determines to be in the public interest:";

(4) by redesignating paragraphs (1), (2), and (3) as subpara-

graphs (A), (B), and (C):

(5) in each of subparagraphs (A) and (B) (as so redesignated), by striking "consumer product safety rule" each place

- it appears and inserting "rule, regulation, standard, or ban";

 (6) by striking "more (A)" in subparagraph (C), as redesignated, and inserting "more (i)";

 (7) by striking "or (B)" in subparagraph (C), as redesignated, and inserting "or (ii)";

 (8) by striking "An order under this subsection may" and inserting:
- inserting:

"(2) An order under this subsection shall";

(9) by striking "satisfactory to the Commission," and inserting "for approval by the Commission,";

- (10) by striking "paragraphs of this subsection under which such person has elected to act" and inserting "subparagraphs under which such person has been ordered to act";
- (11) by striking "if the person to whom the order is directed elects to take the action described in paragraph (3)" and insert "if the Commission orders the action described in subparagraph
- (12) by striking "If an order under this subsection is directed" and all that follows through "has the election under this subsection";
- (13) by striking "described in paragraph (3)." and inserting "described in paragraph (1)(C)."; and

(14) by adding at the end the following:

"(3)(A) If the Commission approves an action plan, it shall

indicate its approval in writing.

"(B) If the Commission finds that an approved action plan is not effective or appropriate under the circumstances, or that the manufacturer, retailer, or distributor is not executing an approved action plan effectively, the Commission may, by order, amend, or require amendment of, the action plan. In determining whether an approved plan is effective or appropriate under the circumstances, the Commission shall consider whether a repair or replacement changes the intended functionality of the product.

(C) If the Commission determines, after notice and opportunity for comment, that a manufacturer, retailer, or distributor has failed to comply substantially with its obligations under its action plan, the Commission may revoke its approval of the action plan. The manufacturer, retailer, or distributor to which the action plan applies may not distribute in commerce the product to which the

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action plan relates after receipt of notice of a revocation of the action plan.".

(c) CONTENT OF NOTICE.—Section 15 (15 U.S.C. 2064) is further

amended by adding at the end the following:

"(i) REQUIREMENTS FOR RECALL NOTICES.-

"(1) GUIDELINES.—Not later than 180 days after the date Deadline. of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall, by rule, establish guidelines setting forth a uniform class of information to be included in any notice required under an order under subsection (c) or (d) of this section or under section 12. Such guidelines shall include any information that the Commission determines would be helpful to consumers in-

"(A) identifying the specific product that is subject to such an order;

"(B) understanding the hazard that has been identified with such product (including information regarding incidents or injuries known to have occurred involving such product); and

"(C) understanding what remedy, if any, is available

to a consumer who has purchased the product.

"(2) CONTENT.—Except to the extent that the Commission determines with respect to a particular product that one or more of the following items is unnecessary or inappropriate under the circumstances, the notice shall include the following:

"(A) description of the product, including-

"(i) the model number or stock keeping unit (SKU) number of the product;

"(ii) the names by which the product is commonly known; and

'(iii) a photograph of the product.

"(B) A description of the action being taken with respect to the product.

"(C) The number of units of the product with respect to which the action is being taken.

"(D) A description of the substantial product hazard

and the reasons for the action. "(E) An identification of the manufacturers and signifi-

cant retailers of the product. "(F) The dates between which the product was manu-

factured and sold.

"(G) The number and a description of any injuries or deaths associated with the product, the ages of any individuals injured or killed, and the dates on which the Commission received information about such injuries or deaths.

"(H) A description of—

"(i) any remedy available to a consumer;

"(ii) any action a consumer must take to obtain

a remedy; and

"(iii) any information a consumer needs in order to obtain a remedy or information about a remedy, such as mailing addresses, telephone numbers, fax numbers, and email addresses.

"(I) Other information the Commission deems appropriate.".

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SEC. 215. INSPECTION OF FIREWALLED CONFORMITY ASSESSMENT BODIES: IDENTIFICATION OF SUPPLY CHAIN.

- (a) Inspection of Firewalled Conformity Assessment Body.—Section 16(a) (15 U.S.C. 2065(a)) is amended—
 - (1) by striking "or (B)" and inserting "(B) any firewalled conformity assessment bodies accredited under section 14(f)(2)(D), or (C)" in paragraph (1); and
 (2) by inserting "firewalled conformity assessment body," after "factory," in paragraph (2).
 (b) IDENTIFICATION OF MANUFACTURERS, IMPORTERS,

RETAILERS, AND DISTRIBUTORS.—Section 16 (15 U.S.C. 2065) is further amended by adding at the end thereof the following:

IMPORTERS, IDENTIFICATION OF MANUFACTURERS, RETAILERS, AND DISTRIBUTORS.—Upon request by an officer or

employee duly designated by the Commission-

- "(1) every importer, retailer, or distributor of a consumer product (or other product or substance over which the Commission has jurisdiction under this or any other Act) shall identify the manufacturer of that product by name, address, or such other identifying information as the officer or employee may request, to the extent that such information is known or can be readily determined by the importer, retailer, or distributor;
- "(2) every manufacturer shall identify by name, address, or such other identifying information as the officer or employee may request-
 - "(A) each retailer or distributor to which the manufacturer directly supplied a given consumer product (or other product or substance over which the Commission has jurisdiction under this or any other Act);
 - "(B) each subcontractor involved in the production or fabrication of such product or substance; and
 - "(C) each subcontractor from which the manufacturer obtained a component thereof.".
- (c) Conforming Amendments.—Section 16 (15 U.S.C. 2065) is further amended-
 - (1) in subsection (a), by inserting "INSPECTION.—" after the subsection designation; and
 - (2) in subsection (b), by inserting "RECORDKEEPING.—" after the subsection designation.

SEC. 216. PROHIBITED ACTS.

- (a) SALE OF RECALLED PRODUCTS.—Section 19(a) (15 U.S.C. 2068(a)) is amended-
 - (1) by striking paragraphs (1) and (2) and inserting the following:
 - "(1) sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product, or other product or substance that is regulated under this Act or any other Act enforced by the Commission, that is not in conformity with an applicable consumer product safety rule under this Act, or any similar rule, regulation, standard, or ban under any other Act enforced by the Commission;

"(2) sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product, or other product or substance that is-

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- "(B) subject to voluntary corrective action taken by the manufacturer, in consultation with the Commission, of which action the Commission has notified the public or if the seller, distributor, or manufacturer knew or should have known of such voluntary corrective action;
- "(C) subject to an order issued under section 12 or 15 of this Act: or
- "(D) a banned hazardous substance within the meaning of section 2(q)(1) of the Federal Hazardous Substances Act (15 U.S.C. 1261(q)(1));"

(2) by amending paragraph (6) to read as follows:

- "(6) fail to furnish a certificate required by this Act or any other Act enforced by the Commission, or to issue a false certificate if such person in the exercise of due care has reason to know that the certificate is false or misleading in any material respect; or to fail to comply with any requirement of section 14 (including the requirement for tracking labels) or any rule or regulation under such section;".
- (3) by striking "or" after the semicolon in paragraph (7); (4) by striking "and" after the semicolon in paragraph (8);
- (5) by striking "insulation)." in paragraph (9) and inserting "insulation);"; and
- (6) by striking the period at the end of paragraph (10) and inserting a semicolon; and

(7) by inserting at the end the following:

"(12) sell, offer for sale, distribute in commerce, or import into the United States any consumer product bearing a registered safety certification mark owned by an accredited conformity assessment body, which mark is known, or should have been known, by such person to be used in a manner unauthorized by the owner of that certification mark;

"(13) misrepresent to any officer or employee of the Commission the scope of consumer products subject to an action required under section 12 or 15, or to make a material misrepresentation to such an officer or employee in the course of an investigation under this Act or any other Act enforced by the Commission: or

"(14) exercise, or attempt to exercise, undue influence on a third party conformity assessment body (as defined in section 14(f)(2)) with respect to the testing, or reporting of the results of testing, of any product for compliance under this Act or any other Act enforced by the Commission.

"(15) export from the United States for purpose of sale any consumer product, or other product or substance regulated by the Commission (other than a consumer product or substance, the export of which is permitted by the Secretary of the Treasury pursuant to section 17(e)) that—

"(A) is subject to an order issued under section 12 or 15 of this Act or is a banned hazardous substance within the meaning of section 2(q)(1) of the Federal Hazardous Substances Act (15 U.S.C. 1261(q)(1)); or

"(B) is subject to a voluntary corrective action taken by the manufacturer, in consultation with the Commission, of which action the Commission has notified the public;

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"(16) violate an order of the Commission issued under section 18(c).".

(b) Conforming Amendment.—Section 17(a)(2) (15 U.S.C.

2066(a)(2)) is amended to read as follows:

"(2) is not accompanied by a certificate required by this Act or any other Act enforced by the Commission, or is accompanied by a false certificate, if the manufacturer in the exercise of due care has reason to know that the certificate is false or misleading in any material respect, or is not accompanied by any label or certificate (including tracking labels) required under section 14 or any rule or regulation under such section;".

SEC. 217. PENALTIES.

- (a) Maximum Civil Penalties of the Consumer Product SAFETY COMMISSION.—
 - (1) Consumer product safety act.—Section 20(a)(1) (15 U.S.C. 2069(a)(1)) is amended-

(A) by striking "\$5,000" and inserting "\$100,000";
(B) by striking "\$1,250,000" both places it appears and inserting "\$15,000,000"; and
(C) by striking "December 1, 1994," in paragraph (3)(B)

and inserting "December 1, 2011,".

- (2) FEDERAL HAZARDOUS SUBSTANCES ACT.—Section 5(c)(1) of the Federal Hazardous Substances Act (15 U.S.C. 1264(c)(1)) is amended-
 - (A) by striking "\$5,000" in paragraph (1) and inserting "\$100,000";
 - (B) by striking "\$1,250,000" both places it appears and inserting "\$15,000,000"; and
 - (C) by striking "December 1, 1994," in paragraph (6)(B) and inserting "December 1, 2011,".
- (3) FLAMMABLE FABRICS ACT.—Section 5(e)(1) of the Flammable Fabrics Act (15 U.S.C. 1194(e)(1)) is amended—

 (A) by striking "\$5,000" in paragraph (1) and inserting
 - "\$100,000"
 - "\$1,250,000" (B) striking and "\$15,000,000"; and
 - (C) by striking "December 1, 1994," in paragraph (6)(B)

and inserting "December 1, 2011,"

(4) Effective date.—The amendments made by this subsection shall take effect on the date that is the earlier of the date on which final regulations are issued under subsection (b)(2) or 1 year after the date of enactment of this Act.

(b) Determination of Penalties by the Consumer Product SAFETY COMMISSION.-

(1) Factors to be considered.—

- (A) Consumer product safety act.—Section 20 (15) U.S.C. 2069) is amended-
 - (i) in subsection (b)—
 - (I) by inserting "the nature, circumstances, extent, and gravity of the violation, including" after "shall consider";

(II) by striking "products distributed, and" and inserting "products distributed,"; and

(III) by inserting ", including how to mitigate undue adverse economic impacts on small

15 USC 1194 note.

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businesses, and such other factors as appropriate" before the period; and (ii) in subsection (c)-

(I) by inserting ", including how to mitigate undue adverse economic impacts on small businesses, the nature, circumstances, extent, and gravity of the violation, including" after "person charged"; and

(II) by inserting ", and such other factors as appropriate" after "products distributed".

(B) Federal Hazardous substances act.—Section 5(c) of the Federal Hazardous Substances Act (15 U.S.C. 1264(c)) is amended-

(i) in paragraph (3)—

(I) by inserting "the nature, circumstances, extent, and gravity of the violation, including" after "shall consider";
(II) by striking "substance distributed, and"

and inserting "substance distributed,"; and

(III) by inserting ", including how to mitigate undue adverse economic impacts on small businesses, and such other factors as appropriate" before the period; and

(ii) in paragraph (4)-

- (I) by inserting ", including how to mitigate undue adverse economic impacts on small businesses, the nature, circumstances, extent, and gravity of the violation, including" after "person charged"; and
- (II) by inserting ", and such other factors as appropriate" after "substance distributed".
- (C) FLAMMABLE FABRICS ACT.—Section 5(e) of the Flammable Fabrics Act (15 U.S.C. 1194(e)) is amended-

(i) in paragraph (2)—

(I) by striking "nature and number" and inserting "nature, circumstances, extent, and gravity'

(II) by striking "absence of injury, and" and

inserting "absence of injury,"; and
(III) by inserting ", and such other factors as appropriate" before the period; and

(ii) in paragraph (3)–

(I) by striking "nature and number" and orting "nature, circumstances, extent, and inserting gravity

gravity";

(II) by striking "absence of injury, and" and inserting "absence of injury,"; and

(III) by inserting ", and such other factors as appropriate" before the period.

(2) CIVIL PENALTY CRITERIA.—Not later than 1 year after the date of enactment of this Act, and in accordance with the procedures of section 553 of title 5, United States Code, the Commission shall issue a final regulation providing its interpretation of the penalty factors described in section 20(b) of the Consumer Product Safety Act (15 U.S.C. 2069(b)), section 5(c)(3) of the Federal Hazardous Substances Act (15 U.S.C.

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1264(c)(3)), and section 5(e)(2) of the Flammable Fabrics Act (15 U.S.C. 1194(e)(2)), as amended by subsection (a). (c) Criminal Penalties.-

(1) IN GENERAL.—Section 21(a) (15 U.S.C. 2070(a)) is amended to read as follows:

"(a) Violation of section 19 of this Act is punishable by—

- "(1) imprisonment for not more than 5 years for a knowing and willful violation of that section;
- "(2) a fine determined under section 3571 of title 18, United States Code; or

"(3) both.".

(2) Directors, officers, and agents.—Section 21(b) (15 U.S.C. 2070(b)) is amended by striking "19, and who has knowledge of notice of noncompliance received by the corporation from the Commission," and inserting "19".

(3) Under the federal hazardous substances act.— Section 5(a) of the Federal Hazardous Substances Act (15 U.S.C. 1264(a)) is amended by striking "one year, or a fine of not more than \$3,000, or both such imprisonment and fine." and inserting "5 years, a fine determined under section 3571 of title 18, United States Code, or both.".

(4) Under the flammable fabrics act.—Section 7 of the Flammable Fabrics Act (15 U.S.C. 1196) is amended to read as follows:

"PENALTIES

"SEC. 7. Violation of section 3 or 8(b) of this Act, or failure to comply with section 15(c) of this Act, is punishable by-

"(1) imprisonment for not more than 5 years for a knowing and willful violation of that section:

"(2) a fine determined under section 3571 of title 18, United States Code; or

"(3) both."

(d) Criminal Penalties To Include Asset Forfeiture.—Section 21 (15 U.S.C. 2070) is amended by adding at the end thereof the following:

"(c)(1) In addition to the penalties provided by subsection (a), the penalty for a criminal violation of this Act or any other Act enforced by the Commission may include the forfeiture of assets associated with the violation.

"(2) In this subsection, the term 'criminal violation' means a violation of this Act or any other Act enforced by the Commission for which the violator is sentenced to pay a fine, be imprisoned, or both.".

SEC. 218. ENFORCEMENT BY STATE ATTORNEYS GENERAL.

- (a) IN GENERAL.—Section 24 (15 U.S.C. 2073) is amended—
- (1) by striking "PRIVATE" in the section heading and inserting "ADDITIONAL";
 (2) by inserting "(a) IN GENERAL.—" before "Any interested
- person"; and
 (3) by adding at the end the following:

"(b) STATE ATTORNEY GENERAL ENFORCEMENT.—

"(1) RIGHT OF ACTION.—Except as provided in paragraph (5), the attorney general of a State, or other authorized State officer, alleging a violation of section 19(a)(1), (2), (5), (6), (7), (9), or (12) of this Act that affects or may affect such State

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or its residents may bring an action on behalf of the residents of the State in any United States district court for the district in which the defendant is found or transacts business to obtain appropriate injunctive relief.

"(2) Initiation of civil action.—

"(A) NOTICE TO COMMISSION REQUIRED IN ALL CASES.— A State shall provide written notice to the Commission regarding any civil action under paragraph (1). Except when proceeding under subparagraph (C), the State shall provide the notice at least 30 days before the date on which the State intends to initiate the civil action by filing a complaint.

"(B) FILING OF COMPLAINT.—A State may initiate the

civil action by filing a complaint-

"(i) at any time after the date on which the 30-

day period ends; or

(ii) earlier than such date if the Commission consents to an earlier initiation of the civil action by the State.

- "(C) ACTIONS INVOLVING SUBSTANTIAL PRODUCT HAZARD.—Notwithstanding subparagraph (B), a State may initiate a civil action under paragraph (1) by filing a com-plaint immediately after notifying the Commission of the State's determination that such immediate action is necessary to protect the residents of the State from a substantial product hazard (as defined in section 15(a)).
- (D) FORM OF NOTICE.—The written notice required by this paragraph may be provided by electronic mail, facsimile machine, or any other means of communication accepted by the Commission.

"(E) COPY OF COMPLAINT.—A State shall provide a copy of the complaint to the Commission upon filing the

complaint or as soon as possible thereafter.

"(3) Intervention by the commission.—The Commission may intervene in such civil action and upon intervening-

"(A) be heard on all matters arising in such civil action;

and

"(B) file petitions for appeal of a decision in such civil

"(4) Construction.—Nothing in this section, section 5(d) of the Federal Hazardous Substances Act (15 U.S.C. 1264(d)), section 9 of the Poison Prevention Packaging Act of 1970, or section 5(a) of the Flammable Fabrics Act (15 U.S.C. 1194(d)) shall be construed-

"(A) to prevent the attorney general of a State, or other authorized State officer, from exercising the powers conferred on the attorney general, or other authorized State officer, by the laws of such State; or

(B) to prohibit the attorney general of a State, or other authorized State officer, from proceeding in State or Federal court on the basis of an alleged violation of

any civil or criminal statute of that State.

"(5) LIMITATION.—No separate suit shall be brought under this subsection (other than a suit alleging a violation of paragraph (1) or (2) of section 19(a)) if, at the time the suit is brought, the same alleged violation is the subject of a pending civil or criminal action by the United States under this Act.

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"(6) RESTRICTIONS ON PRIVATE COUNSEL.—If private counsel is retained to assist in any civil action under paragraph (1), the private counsel retained to assist the State may not—

"(A) share with participants in other private civil actions that arise out of the same operative facts any information that is—

"(i) subject to attorney-client or work product privi-

lege; and

"(ii) was obtained during discovery in the action

under paragraph (1); or

"(B) use any information that is subject to attorneyclient or work product privilege that was obtained while assisting the State in the action under paragraph (1) in any other private civil actions that arise out of the same operative facts.".

(b) CONFORMING AMENDMENTS.—

SEC. 219. WHISTLEBLOWER PROTECTIONS.

(1) POISON PREVENTION PACKAGING ACT.—The Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) is amended by adding at the end the following:

15 USC 1477.

"SEC. 9. ENFORCEMENT BY STATE ATTORNEYS GENERAL.

"The attorney general of a State, or other authorized State officer, alleging a violation of a standard or rule promulgated under section 3 that affects or may affect such State or its residents, may bring an action on behalf of the residents of the State in any United States district court for the district in which the defendant is found or transacts business to obtain appropriate injunctive relief. The procedural requirements of section 24(b) of the Consumer Product Safety Act (15 U.S.C. 2073(b)) shall apply to any such action."

Applicability.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 (15 U.S.C. 2051 note) is amended by striking the item relating to section 24 and inserting the following:

"Sec. 24. Additional enforcement of product safety rules and of section 15 orders.".

(a) IN GENERAL.—The Act (15 U.S.C. 2051 et seq.), as amended by section 206 of this Act, is further amended by adding at the end the following:

"WHISTLEBLOWER PROTECTION

15 USC 2087.

"Sec. 40. (a) No manufacturer, private labeler, distributor, or retailer, may discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee)—

"(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this Act or any other Act enforced by the Commission, or any order, rule, regulation, standard, or ban under any such Acts;

"(2) testified or is about to testify in a proceeding concerning

such violation;

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"(3) assisted or participated or is about to assist or participate in such a proceeding; or

"(4) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this Act or any other Act enforced by the Commission, or any order, rule, regulation, standard, or ban under any such Acts.

"(b)(1) A person who believes that he or she has been discharged or otherwise discriminated against by any person in violation of subsection (a) may, not later than 180 days after the date on which such violation occurs, file (or have any person file on his or her behalf) a complaint with the Secretary of Labor alleging such discharge or discrimination and identifying the person responsible for such act. Upon receipt of such a complaint, the Secretary shall notify, in writing, the person named in the complaint of the filing of the complaint, of the allegations contained in the complaint, of the substance of evidence supporting the complaint, and of the opportunities that will be afforded to such person under

paragraph (2).

(2)(A) Not later than 60 days after the date of receipt of a complaint filed under paragraph (1) and after affording the complainant and the person named in the complaint an opportunity to submit to the Secretary a written response to the complaint and an opportunity to meet with a representative of the Secretary to present statements from witnesses, the Secretary shall initiate an investigation and determine whether there is reasonable cause to believe that the complaint has merit and notify, in writing, the complainant and the person alleged to have committed a viola-tion of subsection (a) of the Secretary's findings. If the Secretary concludes that there is reasonable cause to believe that a violation of subsection (a) has occurred, the Secretary shall accompany the Secretary's findings with a preliminary order providing the relief prescribed by paragraph (3)(B). Not later than 30 days after the date of notification of findings under this paragraph, either the person alleged to have committed the violation or the complainant may file objections to the findings or preliminary order, or both, and request a hearing on the record. The filing of such objections shall not operate to stay any reinstatement remedy contained in the preliminary order. Any such hearing shall be conducted expeditiously. If a hearing is not requested in such 30-day period, the preliminary order shall be deemed a final order that is not subject to judicial review.

"(B)(i) The Secretary shall dismiss a complaint filed under this subsection and shall not conduct an investigation otherwise required under subparagraph (A) unless the complainant makes a prima facie showing that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the

unfavorable personnel action alleged in the complaint.

"(ii) Notwithstanding a finding by the Secretary that the complainant has made the showing required under clause (i), no investigation otherwise required under subparagraph (A) shall be conducted if the employer demonstrates, by clear and convincing evidence, that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

"(iii) The Secretary may determine that a violation of subsection (a) has occurred only if the complainant demonstrates that any Discrimination.

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behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

"(iv) Relief may not be ordered under subparagraph (A) if the employer demonstrates by clear and convincing evidence that the employer would have taken the same unfavorable personnel action in the change of that behavior

action in the absence of that behavior.

"(3)(A) Not later than 120 days after the date of conclusion of any hearing under paragraph (2), the Secretary shall issue a final order providing the relief prescribed by this paragraph or denying the complaint. At any time before issuance of a final order, a proceeding under this subsection may be terminated on the basis of a settlement agreement entered into by the Secretary, the complainant, and the person alleged to have committed the violation.

"(B) If, in response to a complaint filed under paragraph (1), the Secretary determines that a violation of subsection (a) has occurred, the Secretary shall order the person who committed such violation—

"(i) to take affirmative action to abate the violation;

"(ii) to reinstate the complainant to his or her former position together with compensation (including back pay) and restore the terms, conditions, and privileges associated with

his or her employment; and

"(iii) to provide compensatory damages to the complainant. If such an order is issued under this paragraph, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys' and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

"(C) If the Secretary finds that a complaint under paragraph (1) is frivolous or has been brought in bad faith, the Secretary may award to the prevailing employer a reasonable attorneys' fee,

not exceeding \$1,000, to be paid by the complainant.

"(4) If the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination, the complainant may bring an action at law or equity for *de novo* review in the appropriate district court of the United States with jurisdiction, which shall have jurisdiction over such an action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury. The proceedings shall be governed by the same legal burdens of proof specified in paragraph (2)(B). The court shall have jurisdiction to grant all relief necessary to make the employee whole, including injunctive relief and compensatory damages, including—

"(A) reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimi-

nation;

'(B) the amount of back pay, with interest; and

"(C) compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorney's fees.

"(5)(A) Unless the complainant brings an action under paragraph (4), any person adversely affected or aggrieved by a final

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order issued under paragraph (3) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred or the circuit in which the complainant resided on the date of such violation. The petition for review must be filed not later than 60 days after the date of the issuance of the final order of the Secretary. Review shall conform to chapter 7 of title 5, United States Code. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the order.

"(B) An order of the Secretary with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

"(6) Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory damages.

"(7)(A) A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom such order was issued to require compliance with such order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizen-

ship of the parties, to enforce such order.

"(B) The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys' and expert witness fees) to any party whenever the court determines such award is appropriate.

"(c) Any nondiscretionary duty imposed by this section shall be enforceable in a mandamus proceeding brought under section

1361 of title 28, United States Code.

- "(d) Subsection (a) shall not apply with respect to an employee of a manufacturer, private labeler, distributor, or retailer who, acting without direction from such manufacturer, private labeler, distributor, or retailer (or such person's agent), deliberately causes a violation of any requirement relating to any violation or alleged violation of any order, regulation, or consumer product safety standard under this Act or any other law enforced by the Commission."
- (b) CONFORMING AMENDMENT.—The table of contents, as amended by section 206 of this Act, is further amended by inserting after the item relating to section 39 the following:

"Sec. 40. Whistleblower protection.".

Subtitle C—Specific Import-Export Provisions

SEC. 221. EXPORT OF RECALLED AND NON-CONFORMING PRODUCTS.

(a) IN GENERAL.—Section 18 (15 U.S.C. 2067) is amended—
(1) in subsection (b), by striking "any product—" and all that follows through "promulgated under section 9," and inserting "any product which is not in conformity with an

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applicable consumer product safety rule in effect under this Act,"; and

(2) by adding at the end the following:

Notification. Deadline.

- "(c) The Commission may prohibit a person from exporting from the United States for purpose of sale any consumer product that is not in conformity with an applicable consumer product safety rule under this Act, unless the importing country has notified the Commission that such country accepts the importation of such consumer product, provided that if the importing country has not so notified the Commission within 30 days after the Commission has provided notice to the importing country of the impending shipment, the Commission may take such action as appropriate within its authority with respect to the disposition of the product under the circumstances.
- "(d) Nothing in this section shall apply to any consumer product, the export of which is permitted by the Secretary of the Treasury pursuant to section 17(e).".

(b) CONFORMING AMENDMENTS TO FLAMMABLE FABRICS ACT.— Section 15 of the Flammable Fabrics Act (15 U.S.C. 1202) is

amended by adding at the end the following:

Notification. Deadline.

- "(d) Notwithstanding any other provision of this section, the Consumer Product Safety Commission may prohibit, by order, a person from exporting from the United States for purpose of sale any fabric or related material that the Commission determines is not in conformity with an applicable standard or rule under this Act, unless the importing country has notified the Commission that such country accepts the importation of such fabric or related material, provided that if the importing country has not so notified the Commission within 30 days after the Commission has provided notice to the importing country of the impending shipment, the Commission may take such action as is appropriate with respect to the disposition of the fabric or related material under the circumstances.
- "(e) Nothing in this section shall apply to any fabric or related material, the export of which is permitted by the Secretary of the Treasury pursuant to section 17(e).".

15 USC 2066 note.

SEC. 222. IMPORT SAFETY MANAGEMENT AND INTERAGENCY COOPERATION.

Deadline.

- (a) RISK ASSESSMENT METHODOLOGY.—Not later than 2 years after the date of enactment of this Act, the Commission shall develop a risk assessment methodology for the identification of shipments of consumer products that are—
 - (1) intended for import into the United States; and
 - (2) likely to include consumer products in violation of section 17(a) of the Consumer Product Safety Act (15 U.S.C. 2066(a)) or other import provisions enforced by the Commission.
- (b) USE OF INTERNATIONAL TRADE DATA SYSTEM AND OTHER DATABASES.—In developing the methodology required under subsection (a), the Commission shall—
 - (1) provide for the use of the International Trade Data System, insofar as is practicable, established under section 411(d) of the Tariff Act of 1930 (19 U.S.C. 1411(d)) to evaluate and assess information about shipments of consumer products intended for import into the customs territory of the United States;

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(2) incorporate the risk assessment methodology required under this section into its information technology modernization plan;

(3) examine, in consultation with U.S. Customs and Border Protection, how to share information collected and retained by the Commission, including information in the database required under section 6A of the Consumer Product Safety Act, for the purpose of identifying shipments of consumer products in violation of section 17(a) of such Act (15 U.S.C. 2066(a)) or other import provisions enforced by the Commission; and

(4) examine, in consultation with U.S. Customs and Border Protection, how to share information required by section 15(j) of the CPSA as added by section 223 of this Act for the purpose of identifying shipments of consumer products in violation of section 17(a) of the Consumer Product Safety Act (15 U.S.C. 2066(a)) or other import provisions enforced by the Commission.

(c) COOPERATION WITH U.S. CUSTOMS AND BORDER PROTECTION.—Not later than 1 year after the date of enactment of this Act, the Commission shall develop a plan for sharing information and coordinating with U.S. Customs and Border Protection that considers, at a minimum, the following:

(1) The number of full-time equivalent personnel employed by the Commission that should be stationed at U.S. ports of entry for the purpose of identifying shipments of consumer products that are in violation of section 17(a) of the Consumer Product Safety Act (15 U.S.C. 2066(a)) or other import provisions enforced by the Commission.

(2) The extent and nature of cooperation between the Commission and U.S. Customs and Border Protection personnel stationed at ports of entry in the identification of shipments of consumer product that are in violation of section 17(a) of the Consumer Product Safety Act (15 U.S.C. 2066(a)) or other import provisions enforced by the Commission under this Act or any other provision of law.

(3) The number of full-time equivalent personnel employed by the Commission that should be stationed at the National Targeting Center (or its equivalent) of U.S. Customs and Border Protection, including—

(A) the extent and nature of cooperation between Commission and U.S. Customs and Border Protection personnel stationed at the National Targeting Center (or its equivalent), as well as at United States ports of entry;

(B) the responsibilities of Commission personnel assigned to the National Targeting Center (or its equivalent) under subsection (b)(3); and

(C) whether the information available at the National Targeting Center (or its equivalent) would be useful to the Commission or U.S. Customs and Border Protection in identifying the consumer products described in subsection (a).

(4) The development of rule sets for the Automated Targeting System and expedited access for the Commission to the Automated Targeting System.

(5) The information and resources necessary for the development, updating, and effective implementation of the risk assessment methodology required in subsection (a).

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(d) REPORT TO CONGRESS.—Not later than 180 days after completion of the risk assessment methodology required under this section, the Commission shall submit a report to the appropriate Congressional committees concerning, at a minimum, the following:

(1) The Commission's plan for implementing the risk

assessment methodology required under this section.

(2) The changes made or necessary to be made to the Commission's memorandum of understanding with U.S. Customs and Border Protection.

(3) The status of—

(A) the development of the Automated Targeting System rule set required under subsection (c)(4) of this section;

(B) the Commission's access to the Automated Tar-

geting System; and

- (C) the effectiveness of the International Trade Data System in enhancing cooperation between the Commission and U.S. Customs and Border Protection for the purpose of identifying shipments of consumer products in violation of section 17(a) of the Consumer Product Safety Act (15 U.S.C. 2066(a)) or other import provisions enforced by the Commission;
- (4) Whether the Commission requires additional statutory authority under the Consumer Product Safety Act, the Federal Hazardous Substances Act, the Flammable Fabrics Act, or the Poison Prevention Packaging Act of 1970 in order to implement the risk assessment methodology required under this section.

(5) The level of appropriations necessary to implement the risk assessment methodology required under this section.

SEC. 223. SUBSTANTIAL PRODUCT HAZARD LIST AND DESTRUCTION OF NONCOMPLIANT IMPORTED PRODUCTS.

(a) IDENTIFICATION OF SUBSTANTIAL HAZARDS.—Section 15 (15 U.S.C. 2064), as amended by section 214, is amended by adding at the end thereof the following:

"(j) Substantial Product Hazard List.—

"(1) IN GENERAL.—The Commission may specify, by rule, for any consumer product or class of consumer products, characteristics whose existence or absence shall be deemed a substantial product hazard under subsection (a)(2), if the Commission determines that—

"(A) such characteristics are readily observable and have been addressed by voluntary standards; and

"(B) such standards have been effective in reducing the risk of injury from consumer products and that there is substantial compliance with such standards.

"(2) JUDICIAL REVIEW.—Not later than 60 days after promulgation of a rule under paragraph (1), any person adversely affected by such rule may file a petition for review under the procedures set forth in section 11 of this Act.".

(b) Destruction of Noncompliant Imported Products.—Section 17(e) (15 U.S.C. 2066(e)) is amended to read as follows:

"(e) Products refused admission into the customs territory of the United States shall be destroyed unless, upon application by the owner, consignee, or importer of record, the Secretary of the Treasury permits the export of the product in lieu of destruction. If the owner, consignee, or importer of record does not export

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Manufacturers.

the product within 90 days of approval to export, such product

- shall be destroyed.".
 (c) Inspection and Recordkeeping Requirement.—The Act is further amended—
 - (1) by amending section 17(g) (15 U.S.C. 2066(g)) to read as follows:
- "(g) Manufacturers of imported products shall be in compliance with all inspection and recordkeeping requirements under section 16 applicable to such products, and the Commission shall advise the Secretary of the Treasury of any manufacturer who is not in compliance with all inspection and recordkeeping requirements under section 16."; and

(2) by adding at the end of section 16 (15 U.S.C. 2065)

the following:

"(d) The Commission shall, by rule, condition the manufacturing for sale, offering for sale, distribution in commerce, or importation into the United States of any consumer product or other product on the manufacturer's compliance with the inspection and recordkeeping requirements of this Act and the Commission's rules with respect to such requirements."

SEC. 224. FINANCIAL RESPONSIBILITY.

(a) IN GENERAL.—The Act (15 U.S.C. 2051 et seq.), as amended by section 219, is further amended by adding at the end the following:

"SEC. 41. FINANCIAL RESPONSIBILITY.

15 USC 2088.

"(a) Identification and Determination of Bond.—The Commission, in consultation with U.S. Customs and Border Protection and other relevant Federal agencies, shall identify any consumer product, or other product or substance that is regulated under this Act or any other Act enforced by the Commission, for which the cost of destruction would normally exceed bond amounts determined under sections 623 and 624 of the Tariff Act of 1930 (19 U.S.C. 1623, 1624) and shall recommend to U.S. Customs and Border Protection a bond amount sufficient to cover the cost of destruction of such products or substances.

"(b) Study of Requiring Escrow for Recalls and Destruc-TION OF PRODUCTS.-

"(1) STUDY.—The Comptroller General shall conduct a

study to determine the feasibility of requiring—

"(A) the posting of an escrow, proof of insurance, or

security sufficient in amount to cover the cost of destruction of a domestically-produced product or substance regulated under this Act or any other Act enforced by the Commis-

"(B) the posting of an escrow, proof of insurance, or security sufficient in amount to cover the cost of an effective recall of a product or substance, domestic or imported, regulated under this Act or any other Act enforced by the Commission.

"(2) REPORT.—Not later than 180 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Comptroller General shall transmit to the appropriate Congressional committees a report on the conclusions of the study required under paragraph (1), including an assessment of whether such an escrow requirement could be implemented and any recommendations for such implementation.".

Recommen-

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(b) Conforming Amendments.—The table of contents in section 1 (15 U.S.C. 2051 note), as amended by section 219, is amended by adding at the end the following:

"Sec. 41. Financial responsibility.".

SEC. 225. STUDY AND REPORT ON EFFECTIVENESS OF AUTHORITIES RELATING TO SAFETY OF IMPORTED CONSUMER PROD-UCTS.

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall-

(1) conduct a study of the authorities and provisions of the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) to assess the effectiveness of such authorities and provisions in preventing unsafe consumer products from entering the customs territory of the United States;

(2) review and provide recommendations with respect to plans to prevent unsafe consumer products from entering the

customs territory of the United States; and
(3) submit to the appropriate Congressional committees a report on the findings of the Comptroller General with respect to paragraphs (1) and (2), including legislative recommendations related to, at a minimum-

(A) inspection of foreign manufacturing plants by the

Commission; and

(B) requiring foreign manufacturers to consent to the jurisdiction of United States courts with respect to enforcement actions by the Commission.

Subtitle D—Miscellaneous Provisions and **Conforming Amendments**

15 USC 2051 note.

Recommendations.

Manufacturers.

SEC. 231. PREEMPTION.

(a) RULE WITH REGARD TO PREEMPTION.—The provisions of sections 25 and 26 of the Consumer Product Safety Act (15 U.S.C. 2074 and 2075, respectively), section 18 of the Federal Hazardous Substances Act (15 U.S.C. 1261 note), section 16 of the Flammable Fabrics Act (15 U.S.C. 1203), and section 7 of the Poison Packaging Prevention Act of 1970 (15 U.S.C. 1476) establishing the extent to which those Acts preempt, limit, or otherwise affect any other Federal, State, or local law, any rule, procedure, or regulation, or any cause of action under State or local law may not be expanded or contracted in scope, or limited, modified or extended in application, by any rule or regulation thereunder, or by reference in any preamble, statement of policy, executive branch statements, or other matter associated with the publication of any such rule or regulation. In accordance with the provisions of those Acts, the Commission may not construe any such Act as preempting any cause of action under State or local common law or State statutory law regarding damage claims.

(b) Preservation of Certain State Law.—Nothing in this Act or the Federal Hazardous Substances Act shall be construed to preempt or otherwise affect any warning requirement relating to consumer products or substances that is established pursuant

to State law that was in effect on August 31, 2003.

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SEC. 232. ALL-TERRAIN VEHICLE STANDARD.

(a) IN GENERAL.—The Act (15 U.S.C. 2051 et seq.), as amended by section 224, is further amended by adding at the end thereof the following:

"SEC. 42. ALL-TERRAIN VEHICLES.

15 USC 2089.

"(a) IN GENERAL.—

"(1) MANDATORY STANDARD.—Notwithstanding any other provision of law, within 90 days after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall publish in the Federal Register as a mandatory consumer product safety standard the American National Standard for Four Wheel All-Terrain Vehicles Equipment Configuration, and Performance Requirements developed by the Specialty Vehicle Institute of America (American National Standard ANSI/SVIA -1-2007). The standard shall take effect 150 days after it is published.

Deadline. Federal Register, publication.

"(2) COMPLIANCE WITH STANDARD.—After the standard takes effect, it shall be unlawful for any manufacturer or distributor to import into or distribute in commerce in the United States any new assembled or unassembled all-terrain vehicle unless-

Effective date.

Manufacturers. Exports and imports.

"(A) the all-terrain vehicle complies with each applicable provision of the standard;

"(B) the ATV is subject to an ATV action plan filed with the Commission before the date of enactment of the Act, or subsequently filed with and approved by the Commission, and bears a label certifying such compliance and identifying the manufacturer, importer or private labeler and the ATV action plan to which it is subject;

"(C) the manufacturer or distributor is in compliance with all provisions of the applicable ATV action plan.

- "(3) VIOLATION.—The failure to comply with any requirement of paragraph (2) shall be deemed to be a failure to comply with a consumer product safety standard under this Act and subject to all of the penalties and remedies available under this Act.
- '(4) Compliant models with additional features.— Paragraph (2) shall not be construed to prohibit the distribution in commerce of new all-terrain vehicles that comply with the requirements of that paragraph but also incorporate characteristics or components that are not covered by those requirements. Any such characteristics or components shall be subject to the requirements of section 15 of this Act.

"(b) Modification of Standard.-

"(1) ANSI REVISIONS.—If the American National Standard Notification. ANSI/SVIA-1-2007 is revised through the applicable consensus standards development process after the date on which the product safety standard for all-terrain vehicles is published in the Federal Register, the American National Standards Institute shall notify the Commission of the revision.

"(2) COMMISSION ACTION.—Within 120 days after it receives notice of such a revision by the American National Standards Institute, the Commission shall issue a notice of proposed rulemaking in accordance with section 553 of title 5, United States Code, to amend the product safety standard for all-terrain

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vehicles to include any such revision that the Commission determines is reasonably related to the safe performance of all-terrain vehicles, and notify the Institute of any provision it has determined not to be so related. The Commission shall promulgate an amendment to the standard for all-terrain vehicles within 180 days after the date on which the notice of proposed rulemaking for the amendment is published in the Federal Register.

"(3) UNREASONABLE RISK OF INJURY.—Notwithstanding any other provision of this Act, the Commission may, pursuant to sections 7 and 9 of this Act, amend the product safety standard for all-terrain vehicles to include any additional provision that the Commission determines is reasonably necessary to reduce an unreasonable risk of injury associated with the

performance of all-terrain vehicles.

(4) CERTAIN PROVISIONS NOT APPLICABLE.—Sections 7 and 9 of this Act shall not apply to promulgation of any amendment of the product safety standard under paragraph (2). Judicial review of any amendment of the standard under paragraph (2) shall be in accordance with chapter 7 of title 5, United States Code.

"(c) Requirements for 3-Wheeled All-Terrain Vehicles.— Until a mandatory consumer product safety standard applicable to 3-wheeled all-terrain vehicles promulgated pursuant to this Act is in effect, new 3-wheeled all-terrain vehicles may not be imported into or distributed in commerce in the United States. Any violation of this subsection shall be considered to be a violation of section 19(a)(1) of this Act and may also be enforced under section 17 of this Act.

"(d) Further Proceedings.—

(1) DEADLINE.—The Commission shall issue a final rule in its proceeding entitled 'Standards for All Terrain Vehicles and Ban of Three-wheeled All Terrain Vehicles'.

(2) CATEGORIES OF YOUTH ATVS.—In the final rule, the Commission, in consultation with the National Highway Traffic Safety Administration, may provide for a multiple factor method of categorization that, at a minimum, takes into account-

"(A) the weight of the ATV;
"(B) the maximum speed of the ATV

"(C) the velocity at which an ATV of a given weight

is traveling at the maximum speed of the ATV;

"(D) the age of children for whose operation the ATV is designed or who may reasonably be expected to operate the ATV: and

"(E) the average weight of children for whose operation the ATV is designed or who may reasonably be expected

to operate the ATV.

"(3) Additional safety standards.—In the final rule, the Commission, in consultation with the National Highway Traffic Safety Administration, shall review the standard published under subsection (a)(1) and establish additional safety standards for all-terrain vehicles to the extent necessary to protect the public health and safety. As part of its review, the Commission shall consider, at a minimum, establishing or strengthening standards on-

"(A) suspension;

"(B) brake performance;

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- "(C) speed governors;
- "(D) warning labels;
- "(E) marketing; and "(F) dynamic stability.
- "(e) DEFINITIONS.—In this section:
- "(1) ALL-TERRAIN VEHICLE OR ATV.—The term 'all-terrain vehicle' or 'ATV' means—
 - "(A) any motorized, off-highway vehicle designed to travel on 3 or 4 wheels, having a seat designed to be straddled by the operator and handlebars for steering control; but
 - "(B) does not include a prototype of a motorized, offhighway, all-terrain vehicle or other motorized, off-highway, all-terrain vehicle that is intended exclusively for research and development purposes unless the vehicle is offered for sale.
- "(2) ATV ACTION PLAN.—The term 'ATV action plan' means a written plan or letter of undertaking that describes actions the manufacturer or distributor agrees to take to promote ATV safety, including rider training, dissemination of safety information, age recommendations, other policies governing marketing and sale of the ATVs, the monitoring of such sales, and other safety related measures, and that is substantially similar to the plans described under the heading 'The Undertakings of the Companies in the Commission Notice' published in the Federal Register on September 9, 1998 (63 FR 48199–48204).".
- (b) GAO STUDY.—The Comptroller General shall conduct a study of the utility, recreational, and other benefits of all-terrain vehicles to which section 42 of the Consumer Product Safety Act (15 U.S.C. 2085) applies, and the costs associated with all-terrain vehicle-related accidents and injuries.
- (c) CONFORMING AMENDMENT.—The table of contents of this Act is further amended by inserting after the item relating to section 42 the following:

"Sec. 42. All-terrain vehicles.".

SEC. 233. COST-BENEFIT ANALYSIS UNDER THE POISON PREVENTION PACKAGING ACT OF 1970.

Section 3 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1472) is amended by adding at the end thereof the following:

"(e) Nothing in this Act shall be construed to require the Consumer Product Safety Commission, in establishing a standard under this section, to prepare a comparison of the costs that would be incurred in complying with such standard with the benefits of such standard."

SEC. 234. STUDY ON USE OF FORMALDEHYDE IN MANUFACTURING OF TEXTILE AND APPAREL ARTICLES.

Not later than 2 years after the date of enactment of this Act, the Comptroller General, in consultation with the Commission, shall conduct a study on the use of formaldehyde in the manufacture of textile and apparel articles, or in any component of such articles, to identify any risks to consumers caused by the use of formaldehyde in the manufacturing of such articles, or components of such articles.

Deadline.

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SEC. 235. TECHNICAL AND CONFORMING CHANGES.

(a) Definitions.—Section 3(a) (15 U.S.C. 2052) is amended by adding at the end the following:

(15) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term 'appropriate Congressional committees' means the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate.

"(16) CHILDREN'S PRODUCT.—The term 'children's product' means a consumer product designed or intended primarily for children 12 years of age or younger. In determining whether a consumer product is primarily intended for a child 12 years of age or younger, the following factors shall be considered:

"(Å) A statement by a manufacturer about the intended use of such product, including a label on such product

if such statement is reasonable.

"(B) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger.

"(C) Whether the product is commonly recognized by consumers as being intended for use by a child 12 years

of age or younger.

"(D) The Age Determination Guidelines issued by the Commission staff in September 2002, and any successor

to such guidelines.

- "(17) THIRD-PARTY LOGISTICS PROVIDER.—The term 'thirdparty logistics provider' means a person who solely receives, holds, or otherwise transports a consumer product in the ordinary course of business but who does not take title to the product.".
- (b) MISCELLANEOUS.—Section 3 (15 U.S.C. 2052) is amended—
 (1) by striking "(a) for purposes of this Act:" and inserting "(a) IN GENERAL.—In this Act:";

(2) by indenting each paragraph and subparagraph of sub-

section (a) 2 em spaces;

- (3) by inserting a heading, in a form consistent with the form of the heading of this subsection consisting of the term defined by such paragraph, after the designation of each paragraph of subsection (a);
- (4) by reordering such paragraphs and the additional paragraphs added by paragraph (1) of this subsection in alphabetical order based on the headings of such paragraphs and renumbering such paragraphs as so reordered; and

(5) by inserting "common carriers, contract carriers, and freight forwarders" after "(b)" in subsection (b).

(c) CONFORMING AMENDMENTS.—

(1) Section 3(b) (15 U.S.C. 2052(b) is amended by inserting "third-party logistics provider," after "contract carrier,".

(2) Section 6(e)(4) (15 U.S.C. 2055(e)(4)) is amended by striking "the Committee on Commerce, Science, and Transportation of the Senate or the Committee on Energy and Commerce of the Henry of Paparagentatives or any subammittee of graph of the House of Representatives or any subcommittee of such committee," and insert "either of the appropriate Congressional committees or any subcommittee thereof,"

(3) Sections 9(a), 9(c), and 35(c)(2)(D)(iii) (15 U.S.C. 2058(a), (c), and 2082(c)(2)(D)(iii), and 2082(e)(1), respectively) are each amended by striking "the Committee on Commerce, Science,

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and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives" each place it appears, and inserting "the appropriate Congressional committees'

(4) Section 32(b)(1) (15 U.S.C. 2050(b)(1)) is amended by 15 USC 2081. striking "the Committee on Energy and Commerce of the House of Representatives, and by the Committee on Commerce, Science, and Transportation of the Senate." and inserting "the appropriate Congressional committees."

(5) Section 35(e)(1) (15 U.S.C. 2082(e)(1)) is amended by striking "the Committee on Commerce, Science, and Transportation of the Senate and to the Committee on Energy and Commerce of the House of Representatives" and insert "the appropriate Congressional committees".

(6) Sections 17(h)(3), 28(j)(10)(F), and 28(k)(1) and (2) (15 U.S.C. 2066(h)(3), 2077(j)(10)(F), and 2077(k)(1) and (2), respectively) are each amended by striking "the Congress"

inserting "the appropriate Congressional committees".

(7) Section 29(e) (15 U.S.C. 2078(e)) is amended by striking "The Commission" and inserting "Notwithstanding section 6(a)(3), the Commission".

SEC. 236. EXPEDITED JUDICIAL REVIEW.

(a) IN GENERAL.—Section 11 (15 U.S.C. 2060) is amended by adding at the end thereof the following:

"(g) Expedited Judicial Review.-

"(1) APPLICATION.—This subsection applies, in lieu of the preceding subsections of this section, to judicial review of-

(A) any consumer product safety rule promulgated by the Commission pursuant to section 15(j) (relating to identification of substantial hazards);

"(B) any consumer product safety standard promulgated by the Commission pursuant to section 42 (relating to all-terrain vehicles);

"(C) any standard promulgated by the Commission under section 104 of the Consumer Product Safety Improvement Act of 2008 (relating to durable infant and toddler products); and

(D) any consumer product safety standard promulgated by the Commission under section 106 of the Consumer Product Safety Improvement Act of 2008 (relating

to mandatory toy safety standards).

"(2) IN GENERAL.—Not later than 60 days after the promulgation, by the Commission, of a rule or standard to which this subsection applies, any person adversely affected by such rule or standard may file a petition with the United States Court of Appeals for the District of Columbia Circuit for judicial review of such rule. Copies of the petition shall be forthwith transmitted by the clerk of the court to the Commission or other officer designated by it for that purpose and to the Attorney General. The record of the proceedings on which the Commission based its rule shall be filed in the court as provided for in section 2112 of title 28, United States Code.

"(3) REVIEW.—Upon the filing of the petition under paragraph (2) of this subsection, the court shall have jurisdiction to review the rule in accordance with chapter 7 of title 5,

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United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter.

"(4) CONCLUSIVENESS OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any final rule under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

"(5) FURTHER REVIEW.—A rule or standard with respect to which this subsection applies shall not be subject to judicial review in proceedings under section 17 (relating to imported products) or in civil or criminal proceedings for enforcement.".

(b) PENDING ACTIONS UNAFFECTED.—The amendment made by subsection (a) shall not apply to any petition filed before the date of enactment of this Act for judicial review of any action by the Consumer Product Safety Commission.

SEC. 237. REPEAL.

Section 30 (15 U.S.C. 2079) is amended by striking subsection (d).

SEC. 238. POOL AND SPA SAFETY ACT TECHNICAL AMENDMENTS.

Title XIV of the Energy Independence and Security Act of 2007 (Public Law 110–140) is amended—

15 USC 8002.

15 USC 2060 note.

(1) in section 1403 by adding at the end the following: "(8) STATE.—The term 'State' has the meaning given such term in section 3(10) of the Consumer Product Safety Act (15 U.S.C. 2052(10)), and includes the Northern Mariana Islands.".

15 USC 8003. Notification. Deadline. (2) in section 1404 by adding at the end of subsection (b) the following: "If a successor standard is proposed, the American Society of Mechanical Engineers shall notify the Commission of the proposed revision. If the Commission determines that the proposed revision is in the public interest, it shall incorporate the revision into the standard after providing 30 days notice to the public."; and

(3) by adding at the end the following:

15 USC 8008.

"SEC. 1409. APPLICABILITY.

"This Act is applicable to the United States and its territories, including American Samoa, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, and the United States Virgin Islands.".

SEC. 239. EFFECTIVE DATES AND SEVERABILITY.

15 USC 2051 note.

(a) Effective Dates.—

(1) IN GENERAL.—Except as otherwise specifically provided in this Act, this Act and the amendments made by this Act shall take effect on the date of enactment of this Act.

(2) CERTAIN DELAYED EFFECTIVE DATES.—The amendments made by sections 103(c) and 214(a)(2) shall take effect on the date that is 60 days after the date of enactment of this Act. Subsection (c) of section 42 of the Consumer Product Safety Act, as added by section 232 of this Act, and the amendments made by sections 216 and 223(b) shall take effect on the date that is 30 days after the date of enactment of this Act.

15 USC 2051

(b) SEVERABILITY.—If any provision of this Act or the amendments made by this Act, or the application of such provision to

122 STAT. 3077

any person or circumstance, is held invalid, the remainder of this Act and the amendments made by this Act, and the application of such provision to other persons not similarly situated or to other circumstances, shall not be affected by such invalidation.

Approved August 14, 2008.

LEGISLATIVE HISTORY—H.R. 4040 (S. 2045) (S. 2663):

HOUSE REPORTS: Nos. 110–501 (Comm. on Energy and Commerce) and 110–787 (Comm. of Conference).

SENATE REPORTS: No. 110–265 accompanying S. 2045 (Comm. on Commerce, Science, and Transportation).

CONGRESSIONAL RECORD:

Vol. 153 (2007): Dec. 19, considered and passed House.

Vol. 154 (2008): Mar. 6, considered and passed Senate, amended, in lieu of S. 2663.

July 30, House agreed to conference report.

July 31, Senate agreed to conference report. HOUSE REPORTS: Nos. 110-501 (Comm. on Energy and Commerce) and 110-787



BALLOT VO	OTE SHEET	Date:	JUL 3 1 2009
то :	The Commission Todd Stevenson, Secretary	,	
THROUGH:	Jacqueline Elder, Acting Executive Direct	tor	
FROM :	Cheryl Falvey, General Counsel CAF David M. DiMatteo, Attorney P		
SUBJECT :	Statement of Policy: Testing of Componer of the Consumer Product Safety Improver		th Respect to Section 108
	Ballot Vote Due: AUG - 6 2009		
I. Approv	indicate your vote on the following options ve the draft Statement of Policy and the issu of Availability as drafted.		draft Federal Register
	Signature		Date
	ve the draft Statement of Policy and the issu of Availability with the following changes		•
-			
	Signature		

CPSA 6(b)(1) CLEARED for PUBLIC
NO MFRS PRVTLBLRS OR
PRODUCTS IDENTIFIED

Signature	Date
Take other action. (Please specify.)	
	- <u>-</u>

Memorandum

Date: July 30, 2009

TO : The Commission

Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF

Jacqueline Elder, Acting Executive Director/e

FROM : Robert J. Howell, Assistant Executive Director

Office of Hazard Identification and Reduction

Michael A. Babich, Ph.D., Project Manager for Phthalates and B

Directorate for Health Sciences

SUBJECT: Section 108 of the Consumer Product Safety Improvement Act—

Staff Recommendation to Test the Plasticized Components Rather than the

Entire Product

Introduction

The Consumer Product Safety Improvement Act of 2008 (CPSIA)¹ was enacted on August 14, 2008. Section 108 of the CPSIA permanently prohibits the sale of any "children's toy or child care article" containing concentrations of more than 0.1 percent of three specified phthalates.^{2, 3} Section 108 also prohibits on an interim basis the sale of "any children's toy that can be placed in a child's mouth" or "child care article" containing concentrations of more than 0.1 percent of three additional phthalates, pending the recommendation of a Chronic Hazard Advisory Panel (CHAP).^{4, 5} The CHAP will recommend to the Commission whether any phthalates or phthalate alternatives other than those permanently banned should be declared banned hazardous substances. The terms "children's toy," "children's toy that can be placed in a child's mouth," and "child care article" are defined in section 108. These prohibitions became effective on February 10, 2009. In addition, manufacturers of certain children's products, including those subject to section 108, will be required to certify that their products comply with section 108 based on testing by a third party conformity assessment body that is accredited by CPSC.⁶ The testing and certification requirements have been stayed by the Commission until February 10, 2010, insofar as compliance with the section 108 requirements is concerned.⁷

Discussion

The CPSC staff issued a test method for measuring the concentration of phthalates in articles subject to section 108 of the CPSIA.⁸ This test method measures the phthalate concentration in the entire product, rather than the component parts of the product. However, measuring phthalates in the entire product raises a number of concerns about this approach: sample

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preparation is more difficult, the phthalate concentration may be diluted by the presence of non-plasticized components, and this approach differs from similar regulations issued by other jurisdictions. Public comments and questions on the test method tend to support the staff's concerns. Furthermore, the CPSC staff believes and public comments support, that, given the expense of phthalate testing, testing for phthalates should be done on only those parts of children's toys and child care articles likely to contain phthalates, which are referred to below as "plasticized parts." Materials that are likely to contain phthalates are discussed later in this memorandum.

Testing the entire product as opposed to each of the plasticized parts may not reflect the intent of Congress; rather, it may result in a less stringent and less health-protective regulation. For these reasons, the CPSC staff recommends that: (1) each *component part* of a "children's toy" or "child care article" (as those terms are defined in the CPSIA) be required to meet the 0.1% phthalates limit individually, and (2) third party testing be required on only those component parts of those products that are likely to contain phthalates. While non-plasticized parts would not require third-party testing, they would still be required to meet the 0.1% limit on the specified phthalates. Manufacturers must test all components that contain the specified phthalates. This memorandum discusses the practical implications of testing only plasticized component parts, as opposed to the entire product, and the scientific basis to support the staff recommendation.

Testing

The current CPSC staff test method for measuring phthalate concentrations, which was published in March 2009, provides two approaches to sample preparation. First, the entire product may be mechanically ground into a homogeneous powder. Then, the powder is tested to determine the phthalate concentration in the entire product. However, a sufficiently homogeneous powder can be difficult to achieve, especially if the product is large or contains metal parts. The grinding process itself can create dusts that could present a hazard to laboratory personnel, especially if the product contains electronic or other components that may contain hazardous materials. In the second approach of the current test method, each individual component of the product is tested, except for metal, glass, or ceramic parts. Then the overall concentration of phthalate in the entire product, including the metal, glass, or ceramic parts, is calculated mathematically. The staff has prepared a revised test method based on testing only the plasticized component parts. In the revised method, the phthalate concentration is measured and reported individually for each plasticized part.

Other Phthalates Regulations

The European Commission (EC) has previously issued regulations on phthalates in children's products. The EC limits the specified phthalates to 0.1 percent by weight in the "plasticized material." The State of California has also issued a phthalates regulation for children's products. The California Deputy Attorney General has informed the CPSC staff that the California regulation will be applied to only the plasticized material. The differences between the CPSIA and other similar regulations have created some confusion on the part of manufacturers and test laboratories.

Harmonization with other jurisdictions and entities presents certain advantages to manufacturers and retailers. While this alone is not a compelling reason to amend a regulation or change its interpretation, it is reasonable to consider the benefits of harmonization as part of the regulatory process.

Testing Component Parts, as Compared to Entire Products

This section discusses the effect of measuring the phthalate concentration on the basis of component parts, as compared to the entire products. Suppose a product contains a plastic component part with a high concentration of a banned phthalate. If the entire product is tested, it might still meet the requirements of section 108, because the phthalate content in the plastic component is essentially diluted by the non-plasticized components comprising the rest of the product. Thus, a product that would be banned in Europe could be allowed for sale in the U.S. Furthermore, it would be reasonable to conclude that the component part containing the high concentration of a banned phthalate violates the spirit, if not the letter, of the CPSIA. In this regard, the current CPSC approach (where the phthalate concentration is not *more than* 0.1% of the entire product), results in a less stringent and presumably less health-protective regulation, compared to the European and California regulations.

For example, suppose a toy weighs 1,000 grams (about 2 pounds), including a 10 gram plasticized part with 10% DEHP. If we consider the test results of only the plasticized component part, the part exceeds the 0.1% limit and the toy would be banned in Europe. However, if we consider the entire toy, then the overall DEHP concentration is based on the weight of the entire toy (1,000 grams) and would therefore be 0.1%; the toy could be sold in the U.S.

Burden of Testing

Many manufacturers, especially small companies and individuals, have commented that the cost of third-party testing and certification requirements in section 102 of the CPSIA presents a significant economic burden and has resulted in the closing of numerous small businesses. These manufacturers also commented that the requirement to test materials such as yarn and wood for phthalates is unreasonable and unnecessarily burdensome. The cost of testing would be reduced if it were not necessary to test all materials. One advocacy group has stated that there is no need to test all materials for phthalates, and that the current CPSC approach is less health protective.

Materials That May Contain Phthalates

Phthalates are primarily used as plasticizers (softeners) in polyvinyl chloride (PVC) plastics. PVC is used in a plethora of products including, toys, floor and wall coverings, household furnishings, building materials, wire and cable insulation, footwear, rainwear, and automobile interiors. Phthalates may be used as plasticizers in other plastics including polyvinyl acetate (PVA), polyvinylidene chloride (PVDC), and polyurethane (PU). Phthalates are also used as solvents and/or plasticizers in paints, inks, adhesives, sealants, air fresheners, and scented

products. Phthalates are more likely to be used in paints, adhesives, or sealants when the finished product must be flexible, such as a printed design on apparel or other flexible substrates.

Because phthalates are widely used, and because manufacturers are not required to disclose the ingredients in their products to the Commission, the CPSC staff does not know all of the possible uses of phthalates in consumer products. Nonetheless, certain materials are generally known not to contain phthalates. For example, unfinished metals, unfinished wood, and natural fibers such as cotton and wool are not expected to contain phthalates, which are synthetic chemicals. However, any coatings or printing on these materials may contain phthalates. Adhesives and finishes used to manufacture wooden toys, for example, may contain phthalates. Printed designs, non-slip coatings, back coatings, and elastic materials on apparel (specifically, sleepwear) may also contain phthalates.

Certain plastics, such as polyethylene and polypropylene, generally do not require plasticizers. However, surface coatings and adhesives may contain phthalates. In addition, phthalates could be used in some plastics even though they are not required. Phthalates might also be used in some elastomers or synthetic rubbers. Most natural and synthetic fibers and textiles are not expected to contain phthalates, ¹⁵ except for PVC and related materials. However, printed designs, surface treatments, and elastic components may contain phthalates.

Some examples of materials that <u>may</u> contain phthalates include:

- Polyvinyl chloride (PVC) and related polymers, such as polyvinylidene chloride (PVDC) and polyvinyl acetate (PVA). These materials should always be tested.
- Soft or flexible plastics, except polyolefins.
- Soft or flexible rubber, except silicone rubber and natural latex.
- Foam rubber or foam plastic, such as polyurethane (PU).
- Surface coatings, finishes, decals, and printed designs.
- Adhesives and sealants.
- Electrical insulation.

Some examples of materials that do <u>not</u> normally contain phthalates and, therefore, <u>might</u> not require testing include:

- Unfinished metal.
- Natural wood, except for coatings and adhesives.
- Textiles made from natural fibers, except for printed decorations, water-proof coatings or other surface treatments, back coatings, and elastic materials.
- Textiles made from common synthetic fibers, such as polyester, acrylic, and nylon, except for printed decorations, water-proof coatings or other surface treatments, and elastic materials. However, any textiles containing PVC or related polymers must be tested.
- Polyethylene and polypropylene (polyolefins).

- Silicone rubber and natural latex.
- Mineral products such as play sand, glass, and crystal.

Recommendation

Under section 108 of the CPSIA, the sale of children's toys and child care articles containing more than 0.1% of certain phthalates is prohibited. The CPSC staff recommends that this phrase be interpreted to mean that the sale of children's toys and child care articles containing more than 0.1% of the specified phthalates *in each individual plasticized component part* is prohibited. This interpretation has two effects. First, the phthalate concentration will be calculated on the basis of the weight (mass) of the plasticized component part, rather than the entire article. Second, it will not be necessary to test components or materials that are not plasticized. While non-plasticized parts would not require third-party testing, they would still be required to meet the 0.1% limit on the specified phthalates. Manufacturers must know whether their products contain phthalates and will be responsible for testing those components to ensure compliance with the limits. The staff's recommendation would make section 108 more stringent and more health-protective. It would also simplify the testing process, eliminate the unnecessary testing of products that do not contain phthalates, reduce the cost of testing, and harmonize with the European Commission and the State of California.

References

- ¹ Public Law 110-314.
- ² Di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP).
- ³ CPSIA §108(a).
- ⁴ Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-*n*-octyl phthalate (DnOP).
- ⁵ CPSIA §108(b)(1).
- ⁶ CPSIA §102(a)(2).
- Notice of Stay of Enforcement of Testing and Certification Requirements. 74 Fed. Reg. 6396-6399. Monday, February 9, 2009.
- ⁸ Test Method: CPSC-CH-C1001-09.1. Standard Operating Procedure for Determination of Phthalates. U.S. Consumer Product Safety Commission. March 3, 2009.
- ⁹ Ibid.
- ¹⁰ Test Method: CPSC-CH-C1001-09.2. Standard Operating Procedure for Determination of Phthalates. U.S. Consumer Product Safety Commission. July 13, 2009.
- Directive 2005/84/EC of the European Parliament and of the Council. Official Journal of the European Union. December 27, 2005.
- Letter from Timothy E. Sullivan, Deputy Attorney General, State of California, to the Office of the Secretary, U.S. Consumer Product Safety Commission. March 25, 2009
- Report to the U.S. Consumer Product Safety Commission of the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP). June 2001.
- Letter from Carter Keithley, President, Toy Industry Association to Cheryl Falvey, General Counsel and Gib Mullan, Assistant Executive Director for Compliance and Field Operations. January 12, 2009. Comments in response to "Prohibition on the Sale of Certain Products Containing Specified Phthalates; Section 108 of the Consumer Product Safety Improvement Act, Request for Comments and Information. U.S. Consumer Product Safety Commission. November 13, 2008. http://www.cpsc.gov/about/cpsia/108rfc.pdf
- Survey of Chemicals in Consumer Products, No. 23. Survey of Chemical Compounds in Textile Fabrics. Danish Environmental Protection Agency. 2003.
 http://www.mst.dk/English/Chemicals/Consumer_Products/Surveys-on-chemicals-in-consumer-products.htm

Statement of Policy: Testing of Component Parts With Respect To Section 108 of the Consumer Product Safety Improvement Act

Statement of Policy: Testing of Component Parts With Respect To Section 108 of the Consumer Product Safety Improvement Act

A. Background

The Consumer Product Safety Improvement Act (CPSIA) was enacted on August 14, 2008 (Pub. L. 110-314). Section 108 of the CPSIA permanently prohibits the sale of any "children's toy or child care article" containing concentrations of more than 0.1 percent of three specified phthalates. Section 108 also prohibits, on an interim basis, the sale of "any children's toy that can be placed in a child's mouth or child care article" containing concentrations of more than 0.1 percent of three additional phthalates pending the recommendation of a Chronic Hazard Advisory Panel (CHAP). The CHAP will recommend to the Commission whether to make the interim ban permanent and whether other phthalates or phthalate alternatives should be declared banned hazardous substances. The terms "children's toy," "children's toy that can be placed in a child's mouth," and "child care article" are defined in section 108 of the CPSIA. These prohibitions became effective on February 10, 2009.

To gather comments and information about implementation of this section of the CPSIA, the Commission published a "Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA section 108; Request for Comments and Information," on February 23, 2009 (74 FR 8058). Comments in response to the Notice demonstrate that many questions and concerns exist about the requirement that products comply with the phthalates limits of section 108 of the CPSIA and, specifically, the testing procedures used to determine the percentage of phthalates in such products.

In the present statement of policy, the Commission describes its current position on component part testing with respect to section 108 of the CPSIA. It does not create or confer any rights for or on any person and does not operate to bind CPSC or the public beyond the existing statutory requirements of the CPSIA. You can use an alternative approach if the approach satisfies the requirements of the CPSIA.

B. Purpose of Section 108 of the CPSIA

The purpose of section 108 of the CPSIA, generally, is to ensure that children are not exposed to certain specified phthalates while playing, sleeping, or eating. In general, phthalates are chemicals that are added to plastic to make the plastic more flexible or resilient, and concerns have been raised about possible adverse health effects resulting from exposure to phthalates.

In March of 2009, the Commission staff sought comment on a method for testing phthalate content as a percentage of the entire toy or child care article. Given that testing the phthalate

Di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP).

² Section 108(a) of the CPSIA.

³ Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-*n*-octyl phthalate (DnOP).

⁴ Section108(b)(1) of the CPSIA.

content of an entire children's toy or child care article presents certain difficulties, may lead to dilution of the phthalate concentrations compared to that in one or more of its component parts, differs from similar regulations issued by other jurisdictions, and can be prohibitively expensive, the Commission believes that phthalate testing should be limited to those plastic parts or other product parts which could conceivably contain phthalates ("plasticized component parts"). Testing component parts to the phthalates limits established in section 108 is more protective of human health and effectuates the intent of Congress to limit children's exposure to phthalates. The benefits of the component approach are two-fold, in addition to providing more protection for children, it also may significantly reduce the testing costs for manufacturers in certain circumstances.

In addition, requiring component part testing is supported by the statutory language. The CPSIA permanently bans the sale of any children's toy or child care article containing concentrations of more than 0.1% of DEHP, DBP or BBP. A "children's toy" is defined in the CPSIA as "...a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays." The term "child care article" is defined in the CPSIA as "...a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." Both definitions use the term "consumer product," which section 3 of the Consumer Product Safety Act (CPSA) defines, in part, as:

any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise . . . (Emphasis added.)

This definition of consumer product also applies to the more limited definition of "children's toy that can be placed in a child's mouth" to which the interim ban on DINP, DIDP and DnOP applies.

Because the term consumer product includes components of an article, the Commission believes that the phthalate limits in section 108 of the CPSIA apply to each component part of any article. The Commission has developed a method to test component parts for the specified phthalates and will only require testing of plasticized component parts as defined above.

Therefore, when testing for phthalates in children's toys and child care articles subject to section 108 of the CPSIA, CPSC staff will use test method CPSC-CH-C1001-09.2, which is published separately and in conjunction with this Policy. This test method can be found on our website at [insert web address after vote].

⁵ Section 108(e) of the CPSIA.

C. Testing: How to Identify Component Parts That May Require Testing.

Phthalates are primarily used as plasticizers (softeners) in polyvinyl chloride (PVC) plastics. PVC is used in many products, including, toys, floor and wall coverings, household furnishings, building materials, wire and cable insulation, footwear, rainwear, and automobile interiors. Phthalates may be used as plasticizers in other plastics including polyvinyl acetate (PVA), polyvinylidene chloride (PVDC), and polyurethane (PU).^{6.7} Phthalates also are used as solvents and/or plasticizers in paints, inks, adhesives, sealants, air fresheners, and scented products. Phthalates are more likely to be used in paints, adhesives, or sealants when the finished product must be flexible, such as a printed design on apparel or other flexible substrates.

Not all plastics, however, contain phthalates. Certain plastics, such as polyethylene and polypropylene, generally do not require plasticizers. However, surface coatings and adhesives may contain phthalates. In addition, phthalates could be used in some plastics even though they are not required. Phthalates might also be used in some elastomers or synthetic rubbers. Most natural and synthetic fibers and textiles are not expected to contain phthalates, except for PVC and related materials. Printed designs, coatings, surface treatments, and elastic components may contain phthalates.

Examples of materials that may contain phthalates are:

- Polyvinyl chloride (PVC) and related polymers, such as polyvinylidene chloride (PVDC) and polyvinyl acetate (PVA). These materials should always be tested.
- Soft or flexible plastics, except polyolefins.
- Soft or flexible rubber, except silicone rubber and natural latex.
- Foam rubber or foam plastic, such as polyurethane (PU).
- Surface coatings, non-slip coatings, finishes, decals, and printed designs.
- Elastic materials on apparel, such as sleepware.
- Adhesives and sealants.
- Electrical insulation.

Report to the U.S. Consumer Product Safety Commission of the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP). June 2001.

Letter from Carter Keithley, President, Toy Industry Association to Cheryl Falvey, General Counsel and Gib Mullan, Assistant Executive Director for Compliance and Field Operations. January 12, 2009. Comments in response to "Prohibition on the Sale of Certain Products Containing Specified Phthalates; Section 108 of the Consumer Product Safety Improvement Act, Request for Comments and Information. U.S. Consumer Product Safety Commission. November 13, 2008. http://www.cpsc.gov/about/cpsia/108rfc.pdf

Survey of Chemicals in Consumer Products, No. 23. Survey of Chemical Compounds in Textile Fabrics. Danish Environmental Protection Agency. 2003.
http://www.mst.dk/English/Chemicals/Consumer_Products/Surveys-on-chemicals-in-consumer-products.htm

Examples of materials that do <u>not</u> normally contain phthalates and, therefore, <u>might</u> not require testing or certification are:

- Unfinished metal.
- Natural wood, except for coatings and adhesives added to wood.
- Textiles made from natural fibers, such as cotton or wool, except for printed decorations, waterproof coatings or other surface treatments, back coatings, and elastic materials (especially sleepwear).
- Textiles made from common synthetic fibers, such as polyester, acrylic, and nylon, except for printed decorations, waterproof coatings or other surface treatments, and elastic materials. However, any textiles containing PVC or related polymers must be tested.
- Polyethylene and polypropylene (polyolefins).
- Silicone rubber and natural latex.
- Mineral products such as play sand, glass, and crystal.

D. Who Is Responsible for Deciding Whether to Test for Phthalates?

Manufacturers either know or should know what materials and components go into the products they make, and if the product or its components contain one of the plasticizers specified in section 108 of the CPSIA, the manufacturer or importer certifying the product must test the component or product to ensure that it complies with the CPSIA. Failure to comply with section 108 of the CPSIA is a prohibited act under section 19 of the Consumer Product Safety Act (CPSA) and can result in civil and criminal penalties. Likewise, failure to have a product subject to section 108 of the CPSIA tested by an accredited third-party laboratory and have the appropriate certification for that product is also a prohibited act under section 19 (CPSA).

* * *

Draft Federal Register Notice
Notice of Availability of a Statement of Policy: Testing of Component Parts
With Respect to Section 108 of the Consumer Product Safety Improvement
Act

[Billing Code 6355-01-P] CONSUMER PRODUCT SAFETY COMMISSION

Notice of Availability of a Statement of Policy: Testing of Component Parts With Respect to Section 108 of the Consumer Product Safety Improvement Act

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Availability.

SUMMARY: The Consumer Product Safety Commission

("Commission") is announcing the availability of a document titled, "Statement of Policy: Testing of Component Parts

With Respect to Section 108 of the Consumer Product Safety

Improvement Act" ("Statement of Policy"). Section 108 of the Consumer Product Safety Improvement Act of 2008

("CPSIA") prohibits the sale of certain products containing specified phthalates. The Statement of Policy establishes the Commission's position with respect to testing products to determine whether they contain phthalates in excess of the statutory limits.

ADDRESSES: The Statement of Policy is available from the Commission's website at [INSERT CITE]. Copies also may be obtained from the Consumer Product Safety Commission,

Office of the Secretary, Room 502, 4330 East-West Highway,

Bethesda, Maryland 20814; 301-504-7923.

FOR FURTHER INFORMATION CONTACT: Michael A. Babich, Ph.D.,
Consumer Product Safety Commission, 4330 East West Highway,

Bethesda, MD 20814; telephone (301) 504-7253; mbabich@cpsc.gov.

SUPPLEMENTARY INFORMATION:

On August 14, 2008, the CPSIA (Public Law 110-314)
was enacted. Section 108 of the CPSIA, titled "Prohibition
on Sale of Certain Products Containing Specified
Phthalates," permanently prohibits the sale of any
"children's toy or child care article" containing more than
0.1 percent of three specified phthalates (Di-(2ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), and
benzyl butyl phthalate (BBP)). Section 108 of the CPSIA
also prohibits, on an interim basis, "toys that can be
placed in a child's mouth"' or "child care articles"
containing more than 0.1 percent of three additional
phthalates (diisononyl phthalate (DINP), diisodecyl
phthalate (DIDP), and di-n-octyl phthalate (DnOP)). These
prohibitions became effective on February 10, 2009.

The terms "children's toy," "toy that can be placed in a child's mouth,"' and "child care article" are defined in section 108 of the CPSIA. For example, section 108 of the CPSIA defines a "children's toy" as a "consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays." It is noteworthy that the definition uses the term

"consumer product" because section 3(a)(5) of the Consumer Product Safety Act (CPSA) defines "consumer product," in relevant part, as "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise..."

In the FEDERAL REGISTER of February 23, 2009 (74 FR 8058), the Commission published a notice of availability regarding a draft guidance discussing which children's products are subject section 108 of the CPSIA. The notice invited comment on various questions and also on the Commission's test method for phthalates. The test method (Test Method: CPSC-CH-Cl001-09.1, "Standard Operating Procedure for Determination of Phthalates," dated March 3, 2009) generated some controversy in that it suggested testing the entire product or testing components and then mathematically combining the results.

The Commission has reexamined the question of product testing and has prepared a document titled "Statement of Policy: Testing of Component Parts with Respect to Section 108 of the Consumer Product Safety Improvement Act." The

Statement of Policy describes the Commission's position regarding component testing, and the Commission will issue a new test method in the near future. The Statement of Policy is available on the Commission's website at [INSERT CITE] and from the Commission's Office of the Secretary at the location listed in the ADDRESSES section of this notice.

Dated:

Todd Stevenson, Secretary
Consumer Product Safety Commission



BALL	OT VO	TE SHEET Date:	JUL 3 1 2009
ТО	:	The Commission Todd Stevenson, Secretary	
THRO		Jacqueline Elder, Acting Executive Director	
FROM	:	Cheryl Falvey, General Counsel CAF Patricia M. Pollitzer, Attorney	
SUBJE		Statement of Policy Concerning Tracking Label Roof the CPSIA: Notice of Availability	equirement in Section 103(a)
		Ballot Vote Due:	
	nounces	fice of the General Counsel is forwarding to you a dethe availability of a Statement of Policy concerning duct Safety Improvement Act ("CPSIA").	
	Please i	indicate your vote on the following options.	
I.	Approv	ve the draft Federal Register Notice of Availability a	s drafted.
		Signature	Date
II		re the draft Federal Register Notice of Availability was specify):	ith the following changes
		Signature	Date

Note: This document has not been reviewed or accepted by the Commission. Initials Date 7-31-09

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CPSA 6(b)(1) CL FARED for PUBLIC
NO MFRS/PRVTLBLRS OR
PRODUCTS IDENTIFIED

Signature	Date
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<u>CPSC Home</u> > <u>About CPSC</u> > <u>CPSIA</u> > <u>FAQs</u> > Current

Consumer Product Safety Improvement Act

Back to FAQs | Section 103 Page

FAQs For Section 103: Tracking Labels for Children's Products

Are tracking labels required on domestically made products or are they only required for imported products?

Tracking labels are required for all children's products manufactured one year after enactment of the CPSIA (August 14, 2009) regardless of whether they are domestic or imported products.

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Will the tracking label requirement be met if premiums are labeled with a date of distribution, a production date and trademark information?

Section 103 of the CPSIA requires that the tracking label provide, "to the extent practicable," marks that will enable the ultimate purchaser to ascertain the manufacturer or private labeler, the location and date of production of the product and cohort information. A label stating only the date of distribution, a production date and trademark information would not satisfy the requirements of section 103. Such a label would lack information identifying the manufacturer or private labeler, the place of production and cohort information.

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Could hangtags and adhesive labels be used as tracking labels for textile-type items?

No. The law requires that markings with the specified information be permanent. Hangtags and adhesive labels are not permanent.

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The law requires manufacturers to start labeling product and packaging one year after enactment. Does that mean it would affect products manufactured for the 2010 retail season or that items in retail stores would already have to have tracking labels as of August 2009?

The law requires that one year after enactment, or August 14, 2009, manufacturers of children's products must place **permanent** marks on their product providing the information specified. Thus, the Commission staff believes that the tracking label requirement applies to children's products manufactured on or after August 14, 2009.

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Will the Commission be providing specifications or guidelines as to size, location and format of the tracking

information required by section 103? Or as to the meaning of "to the extent practicable"?

The Commission may issue implementing guidance on these issues. It should be noted, however, that the requirement to provide tracking information is mandatory regardless of whether the Commission provides such guidance.

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What information needs to be provided on the product to meet the tracking label requirements of section 103? Does section 103 of the CPSIA require that a manufacturer's name be present on a tracking label?

Section 103 of the CPSIA provides that the tracking label must contain information that will enable the manufacturer to ascertain the location and date of production of the product and cohort information (including the batch, run number, or other identifying characteristic) and any other information determined by the manufacturer to facilitate ascertaining the specific source of the product by reference to those marks.

Section 103 of the CPSIA further provides that the tracking label must contain information that will enable the ultimate purchaser to ascertain the manufacturer or private labeler, location and date of production of the product, and cohort information (including the batch, run number, or other identifying characteristic.) Thus, section 103 of the CPSIA does require that the tracking label contain information sufficient for the purchaser to ascertain the manufacturer of the product.

Watch the Commission's website for postings regarding further guidance on this issue. The Commission will seek comments from the public during this process.

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My company manufactures and imports various beds, as well as night stands, dressers, chest of drawers and mirrors. Are tracking labels required for furniture for children? Are these labels required for each piece of a bed, in one place after the bed is assembled, or in the box the product comes in?

Tracking labels will be required for products if they are primarily intended for children 12 years of age or younger. The label must be on the product (only once) and on the packaging. Section 103 specifies the information that must be provided on the label. This tracking label requirement will take effect for products manufactured on and after August 14, 2009.

Posted 12/04/2008.

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I make hand-crafted goods in my home. What do I need to do to be in compliance on August 14, 2009?

The Commission has received a great deal of comment and input from hand-crafters regarding the implementation of Section 103(a). As noted in the Statement of Policy, the Commission anticipates that there will be a period of education after the new requirements go into effect and expects that each manufacturer, large and small, will consider how to apply these requirements to their business.

Hand-crafters should consider the following:

- 1. What kind of tracking system do you currently use? You do not necessarily have to create a new system of lot, batch or run numbers to identify when you made your products, however your products and their packaging should identify your company in sufficient detail to enable a consumer to reach you so that the required information may be ascertained.
- 2. What information can be ascertained about your product? If someone handed you one of your products sold last year, what would you be able to tell them about the materials used? Keeping your receipts and purchase orders will help you to better know the source of your product and its components and when you began using them. Ask your fellow hand crafters if they

have any tips or ideas that can help.

- 3. How is your product marked? If someone had one of your products sold last year, would they know who to call if there was a problem? Absent any unusual circumstances, your business name should be on your product with sufficient detail to enable a consumer to reach you. Congress recognized that there could be instances where marking a product might not be practicable, such as where the product is very small. Consider the examples outlined in the Statement of Policy where it might not be practicable to mark a product.
- 4. How is your packaging marked? Can a retailer of your product see from the packaging (or from the product if the product marking is still fully visible) information that they could use to take just your products from the shelf in the event of a recall?

Compliance with the new requirements will call on a number of small hand crafters to rethink the way they maintain their records and mark their products.

Posted 07/21/2009.

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I make children's wooden blocks that have twenty in a set. How do I mark these products?

Congress recognized that it might not be practicable to mark every part of a child's game that has a board and small game pieces. Apply this idea to your product and it may be unnecessary to mark all twenty of the blocks in each of your sets. Depending on the nature of your blocks it might also be reasonable to mark one side of one block. If the blocks come with a storage box or bag, these would be areas to place a mark

Posted 07/21/2009.

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I make socks. Am I required to attach labels to each item?

No. The reasonableness of attaching a label to hosiery has already been thoroughly considered in the application of the federal Care Labeling rules. Those rules can be a guide to what is practicable in this case.

Posted 07/21/2009.

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Is the information ascertainable if I mark my product and packaging with a code and website address where all the required information can be found?

Yes, provided the name of a manufacturer or private labeler is also identified so a consumer without access to the internet can know whom to contact directly to also obtain the required information.

Posted 07/21/2009.

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You didn't tell us what "to the extent practicable" means in Section 103(a). Is there further insight you might offer?

Section 103(a) mandates distinguishing marks that will enable certain required information to be ascertainable from a product and its

packaging. The Statement of Policy says that the Commission expects a manufacturer to depart from the specific requirements of Section 103(a) only for considered and definable reasons. Each manufacturer is ultimately responsible for making a reasonable judgment about what information can be marked on their product and packaging, given the character and type of their product and packaging, and what required information can be ascertainable, given the character and type of their business. When considering the reasonableness of a manufacturer's decision regarding what information to include in its markings, the Commission intends to look at the individual manufacturer's situation along with the practices of peer manufacturers.

As questions arise, we may provide more information about the interpretation of this phrase.

Posted 07/21/2009.

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Will you post more answers to frequently asked questions?

Additional information in the form of frequently asked questions will be posted as necessary to respond to common issues and concerns that arise.

Posted 07/21/2009.

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For more information on the CPSIA contact the Consumer Product Safety Commission at http://www.cpsc.gov/cgibin/newleg.aspx, and we will address the most frequently asked questions.

These FAQs are unofficial descriptions and interpretations of various features of CPSIA and do not replace or supersede the statutory requirements of the new legislation. These FAQs were prepared by CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission. Some FAQs may be subject to change based on Commission action.

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http://www.cpsc.gov/about/cpsia/faq/103faq.html#domestic

Proposed Rules

Federal Register

Vol. 74, No. 53

Friday, March 20, 2009

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1115

Guidelines and Requirements for Mandatory Recall Notices: Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 requires the United States Consumer Product Safety Commission ("Commission") to establish by rule guidelines and requirements for recall notices ordered by the Commission or by a United States District Court under the Consumer Product Safety Act. This proposal would establish the guidelines and requirements to satisfy that requirement.

DATES: Written comments must be received by April 20, 2009.

ADDRESSES: Comments should be emailed to

mandatoryrecallnotices@cpsc.gov.
Comments also may be mailed,
preferably in five copies, to the Office of
the Secretary, Consumer Product Safety
Commission, Room 502, 4330 East West
Highway, Bethesda, Maryland 20814, or
delivered to the same address
(telephone (301) 504–7923. Comments
may also be filed by facsimile to (301)
504–0127. Comments should be
captioned "Section 15(i) NPR."

FOR FURTHER INFORMATION CONTACT:

Marc Schoem, Deputy Director, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7520.

SUPPLEMENTARY INFORMATION:

A. Background

The Consumer Product Safety Improvement Act of 2008 ("CPSIA", Pub. L. 110–314) was enacted on August 14, 2008. The CPSIA amends statutes that the U.S. Consumer Product Safety Commission ("Commission") administers, adding requirements with broad applicability and some productspecific provisions as well.

B. CPSIA Requirements

Section 214 of the CPSIA amends section 15 of the Consumer Product Safety Act ("CPSA") to add a new subsection (i). That section requires that, "not later than 180 days after the date of enactment of the CPSIA, the Commission shall, by rule, establish guidelines setting forth a uniform class of information to be included in any notice required by an order under" sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)). Public Law 110-314, section 214(c), 122 Stat. 3016 (August 14, 2008). The guidelines must include information that would be helpful in identifying the product, hazard, and remedy associated with a recall. 15 U.S.C. 2064, as added by CPSIA § 214.

Section 214 of the CPSIA also requires that a recall notice include certain specific information, unless the Commission determines otherwise. This information includes, but is not limited to, descriptions of the product, hazard, injuries, deaths, action being taken, and remedy; identification of the manufacturer and retailers; identification of relevant dates; and any other information the Commission deems appropriate. *Id*.

C. Basis for Proposed Rule

The Commission and Commission staff have been using recall notifications since the Commission's inception. Under section 15(c) of the CPSA, if the Commission determines that notification is required to adequately protect the public from a substantial product hazard, the Commission may order a manufacturer, retailer, or distributor to provide notice to certain persons. 15 U.S.C. 2064(c). In addition, for many years, the Commission has made information concerning recall notices publicly available, including, for example, in the agency's Recall Handbook (http://www.cpsc.gov/ BUSINFO/8002.html).

This proposed rule has been written based upon, and with the benefit of, the Commission and Commission staff's many years of experience with recalls and recall effectiveness. The proposal is also based on related agency expertise and on information contained in agency recall guidance materials, including, but not limited to, the Recall Handbook.

D. Description of the Proposed Rule

In general, the proposed rule would establish a new subpart C, titled, "Guidelines and Requirements for Mandatory Recall Notices," in part 1115 of title 16 of the Code of Federal Regulations.

1. Proposed § 1115.23—Purpose

Proposed § 1115.23 would describe the purpose for a new subpart C, "Guidelines and Requirements for Mandatory Recall Notices." In accordance with direction in the CPSIA, the proposed rule would set out guidelines and requirements for recall notices issued under section 15(c) and (d) or section 12 of the CPSA. The proposed guidelines would provide guidance concerning the content and form of such notices. As required by the CPSIA, the proposed rule also would specify the content required in such recall notices.

2. Proposed § 1115.24—Applicability

Consistent with section 15(i) of the CPSA, as added by section 214 of the CPSIA, the proposed rule would apply only to mandatory recall notices, i.e., recall notices issued pursuant to an order of the Commission under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or pursuant to an order of a U.S. district court under section 12 of the CPSA (15 U.S.C. 2061).

Proposed § 1115.24, therefore, would explain that the requirements in subpart C apply to manufacturers (including importers), retailers, and distributors of consumer products.

The proposed rule would not contain requirements for recalls and recall notices that are voluntary and result from corrective action settlement agreements with Commission staff. If the Commission decides to extend the requirements to voluntary recalls, it would proceed with a separate rulemaking initiated by a separate notice of proposed rulemaking. Unless and until the Commission issues a rule containing requirements for voluntary recall notices, the proposed rule would serve as a guide for voluntary recall notices.

3. Proposed § 1115.25—Definitions

Proposed \S 1115.25 would define certain terms used in subpart C. For

example, proposed § 1115.25(a) would define "recall" as "any one or more of the actions required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d))." The proposed definitions in this section are based on the staff's experience with recalls under section 15. Additionally, proposed § 1115.25 would state that the definitions in section 3 of the CPSA (15 U.S.C. 2052) apply.

4. Proposed § 1115.26—Guidelines and Policies

Proposed § 1115.26 would provide general guidance and describe the policies pertaining to recall notices. The proposed guidelines would restate the goals delineated in section 214 of the CPSIA. The CPSIA requires the guidelines to include information helpful to consumers. The Commission believes, however, that recall notices are intended to be of benefit and importance not only to consumers, but also to "other persons," and proposed § 1115.26(a) would reflect this position. The latter broader category is intended to encompass the wide range of persons and broader public referenced in section 15(c) or (d) and in section 12 of the CPSA (15 U.S.C. 2061, 2064(c) or (d)). As used here, the term "other persons" would include, but would not be limited to, consumer safety advocacy organizations, public interest groups, trade associations, other State, local and federal government agencies, and the media. Historically, these persons have played significant roles in assisting with the dissemination of recall notice information. The Commission anticipates that these roles will continue.

In general, proposed § 1115.26(a) would state general principles that are important for recall notices to be effective. For example, proposed § 1115.26(a)(1) would state that a recall notice should provide information that enables consumers and other persons to identify the product and take a stated action. Proposed § 1115.26(a)(2) through (a)(4) would provide guidance on the form of the recall notice, recognizing the various forms of notice and providing guidance concerning direct recall notices and Web site recall notices.

Proposed § 1115.26(a)(4) would recognize that a direct recall notice is the most effective form of a recall notice, and proposed § 1115.26(b)(2) would state that when firms have contact information they should issue direct recall notices. By necessity due to lack of specific contact information, most recall notices are disseminated to broad or, on occasion, partially-targeted audiences. A direct recall notice, on the

other hand, is sent directly to specific, identifiable consumers of the recalled product. In most instances, these consumers will be the purchasers of the recalled product. In other instances, the purchasers may have given the product to other consumers, for example, as a gift. In the latter case, if the purchaser received the recall notice, the purchaser will generally know to whom the purchaser gave the product and will likely be able to contact the recipient about the recall notice. In either case, the persons exposed to the product and its hazard will be more likely to receive the direct recall notice than to receive a broadly-disseminated recall notice.

Proposed § 1115.26(b)(1) would describe other possible forms of recall notices (such as letters, electronic mail, and video news releases), and proposed § 1115.26(b)(3) would discuss Web site

recall notices.

Proposed § 1115.26(c) would provide that, where the Commission or a court deems it to be necessary or appropriate, the Commission may direct that the recall notice be in languages in addition to English.

5. Proposed § 1115.27—Recall Notice Content Requirements

In addition to requiring the Commission to issue guidelines for recall notices required under sections 12 and 15(c) and (d) of the CPSA, the CPSIA sets out specific content requirements. The CPSIA states that such recall notices shall include the specified information, including other information that the Commission or a court deems appropriate, unless the Commission or a court determines that including the information would not be appropriate in the particular recall notice. Thus, proposed § 1115.27 would set forth the recall notice content requirements specified in the CPSIA and would provide further details where appropriate.

For example, proposed § 1115.27(a) would require that a recall notice include the word "recall" in the heading and text. Although the CPSIA does not explicitly require use of the word "recall," it does require a "description of the action being taken." For many years, the Commission staff's Recall Handbook has directed that this term should be used. The objectives of a recall include locating the recalled products, removing the recalled products from the distribution chain and from consumers, and communicating information to the public about the recalled product and the remedy offered to consumers. A recall notice should motivate firms and media to widely publicize the recall

information, and it should motivate consumers to act on the recall for the sake of safety. To those ends, the word "recall" draws media and consumer attention to the notice and to the information contained in the notice, and it does so more effectively than omitting the term or using an alternative term. A recall notice must be read to be effective, and drawing attention to the notice through the use of the word "recall" increases the likelihood that it will be read and, therefore, effectuates the purposes of the CPSA and CPSIA.

Proposed § 1115.27(b) would require the recall notice to contain the date of its release, issuance, posting, or

publication.

The CPSIA requires that a recall notice include a description of the product, including the model number or SKU number, the names of the product, and a photograph. Proposed § 1115.27(c) would further flesh out information needed to describe the product by adding such items as the product's color, and identifying tags or labels.

Proposed § 1115.27(d) would require the recall notice to contain a clear and concise statement of the actions that a firm is taking concerning the product. This is required by the CPSIA.

Proposed § 1115.27(e) would require the recall notice to state the approximate number of units covered by the recall, including all product units manufactured, imported, and/or distributed in commerce. This information is required by the CPSIA.

The statute requires that a recall notice include a description of the substantial product hazard. Proposed § 1115.27(f) would clarify this requirement by stating that the description must enable consumers to identify the risks of potential injury or death associated with the product, and it must identify the problem giving rise to the recall and the type of hazard or risk at issue (e.g., burn, laceration). Proposed § 1115.27(f)(1) through (f)(2) would provide greater detail as to what the description must include; for example, the description must include the product defect, fault, failure, flaw, and/or problem giving rise to the recall.

The statute requires identification of the manufacturers and significant retailers. Proposed § 1115.27(g) would state that the recall notice must identify the firm conducting the recall and also would clarify that, under the CPSA, the term "manufacturer" includes an importer. Proposed § 1115.27(h) would describe how the manufacturer must be identified (e.g., legal name, location of headquarters).

The statute does not define "significant retailer." Identifying these retailers will help consumers determine whether or not they shopped at the identified retailer, and, in turn, whether or not they might have the product. In the absence of a statutory definition, and based on its experience with recalls, the Commission believes that a significant retailer can be determined on the basis of several factors, and proposed § 1115.27(i) would describe those factors.

First, under proposed § 1115.27(i), a product's retailer is significant if it was the exclusive retailer of the product. Identifying an exclusive retailer is valuable because it can help consumers to conclude that, if they did not shop at that retailer, they are not likely to have the product, and, conversely, if they did shop at that retailer, they may have the product.

Second, a product's retailer is significant if it was an importer of the product. As an importer, a retailer will typically have greater information, and greater access to information, about a product, than a retailer that was not an

importer.

Third, a product's retailer is significant if it is a nationwide or regionally-located retailer. Retailers that are located nationwide will be likely to have sold more units of the product, or to have sold the product to more consumers, than retailers that are not located nationwide. Therefore, nationwide retailers are likely to be more familiar to consumers than are retailers that are not nationwide. In addition, a regionally-located retailer, such as a retailer with a number of stores in several states, will be likely to be better known to consumers in those states or that region.

Fourth, a retailer that sold, or held for purposes of sale or distribution in commerce, a significant number of the total manufactured, imported, or distributed units of the product, will have sold the product to, and affected, more consumers, than a retailer that sold fewer units of the product.

Fifth, a product's retailer is significant if identification of the retailer is in the public interest. Recalls and products vary from one to the next, and there may be reasons other than those stated above that consumers will benefit from knowing the identities of certain retailers. Basing identification of a retailer on the public interest allows the Commission and firms flexibility to meet consumers' needs in a particular recall and to, in general, seek the best possible recall effectiveness.

Proposed § 1115.27(j) would require the recall notice to state the month and year in which the manufacture of the product began and ended and the month and year in which the retail sales began and ended. These dates would be included for each make and model of the product covered by the recall notice. This information is required by the CPSIA.

Although the statute does not list price of the product among the information required in a recall notice, proposed § 1115.27(k) would require the recall notice to state the approximate price of the product or a price range. Information about the price will help consumers to identify the product and be aware of the appropriate amount for a refund if that is the remedy.

Proposed § 1115.27(l) would require the recall notice to state the number and describe any injuries and deaths associated with the product, state the ages of any individuals injured or killed and the dates or range of dates on which the Commission received information about the injuries or deaths. Proposed § 1115.27(m) would require the recall notice to provide a description of any remedy available to the consumer, what actions the consumer must take to obtain a remedy, and any information the consumer needs in order to obtain a remedy. Proposed § 1115.27(n) would require the recall notice to contain any other information that the Commission or a court deems appropriate and orders. This information is all required by the CPSIA.

6. Proposed § 1115.28—Multiple Products or Models

Proposed § 1115.28 would require the notice for each product or model covered by a recall notice to meet the requirements of this subpart.

7. Proposed § 1115.29—Final Determination Regarding Form and Content

Proposed § 1115.29(a) would provide, in accordance with the statute, that the Commission (in the case of a recall notice under section 15(c) or (d)) or a court (in the case of a recall notice under section 12) makes the final determination regarding the form and content of a recall notice. Additionally, proposed § 1115.29(b) would allow the Commission to determine that one or more recall notice requirements set forth in subpart C is not required and will not be included in a recall notice. Proposed § 1115.29(c) would state that the Commission must review and agree, in writing, to all aspects of a recall notice before a firm may publish, broadcast, or otherwise disseminate a recall notice that is to be issued pursuant to an order under section 15(c) or (d) of the CPSA.

E. Effective Date

The Administrative Procedure Act ("APA") generally requires that the effective date of a rule be at least 30 days after publication of the final rule. Id. 553(d). However, an earlier effective date is permitted for statements of policy and "as otherwise provided by the agency for good cause found and published with the rule." Id. The guidelines are essentially a statement of policy. The requirements for the content of mandatory recall notices are largely dictated by the CPSIA with some further clarifications by the Commission. The statutory requirements for the content of mandatory recall notices are already in effect. Therefore, the Commission finds that good cause exists for the guidelines and requirements to become effective when published in final and proposes that the effective date be the date of publication of a final rule in the **Federal** Register.

F. Regulatory Flexibility Certification

The Regulatory Flexibility Act ("RFA") generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. Section 603 of the RFA calls for agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. 5 U.S.C. 603. However, section 605(b) of the RFA states that this requirement does not apply if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, and the agency provides an explanation for that conclusion.

This rulemaking will have little or no effect on small businesses. This rulemaking consists of guidelines (which do not require a regulatory flexibility analysis) and recall notice content requirements that are largely dictated by the CPSIA. The requirement to issue a recall notice for recalls under section 12 or 15(c) or (d) of the CPSA does not come from this rulemaking, but from the existing provisions of section 15 and 12 of the CPSA. Moreover, the guidelines and requirements will only come into play in the context of an administratively adjudicated order to a specific party. Such mandatory recalls have occurred infrequently in the Commission's history. Therefore, the Commission concludes that the proposed guidelines and requirements will not have a significant economic impact on a substantial number of small entities.

G. Paperwork Reduction Act

This proposed rule does not impose any information collection requirements. It sets out proposed guidelines and content requirements for recall notices that are required by statute to be imposed in individual enforcement actions under existing law pursuant to section 15(c) or (d) or section 12 of the CPSA. Accordingly, it is not subject to the Paperwork Reduction Act, 44 U.S.C. sections 3501 through 3520.

H. Environmental Considerations

The Commission's regulations provide a categorical exemption for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement as they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This proposed rule falls within the categorical exemption.

List of Subjects in 16 CFR Part 1115

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

Therefore, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1115—SUBSTANTIAL PRODUCT HAZARD REPORTS

1. The authority for part 1115 continues to read as follows:

Authority: 15 U.S.C. 2061, 2064, 2065, 2066(a), 2068, 2069, 2070, 2071, 2073, 2076, 2079, and 2080.

2. Add a new Subpart C to read as follows:

* * * * *

Subpart C—Guidelines and Requirements for Mandatory Recall Notices

Sec.

1115.23 Purpose.

1115.24 Applicability.

1115.25 Definitions.

1115.26 Guidelines and policies.

1115.27 Recall notice content requirements.

1115.27 Recall notice content requirements 1115.28 Multiple products or models.

1115.29 Final determination regarding form

and content.

* * * * * *

Subpart C—Guidelines and Requirements for Mandatory Recall Notices

§1115.23 Purpose.

(a) The Commission establishes these guidelines and requirements for recall notices as required by section 15(i) of the Consumer Product Safety Act, as amended (CPSA) (15 U.S.C. 2064(i)).

The guidelines and requirements set forth the information to be included in a notice required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)). Unless otherwise ordered by the Commission under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or by a U.S. district court under section 12 of the CPSA (15 U.S.C. 2061), the content information required in this subpart must be included in every such notice.

- (b) The Commission establishes these guidelines and requirements to ensure that every recall notice effectively helps consumers and other persons to:
- (1) Identify the specific product to which the recall notice pertains;
- (2) Understand the product's actual or potential hazards to which the recall notice pertains, and information relating to such hazards; and
- (3) Understand all remedies available to consumers concerning the product to which the recall notice pertains.

§1115.24 Applicability.

This subpart applies to manufacturers (including importers), retailers, and distributors of consumer products as those terms are defined herein and in the CPSA.

§1115.25 Definitions.

In addition to the definitions given in section 3 of the CPSA (15 U.S.C. 2052), the following definitions apply:

(a) Recall means any one or more of the actions required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)).

(b) Recall notice means a notification required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)).

- (c) Direct recall notice means a notification required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)), that is sent directly to specifically-identified consumers.
- (d) Firm means a manufacturer (including an importer), retailer, or distributor as those terms are defined in the CPSA.

§ 1115.26 Guidelines and policies.

- (a) General. (1) A recall notice should provide sufficient information and motivation for consumers and other persons to identify the product and its actual or potential hazards, and to respond and take the stated action. A recall notice should clearly and concisely state the potential for injury or death.
- (2) A recall notice should be written in language designed for, and readily

understood by, the targeted consumers or other persons. The language should be simple and should avoid or minimize the use of highly technical or legal terminology.

(3) Firms should use recall notices targeted and tailored to the specific product and circumstances. In determining the form and content of a recall notice, firms should consider the manner in which the product was advertised and marketed.

(4) A direct recall notice is the most effective form of a recall notice.

- (b) Form of recall notice—(1) Possible forms. A recall notice may be written, electronic, audio, visual, or in any other form ordered by the Commission in an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or by a U.S. district court under section 12 of the CPSA (15 U.S.C. 2061). The forms of, and means for communicating, recall notices include, but are not limited to:
- (i) Letter, Web site posting, electronic mail, RSS feed, or text message;
- (ii) Computer, radio, television, or other electronic transmission or medium:
- (iii) Video news release, press release, recall alert, Web stream, or other form of news release;
- (iv) Newspaper, magazine, catalog, or other publication; and
- (v) Advertisement, newsletter, and service bulletin.
- (2) Direct recall notice. A direct recall notice should be used for each consumer for whom a firm has direct contact information. Direct contact information includes, but is not limited to, name and address, and electronic mail address. Forms of direct recall notice include, but are not limited to, United States mail, electronic mail, and telephone calls. A direct recall notice should prominently show its importance over other consumer notices or mail by including "Safety Recall" or other appropriate terms in an electronic mail subject line, and, in large bold red typeface, on the front of an envelope and in the body of a recall notice.
- (3) Web site recall notice. A Web site recall notice should be on a Web site's first entry point such as a home page, should be clear and prominent, and should be interactive by permitting consumers and other persons to obtain recall information and request a remedy directly on the Web site.
- (c) Languages. Where the Commission for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or a U.S. district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), determines that it is necessary or appropriate to adequately inform and

protect the public, a recall notice may be required to be in languages in addition to English.

§ 1115.27 Recall notice content requirements.

Except as provided in § 1115.29, every recall notice must include the information set forth below:

- (a) *Terms*. A recall notice must include the word "recall" in the heading and text.
- (b) Date. A recall notice must include its date of release, issuance, posting, or publication.
- (c) Description of product. A recall notice must include a clear and concise statement of the information that will enable consumers and other persons to readily and accurately identify the specific product and distinguish it from similar products. The information must enable consumers to readily determine whether or not they have, or may be exposed to, the product. Description information includes but is not limited to:
- (1) The product's names, including informal and abbreviated names, by which consumers and other persons should know or recognize the product;
- (2) The product's intended or targeted use population (*e.g.*, infants, children, or adults):
 - (3) The product's colors and sizes;
- (4) The product's model numbers, serial numbers, date codes, stock keeping unit (SKU) numbers, and tracking labels, including their exact locations on the product;
- (5) Identification and exact locations of product tags, labels, and other identifying parts, and a statement of the specific identifying information found on each part; and
- (6) Product photographs. A firm must provide photographs. Each photograph must be electronic or digital, in color, of high resolution and quality, and in a format readily transferable with high quality to a Web site or other appropriate medium. As needed for effective notification, multiple photographs and photograph angles may be required.
- (d) Description of action being taken. A recall notice must contain a clear and concise statement of the actions that a firm is taking concerning the product. These actions may include, but are not limited to, one or more of the following: Stop sale and distribution in commerce; recall to the distributor, retailer, or consumer level; repair; request return and provide a replacement; and request return and provide a refund.
- (e) Statement of number of product units. A recall notice must state the approximate number of product units

covered by the recall, including all product units manufactured, imported, and/or distributed in commerce.

- (f) Description of substantial product hazard. A recall notice must contain a clear and concise description of the product's actual or potential hazards that result from the product condition or circumstances giving rise to the recall. The description must enable consumers and other persons to readily identify the reasons that a firm is conducting a recall. The description must also enable consumers and other persons to readily identify and understand the risks and potential injuries or deaths associated with the product conditions and circumstances giving rise to the recall. The description must include:
- (1) The product defect, fault, failure, flaw, and/or problem giving rise to the recall; and
- (2) The type of hazard or risk, including, by way of example only, burn, fall, choking, laceration, entrapment, and/or death.
- (g) Identification of recalling firm. A recall notice must identify the firm conducting the recall by stating the firm's legal name and commonly known trade name, and the city and state of its headquarters. The notice must state whether the recalling firm is a manufacturer (including importer), retailer, or distributor.
- (h) Identification of manufacturers. A recall notice must identify each manufacturer (including importer) of the product and the country of manufacture. Under the definition in section 3(a)(11) of the CPSA (15 U.S.C. 2052(a)(11)), a manufacturer means "any person who manufactures or imports a consumer product." If a product has been manufactured outside of the U.S., a recall notice must identify the foreign manufacturer and the U.S. importer. A recall notice must identify the manufacturer by stating the manufacturer's legal name and the city and state of its headquarters, or, if a foreign manufacturer, the city and country of its headquarters.
- (i) Identification of significant retailers. A recall notice must identify each significant retailer of the product. A recall notice must identify such a retailer by stating the retailer's commonly known trade name. Under the definition in section 3(a)(13) of the CPSA (15 U.S.C. 2052(a)(13)), a retailer means "a person to whom a consumer product is delivered or sold for purposes of sale or distribution by such person to a consumer." A product's retailer is "significant" if, upon the Commission's information and belief, and in the sole discretion of the Commission for purposes of an order

- under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or in the sole discretion of a U.S. district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), any one or more of the circumstances set forth below is present (the Commission may require manufacturers (including importers), retailers, and distributors to provide information relating to these circumstances):
- (1) The retailer was the exclusive retailer of the product;
- (2) The retailer was an importer of the product;
- (3) The retailer has stores nationwide or regionally-located;
- (4) The retailer sold, or held for purposes of sale or distribution in commerce, a significant number of the total manufactured, imported, or distributed units of the product; or
- (5) Identification of the retailer is in the public interest.
- (j) Dates of manufacture and sale. A recall notice must state the month and year in which the manufacture of the product began and ended, and the month and year in which the retail sales of the product began and ended. These dates must be included for each make and model of the product.
- (k) *Price*. A recall notice must state the approximate retail price or price range of the product.
- (l) Description of incidents, injuries, and deaths. A recall notice must contain a clear and concise summary description of all incidents (including, but not limited to, property damage), injuries, and deaths associated with the product conditions or circumstances giving rise to the recall, as well as a statement of the number of such incidents, injuries, and deaths. The description must enable consumers and other persons to readily understand the nature and extent of the incidents and injuries. A recall notice must state the ages of all persons injured and killed. A recall notice must state the dates or range of dates on which the Commission received information about injuries and
- (m) Description of remedy. A recall notice must contain a clear and concise statement, readily understandable by consumers and other persons, of:
- (1) Each remedy available to a consumer for the product conditions or circumstances giving rise to the recall. Remedies include, but are not limited to, refunds, product repairs, product replacements, rebates, coupons, gifts, premiums, and other incentives.
- (2) All specific actions that a consumer must take to obtain each remedy, including, but not limited to, instructions on how to participate in the

recall. These actions may include, but are not limited to, contacting a firm, removing the product from use, discarding the product, returning part or all of the product, or removing or disabling part of the product.

(3) All specific information that a consumer needs in order to obtain each remedy and to obtain all information about each remedy. This information may include, but is not limited to, the following: Manufacturer, retailer, and distributor contact information (such as name, address, telephone and facsimile numbers, e-mail address, and Web site address); whether telephone calls will be toll-free or collect; and telephone number days and hours of operation including time zone.

(n) Other information. A recall notice must contain such other information as the Commission for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or a U.S. district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), deems appropriate and orders.

§ 1115.28 Multiple products or models.

For each product or model covered by a recall notice, the notice must meet the requirements of this subpart.

§ 1115.29 Final determination regarding form and content.

(a) Commission or court discretion. The recall notice content required by this subpart must be included in a recall notice whether or not the firm admits the existence of a defect or of an actual or potential hazard, and whether or not the firm concedes the accuracy or applicability of all of the information contained in the recall notice. The Commission will make the final determination as to the form and content of the recall notice for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), and a U.S. district court will make the final determination as to the form and content of a recall notice for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061).

(b) Recall notice exceptions. The Commission for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or a U.S. district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), may determine that one or more of the recall notice requirements set forth in this subpart is not required, and will not be included, in a recall notice.

(c) Commission approval. Before a firm may publish, broadcast, or otherwise disseminate a recall notice to be issued pursuant to an order under

section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), the Commission must review and agree in writing to all aspects of the notice.

Dated: March 13, 2009.

Todd Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. E9–6021 Filed 3–19–09; 8:45 am] BILLING CODE 6355–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-150066-08]

RIN 1545-BI45

Guidance Regarding Foreign Base Company Sales Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing; correction.

SUMMARY: This document contains corrections to a notice of proposed rulemaking and notice of public hearing that was published in the **Federal Register** on Monday, December 29, 2008 (73 FR 79421), relating to foreign base company sales income.

FOR FURTHER INFORMATION CONTACT: Jeffery Mitchell, (202) 622–7034 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking and notice of public hearing that is subject to these corrections are under section 954 of the Internal Revenue Code.

Need for Correction

As published the notice of proposed rulemaking and notice of public hearing contains errors that may prove to be misleading and are in need of correction.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking and notice of public hearing (REG-150066-08), which was the subject of FR Doc. E8-30729, is corrected as follows:

1. On page 79422, column 1, in the preamble under the heading Background and Explanation of Provision, the last sentence, the language "The preamble to the

temporary regulations explains these proposed regulations." is corrected to read "The preamble to the temporary regulations explains the amendments."

- 2. On page 79422, column 2, in the preamble under the heading Comments and Public Hearing, the first paragraph, line 3, the language "consideration will be give to any written" is corrected to read "consideration will be given to any written".
- 3. On page 79422, column 3, in the preamble under the heading Part 1—Income Taxes, instructional paragraph 2, lines 5 and 6, the language "(b)(2)(ii)(e), (b)(4) Example (3), (c), and (d), and adding Examples 8 and 9 to" is corrected to read "(b)(2)(ii)(e) and (b)(4) Example (3), and adding Examples 8 and 9 to".
- 4. On page 79423, column 1, § 1.954–3, the third sentence of *Example 8*, the language "8 is the same as the text of § 1.954–3T" is corrected to read "8 is the same as the text of § 1.954–3T(b)(4)".
- 5. On page 79423, column 1, § 1.954–3, the third sentence of *Example 9*, the language "9 is the same as the text of § 1.954–3T" is corrected to read "9 is the same as the text of § 1.954–3T(b)(4)".

Guy R. Traynor,

Federal Register Liaison, Procedure & Administration, Associate Chief Counsel, Publications & Regulations.

[FR Doc. E9–5892 Filed 3–19–09; 8:45 am] BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2005-TX-0026; FRL-8780-4]

Approval and Promulgation of Implementation Plans; Texas; Revisions to Permits by Rule and Regulations for Control of Air Pollution by Permits for New Construction or Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve portions of three revisions to the Texas State Implementation Plan (SIP) submitted by the State of Texas on July 22, 1998, October 4, 2002, and September 25, 2003; these revisions amend existing sections and create new sections in Title 30 of the Texas Administrative Code (TAC), Chapter 106—Permits by Rule and Chapter



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Consumer Product Safety Improvement Act

Section 219. Whistleblower Protections

Brief Summary

Brief Summary

Section 219 establishes new whistleblower protections for employees of manufacturers, private labelers, distributors, or retailers of consumer products. Covered employees are protected from discharge or any other form of retaliation resulting from the employee's provision to the employer, the Federal Government, or a State attorney general of information relating to any violation of statutes or regulations enforced by the CPSC. The whistleblower protections in new Section 40 of the Consumer Product Safety Act do not extend to government employees.

An employee of a manufacturer, private labeler, distributor, or retailer of consumer products who believes he or she has suffered an adverse employment action as a result of the employee's provision of information relating to a violation of statutes or regulations enforced by the CPSC may file a complaint with the Secretary of Labor seeking redress. A complaint setting forth the facts and identifying the responsible party must be filed with the Secretary of Labor no later than 180 days after the date on which the violation occurs.

Effective Date: This provision became effective upon enactment, August 14, 2008.

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For more information on the CPSIA contact the Consumer Product Safety Commission at http://www.cpsc.gov/cgibin/newleg.aspx.

This document is an unofficial description of one of the sections of the CPSIA and does not replace or supersede the statutory requirements of the new legislation. The dates used follow the legislation. Some may be subject to change based on final Commission action. These summaries are those of the CPSC staff and have not been reviewed or approved by, and may not necessarily reflect the views of the Commission.

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http://www.cpsc.gov/about/cpsia/sect219.html#summary

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) and implementing regulations, notification is hereby given that a 1year letter of authorization (LOA) has been issued to the U.S Navy (Navy) for the incidental take of marine mammals during training, maintenance, and research, development, testing, and evaluation (RDT&E) activities conducted within the Navy's Hawaii Range Complex (HRC). These activities are considered military readiness activities pursuant to the Marine Mammal Protection Act (MMPA), as amended by the National Defense Authorization Act of 2004 (NDAA).

DATES: Effective January 8, 2009, through January 7, 2010.

ADDRESSES: The LOA and supporting documentation are available by writing to Michael Payne, Chief, Permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, by telephoning one of the contacts listed here (FOR FURTHER INFORMATION CONTACT), or online at: http://www.nmfs.noaa.gov/pr/permits/incidental.htm.

FOR FURTHER INFORMATION CONTACT: Jolie Harrison, Office of Protected Resources, NMFS.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 et seq.) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) during periods of not more than five consecutive years each if certain findings are made and regulations are issued or, if the taking is limited to harassment and of no more than 1 year, the Secretary shall issue a notice of proposed authorization for public review.

Authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses, and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking are set forth.

NMFS has defined "negligible impact" in 50 CFR 216.103 as:

an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The NDAA (Public Law 108–136) removed the "small numbers" and "specified geographical region" limitations and amended the definition of "harassment" as it applies to a "military readiness activity" to read as follows (Section 3(18)(B) of the MMPA):

(i) any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild [Level A Harassment]; or (ii) any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered [Level B Harassment].

Summary of Request

On June 25, 2007, NMFS received an application from the Navy requesting authorization for the take of 24 species of marine mammals incidental to upcoming Navy training activities to be conducted within the HRC, which covers 235,000 nm² around the Main Hawaiian Islands (see map on page 17 of the application), over the course of 5 years. These training activities are classified as military readiness activities. These training activities may incidentally take marine mammals present within the HRC by exposing them to sound from mid-frequency or high frequency active sonar (MFAS/ HFAS) or to underwater detonations at levels that NMFS associates with the take of marine mammals. The Navy requested authorization to take individuals of 24 species of marine mammals by Level B Harassment. Further, though they do not anticipate it to occur, the Navy requested authorization to take, by injury or mortality, up to 10 individuals each of 11 species over the course of the 5-year period (bottlenose dolphin, Kogia spp., melon-headed whale, pantropical spotted dolphin, pygmy killer whale, short-finned pilot whale, striped dolphin, and Cuvier's, Longman's, and Blainville's beaked whale).

Authorization

On January 5, 2009, NMFS' final rule governing the take of marine mammals incidental to U.S. Navy Training in the Hawaii Range Complex became effective. In accordance with the final rule, NMFS issued an LOA to the Navy on January 8, 2009, authorizing Level B harassment of 24 species of marine mammals and mortality of 11 species of marine mammals incidental to U.S. Navy training, maintenance, and RDT&E activities in the HRC. Issuance of this LOA is based on findings, described in the preamble to the final rule (74 FR

1456, January 12, 2009), that the taking resulting from the activities described in this LOA will have a negligible impact on marine mammal stocks and will not have an unmitigable adverse impact on the availability of the affected marine mammal stock for subsistence uses. The LOA describes the permissible methods of taking and includes requirements pertaining to the mitigation, monitoring and reporting of such taking.

Dated: February 4, 2009.

P. Michael Payne,

Chief, Permits, Conservation, and Recreation, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E9–2661 Filed 2–6–09; 8:45 am] **BILLING CODE 3510–22–S**

CONSUMER PRODUCT SAFETY COMMISSION

Notice of Stay of Enforcement of Testing and Certification Requirements

AGENCY: Consumer Product Safety Commission.

ACTION: Stay of enforcement.

SUMMARY: This notice announces the decision of the Consumer Product Safety Commission ("CPSC" or "Commission") to stay enforcement of certain provisions of subsection 14(a) of the Consumer Product Safety Act ("CPSA") as amended by section 102(a) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), Public Law 110-314. Specifically, the Commission is staying certain of the requirements of paragraphs 14(a)(1), (2), and (3) that otherwise require testing and issuance of certificates of compliance by manufacturers, including importers, of products subject to an applicable consumer product safety rule as defined in the CPSA or similar rule, ban, standard, or regulation under any other Act enforced by the Commission. This stay covers all such requirements with the exception of:

- (1) Those where testing and certification was required by subsection 14(a) of the CPSA prior to enactment of the CPSIA; and
- (2) Those requirements, when they become effective, applicable to children's product certifications required to be supported by third party testing for which the Commission has issued requirements for acceptance of accreditation of third party testing laboratories to test for:
- Lead paint (effective for products manufactured after December 21, 2008),
- Full-size and non-full size cribs and pacifiers (effective for products manufactured after January 20, 2009),

- Small parts (effective for products manufactured after February 15, 2009), and
- Metal components of children's metal jewelry (effective for products manufactured after March 23, 2009);
- (3) Any and all certifications expressly required by CPSC regulations; and
- (4) The certifications required due to certain requirements of the Virginia Graeme Baker Pool & Spa Safety Act being defined as consumer product safety "rules;" and
- (5) The certifications of compliance required for ATVs in section 42(a)(2) of the CPSA which were added by CPSIA; and

(6) Any voluntary guarantees provided for in the Flammable Fabrics Act ("FFA") or otherwise (to the extent a guarantor wishes to issue one).

This stay will remain in effect until February 10, 2010, at which time the Commission will vote to terminate the stay. This stay does not alter or postpone the requirement that all products meet applicable consumer product safety rules as defined in the CPSA or similar rules, bans, standards, or regulations under any other Act enforced by the Commission.

DATES: *Effective Date:* This stay is effective February 10, 2009.¹

FOR FURTHER INFORMATION CONTACT: John "Gib" Mullan, Assistant Executive Director for Compliance and Field Operations, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail jmullan@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission is aware that there is substantial confusion as to which testing and certification requirements of subsection 14(a) of the CPSA apply to which products under the Commission's jurisdiction, what sort of testing is required where the provisions do apply, whether testing is necessary for children's products that may not by their nature contain lead, whether testing to demonstrate compliance must be conducted on the final product rather than on its parts prior to assembly or manufacture, whether manufacturers and importers must issue certificates of compliance to address the labeling requirements under the Federal Hazardous Substance Act ("FHSA"), and what sort of certificate must be

issued and by whom. The Commission has received literally thousands of email, telephone, and written inquiries as to how to comply, when to comply, what is required in support of the various certifications, what form the required certificates must take, and who must issue them. Likewise, the Commission has received innumerable inquiries seeking relief from the expense of testing children's products that either may not contain lead or may be subject to exemptions that the Commission may announce in the near future as a result of ongoing rulemakings either required or permitted by the CPSIA.² Commission staff has been unable to respond to many of these inquiries due to the press of its usual regulatory and compliance activities and the additional burden of the very early, multiple statutory deadlines imposed on the agency by the CPSIA, including those necessitating issuance of fourteen proposed and final rules in the six months since CPSIA was signed into law on August 14, 2008. Furthermore, the Commission is operating in fiscal year 2009 with the same level of funding appropriated to it for fiscal year 2008, before the CPSIA as well as two other acts also requiring significant additional Commission efforts—the Virginia Graeme Baker Pool and Spa Safety Act and the Children's Gasoline Burn Prevention Act—were enacted. This funding constraint is a severe handicap on the Commission's ability to staff up to address the numerous new requirements imposed by the CPSIA.

The Commission has embarked on four rulemakings to address many of these issues ³ as they relate to the lead content of children's products:

- Determinations that certain materials inherently will not exceed the statutory CPSIA limits on the lead content of children's products. 74 FR 2433 (January 15, 2009).
- Exemption of certain electronic devices from otherwise applicable limits on lead in children's products. 74 FR 2435 (January 15, 2009).
- Guidance on determining inaccessibility of components of children's products containing lead. 74 FR 2439 (January 15, 2009).

• Procedures for seeking determinations as to lead content of materials or products and exclusions from otherwise applicable limits on lead content of children's products. 74 FR 2428 (January 15, 2009).

These proposed rules present complex scientific, technical, and procedural issues that will not be resolved by February 10, 2009, the effective date of CPSIA's initial 600 parts per million ("ppm") limit on the lead content of children's products. Moreover, on that same date—February 10, 2009—additional sweeping requirements of the CPSIA come into effect, including those related to the phthalates content of children's toys and child care articles, the myriad requirements of the ASTM F963 voluntary toy standard becoming mandatory CPSC consumer product safety standards,4 and the recently issued CPSIA regulations related to print and catalog advertising of certain children's products.

These extensive changes to the regulatory landscape cut a broad swath through the business community from books to children's apparel to toys and sporting goods to children's electronic products. Many firms making consumer products, especially children's products, are small businesses. Bureau of Census data indicates that approximately ninety-eight percent of the domestic manufacturers of toys, dolls and games fall into the Small Business Administration's traditional definition of small business (less than 500 employees), approximately eighty one percent of manufacturers of such products have fewer than twenty employees, and over fifty percent have fewer than five employees. According to the same source, over 99 percent of firms making apparel (including clothing for children and infants) are small businesses. Moreover, the testing and certification requirements affect companies that have not previously been regulated (or did not realize that they could be regulated) by the Commission, such as book publishers and craft makers. These entities too are dominated by small businesses. According to a 2000 survey conducted by the Craft Organization Directors Association, 64 percent of craftspeople

¹ The Commission voted 2–0 to implement the stay. The Commissioners' statements concerning the stay are available on the Commission Web site at http://www.cpsc.gov.

² "Children's products" are defined in section 3(a)(2) of Consumer Product Safety Act, as amended, as consumer products "designed or intended primarily for children 12 years of age or younger."

³ The Commission has also requested comments on section 102 of the CPSIA, entitled "Mandatory Third-Party Testing for Certain Children's Products," specifically seeking input on the possibility of testing of component parts rather than the final children's products. http://www.cpsc.gov/about/cpsia/ComponentPartsComments.pdf.

⁴To add even further complexity with respect to the F963 toy standard, while the CPSIA explicitly states that the version of F963 as it existed on the date of enactment of CPSIA (August 14, 2008) presumably F963–07, is what becomes mandatory on February 10, 2009, the Commission understands that ASTM either has issued or intends to issue a new version of F963–F963–08—in the very near future.

worked alone, and nearly all of them employed fewer than 5 people.

The new requirements pose many significant technical challenges. Since the passage of the CPSIA, the Commission's technical staff has had to verify testing methods for total lead in metallic substrates. The staff has also been working diligently to validate testing methodologies for lead in plastics and other organic substrates to meet the lead content requirements of section 101 of the CPSIA. As soon as those methodologies are confirmed, they will be announced publicly. A method for testing for phthalates was identified by staff, but the extremely tight timeframe precluded meaningful public comment and input from the laboratories that will ultimately have to perform the testing. While the x-ray fluorescence screening method for lead has proven a useful tool, there is presently no similar screening method for preliminary testing for phthalates, although several promising ideas are under development. Finding appropriate screening tests for phthalates is essential given the costly and burdensome destructive testing currently required for the chemical analysis measuring phthalate concentrations. Commission staff needs time to work with laboratories to assure uniform understanding of the testing requirements adequate to support certification of compliance. We also need time to educate the numerous businesses, both big and small, for which this expansion of mandatory regulatory requirements is all new.

Smaller businesses that make up a significant portion of companies manufacturing products under the Commission's jurisdiction do not have laboratory test facilities and must turn to outside labs. The testing required to confirm compliance with requirements of the F963 toy standard ranges from chemical tests for antimony, arsenic, barium, cadmium, and chromium in surface coatings to various acoustic measurements for sound producing toys, tests for surface temperatures in battery operated toys, and tests for breakaway features on cords, straps, and elastic, among other things. To enforce certification on February 10, 2009, without the Commission having identified the labs accredited to do such testing disadvantages these small businesses and could result in these businesses paying for testing twice if the accreditation of the laboratory they choose for testing is not later accepted by the Commission. Also, the Commission has not had enough time or resources to educate the craft and handmade toy businesses on these new

standards and testing requirements. While many of the larger manufacturers may already be conducting testing and certification, many smaller companies are only just learning which CPSIA requirements apply to them. Companies cannot test and certify products when it is still unclear to them what standards apply.

apply.
Furthermore, the CPSIA tasks the Commission with issuing a number of additional rules within the first 15 months of enactment addressing testing and certification of compliance of children's products that will help to clarify the responsibilities of importers, manufacturers, distributors, retailers, and testing labs. These include requirements addressing mandatory third party testing to all applicable children's product safety rules 5 due by statute in June 2009, rules addressing auditing of accredited children's product testing laboratories also due in June 2009, and comprehensive rules addressing compliance labeling of consumer products and production testing of children's products subject to third party testing and certification for continued compliance with applicable requirements, including random sampling protocols, required by CPSIA to be issued in November of 2009. These rules will define, among other things, which tests on what products will be required and how frequently those tests will need to be conducted. These answers are needed to ensure that the right tests are run on the right products without unnecessary and expensive testing on products likely to be exempted in some manner by the Commission in the coming months.⁶

The Commission anticipates that when these rules are finalized and our ongoing stakeholder information and education efforts have been in place for sufficient time for the new requirements to become known and understood within the regulated community, implementation of the stayed testing and certification requirements could

move forward by Commission action in orderly fashion supported by sound scientific and technical analysis and determinations. Accordingly, the stay will remain in effect until February 10, 2010, at which time the Commission will vote to terminate the stay. We believe at this time that the stay will give us the time needed to develop sound rules and requirements as well as implement outreach efforts to explain these requirements of the CPSIA and their applicability.

The stay will provide the Commission with the ability to focus in the immediate future on high priority enforcement matters such as those related to cribs, where the Commission has recognized the need for a thorough investigation of what appear to be potentially widespread safety issues (see 73 FR 71570), small parts, and lead in children's metal jewelry. Also, the Commission's technical and scientific staff will be able to focus on areas such as children's wearing apparel and children's books where certain of the pending rulemakings noted above may be able to provide appropriate relief, well in advance of the lifting of this stay, assuming that those industries provide the additional information requested by our staff in a timely manner. Among the children's products issues staff will need to address are bicycles intended or designed primarily for children 12 and under, where spokes and tire inflation valves raise complex issues related to the lead provisions of CPSIA.

Leaving in place the manufacturer, including importer, certification and testing requirements for lead paint, fullsize and non-full-size cribs, pacifiers, small parts, and lead in metal components of children's metal jewelry, where laboratory accreditation requirements have been issued by the Commission will provide a high degree of assurance of safety in children's products manufactured during the pendency of the stay and reflects the priorities attached to those products by Congress in the CPSIA. Also, the Commission emphasizes that the stay only applies to testing and certification, not to the sale of products that do not comply with applicable mandatory safety requirements. All children's products must comply with all applicable children's product safety rules, including, but not limited to, the upcoming limits on lead and phthalates in the CPSIA.⁷ Failure to comply with

⁵ Children's product safety rule means "a consumer product safety rule under this Act [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." CPSA at § 14(f)(1), as amended by CPSIA § 102(b).

⁶ Because of the tremendous burden all of this has placed on the agency, the Commission staff has been unable to respond to questions from businesses small and large on the general certification requirements for all consumer product safety rules and similar rules which went into effect on November 12, 2008. Indeed, several requests for relief from those provisions have not yet been acted upon by the Commission. This stay provides relief from those certification requirements as well but does not provide any defense or excuse for noncompliance with the underlying standards or bans.

⁷ Children's product safety rule means "a consumer product safety rule under this Act [the CPSA] or similar rule, regulation, standard, or ban under any other Act enforced by the Commission,

all applicable product safety rules as defined in the CPSA or similar rules, bans, standards, or regulations under any other Act enforced by the Commission will remain prohibited in accordance with section 19 of the CPSA as amended by CPSIA.

II. The Stay

The United States Consumer Product Safety Commission hereby stays applicability to manufacturers, including importers, of the requirements for testing and certification 8 of products set forth in paragraphs 14(a)(1), (2) and (3) of the CPSA, as amended by subsection 102(a) of CPSIA, with the

exception of:

- (1) The requirements of any CPSC regulation, or of subsection 14(a) of the CPSA as it existed prior to amendment by the CPSIA, for product testing and certification, including existing requirements for certification of automatic residential garage door openers, bike helmets, candles with metal core wicks, lawnmowers, lighters, mattresses, and swimming pool slides; 9 and
- (2) The certifications required due to certain requirements of the Virginia Graeme Baker Pool & Spa Safety Act being defined as consumer product safety "rules;" and
- (3) The certifications of compliance required for ATVs in section 42(a)(2) of the CPSA which were added by CPSIA; and
- (4) Any voluntary guarantees provided for in the Flammable Fabrics Act ("FFA") or otherwise (to the extent a guarantor wishes to issue one); and
- (5) The requirements on manufacturers, including importers, of children's products to use third party laboratories to test and to certify, on the basis of that testing, compliance of children's products with:
- Requirements on the lead content of paint and other surface coatings effective for products manufactured after December 21, 2008;

including a rule declaring a consumer product to be a banned hazardous product or substance. CPSA at § 14(f)(1), as amended by CPSIA § 102(b).

- ⁸ By immediate final rule published November 18, 2008 (73 FR 68,328-32), the Commission limited the testing and certification requirement to importers and U.S. domestic manufacturers.
- ⁹ Prior to amendment by the CPSIA, § 14(a) of the CPSA required testing and issuance of a certification for each product subject to a CPSA consumer product safety standard, namely a product subject any requirement of 16 CFR parts 1201 through 1213, *e.g.*, part 1205 for walk-behind power mowers or part 1211 for automatic residential garage door operators. Certain CPSC regulations themselves require certification of compliance or a statement of conformity. See, e.g. 16 CFR part 1633 for flammability (open flame) of mattresses or 16 CFR 1500.17(a)(13(i)(B) for candles made with metal-cored wicks.

- Requirements applicable to full-size and non-full-size cribs and pacifiers effective for products manufactured after January 20, 2009;
- Requirements concerning small parts effective for products manufactured after February 15, 2009; and
- Requirements on the lead content of metal components of children's metal jewelry effective for products manufactured after March 23, 2009.

This action by the Commission does not stay the requirement that products meet all applicable product safety rules as defined in the CPSA or similar rules, bans, standards, or regulations under any other Act enforced by the Commission.

Dated: February 2, 2009.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E9-2590 Filed 2-6-09; 8:45 am] BILLING CODE 6355-01-P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant a Partially Exclusive Patent License; Intellikine,

AGENCY: Department of the Navy, DoD. **ACTION:** Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Intellikine, Inc., a revocable, nonassignable, partially exclusive license to practice worldwide the Government owned inventions described in U.S. Patent 6,632,789 entitled "Methods for Modulating T Cell Responses by Manipulating Intracellular Signal Transduction" issued 14 October 2003 and related foreign filings in the fields of diagnosis, prevention and/or treatment of disease in humans and/or animals utilizing methods for modulating T cell responses by manipulating intracellular signals associated with T cell costimulation.

DATE: Anyone wishing to object to the grant of this license has fifteen (15) days from the date of this notice to file written objections along with supporting evidence, if any. Written objections are to be filed with the Office of Technology Transfer, Naval Medical Research Center, 503 Robert Grant Ave... Silver Spring, MD 20910-7500, telephone: 301-319-7428.

ADDRESSES: Written objections are to be filed with the Office of Technology Transfer, Naval Medical Research

Center, 503 Robert Grant Ave., Silver Spring, MD 20910-7500.

FOR FURTHER INFORMATION CONTACT: Dr. Charles Schlagel, Director, Office of Technology Transfer, Naval Medical Research Center, 503 Robert Grant Ave., Silver Spring, MD 20910-7500, telephone: 301-319-7428.

Dated: February 3, 2009.

A.M. Vallandingham,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E9–2614 Filed 2–6–09; 8:45 am] BILLING CODE 3810-FF-P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education. **SUMMARY:** The Director, Information Collection Clearance Division. Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before April 10, 2009.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment

ACC Extras

Supplemental resources available on www.acc.com

An Overview of the Consumer Product Safety Improvement Act of 2008. Program Material. 2008

http://www.acc.com/committees/sldc/loader.cfm?csModule=security/getfile&pageid=138284&page=/valuechallenge/relationships.cfm&qstring=startrow=381&title=CPSC%20Overview%20%26amp%3B%20Timetable%20Document