Product Responsibility

It's a Journey
Product Safety Basics

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Agenda

• US Federal Regulations

• Requirements by Product Category

• CPSC’s “Reasonable Testing Program”
CPSC Regulations

- Federal Hazardous Substances Act
- Flammable Fabrics Act
- Consumer Product Safety Act
- Poison Prevention Packaging Act
- Refrigerator Safety Act
- Pool and Spa Safety Act
FDA Regulations

- Food and beverages
- Food contact items
- Dietary Supplements
- Pharmaceuticals
- Cosmetics
- Health and beauty aids
- Household chemicals
2007 - The Year of the Recall
Consumer Product Safety Improvement Act

- Enacted on August 14, 2008
- Applies to all CPSC-regulated consumer products
- Comprehensive overhaul of consumer product safety rules
- Compliance is mandatory
- Third party testing is mandatory for all children’s products
Recalls are down…

- 172 toy recalls in fiscal year 2008
- 50 toy recalls in FY 2009
- 46 toy recalls in FY 2010
- 34 toy recalls in FY 2011
- 38 toy recalls in FY 2012
- 31 toy recalls in FY 2013
Port Stoppages are up…

- CPSC using risk assessment methodology (RAM) pilot targeting system to analyze CBP data and identify high-risk shipments of consumer products arriving at U.S. ports of entry, and then make calculated and effective decisions about which shipments to inspect.
Commercial Targeting and Analysis Center

- CBP hosts 10 federal agencies at the CTAC:
  - FWS
  - CPSC
  - NOAA
  - HSI
  - NHTSA
  - FDA
  - PHMSA
  - EPA
  - APHIS
  - FSIS

- Partner agencies have signed a collective Memorandum of Understanding to share information and systems access

- Other appropriate federal agencies may be added to CTAC in the future
CPSC Letters of Advice

• Sent to firms with a regulatory violation
• Remedies vary:
  – Seizure most common, if it’s a repeat offender and product cannot be reconditioned
  – Correct future production
  – Stop sale and correct future production
  – Distribution level recall
  – Retail level recall
  – Consumer level recall
• Informed Compliance inspections
Common Import Violations/Defects

- Children Products
  - Tracking labels
  - Certifications
  - Lead(content)
  - Phthalates
  - Small parts
  - Lead(paint)
  - Toy standard
  - Art materials labeling

- Non-Children Products
  - Fireworks
  - Hair dryers
  - Holiday lights
  - Cigarette & multi-purpose lighters
  - Bicycle helmets
  - Certifications
  - Luminaries
  - Mattress flammability
  - Extension cords
CPSIA Overview

Section 101 – Children’s Products Containing Lead; Lead Paint Rule

Section 102 – Mandatory Third Party Testing and Certification for Certain Children’s Products

Section 103 – Tracking Labels for Children’s Products

Section 105 – Labeling Requirements for Advertising Toys & Games

Section 106 – Mandatory Toy Safety Standards

Section 108 – Prohibition on Sale of Certain Products Containing Specified Phthalates
Definition of a Children’s Product

• A children’s product is defined as a consumer product primarily intended for children 12 years of age or younger
CPSIA Factors to Consider

- A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.

- Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger.

- Whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger.

- The Age Determination Guidelines issued by CPSC staff (http://www.cpsc.gov/BUSINFO/adg.pdf)
Other Factors to Consider

- Size and Shape
- Materials Used
- Number of Parts
- Motor Skills Required
- Classic Product
- Colors
- Cause & Effect
- Sensory Elements
- Level of Realism & Detail
- Licensing & Theme
Challenges of Promotional Product Industry

- Products are often intended for use by adults, given out at trade shows and workplaces, but end up in the hands of children.

- How to determine whether a product is a general consumer product or a children’s product, especially if producing just the blank?

- Who bears the responsibility for determining if a product is a children’s product?
Section 101
Children’s Products Containing Lead; Lead Paint Rule
Lead Paint Rule

Ban of Lead-Containing Paint

• 16 CFR 1303 in effect since 1978 at 600 ppm

• As of August 14, 2009, sets limit at **90 ppm**

  » Compliance is required
  » GCC/CPC is required
  » Can test at ink stage, must have “traceability”
  » Third party testing is required
  » Composite Testing is allowed
  » Wet paint can be tested
  » HD XRF test method allowed
Children’s Products Containing Lead

• A **substrate** is the material of which something is made, and to which surface coating (i.e., paint) may be applied

• As of August 14, 2011 - 100 ppm limit

  » Compliance is required
  » GCC/CPC is required
  » Component testing is allowed, must have “traceability”
  » Third party testing is required
  » Composite Testing of ‘like materials’ is allowed
  » XRF test method allowed
Material Testing Exemptions

- Pure Wood (not plywood or other composites)
- Paper
- CMYK printing inks
- Certain precious and semi-precious gemstones
- Pearls
- Stainless steel
- Precious metals
- 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
- Manufactured fibers (dyed or undyed) including, but not limited to: rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, and spandex
Section 102
Mandatory Third Party Testing for Certain Children’s Products
General Conformity Certification

• As of January 1, 2012, third party testing is required on essentially all children’s products and tests
  » See www.cpsc.gov for approved laboratories

• Certification is responsibility of Importer (if produced outside US) or Domestic Manufacturer

• Applies to consumer products covered by CPSC-enforced regulations

• Suggested format of GCC/CPC on CPSC website
Requirements for GCC / CPC

1. Identification of the product covered by this Certificate
2. Citation to each CPSC product safety regulation to which this product is being certified
3. Identification of the US importer, if applicable, or domestic (US) manufacturer certifying compliance of the product
4. Contact information for the individual maintaining records of test results
5. Date and place where this product was manufactured
6. Date and place where this product was tested for compliance with the regulation(s) cited above
7. Identification of any third-party laboratory on whose testing the certificate depends
Section 103
Tracking Labels for Children’s Products
Tracking Label Requirement

Permanent, distinguishing marks on product (to the extent practicable) and packaging manufactured as of August 14, 2009

- Required for all children’s products, both imported and domestically manufactured

- Basic information required:
  » Manufacturer or private labeler name
  » Location of production
  » Date of production
  » Other tracking information (batch, run number, sources)
Tracking Labels

- The CPSC has not issued firm direction on:
  - What is meant by “to the Extent Practicable”
  - The size and location of the label
- The Federal Care Labeling rules can be a guide on what is practicable labeling
- When evaluating your labeling, the CPSC will consider the reasonableness of your marking/labeling decision and consider the practices of your peers.
- Therefore, markings on hangtags or adhesive labels do not meet the “permanent” requirements.
Tracking Labels for Promotional Products

- Supplier should include tracking label information on the blank
- Depending on changes made to the supplier’s product, distributor may need to include additional tracking label markings

*Tracking labels are a key area for CPSC Compliance focus, and are evaluated during port surveillance.*
PPAI Tracking Label System

• PPAI has developed an electronic system for maintaining the tracking label information with a URL code on the product and packaging itself.

• Additional details on this system are available through PPAI.

• Compliant with CPSIA Tracking Label requirement
Section 105
Labeling Requirements for Advertising Toys and Games
Labeling Requirements

• Applicable to both Internet and Catalogue sales where there is direct means for consumer purchase

• Any required cautionary statement under FHSA must be present (16 CFR 1500.19):
  » Small Parts
  » Small Balls
  » Marbles
  » Balloons
Section 106
Mandatory Toy Safety Standards
ASTM F963

- ASTM F963 has long been technically-voluntary industry standard
- Adopted by CPSC as mandatory CPSC safety standard
- ASTM F963-11 compliance is mandatory
  » ASTM committee will continue to update
  » CPSC participates on ASTM committee
- Third-party testing for ASTM F963 compliance required as of January 1, 2012
Section 108
Prohibition on Sale of Certain Products Containing Specified Phthalates
Phthalates

Applies only to Children’s Toys and Child Care Products

• For all such products, DEHP, DBP, BBP – limit of 0.1%

• For all such products or any part of the product that can be placed in a child’s mouth: DINP, DIDP, DnOP – limit of 0.1% (interim prohibition)

• Applies to accessible materials only (before and after use and abuse testing)
Phthalates may be found in following materials:

- Soft or flexible plastics, except polyolefins
- Soft or flexible rubber, except silicone rubber and natural latex
- Foam rubber or foam plastic such as PU foam
- Surface coatings, non-slip coatings, finishes, decals, printed designs
- Elastic materials on apparel, such as sleepwear
- Adhesives and sealants

Phthalates would not likely be found in the following materials:

- Unfinished metal
- Natural wood, except coatings and adhesives added to wood
- Textiles, except printed decorations, waterproof coatings, elastic
- Mineral products such as sand, glass, crystal
Proposed Rulemaking - Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates

• The proposed rule would establish a new regulation on the use of specified phthalates in children’s toys and child care articles.

• Section 108(a) of the CPSIA permanently prohibited the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any “children's toy or child care article” that contains concentrations of more than 0.1 percent of DEHP, DBP and BBP.

• The proposed rule would expand the list of permanently banned phthalates for any “children's toy or child care article” to include any of the following phthalates containing concentrations of more than 0.1 percent, computed individually: DINP and DIBP (both interim banned) and DPENP, DHEXP and DCHP (newly added based on CHAP report).
CPSC Small Batch Manufacturers Registry

• Small batch manufacturers are defined as those who
  » Earned $1 million or less in total gross revenues from sales of all consumer products in calendar year, and
  » Produced in total no more than 7,500 units of at least one consumer product in calendar year

• Registry was launched on December 23, 2011 through the Business Portal of SaferProducts.gov

• Qualifying small batch manufacturers are exempted from certain third party tests; however

• ALL PRODUCTS MUST COMPLY WITH ALL MANDATORY STANDARDS
Registered Small Batch Manufacturers

GROUP A
Must 3rd Party Test
• Lead in paint
• Cribs
• Small parts
• Lead in children’s metal jewelry
• Most durable nursery products

GROUP B
Not Mandatory To Test
• ASTM F963
• Lead Content
• Phthalates
• Bunk Beds
• Wearing apparel
• Rattles
• Others…
Requirements by Product Category
Promotional Product Categories

- Apparel
- Houseware/Drinkware
- Writing instruments
- Electronics
- Jewelry
- Luggage/bags
Additional Considerations

- Seam strength/slippage
- Bursting/tensile strength
- Fabric construction/weight
- Pilling resistance
- Colorfastness of dyes

- Drawstrings are a Substantial Product Hazard!

*BonTon paid $450,000 civil penalty*
Housewares/Drinkware

Federal Regulatory Requirements (FDA)

- 21 CFR – applicable extraction dependent on material
- FDA Guidelines 545.400 & 545.450 – ceramicware
- FDA ban on use of PC in infant bottles/spill proof cups
Additional Considerations

- ASTM C927 – Lip & Rim
- Massachusetts Total Immersion Test
- California Tableware Safety Law
- California Proposition 65

Potential Concerns
- Dishwasher/Microwave compatibility
- Heat retention
- Lid fit and leakage
- Stain resistance
- Breakage
Writing Instruments

Federal Regulatory Requirements

LHAMA, ASTM D4236

- Applies to art materials (crayons, colored pencils, etc.)
Additional Considerations

- Crayons – ANSI Z356.1
- WIMA Voluntary Certification Programs
- Quality tests

Potential Concerns

- Pen cap airflow (BS 7272)
- Lead content in surface coatings
Electronics

Federal Regulatory Requirements

- FCC requirements
- Mercury-containing Battery Management Act
Additional Considerations

- UL standards
- Performance
- California Proposition 65

Potential Concerns
- Battery leakage
- Overheating
- Battery accessibility
Jewelry

Federal Regulatory Requirements

- Adult Jewelry – 16 CFR 23
- Children’s Jewelry – CPSIA Lead Content
Additional Considerations

State regulations (CA, IL, VT…)
  • Not just metal components
  • Not just children’s jewelry

ASTM F2923-11 for Children’s Jewelry
  • Mandatory in Rhode Island

ASTM F2999-13 for Adult Jewelry

Potential Concerns
  • Definition of jewelry
Luggage and Bags

Federal Regulatory Requirements

None!! …for adult items
  • Unless intended to hold food (FDA)

For children’s bags, standard CPSIA requirements apply
Additional Considerations

- Performance
- State restrictions

Potential Concerns
- Plastic bag suffocation warning
- Plastic sheet thickness
- Cords on bags
Test Reports

• Get copy of actual test report

• Test report should identify your product

• Testing should have been performed within the past 12 months

• Testing should be done by an independent third party laboratory
  » Must be CPSC-recognized lab if children’s product

• Test report should list applicable tests

• Test report should include actual test result
PPAI Ink Supplier Testing Guidelines and General Protocol

• Ink Suppliers are encouraged to perform annual testing
  » Pre-certified inks can reduce redundant testing
  » Drive business to ink suppliers with pre-certified inks

• Testing must be performed on inks that are exact composition as used on finished product

• Must be traceability of wet ink to finished product

• Applicable test requirements include Total Lead
  » Soluble Heavy Metals and Phthalates for certain products
Undue Influence Training

Presented by
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Purpose

• Establish protocols and standards for ensuring continued testing of children’s products
• Material change requirements
• **Safeguards against exercise of undue influence**
• Establish program for labeling of consumer products
Testing and Labeling Pertaining to Product Certification

- Codified in 16 CFR 1107
- Effective Date: February 8, 2013

Certification of Children’s Products
  - 1107.20 – General Requirements
  - 1107.21 – Periodic Testing
  - 1107.23 – Material Change
  - 1107.24 – Undue Influence
  - 1107.26 – Recordkeeping

Consumer Product Labeling Program (1107.30)
CPSC’s “Reasonable Testing Program”
General Requirements – Certification Testing

• Third party testing by CPSC approved lab is mandatory on all children’s products to support Certification

• Manufacturers must submit a sufficient number of samples for testing. Number of samples must be sufficient to provide a “high degree of assurance” that the tests accurately demonstrate the ability of the product to meet all applicable safety rules

• Corrective Action Plan: If sample fails Certification testing, manufacturer must investigate reasons for failure and take necessary steps to address the reasons for failure
Periodic Testing

• Must be performed by CPSC approved third party lab at appropriate testing intervals

• Manufacturers must develop a Periodic Testing Plan to ensure “high degree of assurance” in continued compliance. Periodic Testing Plan must include:
  » Tests to be conducted
  » Intervals at which the tests will be conducted
  » Number of samples tested

• At a minimum – Certification testing must be performed once a year… with certain exceptions
  » Material Changes require more frequent testing
  » Certification testing may be performed at least once every 2 years if manufacturer implements a Production Testing Plan
  » Certification testing may be performed at least once every 3 years if Production Testing Plan includes testing by ISO17025 lab
Production Testing Plan

- Production management techniques and tests performed to provide a “high degree of assurance” in continued compliance.

- May include:
  - Recurring testing (must include some testing)
  - Use of process management techniques
    - Control charts
    - Statistical process control programs
    - Failure modes and effects analyses (FMEAs)

- Documentation must include:
  - Description of the Production Testing Plan
  - Specific to each manufacturing site and each children’s product
  - Production testing intervals must provide “high degree of assurance”
Testing Plan Best Practices

- Ensure you follow appropriate sample selection protocols
- Do not test “golden samples”
Material Change
Material Change

• Any change in product’s design, manufacturing process, or sourcing of component parts, tooling or manufacturing facility that could affect the product’s ability to comply with applicable rules, bans, standards, or regulations

• Requires additional Certification testing in order to certify compliance of the ‘new’ product

• Testing dependent on the material change
Undue Influence
What is undue influence?

- Undue influence occurs when one party uses his/her position to influence the other party to gain some advantage.

- Pressure is typically exerted through persuasion rather than coercion.
Why worry about it?

- Undue influence may result in **undermining the integrity of testing data** that can result in defective products that **may injure or kill consumers**, bring **liability to the company** and cause **loss of business**.
What is undue influence training?

- Training to ensure that manufacturers and their employees do not exert undue influence on testing laboratories to alter test methods or test results that serve as the basis for certifying a product’s compliance under federal law.

- CPSC does not provide a model undue influence training course.
Undue Influence

Each manufacturer must establish procedures to safeguard against the exercise of undue influence by manufacturer on a third party lab

- **Written policy** statement from company officials that the exercise of undue influence is not acceptable

- Every **appropriate staff member must receive training** on avoiding undue influence and sign a statement attesting to participation in the training

- Retraining is required for any substantive changes

- **Notify the CPSC** immediately of any attempt by the manufacturer to hide or exert undue influence over test results

- **Inform employees** that allegations of undue influence may be reported confidentially to the CPSC, and how such a report can be made
Written Policy

• This policy should not only satisfy the rule, but also accentuate to staff its importance to the company

• Make the written undue influence policy visible and available to customers and the public

• Consider including the policy in the company code of conduct
Training

• All employees who interact with testing labs must undergo training to ensure that no one engages in actions or makes statements that will be considered undue influence.

• If the undue influence policy changes, all employees must be retrained.

• A digital signature or other electronic attestation (such as a check box), indicating that an employee took the training as part of software or online training, would meet the requirement to “sign a statement attesting to participation in such training.”
Obligation to Exercise Due Care

• Applies to each domestic manufacturer or importer of a children’s product.
  – The importer is **not required to train employees of foreign manufacturers**, but must be sure to exercise due care.

• **Train your factories in your policy** and advise them that their acts of undue influence on labs may cause you to rely on their supplied test reports for CPCs that can be deemed invalid by the CPSC and bring liability to you as the “certifier” for failing to exercise due care in preventing undue influence in your supply chain
  – If the importer receives a test report that is the result of undue influence, the CPSC could **deem the certificate invalid** and the CPSC may **hold the domestic manufacturer/importer responsible** for failing to exercise due care
Reporting

• If you witness or are aware of what you believe is an incident of undue influence, it is your responsibility to report it.

• Ideally, you should report it to your immediate supervisor. If you are not comfortable doing so, you may report it to any company officer.

• The CPSC must be notified immediately of any attempt by the manufacturer to hide or exert undue influence over test results.

• For our purposes, any action or statement that undermines the credibility and validity of the testing process used for the certification of children’s products is undue influence.

• If you have any doubt, report it.
Staff Assurances

• Manufacturers **must inform their employees** that allegations of undue influence may be **reported confidentially to the CPSC**, and manufacturers must tell their employees how to make such confidential reports.

• Reports alleging undue influence should be filed with the CPSC Office of the Secretary.

• You may report incidents of undue influence confidentially directly to the CPSC:
  
  U.S. Consumer Product Safety Commission  
  4330 East West Highway  
  Bethesda, MD 20814  
  301.504.7923 or 800.638.2772  
  www.cpsc.gov
When Undue Influence Occurs

• Employees who have engaged in undue influence should be disciplined in accordance with the company’s policy for employee disciplinary actions

• Discipline may range from a written or verbal warning up and including termination of employment
Best practices to avoid unduly influencing a third party lab

• Don’t threaten to change third party testing providers because of an unsatisfactory test report

• Avoid developing personal relationships with the lab that could somehow influence test results
Recordkeeping
Recordkeeping

Manufacturer must maintain the following records:
• Copy of Children’s Product Certificate (CPC) for each product
• Records of each third party certification test
  » Separate CPC’s and test records required for each manufacturing site
• Records of appropriate periodic tests
  » Periodic test plan and periodic test results
  » Production testing plan, production test results, periodic test results
  » Testing results of tests conducted by ISO 17025 testing lab and periodic test results
• Descriptions of all material changes, and the Certification tests related to these changes
• Records of undue influence procedures, including training materials and training records/attestations

Records must be maintained for 5 years, and made available to CPSC upon request.

Records may be maintained in languages other than English if they can be provided immediately to CPSC and translated accurately into English by manufacturer within 48 hours of a request.
Consumer Product Labeling Program
Consumer Product Labeling Program

- Label must be visible and legible

- Product must comply with all applicable rules, bans, standards and regulations enforced by the CPSC

- Additional labels may be added - Verbiage must not imply that the CPSC has tested, approved, or endorsed the product

MEETS CPSC SAFETY REQUIREMENTS
Product Responsibility Resources

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