

The Consumer Product Safety Improvement Act of 2008

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Agenda

- What Every Product Manufacturer Needs to Know Now
- Litigation Implications
- Global Impact of the CPSIA of 2008: The EU Perspective
- Questions?

Overview

- Introduction
- What All Consumer Product Manufacturers Need to Know Now
- What Manufacturers of Regulated Products Need to Know Now
- What Manufacturers of Children's Products Need to Know Now
- What the Future Holds for Consumer Product Safety Regulation

Introduction

- Consumer Product Safety Improvement Act of 2008
 - Prompted by Toy Recalls in 2007
 - Lead, small magnets were primary issues
 - Lack of tools to stop unsafe imports motivated Congress
- Signed into law on August 14, 2008
- All effective dates in the Statute are measured from this date
 - Many provisions take effect immediately
- Over 40 rulemaking proceedings are required

What All Product Manufacturers Need to Know Now

- Significant increases in penalties for violations of CPSA and sister Acts
- New prohibited acts
 - Improper definition of scope of a recall
 - Ban on sale of recalled products
- Increased restrictions on export of recalled products
- New authorities granted to State Attorneys General
- Changes to public disclosure provisions
- Recall details – increased supervision
- Whistleblower protection

Increased Penalties

- Civil penalties increased to \$100,000/violation and \$15 million/related series of violations
 - Previous penalties were \$5,000/violation and \$1.8 million for a related series of violations
- Criminal penalties increased to felony level (5 years imprisonment and commensurate fine)
 - Previous penalties were misdemeanor level
 - Previously, notice required from Commission before criminal liability could be established

What Gives Rise to a Penalty?

- Most penalties are assessed in one of the following two categories:
 - Sale of a noncompliant product
 - Late reporting of a substantial product hazard or unreasonable risk of serious injury or death
- Noncompliance is generally straightforward
- What constitutes “late reporting” is ***more subjective***

Late Reporting of a Substantial Product Hazard

- Law requires “immediate” reporting under Section 15 of the CPSA when a “substantial product hazard” may be present
 - Regulations allow 10 business days for internal investigation

What is a “Substantial Product Hazard”?

- “Substantial Product Hazard” –
 - a product containing a “defect” which creates a “substantial risk of injury”
 - Not limited to serious injuries
 - A product that fails to comply with an applicable rule or ban
- Reporting also required when information supports conclusion that product creates an “unreasonable risk of serious injury or death” – even when no defect has been identified

Substantial Product Hazard Reporting

- Factors for consideration
 - Pattern of defect
 - Is the problem a random, isolated event? Or not?
 - Number of products in the marketplace
 - Even minor injury risk can trigger reporting obligation if product is widely sold
 - Severity of the risk
 - Severe injury risk is ordinarily reportable immediately, even if exposure is low

What Is A “Defect”?

- “Defect” has its normal meaning
 - Fault, flaw, irregularity, failure to meet specifications
 - Can be an inherent “design defect”
 - Even if product is performing as intended
 - Can be a manufacturing flaw
 - Can be inadequacy in instructions or warnings

What is an “Unreasonable Risk of Serious Injury or Death”?

- Factors to decide if risk is “unreasonable”
 - Utility of product (or relevant component)
 - Level of exposure to consumers
 - Nature/severity of hazard
 - State of the art/competitive performance
 - Availability of alternative designs
 - Feasibility of eliminating risk without compromising utility

What is a “Serious Injury”?

- “Serious” injuries:
 - Hospitalization requiring actual medical treatment
 - Fracture
 - Stitches
 - Concussion
 - Eye, ear, internal injury requiring any medical treatment
 - Injury resulting in more than one day absence from work or school

New Prohibited Acts

- Sale of a noncompliant product
 - Now extends to all CPSC bans and standards
- Sale of a recalled product
 - After CPSC publication of recall notice
- Failure to issue compliance certificate or issuance of false certificate
- Misrepresentation of scope of recall
- Improper influence of third-party lab

Increased Restrictions on Export

- It has long been the case that manufacturers could not lawfully export products that failed to comply with CPSA, FHSA or FFA standards without CPSC permission
- New law adds criteria related to destination country's acceptance of product
- Absent CPSC permission, it remains a prohibited act to export a noncompliant product.

State Attorneys General: Increased Authority

- New law grants expanded authority to State Attorneys General
- State AG's authorized to seek injunctions to enjoin the following violations:
 - Sale of a noncompliant product
 - Sale of a banned hazardous substance
 - Failure to comply with a recall order from CPSC
 - Failure to provide a compliance certificate
 - Issuance of a false compliance certificate
 - Violation of any stockpiling rule
 - Violation of cellulose insulation rule
 - Sale of a product with an unauthorized safety certification mark

State Attorneys General, Continued

- State AGs are not authorized to enforce Section 15 (Substantial Hazard *reporting*)
- State AGs are not authorized to obtain *civil or criminal penalties* under the federal law
- State AGs are authorized to *seek injunctions* to enjoin sale or distribution of products containing “substantial product hazards”

Public Disclosure Provisions and Timelines

- By practice, information designated as “confidential” is protected from disclosure until a FOIA request is filed
 - CPSC will provide notice to manufacturers when FOIA request is filed for information that identifies the firm
- Under previous law, manufacturers had 30 days to submit comments objecting to public disclosure of information that is competitively harmful, unfair or inaccurate
- New law cuts this timeframe to 15 days, and reduces related timeframes in the law

Public Disclosure Provisions, Continued

- Law precludes public release of information submitted under Section 15 except when:
 - The report results in a voluntary recall;
 - The CPSC issues an order for a compelled recall; or
 - The manufacturer consents.
- New law adds a fourth basis for public release: if CPSC publishes a finding that disclosure is necessary for “public health and safety” reasons
- Simplicity crib announcement of late August

Recall Details

- CPSC has new authority to control recall details
 - CPSC can direct details of recall notification
 - CPSC can require “stop sale” notification
 - CPSC can require notice in languages other than English
 - CPSC can require radio and/or television notice
 - CPSC can direct recall remedy
 - Repair, replacement or refund
 - CPSC must now approve corrective action plans in writing and may withhold approval of insufficient plans

Whistleblower Protection

- New law extends substantial whistleblower protection to employees of consumer product manufacturers
- Requires manufacturers to refrain from discharging or discriminating against any employee who gives information about a violation of any CPSC law or standard to a government official
 - Includes good faith belief about a violation
- Provision is very complex

What Manufacturers of Regulated Products Need to Know Now

- What is a “regulated product”?
- General Conformity Certification
- Destruction of Noncompliant Products
- Exports of Noncompliant Products
- Preemption
- ATV Standard

Regulated Products: New Requirements

- Effective November 12, 2008, all regulated products must be certified compliant by their manufacturer
- Certificate must be based on “reasonable test program”
- Certificate must accompany each product or shipment and be furnished to each distributor and retailer
- Imported products lacking certificates will be denied entry to U.S. and may be destroyed

What Is A Regulated Product?

A regulated product:

- A “regulated product” is one covered by a published CPSC regulation, standard or ban
- CPSC has authority to regulate any “consumer product”
- It has issued regulations, standards and bans governing dozens of products
 - Products range from acetaminophen to xylene
- Find whether your product is “regulated” at www.cpsc.gov/businfo/reg1/html

Certificate Requirements

- General Conformity Certificates must:
 - Be in the English language
 - Specify each rule, regulation, standard, or ban applicable to the product
 - Identify the manufacturer or private labeler
 - Name/address/telephone number
 - Specify any third-party lab on whose tests certification is based and date/place of test(s)
 - Name/address/telephone number
 - Specify date/place of manufacture
 - Specify date/place of test (if not third party tested)
 - Specify contact information for person maintaining test records

Certificate Requirements: Open Questions

- It is uncertain whether Importers will be required to issue separate, independent certificates of conformity
- It is uncertain whether assemblers will be permitted to rely on certificates of conformity issued by component suppliers

Destruction of Noncompliant Products

- New law provides for destruction of products denied entry to the U.S. as default rule
 - Exception to destruction permitted if Secretary of Treasury permits export in lieu of destruction

Exports of Noncompliant Products

- New law strengthens prohibition on export of noncompliant products
 - Generally requires CPSC approval to export noncompliant products
 - Generally, approval will not be granted unless destination country has signaled willingness to accept product

Preemption

- Existing law preempts inconsistent state laws governing the same aspect of performance as a CPSC standard, regulation or ban
- New law does not change the scope of preemption except with respect to warning laws established by State laws in effect on 8/31/03
 - Believed to preserve Proposition 65 in California
- New law attempts to prevent CPSC from construing law to preempt tort claims

ATV Standard

- New law makes ATV Standard (ANSI/SVIA-1-2007) a consumer product safety standard
 - Effective April 2009
- New entrants must comply with ATV standard and have an ATV action plan on file with, and approved by, CPSC
- Three-wheeled ATVs are banned unless and until CPSC promulgates a standard applicable to them

What Manufacturers of Children's Products Need to Know Now

- What is a Children's Product?
- Third Party Testing
- Lead Content
- Lead Paint
- Tracking Labels
- Durable Nursery Products
- Advertising (small parts, balloons, etc.)
- Toy Standard
- Phthalates

What Is a Children's Product?

- A consumer product designed or intended primarily for children 12 years of age or younger
 - See *Age Determination Guidelines* of September 2002
- Durable Nursery Product: Under age 5
- Toy/Game Advertising Rules: Under age 6
- Phthalates: Toy (12 or under) or child care article (3 and younger)
- Toy Standard: 14 and under

Third Party Testing

- Children's products are required to have third party testing to confirm compliance with all CPSC regulations, standards and bans
- Third party labs must meet CPSC accreditation guidance
 - CPSC is relying on ILAC standards
- Effective dates are 90 days after CPSC publication of accreditation standards

Lead Content

- Children's products must have no more than 600 ppm of lead content by weight as of February 10, 2009
 - CPSC General Counsel has confirmed by written opinion that this provision bans **retail sale** of nonconforming products as of 2/10/09
- Limit drops to 300 ppm as of August 14, 2009
- Limit drops to 100 ppm as of August 14, 2011
- Inaccessible lead excluded
 - Regulation giving guidance within one year
- Electronic devices (e.g. batteries) may be excluded by rule

Lead Paint

- Current law
 - Maximum of 600 ppm of lead in paint and coatings in children's products
- Limit drops to 90 ppm effective August 14, 2009
- Third party testing of children's products required for products manufactured as of December 21, 2008

Tracking Labels

- Effective August 14, 2009, Children's products must have permanent marks on the product and its packaging showing:
 - Location and date of production of product
 - Cohort Information (batch, run, etc.)
 - Identification of manufacturer or private labeler

Durable Nursery Products

- Registration cards required
 - Effective after CPSC rulemaking
 - Rulemaking required within one year
 - Data can be used only for recalls or safety alerts
 - Must be physically attached to product
- Substantive standards
 - CPSC must adopt voluntary standards or more stringent standards for “durable nursery products” starting in August 2009

Durable Nursery Products, continued

- Durable Nursery Products are defined to include the following:
 - Cribs (full-size and non-full-size)
 - Toddler beds
 - High chairs, booster chairs and hook-on chairs
 - Bath seats
 - Gates and other enclosures for confining a child
 - Play yards

Durable Nursery Products, continued

- Durable Nursery Products, continued
 - Stationary activity centers
 - Infant carriers
 - Strollers
 - Walkers
 - Swings
 - Bassinets and cradles

Advertising: Catalogs and Internet

- Children's products subject to special rules for small parts, balloons, small balls and marbles
- Manufacturers are required to ensure that advertising on Internet or in catalogues contains warnings about any small parts, aspiration hazards, etc.
- Effective December 12, 2008 for advertisements on Internet
- Effective February 10, 2009 for catalogues and printed materials

Toy Standard

- ASTM 963 becomes a Consumer Product Safety Standard on February 10, 2009
 - Contains many requirements that are not otherwise part of CPSC regulations
- CPSC must conduct rulemaking within one year to determine whether to adopt more stringent standards for certain toys

Phthalates

- Children's toys or child care articles must not contain more than 0.1 percent of certain specified phthalates as of February 10, 2009
 - Prohibited phthalates: DEHP, DBP, BBP
 - Interim prohibited phthalates: DINP, DIDP, DnOP
- CPSC may allow resumed use of interim prohibited phthalates after rulemaking

What the Future Holds for Consumer Product Safety Regulation

- CPSC rules or guidance on “reasonable testing program” for general conformity certification
 - May specify sample sizes; testing frequency
- Establishment of Public Consumer Product Safety Database
 - August 2010
 - Includes “Reports of Harm” received from public or third-party professionals (e.g., state agencies, child service providers)
 - Includes Recall Documents

What the Future Holds for Consumer Product Safety Regulation, Continued

- Single-product issues: standards or other action likely
 - Portable power generators
 - Charcoal briquettes (labeling)
 - Carbon monoxide detectors
 - Smoke alarms (public awareness campaign)
 - Cigarette lighters
 - Equestrian helmets
 - Garage door entrapment
 - Lead in ceramic products within CPSC jurisdiction
 - Toys intended for use by household pets
 - Large appliances (tipping hazards)

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- Global Impact of the CPSIA of 2008: The EU Perspective
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Overview

- You need a recall/crisis team in place now
- New CPSC role approving recalls will have litigation impacts
- New role for state AGs could have a significant impact on retailers and manufacturers
- Changing landscape for global recalls

Litigation Implications

- **You need a recall/crisis team in place now**

- Increased regulatory action and public attention necessitates that companies are well prepared to act on a short time frame
- What you do in the investigation/reporting stage will impact any future litigation
- Personnel and roles should be clearly defined
- Try to anticipate litigation impacts, privilege issues, legal hold/preservation concerns, etc.

- **Communication is important**

- Given reporting requirements and dramatically increased fines, information about non-compliance must flow up-stream quickly
 - Develop in-house processes
 - Change post-sale surveillance/analysis?
- CPSC obligation to cooperate re: maintaining privacy but you should assume that whatever information you share will be discoverable and may become public

Litigation Implications

- **CPSC role approving recalls will have litigation impacts**
 - CPSC must approve all recalls/corrective action plans
 - May delay company action which could adversely impact future litigation
 - CPS can direct recall remedies
 - Retail ban after recall can create significant timing problems
- **New role for state AGs could have a significant impact on retailers and manufacturers**
 - CPSCA limits authority, but State AGs may seek to enjoin the sale or distribution of products containing “substantial product hazards”
 - May create lowest common denominator effect – the most aggressive AG controls the standard for the nation
 - Will likely face competing state legislation
 - Must be prepared to act quickly (e.g., new lead regulations)

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- The EU Regulatory Framework
- Differences Between the EU and US Systems
- Recent Product Safety Trends in the EU
- Handling Global Recalls
- International Impact of the New US Products Safety Improvement Act of 2008

The EU Regulatory Framework

- General Product Safety Directive 2001/95/EC (GPSD)
 - Seeks to ensure that only “safe” consumer products can be placed on the EU market
 - Impose a notification obligation on producers and distributors for products which present risks that are incompatible with safety expectations.
 - Applies only to risks not covered by more specific legislation
 - Sets up information exchange systems between Member States for products presenting a risk (RAPEX)
- Directive 85/374/EEC on the Liability of Defective Products
 - Strict liability regime

Differences with the US System

- No centralized EU regulatory body like CPSC
 - Notification and enforcement at Member State level
 - European Commission only has a coordination role
 - No history of heavy fines for lack of reporting or for placing on the market unsafe products
- Virtually no class action; no jury; no contingency fees; no discovery rules, etc.
- Notification based on risk (risk assessment principle) rather than compliance
- Main impact on business = product recalls costs, direct and indirect

Recent Product Safety Trends in the EU

- 2007 voluntary toy recalls highlighted perceived shortcomings in the system, including lack of enforcement
- But no proposals to amend the GPSD or give regulatory powers to the Commission
- Towards a sector specific approach? New notification rules proposed for toys and cosmetics
- Proposed new Toy Directive requires reporting in case of non- “compliance” instead of “risk”. Huge impact in the EU due to many standards if this is copied in other fields
- Commission very active in international dialogue with the USA and China
- Commission initiative to set up collective redress in the EU

Handling Global Recalls

- For products sold globally, producers must address simultaneously regulators in Washington, D.C., Brussels and Beijing (and sometimes other key markets)
- Different regulatory requirements and sensitivities exist which are difficult to reconcile, e.g.
 - US CPSC reporting of non-compliance/confidentiality rules
 - “Made in China” issue limits recall possibilities from China
 - Notification duty in the EU based on risk
- Regulators are aware of the regulatory situation in other regions and are likely to become more critical
- Media picks up issues locally and report globally
- Multinational teams required to handle most recalls

International Impact of New US Law

- Increased CPSC regulatory powers/penalties will likely lead companies to be even more US focused
- EU and other regulatory authorities likely to have to mark their territory vis à vis the US
- New law may give ideas in other regions to strengthen enforcement and reporting rules (e.g. doubt of non-compliance). Hard to fight new proposals if US precedent
- Our advice: Develop contacts with regulators in EU (Commission and local Member State), China and possibly elsewhere to explain issues and gain confidence before the next recall

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