

Product Recalls: Effectively Managing the Process

Product Safety Webinar Series

When Experience Matters®

STEPTOE & JOHNSON LLP

steptoe.com

October 1, 2007

Today's Moderator



James Barnette is a partner in the Government Affairs and Public Policy group in Steptoe's Washington office. He served as General Counsel, counsel, and Deputy Staff Director for the US House of Representatives Committee on Energy and Commerce from 1995-2005. As General Counsel serving under Chairmen Joe Barton (R-TX), Billy Tauzin (R-LA), and Tom Bliley (R-VA), he helped enact over 100 laws, including the landmark Medicare Modernization Act, the Gramm-Leach-Bliley Act, and legislation in areas as diverse as bioterrorism preparedness, energy, telecommunications reform, consumer protection, and e-commerce. He currently focuses his practice on consumer protection, energy, telecommunications, healthcare, and environmental law.

Last Week's Import Safety Webinar

- You can view the slides from last week's webinar, "**Import Safety: Developments on Capitol Hill**" at:

<http://www.steptoelaw.com/news-events-667.html>

Today's Presenters



Tom Barba is a partner in Steptoe's Washington, D.C. office. He has been involved in cases concerning the U.S. Consumer Product Safety Commission for over 22 years, starting when he was Deputy Assistant Attorney General at the U.S. Department of Justice. At Steptoe, Tom has developed the firm's Consumer Products Safety Commission defense practice and has first-chaired scores of recalls for major US companies at the CPSC and the resulting private litigation emerging from those matters. He also helps companies face the challenging decisions on how, when and if to self-report an alleged product defect to the CPSC. As national trial and coordinating counsel for several large US corporations in products matters, Mr. Barba works with company counsel, a network of local counsel he helped develop in all 50 states and around the world, to handle mass tort and products liability litigation.

Today's Presenters



Gwendolyn Prothro is a partner in the Washington office of Steptoe, where she is a member of the Litigation Department. She works on a wide range of product liability matters on behalf of manufacturers, importers, and distributors of consumer products. She has represented clients before the CPSC, filing Section 15 reports, defending against preliminary hazard determinations, negotiating voluntary corrective action plans, and implementing recall programs. She also has extensive experience counseling clients on the development of product safety programs, and working with industry members, associations and the CPSC to update voluntary product safety standards.

Today's Presenters



Jennifer Quinn-Barabanov is a partner in the Washington office of Steptoe & Johnson LLP, where she is a member of the firm's Litigation Department. She helps companies resolve product liability matters that involve inter-connected regulatory, legislative, litigation, and public relations issues. As a litigator, she concentrates on mass torts, class actions, and product liability cases.

Today's Presenters

Dr. Joyce Tsuji is a Principal Scientist at Exponent and the Leader of its Health Sciences Center for Toxicology and Mechanistic Biology. She is a board-certified toxicologist and a Fellow of the Academy of Toxicological Sciences. Her particular areas of interest include exposure assessment and toxicology of a variety of chemicals including those from industrial releases and in consumer products. She has specific experience in design and direction of exposure studies involving health education, environmental sampling, and biomonitoring of populations potentially exposed to lead and other metals in air, soil, water, food, or consumer products. She has been recognized as an expert in metals exposure, toxicology and health risk issues on scientific panels and in testimony to the CPSC and EPA.

CPSC HEADQUARTERS, BETHESDA, MD





US Consumer Product Safety Commission

▶ Consumer Safety

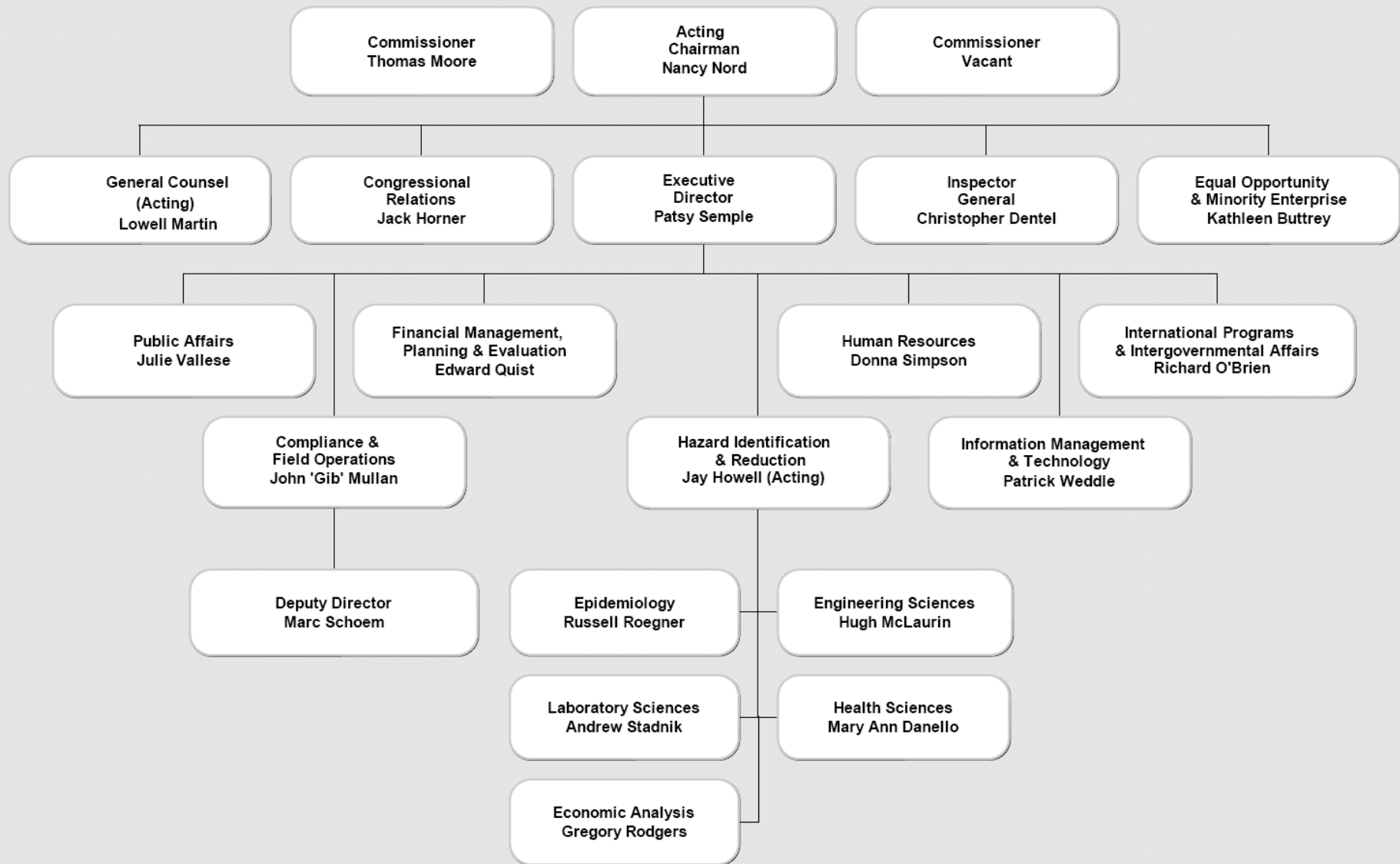
▶ About CPSC

▶ Library - FOIA

▶ Business

- Created by Consumer Product Safety Act in 1972
- Headquartered in Bethesda, MD (Washington suburb)
- Jurisdiction over 15,000 types of products – “consumer products”
- Authority to enforce 5 statutes
 - Focus on the Consumer Product Safety Act
- Enforces its broad safety mandate principally by seeking recalls
 - Less frequently, it promulgates rules or performance requirements

U.S. Consumer Product Safety Commission





US Consumer Product Safety Commission

▶ Consumer Safety

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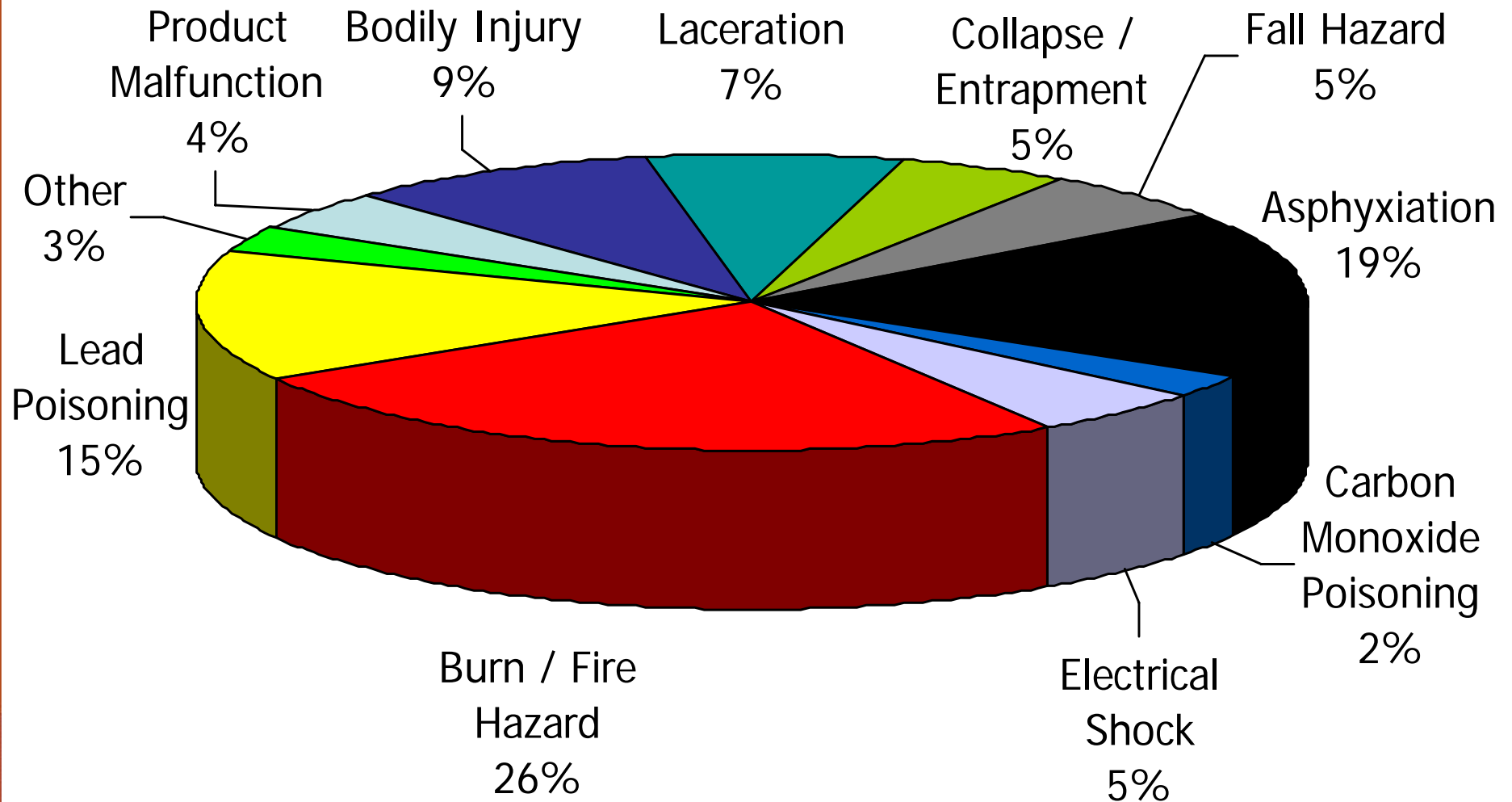
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Design / Manufacture / Distribute Quality Consumer Products

- Product Hazard Analysis
- Product Safety Committee Review (as appropriate)
- Thorough Development Testing
- Compliance with Applicable Standards
- Appropriate Certifications
- Product, Instructions, and Warnings

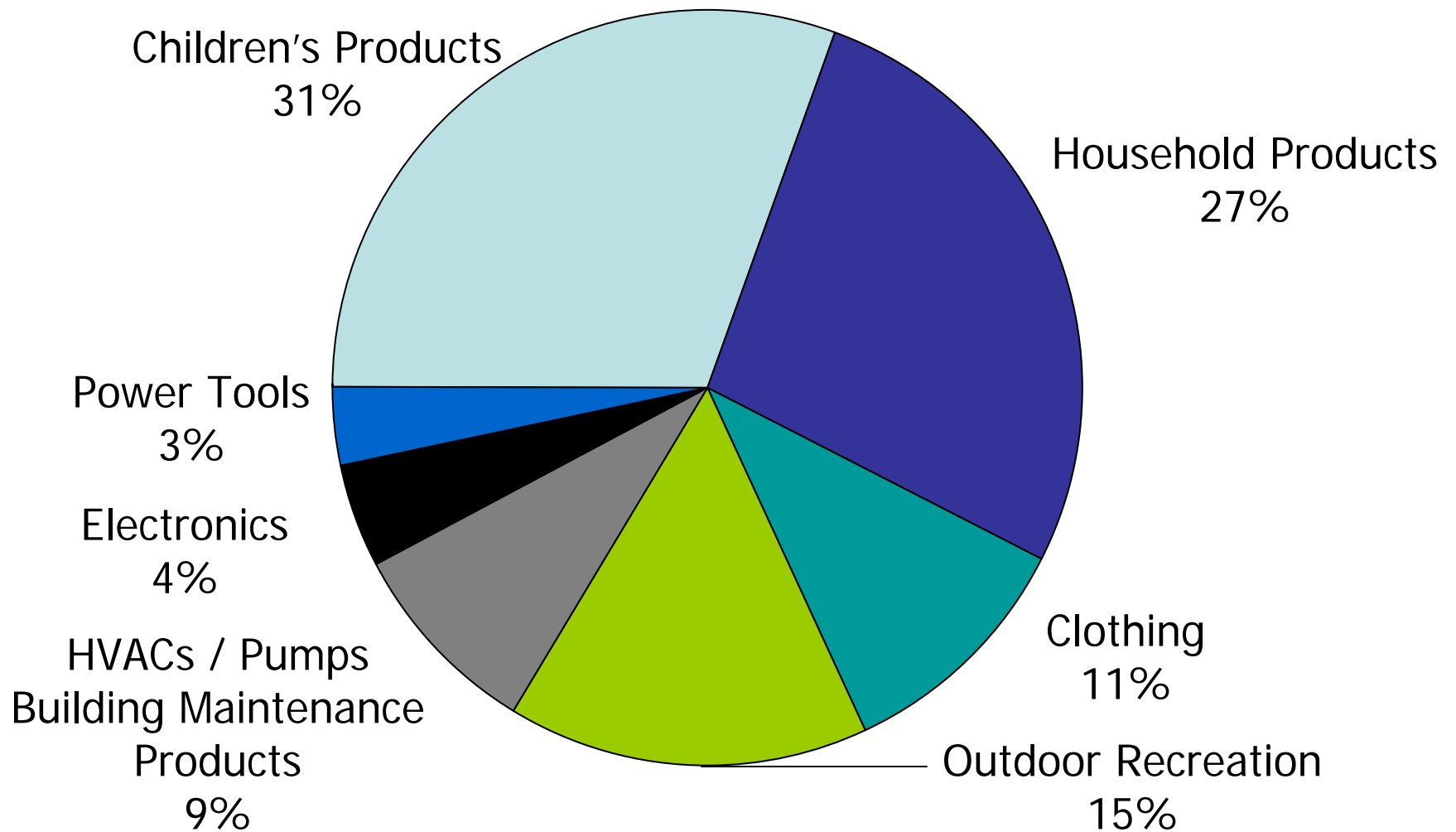
Leading Hazards Addressed

Data compiled from <http://www.cpsc.gov/cpsc/pub/prerel/prerel.html>. Recalls announced between 09/01/2006 and 09/12/2007.



Breakdown of Products Recalled

Data compiled from <http://www.cpsc.gov/cpsc/pub/prerel/prerel.html>. Recalls announced between 09/01/2006 and 09/12/2007.



Manufacturing Defects: The China Phenomenon

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喜

- 15.5 % of all 2006 imports from China
- 86% of all 2006 imports of toys / dolls / games from China
- In the first 8 months of 2007, 82% of all announced recalls involved Chinese products

CPSC Product Priorities

- Frequent or severe injuries.
- High predicted future injuries.
- Unforeseen or unforeseeable risks of injury.
- A vulnerable risk population (e.g., children).
- High probability of exposure to hazard.

CPSC Hazard Priority System

	Very likely	Likely	Not likely but possible
Death	A	A	B
Grievous injury/illness	A	A	B
Serious injury/illness	A	B	C
Moderate injury/illness	B	C	C

CPSC Section 37 Report

The Basics:

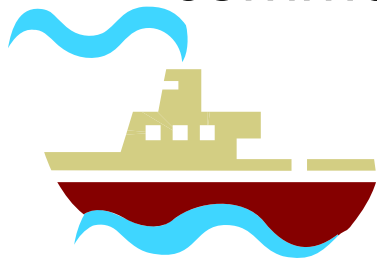
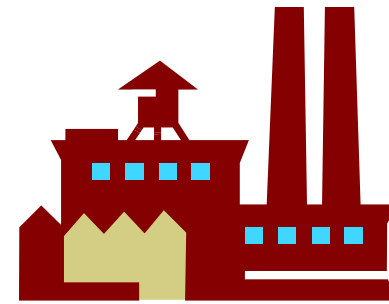
- A manufacturer must report
- Product model subject to 3 or more civil cases
- All alleging death or grievous bodily injury
- In a specified 2-year period, each case that resulted in manufacturer settlement or judgment in favor of plaintiff against manufacturer
- Report within 30 days of last settlement or judgment

SECTION 15 REPORT: CPSC's Favorite Enforcement Tool

- **Who?**

- Every manufacturer,
importer,
distributor, or
retailer

of a consumer product distributed in
commerce.



SECTION 15 REPORT: CPSC's Favorite Enforcement Tool

- **When?**

Within 24 hours of obtaining reportable information on:

- ❑ Product defect could create a substantial risk of consumer injury
- ❑ Failure to comply with an applicable consumer product safety standard, CPSA, or voluntary safety standard upon which CPSC has relied under CPSA
- ❑ Unreasonable risk of serious injury or death

SECTION 15 REPORT: CPSC's Favorite Enforcement Tool

- **What?**

Full report should provide information on:

- ❑ Manufacturer, distributor, et al.
- ❑ The product (quantity, prices, serial numbers, drawings, blueprints, instructions, warnings, dates of manufacture and distribution)
- ❑ Product testing

(cont'd)

SECTION 15 REPORT: CPSC's Favorite Enforcement Tool

- **What?**

Full report should provide information on:

- ❑ Possible defect or risk of injury
- ❑ Incident reports, complaints
- ❑ Distribution chain (number of products in inventory, in pipeline, on retail shelves, in consumer hands, and description of manufacture and distribution process)
- If appropriate, corrective action plan

SECTION 15 REPORT: How do I know if I should report?

- ❑ Testing
- ❑ Industry standards (are they up to date?)
- ❑ Hazard analysis
- ❑ Product safety team review
- ❑ Consumer complaints
- ❑ Incident reports
- ❑ Industry problems



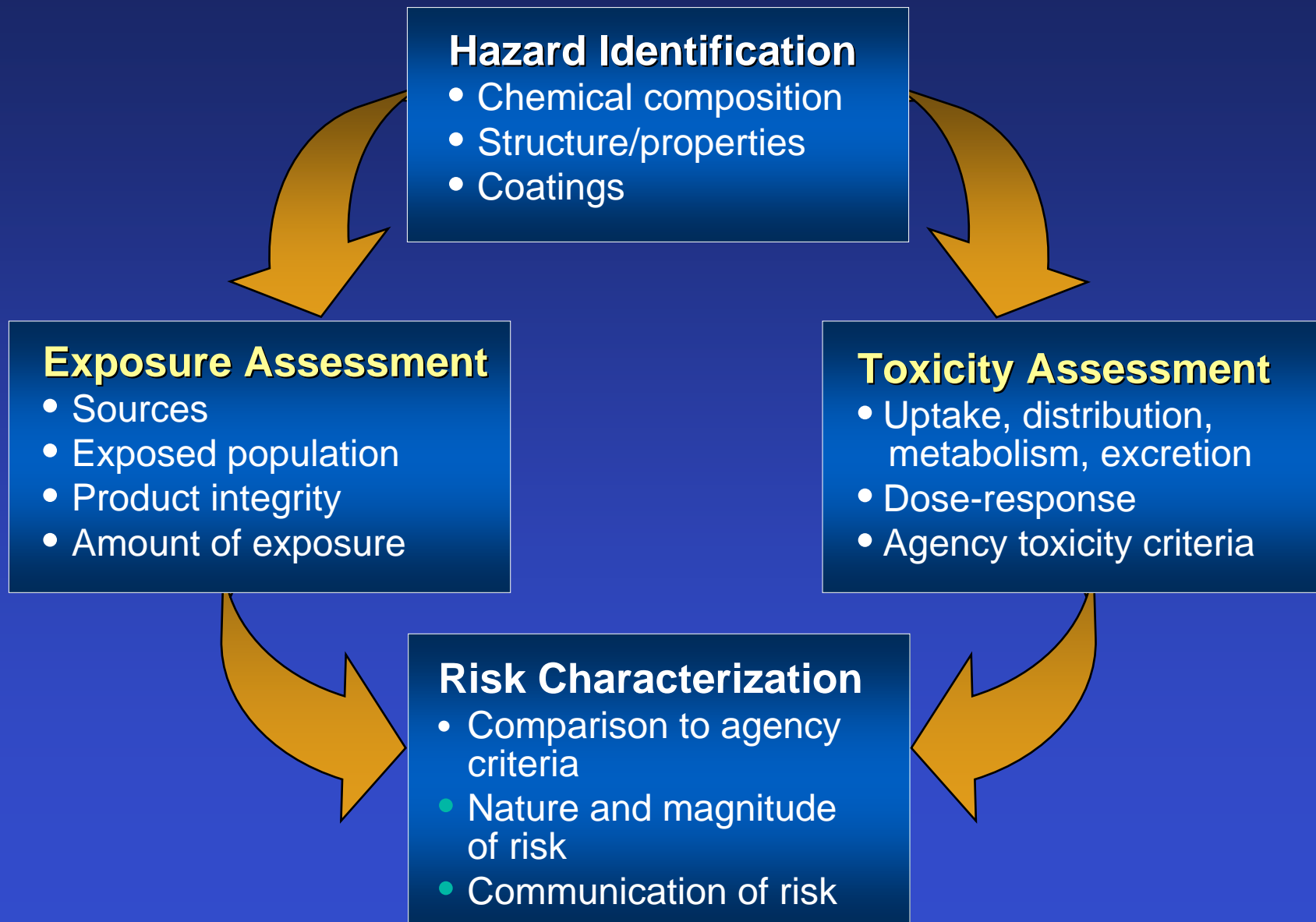
➤ Information flow and data analysis important



Evaluation of Health Risks of Metals in Consumer Products

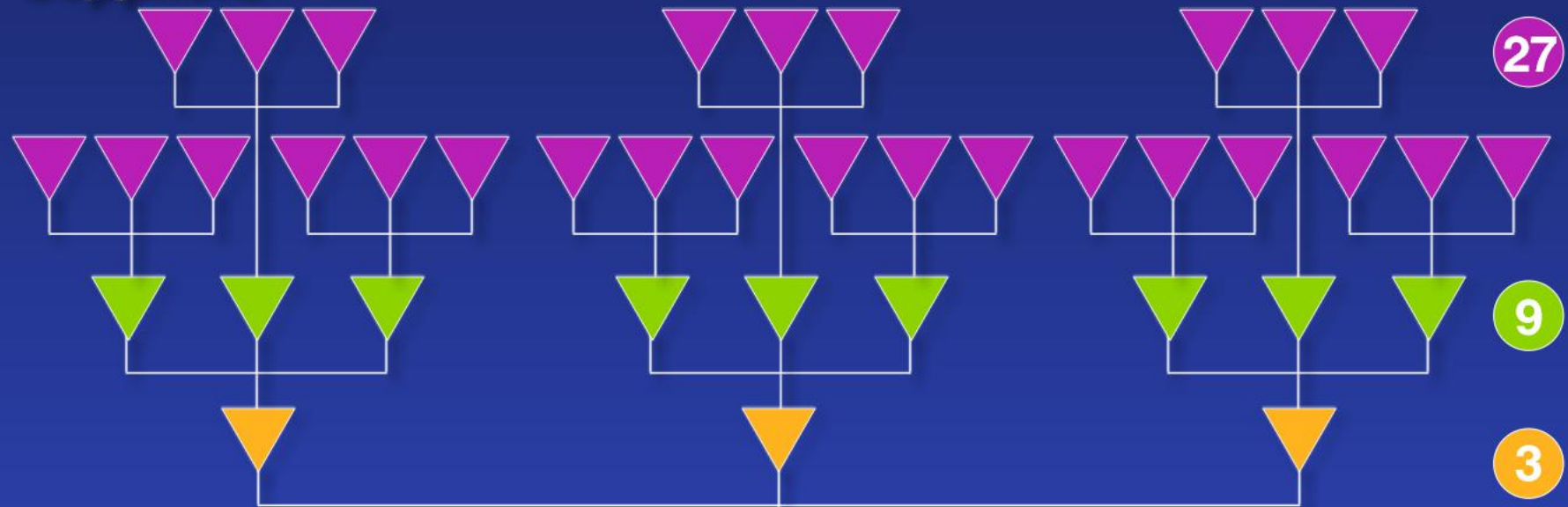
Joyce S. Tsuji, Ph.D., DABT, Fellow ATS
September 28, 2007
Steptoe & Johnson Webinar Seminar

Risk Assessment Framework



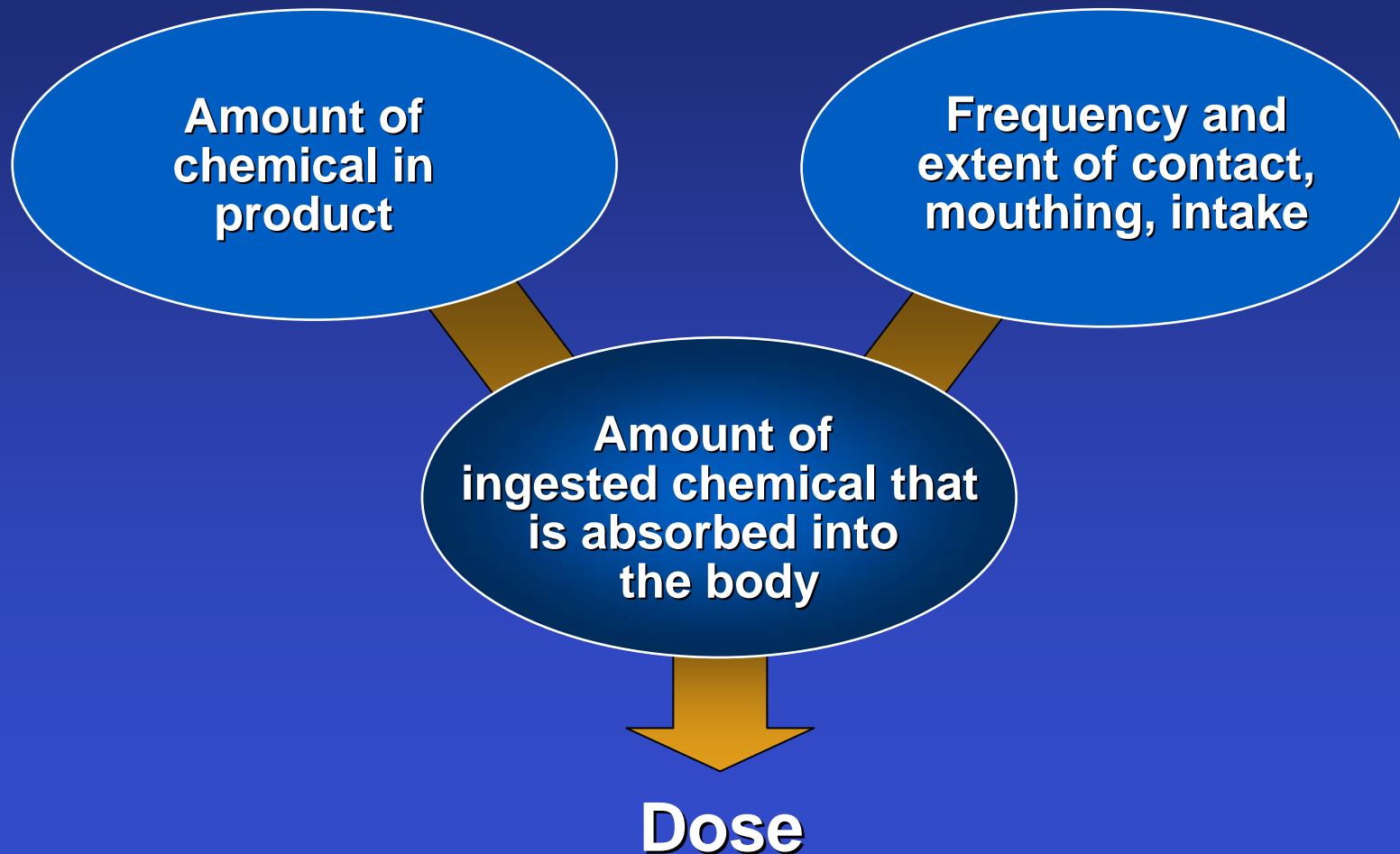
Tracing the Source of Metals in Products

Suppliers



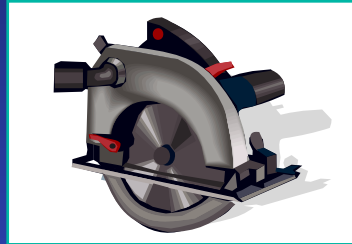
Manufacturer

Exposure: How Much Chemical Gets into the Body?



Type of Product Affects Exposure

- Food containing



- Non-food containing

- Toys or children's products



Measurement of Exposure Depends on the Product

- **Analysis of metal concentration of whole material, surface layer**
- **Wipe sampling for surface dislodgeable metal**
 - Hand-to-mouth exposure
- **Leach testing (especially for lead)**
 - Food contact products—acetic acid
 - Children's products
 - Mouthing—simulated saliva
 - Swallowed—stomach acid

Portable Instrumentation

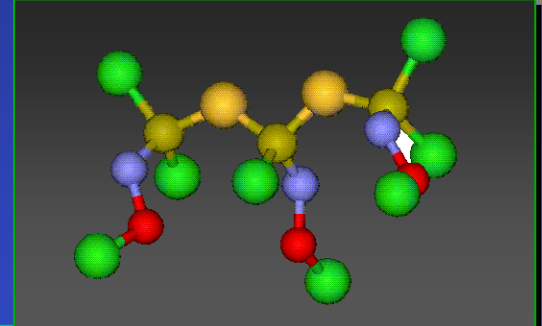
- **Great for metals screening, testing batches, parts of products**
- **Tends to overestimate**
- **Detection limits are higher than laboratory analysis**



Handheld NITON x-ray fluorescence analyzer

Exposure Assessment and Materials Science Evaluation

- **Potential to release metals during**
 - Use
 - Misuse
 - Wear/weathering
 - Removal
 - Disposal



Potential for Health Effects

- **One death of a child attributed to a ingestion of a charm with lead in 2006**
- **Relatively few cases of metal poisoning attributed to non-paint consumer products**
- **Concerns regarding more subtle or long-term health effects**
 - Lead—neurobehavioral deficits in children
 - Arsenic—cancer
 - Cadmium—chronic kidney damage

Basis of CPSC Criteria

- **Lead: blood lead level of $< 10 \mu\text{g/dL}$
Centers for Disease Control screening level**
 - $15 \mu\text{g/day}$ repeatedly^a
 - $175 \mu\text{g}$ one time, acute
- **Cadmium: daily exposure $< 1 \mu\text{g/kg-day}$
EPA chronic reference dose**
 - $9.2 \mu\text{g/day}$ for a 1 year old child^a
- **Arsenic: EPA cancer slope factor^a**

^a CA Prop 65: lead-- $0.5 \mu\text{g/day}$; cadmium— $4.1 \mu\text{g/day}$; arsenic $10 \mu\text{g/day}$; international criteria also may differ

Case-Specific Evaluation: Arsenic in CCA Treated Wood

- **Estimated exposure to arsenic from playing on CCA treated wood is equivalent the amount of inorganic arsenic in a cup of cooked rice**



Conclusions

- **Product uses/misuses determine exposure and thus type of testing**
- **Weathering can affect release of metals from products**
- **Toxicity criteria are based on risk assessment guidelines**
- **Hypothetical risks may also be moderated by background perspective or other information**
- **Reducing metals exposure is prudent given potential changes in future criteria and public perception**

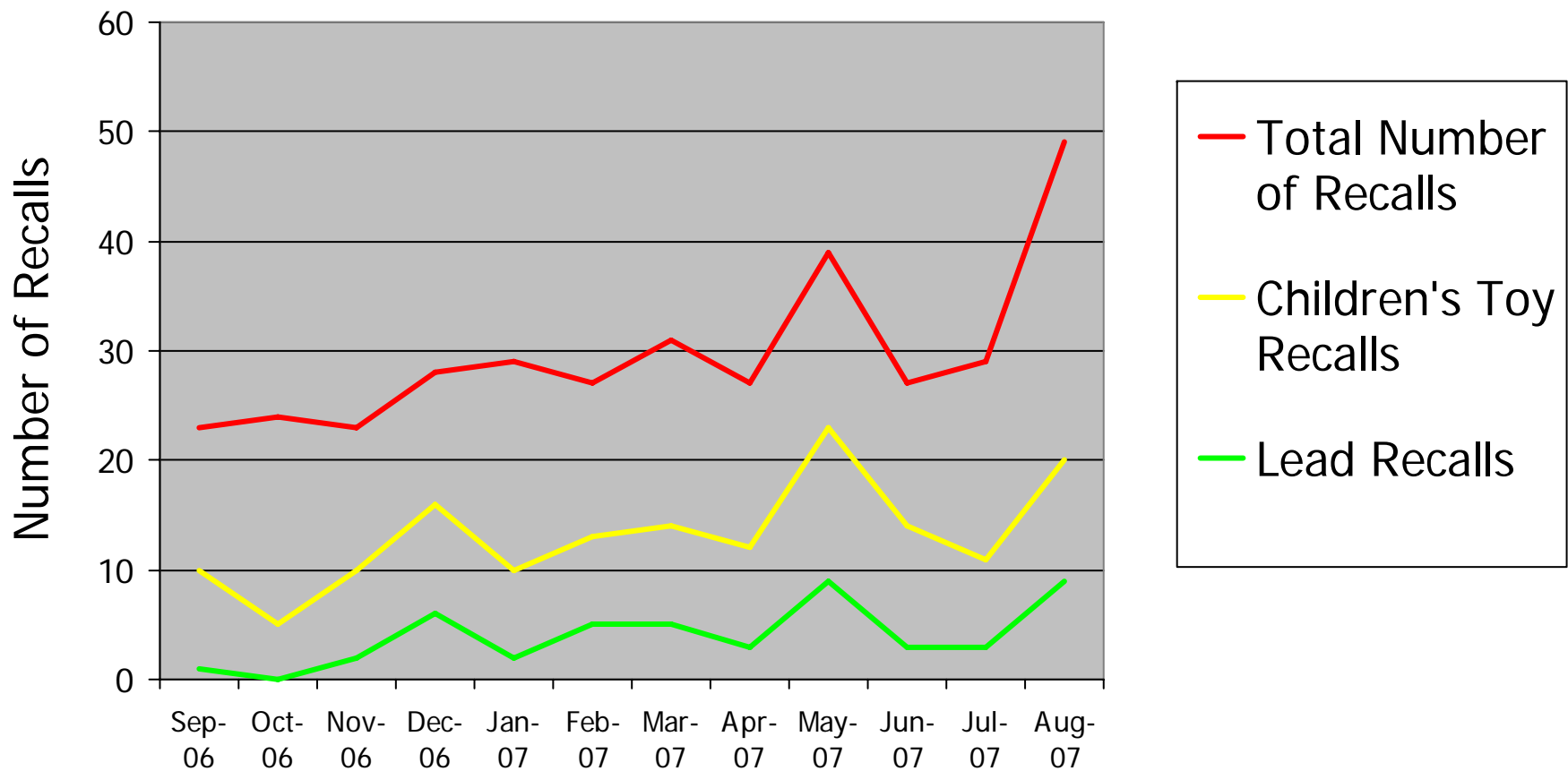
Disclosures and Enforcement

What is the CPSC's typical annual caseload:

- 364 voluntary recalls between September 1, 2006 and September 12, 2007.
- CPSC favors resolution by voluntary recall. A recall can be involuntary– initiated by the CPSC or voluntary; initiated by the manufacturer or distributor.
- VCAPs have no legally binding effect. They allow the CPSC and the companies to work together to address perceived substantial product hazards promptly.

Recalls: A Year in Review

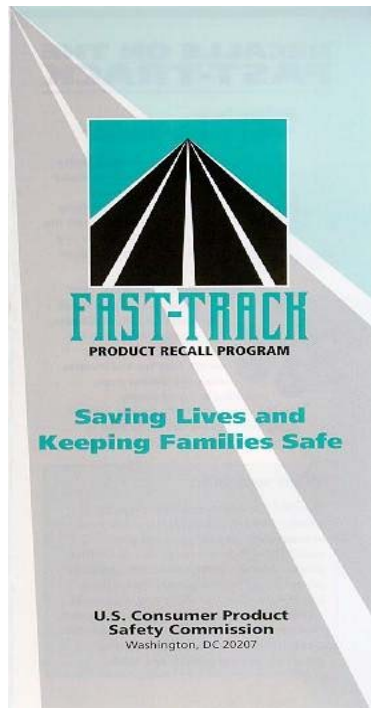
Data compiled from <http://www.cpsc.gov/cpsc/pub/prerel/prerel.html>. Recalls announced between 09/01/2006 and 08/31/2007.



If “Recall” is the only answer? What are the steps?

- You have made your Part 15(b) disclosure and satisfied your self-reporting obligation. What happens next?
- You will probably need to make a CAP proposal to the CPSC, whether “FAST TRACK” or standard track.
- If consumers are being injured there will be pressure to act fast, even if not fast track (media, lawsuits, government).
- You will negotiate the proposed plan with CPSC staff.
- If you cannot reach an agreement on a plan, the CPSC can initiate an administrative proceeding or go to court if there is a perceived need for an injunction.

Fast Track Program



REQUIREMENTS

- Self-report to CPSC (before it contacts you).
- Provide full Section 15 report.
- Be prepared to conduct corrective action plan within 20 days of the report.
- No preliminary determination of hazard.

A big early problem to solve: What is the fix?

- A cash refund can break the company, in that you must send the full purchase price, profit and tax included.
- Can it be repaired? Hard & expensive.
- If replace, with what? Is it available?
- Time is the enemy. Product must be taken out of use. Replacement must be close at hand.

How do I figure out the fix?

- You may need expert help to determine the “root cause” of the defect, so that you can design a repair or specify a safe replacement.
- One thing more expensive than a recall is to recall a recall.
- Good outside experts will help you “cut to the bottom line” and help management hear answers that are not sugar-coated or hedged to accommodate corporate politics.

CPSC FULL REPORT

- If your proposed CAP seems acceptable, CPSC staff will require a “Full Report” under Part 15.
- The Full Report is the equivalent of a party disclosure in civil discovery. Expect to disclose in writing everything about the failure including how and when it was discovered, how many people have been injured and how, the engineering explanation of the problem and the proposed solution. The requirements are set forth in detail in 16 C.F.R. Part 15.

Recall Administration: Things to consider

- Freeze production; divert incoming product; determine date codes, UPCs, Lot Numbers & SKUs; redesign issues; serial number changes; notify retailers; stop sales at the register; point of purchase poster; press release draft.
- How do you notify the customers? Direct mail; warranty cards; club lists; credit card receipts; web sales; mass advertising; press releases, video news releases, paid advertising.
- How will you prevent recurrence?

Voluntary Corrective Action Plan: Repair, Replace or Refund

You will likely need to agree to:

- Acknowledge that the CPSC may monitor the implementation.
- Produce relevant documents
- Agree that the Commission may publicize terms of the CAP.

Recall-Related Litigation

Who is at Risk?

- Any entity in the manufacturing or distribution chain
 - Manufacturers
 - Importers
 - Distributors
 - Retailers
 - Resellers
 - Licensors (apparent manufacturers)

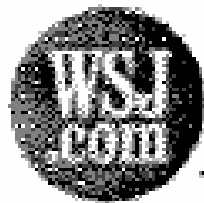
Recall-Related Litigation

- Who is at Risk?
 - Imported products present different issues
 - Manufacturer may not be subject to jurisdiction in US
 - Impacts strategy of whom to sue
 - Distributors & retailers may be targeted by necessity and because of deep pockets
 - Contractual indemnity provisions will not prevent an entity from being sued, only create possibility of recovering cost of judgment/settlement

Recall-Related Litigation

- Theories of Liability
 - Strict Liability
 - Breach of warranty (express, implied)
 - Negligence
 - Unfair & Deceptive Trade Practices
 - Often trigger potential for treble damages
 - Medical Monitoring
 - Lead
 - Arsenic
 - Toxic exposure

Recall-Related Litigation



THE WALL STREET JOURNAL.
O N L I N E

August 20, 2007

Toy Recalls May Push 'Medical Monitoring' Debate

Recall-Related Litigation

- Theories of Liability
 - Medical Monitoring
 - Recognized in about 18 jurisdictions
 - AL, AZ, CA, DC, FL, IL, LA, MI, MN, NJ, NY, OH, PA, TN, UT, VT, WV, Guam
 - Sometimes characterized as an “injury”
 - Sometimes characterized as a form of equitable relief

Recall-Related Litigation

- Theories of Liability
 - Medical Monitoring – Elements
 - Exposure to a toxic substance
 - Which was caused by defendant's negligence
 - Resulting in an increased risk of serious disease, illness or injury
 - For which a medical test for early detection exists
 - Treatment exists for disease/illness/injury (so that test has benefit)
 - Test is recommended by doctors

Recall-Related Litigation

- Theories of Liability
 - Medical Monitoring – Challenges
 - By eliminating the need to establish that a plaintiff has a manifest injury, medical monitoring claims tend to relax or even eliminate the need to prove specific causation (i.e., product (as opposed to other possible causes) resulted in harm to particular plaintiff)

Recall-Related Litigation

- Theories of Liability
 - Medical Monitoring – Challenges
 - Where recognized, claims often certified as class actions
 - Cost of medical monitoring (e.g., lead test) for the entire class adds up to a very large number
 - Potentially increases plaintiffs' settlement leverage
 - If class action, settlement is public because it must be approved by the court
 - Plaintiffs' attorneys' fees are based on the value of the relief to the class

Recall-Related Litigation

- Lead
 - Suits filed
 - Mattel/Fisher-Price
 - RC2/Learning Curve Brands (Thomas Trains)
 - Multiple Claims
 - Multiple Jurisdictions
 - Well-educated plaintiffs' bar re: lead issues
 - Medical Monitoring
 - Ballpark damage numbers

Recall-Related Litigation

- Class Actions
 - Federal – CAFA
 - State
- Individual Plaintiffs
 - Individual claims
 - Opt-outs
- Federal Cases
 - MDL or not?
- State cases

Recall-Related Litigation

- Claims Management Process
 - Coordination
 - Local counsel -- as many as 57 jurisdictions
 - International coordination (e.g., Canada)
 - Discovery responses
 - Legal Arguments

Recall-Related Litigation

- Claims Management Process
 - National Coordinating Counsel may be appropriate
 - Centralized repository for documents, pleadings, discovery responses & motions

Recall-Related Litigation

- Discoverability of Materials Related to Recall
 - Internal Investigation
 - Testing
 - Communications with the CPSC
 - CPSC Determination of Substantial Product Hazard
 - Fact of Recall

Recall-Related Litigation

- Impact of Recall on Liability
 - With CPSC determination of Substantial Product Hazard
 - Without CPSC determination of Substantial Product Hazard
- Impact of Recall on Punitive Damages

Recall-Related Litigation

- Interaction with Congressional Oversight
 - Congressional hearings can generate:
 - Documents
 - Testimony
 - Press
 - Interest from plaintiffs' bar/non-profits - which can contribute to more litigation

Questions?

To ask a question:

1. Click the question mark (Q&A) button located on the tool bar in the bottom right of your screen.
2. Type your question in the rectangular space at the bottom and click the Send button.

Your questions will not be viewed by other attendees.

Thank you!

Thank you for your participation today. Please feel free to contact today's speakers at:

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