Lead Contamination of Imported Goods

Research Paper

Levi D. Smith

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Outline

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Introduction

- Multiple toy recalls in 2007 due to lead paint
- Apply quality engineering techniques to solve problem

Problem Size

- 74 toy recalls in 2007
- 38 recalls due to lead paint levels
- All recalled toys were produced in China and Hong Kong
- No injuries or incidents from recalled toys
- Pareto Analysis
- CPSC published list of recalled toys

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Firm's Recall Hotline: (800) 767-869
CPSC Recall Hotline: (800) 638-277
CPSC Media Contact: (301) 504-790

Schylling Associates Recalls Collectable Toy Robot Due To Violation of Lead Paint Standard

WASHINGTON, D.C. - The U.S. Consumer Product Safety Commission, in cooperation with the firm named below, today announced a voluntary recall of the following consumer products. Consumers should stop using recalled products immediately unless otherwise instructed.

Name of Product: "Robot 2000" collectable tin robot

Units: About 2,600

Importer: Schylling Associates Inc., of Rowley, Mass.

Hazard: Surface paints on the robot contain excessive levels of lead, which violates the federal lead paint standard.

Incidents/Injuries: None reported.

Description: The "Robot 2000" is a battery-operated, tin robot standing 12" tall. It has a red light on the head and chest panels that open.

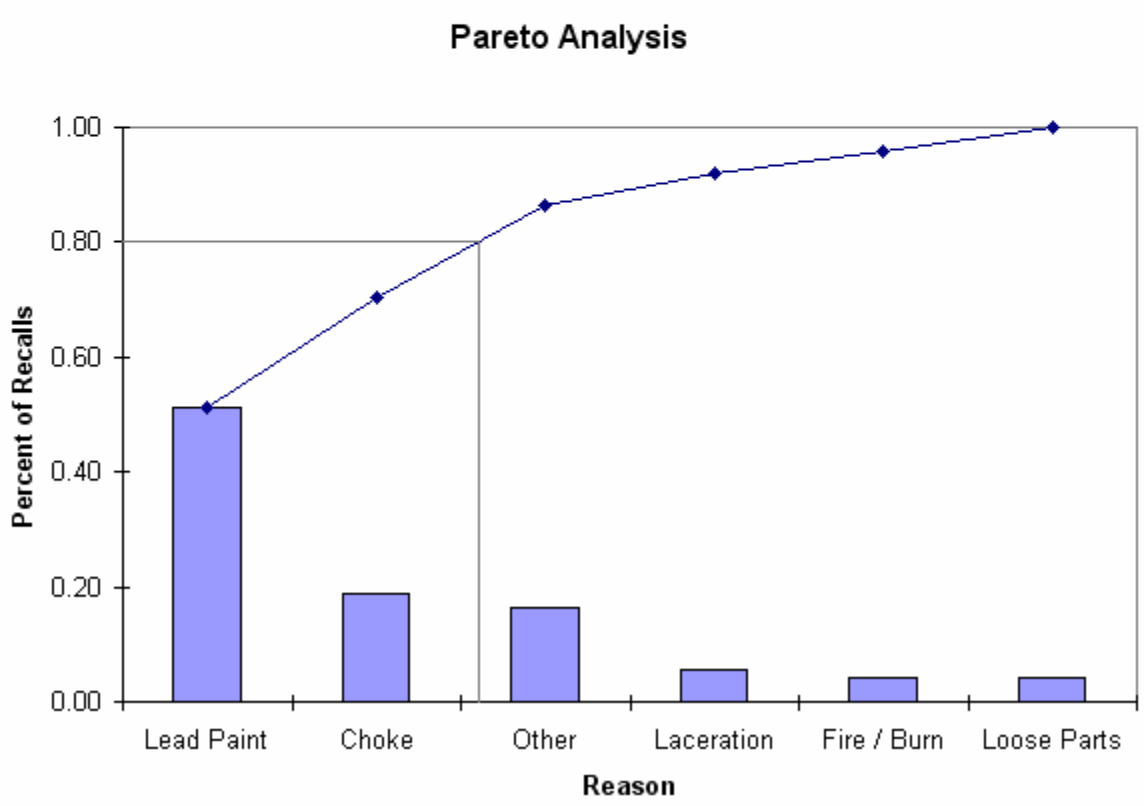
Sold at: Specialty toy stores and gift shops nationwide from October 2006 through September 2007 for about $25.

Manufactured in: China

Remedy: Consumers should immediately take the recalled toy away from children and contact Schylling to receive a refund or free replacement toy.

Consumer Contact: For additional information, contact Schylling at (800) 767-8697 between 9 a.m. and 5 p.m. ET Monday through Friday, or visit the firm's Web site at www.schylling.com

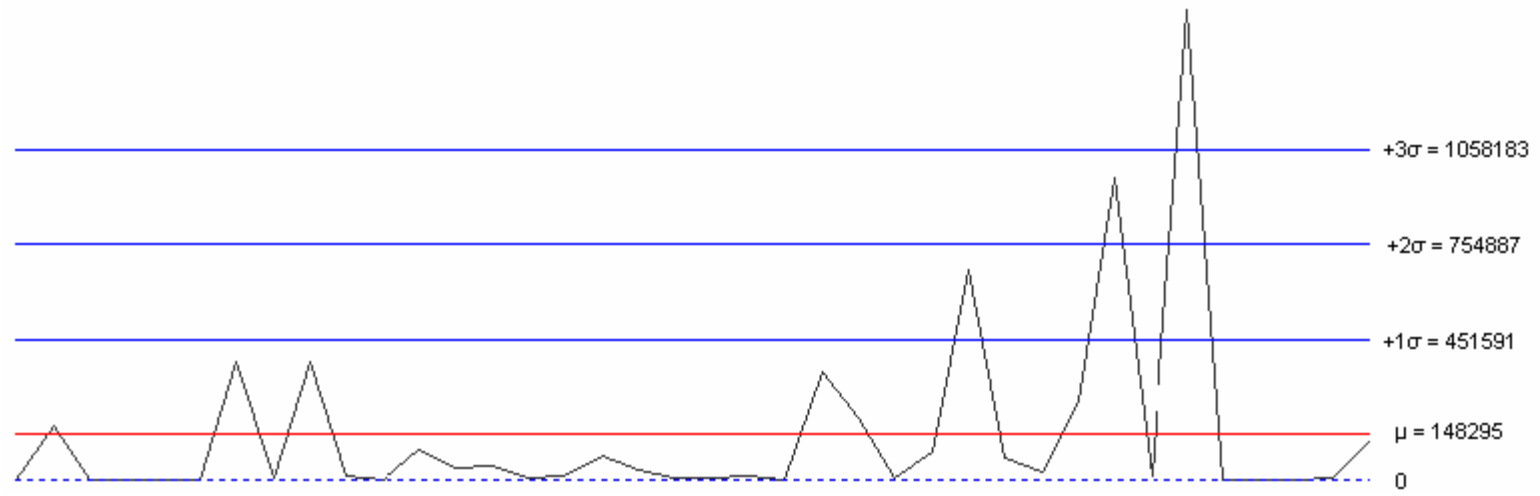
Reason	Count	Percentage	Cumulative Percentage
Lead Paint	38	0.51	0.51
Choke	14	0.19	0.70
Other	12	0.16	0.86
Laceration	4	0.05	0.92
Fire / Burn	3	0.04	0.96
Loose Parts	3	0.04	1.00
Total	74	1.00	



Recalled Units Variance

- Control chart constructed for the number of units affected for each recall
- Initial points in control, later points not in control
- 1 point outside the +1σ control limit
- 1 point outside the +2σ control limit
- 1 point outside the +3σ control limit

Control Chart – Units per Recall



Health Effects

- Studies began in the 1920's
- Low level of lead exposure to children
  - Reduced IQ
  - Learning Disabilities
  - Attention Deficit Disorders
  - Stunted Growth
  - Impaired Hearing Kidney Damage
- High level of lead exposure to children
  - Mental Retardation
  - Coma
  - Death

Biological Impact of Lead

- Lead has no benefit to human body
- Mimics other metals (calcium, iron, zinc)
- Prevents molecules from producing enzymes
- Delta-aminoevulinic acid dehydratase (ALAD)

Blood Lead Levels

- Measured in micro grams per deciliter
- Below 10 µg / dL is normal
- Above 50 µg / dL is a serious concern
- Measured through finger stick or venous sample

Tennessee Childhood Lead Poisoning Prevention Program

NEW Recommended Schedule for a Confirmatory Venous Sample

Screening test result (µg/dL)	Perform a confirmation test within:
10-19	3 months
20-44	1 week - 1 month*
45-59	48 hours
60-69	24 hours
> 70	*Immediately* as an emergency lab test

*The higher the BLL on the screening test, the more urgent the need for confirmatory testing.

Screening Guidelines

1. Blood lead test may be done as a finger stick
2. If the blood lead level comes back 10 µg /dL or greater, the level must be confirmed by a venous blood lead level

Who Should Be Screened?

1. Children at 12 and 24 months old*
2. Children 36-72 months old without a documented blood lead level*
3. Children whose parent/guardian requests a blood lead level
4. Children whose parent/guardian answers "yes" or "don't know" to any questions on risk assessment questionnaire used at well-child checks of 6 and 72 months or when child's risk status changes

*CMS requirements for TennCare recipients

Recommended Schedule for Follow-Up Blood Lead Testing (a)

Venous blood lead level (µg/dL)	Early follow-up (first 2-4 tests after identification)	Late follow-up (after BLL begins to decline)
10-14	3 months (b)	6-9 months
15-19	1-3 months (b)	3-6 months
20-24	1-3 months (b)	1-3 months
25-44	2 weeks-1 month	1 month
> 45	As soon as possible	Chelation with subsequent follow-up

(a) Seasonal variation of BLLs exists and may be more apparent in colder climate areas. Greater exposure in the summer months may necessitate more frequent follow-ups.
(b) Some case managers or PCPs may choose to repeat blood lead tests on all new patients within a month to ensure that their BLL is not rising more quickly than anticipated.

Additional Contact Information

Tennessee Department of Health: http://www2.state.tn.us/health/lead OR call: (615) 741-0355

Tennessee Department of Environment and Conservation: http://www.state.tn.us/environment
OR call: (615) 532-LEAD or the in-state-only hotline at 1-888-771-LEAD (5323)

Lead-based Paint Inspectors, Risk Assessors: http://www.state.tn.us/environment/swm/leadpaint/listprof.htm

http://fcs.tennessee.edu/healthsafety/lead/tnchldleadpois.pdf

Summary of Recommendations for Children with Confirmed (Venous) Elevated Blood Lead Levels

Blood Lead Level (µg/dL)				
10-14	**15-19**	**20-44**	**45-69**	**≥70**
• Lead education - Dietary - Environmental • Follow-up blood lead monitoring	• Lead education - Dietary - Environmental • Follow-up blood lead monitoring • Proceed according to actions for 20-44 µg/dL if: - A follow-up BLL is in this range at least 3 months after initial venous test or - BLLs increase	• Lead education - Dietary - Environmental • Follow-up blood lead monitoring • Complete history and physical exam • Lab work: - Hemoglobin or hematocrit - Iron status • Environmental investigation • Lead hazard reduction • Neurodevelopmental monitoring • Abdominal X-ray (if particulate lead ingestion is suspected) with bowel decontamination if indicated	• Lead education - Dietary - Environmental • Follow-up blood lead monitoring • Complete history and physical exam • Complete neurological exam • Lab work: - Hemoglobin or hematocrit - Iron status - FEP or ZPP • Environmental investigation • Lead hazard reduction • Neurodevelopmental monitoring • Abdominal X-ray with bowel decontamination if indicated • Chelation therapy	• Hospitalize and commence chelation therapy • Proceed according to actions for 45-69 µg/dL

The following actions are NOT recommended at any blood lead level:

- Searching for gingival lead lines
- Testing of neurophysiological function
- Evaluation of renal function (except during chelation with EDTA)
- Testing of hair, teeth or fingernails for lead
- Radiographic imaging of long bones
- X-ray fluorescence of long bones

http://fcs.tennessee.edu/healthsafety/lead/tnchldleadpois.pdf

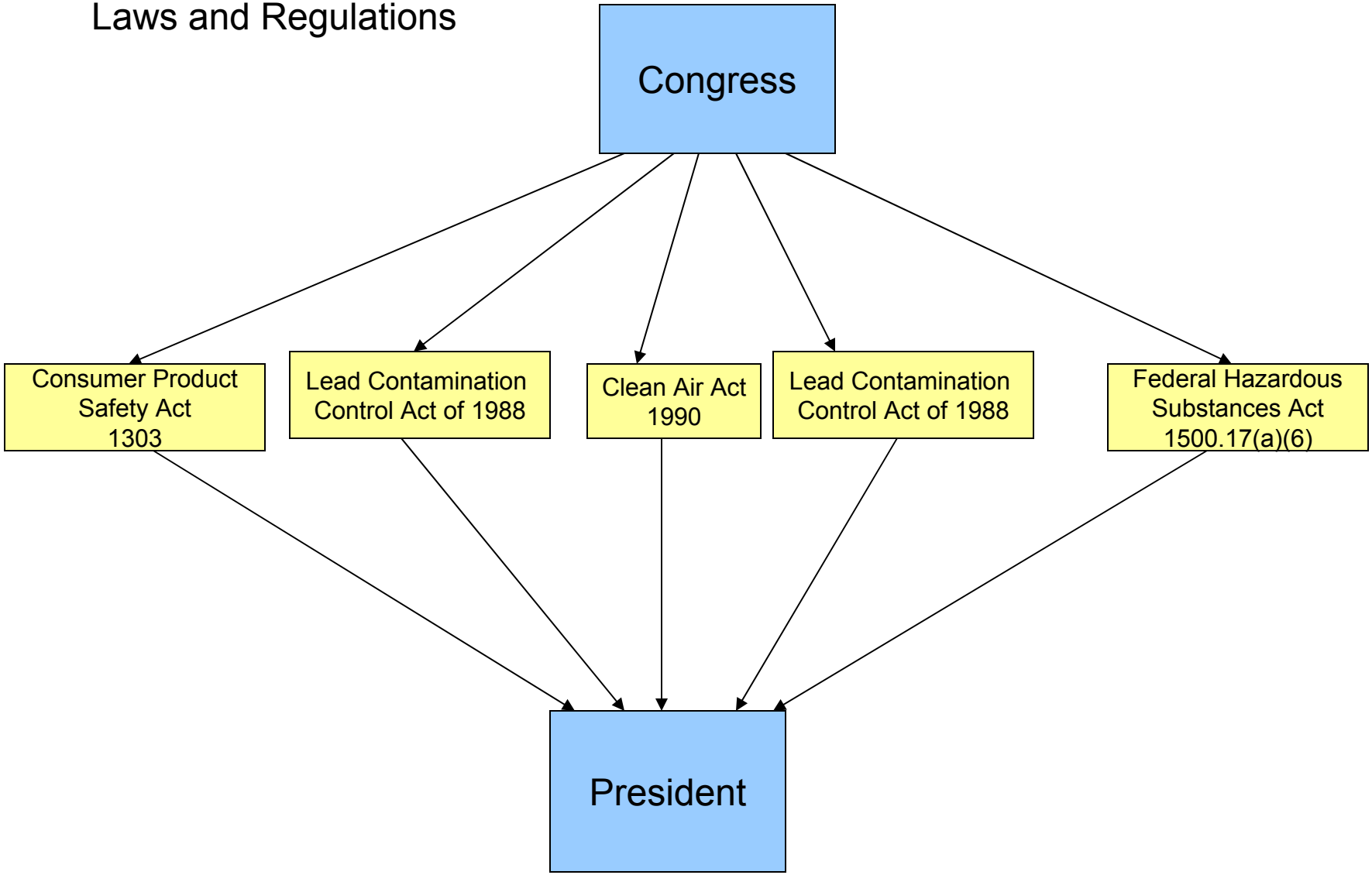
Cases

- Oregon 2003
  - 4 year old swallowed object containing 38.8% lead
  - BLL of 123 µg / dL
  - Hospitalized, but recovered
- Minnesota 2006
  - 4 year old swallowed object containing 99.1% lead
  - BLL of 180 µg / dL
  - Resulted in death
  - 50.52% standard deviation of lead content of similar objects from same manufacturer

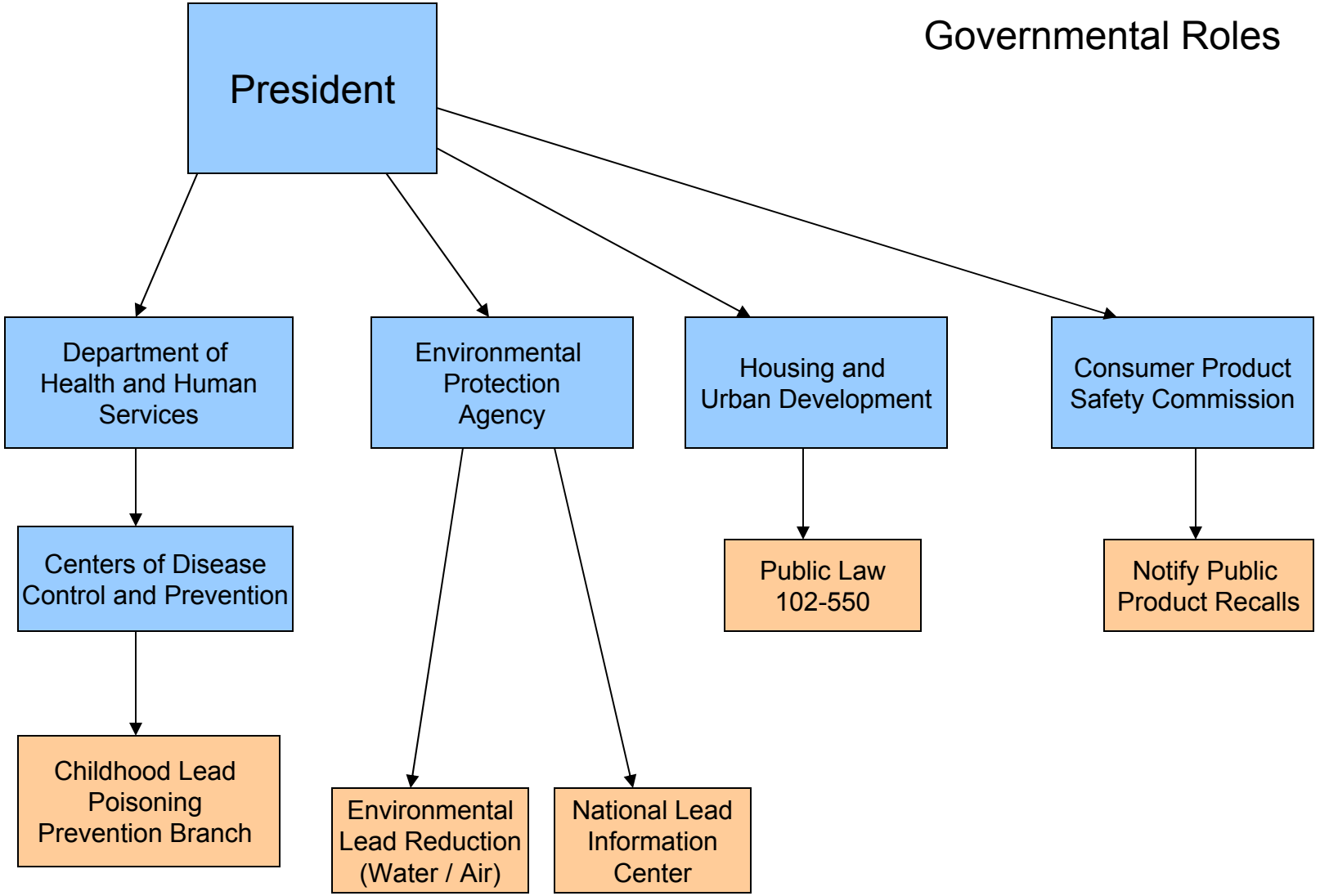
Detection Methods

- Portable X-ray fluorescence (PXRD)
  - Devices cost over $8,000
- Chemical Spot Test
- Household Kits
  - Inaccurate results
  - False positives
  - False negatives

Laws and Regulations



Governmental Roles



Industry Roles

- Disney: Inspecting toys on shelves
- Toys ‘R’ Us: More inspections
- Charities: Checking all toys against recall lists; some rejecting donations
  - Goodwill
  - Salvation Army
  - Toys for Tots

Location of Contamination

- Lee Der Industrial Co
  - Manufacturer in China
  - 967,000 recalled units
  - Chinese government banned company from exporting
  - Executive commits suicide
- Hansheng Wood Products Factory
  - Manufacturer in China
  - 1.5 million recalled units
- Long supply chains in China make finding source difficult

Regulation Enforcement

- No apparent punishment for companies selling contaminated products, aside from economic impact and ruined reputation
- Sale of recalled products over the Internet
- CPSC: 400 employees

Recommendations

- Quality Techniques
  - Detailed Supply Chain
  - Sampling Techniques
  - Operating Characteristic Curve
    - AQL
    - LTPD
    - Producer's Risk
    - Consumer's Risk
  - Six Sigma project to reduce lead in products
  - Control Charts (X bar, R)