

## Lead Contamination of Imported Goods

### Abstract

The amount of lead contained in imported products is a significant quality issue. Exposure to lead can lead to many health problems for children. The number of imported products containing excessive amounts of lead is increasing at an alarming rate. The extent of problem is determined by analyzing the size of recalls, the health effects, the detection methods, and governmental regulations. Quality engineering principles are used to provide suggested solutions to the lead problem.

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Throughout the year of 2007, multiple incidents have occurred causing concern over the quality of imported goods into the United States. Quality engineering tools can be applied to improve the quality of goods imported into the United States. One significant quality concern is the amount of lead in paint used in children's toys. An excessive amount of lead in paint can cause many negative health effects to children. Excessive lead in a human's system is sometimes called plumbism (Merriam-Webster 2007). In order to effectively understand and resolve this problem, an analysis must be performed on the size of the problem, recalls, application of quality methods, the health effects, the biological process, blood lead levels, real cases, detection methods, laws and regulations, the government's role, efforts by corporations, location of problem, enforcement of regulations, and possible solutions.

The United States Consumer Product Safety Commission has issued 74 toy recalls throughout the year 2007 (Toy Hazard 2007). Thirty-eight of the recalls were due to violations of the lead paint standard or risk to lead exposure (Toy Hazard 2007). Thirty-six of the recalls due to lead paint were manufactured in China (Toy Hazard 2007). The remaining two lead paint recalls were manufactured in Hong Kong (Toy Hazard 2007). Therefore, 94.73% of the recalls were produced in China, while 5.26% of the recalls were produced in Hong Kong. There was no mention of any recalls due to lead paint from any other country or the United States itself. In all the recalls issued in 2007, no injuries or incidents were reported (Toy Hazard 2007). Since no injuries or incidents were reported, the harmful effects of lead paint are either not noticeable, or the effects take a long time for symptoms to manifest. A Pareto analysis has been completed showing the causes of toy recalls in 2007 (Figure 1). The data was gathered from the Consumer Product Safety

Commission's published list of recalled children's toys. The Pareto analysis clearly shows that 80% of the recalls are due to violations of the lead paint standard and choking hazards. Additionally, lead paint was 32 percentage points higher than choking.

The total number of toys recalled due to lead paint in 2007 was 5,635,200. The 2000 US census calculated that 21.4% of the United States population was under the age of 15 years, who are the children that are likely to own toys (Population Profile 2001). According to a July 2007 estimate, the current United States population is estimated to be 301,139,947 (World Factbook 2007). A reasonable estimate for the number of total children under the age of 15 years in the United States is 64,443,949, which is the total United States population multiplied by the percentage of children. Therefore, roughly 1 out of every 11 children could have been exposed to a toy with lead paint. This assumes the number of children having more than one toy with lead paint is negligible. This also assumes that all recalled toys were purchased, however many recalled toys may have been pulled before the contaminated products reached the customer.

The number of units affected in each lead paint recall appeared to vary significantly, so a control chart has been constructed (Figure 2). Each sigma level is shown as a solid blue line, the mean is shown as a solid red line, and the zero level is shown as a broken blue line. The number of units recalled is plotted as a solid black line. The mean number of units affected for each recall is 148,295. The calculated standard deviation is 303,296. The number of recalls appears to be out of control, since one point is three standard deviations beyond the mean, which represents the 1.5 million Thomas & Friends Wooden Railway Toys recalled. One point is two standard deviations beyond the mean, which accounts for the 967,000 Sesame Street and Dora the Explorer toys recalled.

The one point that is one standard deviation beyond the mean represents the recall of various Barbie Accessory toys. The calculated value for the lower control limits resulted in negative values. The lower control limits are not shown, since recalling a negative number is not possible. The control chart shows that the variance in the number of units recalled increases towards the end of the chart. One explanation for this behavior could be due to more toys being produced near the end of the year. Therefore, more units would be expected to be recalled, since more toys are being manufactured overall. The United States should try to achieve reducing the variation so that the number of units per recall is within one standard deviation of the mean. Ideally, the number recalled should be as close to zero as possible.

Exposure to lead can lead to many negative health effects. Many studies began in the 1920's, which documented the effects of lead on children (Gooch 2002). According to the National Safety Council, low levels of lead exposure to children can result in reduced IQ, learning disabilities, attention deficit disorders, stunted growth, impaired hearing, and kidney damage (Lead Poisoning 2004). When exposed to high levels of lead, children may face mental retardation, coma, or death (Lead Poisoning 2004). Increased blood lead levels can also lead to juvenile delinquency and criminal behavior according to the National Safety Council, however no evidence or scientific research supporting these claims was presented (Lead Poisoning 2004).

The element lead has no beneficial use in the human body, and its danger comes from its ability to mimic other metals such as calcium, iron, and zinc (Lead Toxicity 2007). Lead prevents molecules in the human body from producing enzymes essential in biological processes (Lead Toxicity 2007). One important enzyme that is affected by

lead is delta-aminolevulinic acid dehydratase (ALAD), which binds to zinc (Lead Toxicity 2007). ALAD is used in the biosynthesis of heme, which is a part of hemoglobin (Lead Toxicity 2007).

The Centers for Disease Control states that long term health effects can occur in people with a blood lead level of 10 to 45 micrograms per deciliter (Managing Elevated 2002). Most children today have blood lead levels below 30 micrograms per deciliter, and few blood lead levels exceed 50 micrograms per deciliter (Managing Elevated 2002). Brain disease can result from having a blood lead level of higher than 50 micrograms per deciliter (Managing Elevated 2002). For children, lead usually enters the system when the child's hand comes into contact with the mouth (Managing Elevated 2002). The Tennessee Department of Health suggests that the blood lead level for all children should be tested at 12 months and 24 months after birth (Tennessee Childhood 2007). Blood lead levels can be tested using a finger stick or through venous sample (Tennessee Childhood 2007).

Recently, there have been two cases involving children suffering from toys containing lead. A 4 year old boy swallowed a toy necklace in Oregon in July 2003 (Brief Report 2007). The boy's symptoms included cramping, vomiting, diarrhea, constipation, and inability to eat and sleep (Brief Report 2007). When the boy was analyzed at the hospital, he had a blood lead level of 123 micrograms per deciliter, which is 12.3 times higher than the CDC's acceptable blood lead level (Brief Report 2007). After the necklace was removed from his stomach, an analysis by the state's environmental quality lab reported that the necklace contained 38.8% lead (Brief Report 2007). The other case involves a 4 year old boy from Minneapolis Minnesota, who

ingested a metallic object from a necklace in February 2006 (Death of a Child 2007). The boy suffered from vomiting and dehydration (Death of a Child 2007). While at the hospital, the boy's blood lead level was measured at 180 micrograms per deciliter, and blood flow to his brain had stopped (Death of a Child 2007). The boy died four days later when he taken off of life support (Death of a Child 2007). The Minneapolis Public Health Department Laboratory determined that the object contained 99.1% lead (Death of a Child 2007). Tests on other identical objects from the same manufacturer contained 67% and 0.07% lead (Death of a Child 2007). The standard deviation of the lead content of the three objects is 50.52%, which may signify that the process for creating the metallic objects was out of control in respect to the lead content.

Multiple methods exist for detecting the amount of lead contained in paint. Two popular forms of lead detection in paint are portable X-ray fluorescence (PXRF) and chemical spot tests (Gooch 2002). Lead has a distinct X-ray fluorescence characteristic when it absorbs high level energy (Gooch 2002). Handheld PXRF devices are commercially available, and test usually only take 1 minute (Gooch 2002). As of June 1992, the cost of a lead detection device ranged from \$8,700 to \$15,690 (Gooch 2002). Chemical spot tests work by exposing the paint to a reagent, and observing if lead reacts through the paint changing colors (Gooch 2002). Studies have shown that the chemical spot tests can result in a high number of false positive results (Gooch 2002). More sophisticated laboratory testing techniques for detecting lead in paint include atomic spectroscopy, x-ray diffraction, electron beam probe, electron spectroscopy for chemical analysis, light microscopy, electron microscopy, infrared spectroscopy, and electron spectroscopy for chemical analysis (Gooch 2002). Household lead detection products

can be purchased from the Internet from approximately \$5 to \$15, however consumers have reported that the tests are unreliable due to difficulty in interpreting results (Homax 2007). The CPSC has reported that consumer lead test kits produce inaccurate results, report false positives, report false negatives, and do not detect lead at the CPSC regulation level (CPSC Staff 2007).

There are many laws and regulations that prevent the use of lead and lead based paint. In 1971, the Lead-Based Paint Poisoning Prevention Act Title 42 Chapter 63 Section 4831 provided the beginning steps in the abolishment of lead based products (Lead-Based Paint 2007). The Lead Contamination Control Act of 1988, which was signed into law by President Ronald Reagan, made many attempts to prevent the spread of lead contamination (Lead Contamination 2007). Implementation of the requirements were the responsibility of the Environmental Protection Agency (EPA) and Health and Human Services (HHS). In the Paint Hazard Reduction Act of 1992, the department of Housing and Urban Development set regulations for reducing the exposure to lead in homes, which is defined in Public Law 102-500 and Title X Section 1012, 1013, and 1018 (Lead Regulations 2007). Title X Section 1018 is also known as the Residential Lead-Based Paint Hazard Reduction Act of 1992 (Lead Regulations 2007). Section 1500.17(a)(6) of the Federal Hazardous Substances Act and Part 1303 of the Consumer Product Safety Act bans any objects intended to be used by children with paint containing more than 0.06% lead (Regulated Products 2007).

The Lead Contamination Control Act of 1988 called for the EPA to reduce lead levels in the environment, by methods such as the removal of all drinking coolers that contained lead components (Lead Contamination 2007). The EPA has established

methods for monitoring the lead levels in the air and water. In 2004, the EPA was accused of disregarding tests that produced readings of high lead content in the water supply in the cities of Philadelphia, Boston, and other cities (Leoning 2004). Multiple U.S. senators called for an investigation into the matter (Leoning 2004). The EPA has established The National Lead Information Center (NLIC), which provides a lead hotline to interface with the public regarding lead issues (Lead in Paint 2007). The EPA was successful in removing lead from gasoline throughout the 1980's, and with the banning of lead gasoline in 1996 (Clean Air 2007).

The HHS would focus on the individuals, by setting up screening of infants and children for elevated blood levels through the Centers for Disease Control and Prevention (CDC) (Lead Contamination 2007). The CDC has created the Childhood Lead Poisoning Prevention Branch, which has the goal to eliminate childhood lead poisoning as a public health problem (About Childhood 2007).

The Consumer Product Safety Commission (CPSC) is responsible for ensuring that the public is informed of recalls and hazardous products. In October 2007, the United States Congress called for the resignation of CPSC Chairwoman Nancy Nord over the issues of recalled Chinese toys (CPSC Head 2007). Congressional committees desire to give CPSC more funding, authority, and missions (Nord 2007). Nord believes that the additional responsibilities would require an additional 125 personnel, since the agency currently only has 400 full time employees (Nord 2007). An increase in funding to \$18 million for the first year would be required to cover all of the new responsibilities requested by the committees (Nord 2007). In her letter to Congress, Nord specifically addresses the lead in children's products issue, and she highlights the fact that the number



one source of lead in children is due to old house paint (Nord 2007). Nord suggests that the subcommittee is planning to adopt a European standard for lead paint in toys, but Nord has doubts and suggests alternative language (Nord 2007).

Corporations in the United States are also helping to ensure that toys are safe for children. The Walt Disney Company has begun to independently test their toys, by hiring companies to purchase their products off of store shelves for testing (Disney 2007). Additionally, the store Toys 'R' Us has increased inspections of toys after the numerous recall of products from Mattel (Disney 2007). Charities such as Goodwill, Salvation Army, and the Marine's Toys for Tots drive are devoting more time towards the inspection of toys, and refusing the donation of toys in some cases (Byrd 2007).

One major recall in 2007 involved the Lee Der Industrial Co that produces Sesame Street toys in China (Report Exec 2007). One of the executives, Chenung Shuhung, committed suicide after the recall of 967,000 toys due to lead paint levels (Report Exec 2007). The Chinese government did take action, by temporarily preventing the Lee Der company from exporting products, and the recall would cost the company \$30 million (Report Exec 2007). The paint containing the high level of lead was not produced by Lee Der, but instead one of their partner companies (Report Exec 2007). Evidence suggests that Chinese manufactures have long supply chains, which makes finding the source of contaminated products difficult (Report Exec 2007). Fortunately, the contamination was found quickly, so over two thirds of the toys were pulled before the products reached store shelves according to the Fisher-Price general manager (Fisher-Price 2007). Fisher-Price claims that there will be an investigation into the matter to determine how lead contaminated paint was used on the imported toys (Fisher-Price

2007). Another case involves the Chinese Hansheng Wood Products Factory, which was also banned from exporting by China's General Administration of Quality, Supervision, Inspection, and Quarantine for exporting wooden toys that contained excessive lead paint (Ramzy 2007).

Another concern is the enforcement of CPSC regulations. The sale of recalled toys over the Internet using auction sites has become an issue (Products Recalled 2007). There are currently no laws that prevent the sale of recalled products, however the U.S. Senate is currently working on legislation, called the CPSC Reform Act, which would address those issues (Products Recalled 2007). In September 2007, a two day congressional hearing was held, and Nord stated that the only consequence for retailers violating federal standards is the loss of sales due to people not buying their products (More Lead 2007). The U.S. Public Interest Research Group (PIRG) says that the CPSC has no power to enforce the regulations, and the toy companies are self-regulated (Weisskopf 2007).

Many approaches could be used to reduce the possibility goods imported into the United States having excessive amounts of lead. Detailed documentation on the supply chain from the foreign country should be provided for all imports. Sampling techniques should be used by the foreign country to ensure that products do not contain an excessive amount of lead. Once samples have been taken, control charts can be constructed showing the average amount of lead content and the various sigma levels of lead content. For all imported lead toys, the United States should set regulations on the acceptable quality level (AQL), producer's risk, lot tolerance percent defective (LTPD), and consumer's risk. From those values, an operating characteristic chart can be constructed,

and the acceptance number can be calculated based on the lot size and sample size for each shipment of imported toys. X bar and R charts could be beneficial to see any trends in the amount of lead contained in imported toys. If the foreign companies are not cooperative in providing information relating to the production processes, then the production of those products should be brought back to the United States. More research should be performed to determine the validity of the 0.06% standard by the CPSC. In order to determine the source of the problem, the point at which the lead enters the production system must be identified. Once found, a Six Sigma project could be established to target that area to reduce the amount of lead entering the system. The government could also place restrictions on lot sizes of imports, to avoid massive recalls of products.

If lead in paint of children's toys is not addressed, then contamination of toys will continue to be a problem. Even more toys will be recalled, resulting in a significant impact on the toy industry as consumers quit purchasing toy products. Over the next few decades, the public will begin to see the extent of the long term effects of lead paint in toys if the problem is not resolved.

Reasons for toy recalls in the United States in 2007

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
<b>Total</b>	<b>74</b>	<b>1.00</b>	

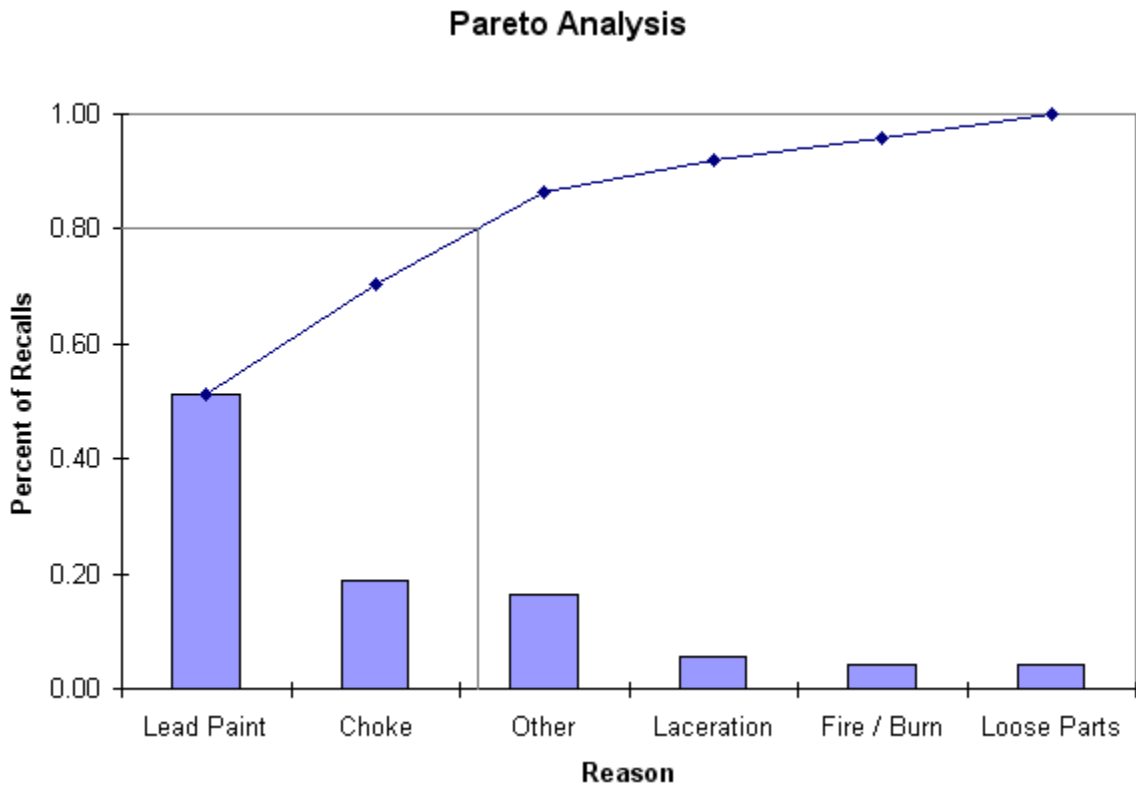


Figure 1 Recall Types Pareto Analysis

Name	Units	Name	Units
Collectible Mini Helmets	1400	Floor Puppet Theaters	10000
Curious George Plush Dolls	175000	Children's Toy Rake	16000
"Robot 2000" collectable tin ro	2600	Britain's "Knights of the Sword" Series Toys	800
Dizzy Ducks Music Box	1300	Happy Giddy Gardening Tools...	350000
Winnie-the-Pooh Spinning Top	3600	Various Thomas and Friends	200000
Duck Family Collectable Wind-Up Toy	3500	Big Big World 6-in-1 Bongo Band toys	8900
Pull-Back Action Toy Cars	380000	Geo Trax Locomotive Toys	90000
Dragster and Funny Car toy	7500	Various Barbie Accessory Toys	675000
"Galaxy Warriors" Toy Figures	380000	Spinning Tops and Tin Pails	70700
Elite Operations Toys	16000	Magnetic Toy Train Sets	27000
Ribbit Board Games	1500	"Sarge" die cast toy cars	253000
Children's Toy Gardening Tools	97000	Sesame Street, Dora the Explorer, and other children's toys	967000
Go Diego Go Animal Rescue Boats	38000	Soldier Bear Brand Toy Sets	13000
Disney™ Deluxe Winnie-the-Pooh 23-Piece Play Sets	49000	Various Thomas & Friends™ Wooden Railway Toys	1500000
Bendable Dinosaur Toys	10000	Eli's Small Drums and Liberty's Large Drums	4500
Children's Toy Decorating Sets	15000	Invincibles Transport Converters Toy Sets	3000
"Pirates of the Caribbean" Medallion Squeeze Lights	79000	Anima – Bamboo Collection Games	5000
Baby Einstein Discover & Play Color Blocks	35000	Stuffed Fun Balls	7200
Wooden Pull-Along Alphabet...	10000	Elite Operations" Toy Sets	128700
<b>Sum</b>	<b>5635200</b>		
<b>Mean (<math>\mu</math>)</b>	<b>148295</b>		
<b>Standard Deviation (<math>\sigma</math>)</b>	<b>303296</b>		
<b>2 * <math>\sigma</math></b>	<b>606592</b>		
<b>3 * <math>\sigma</math></b>	<b>909888</b>		

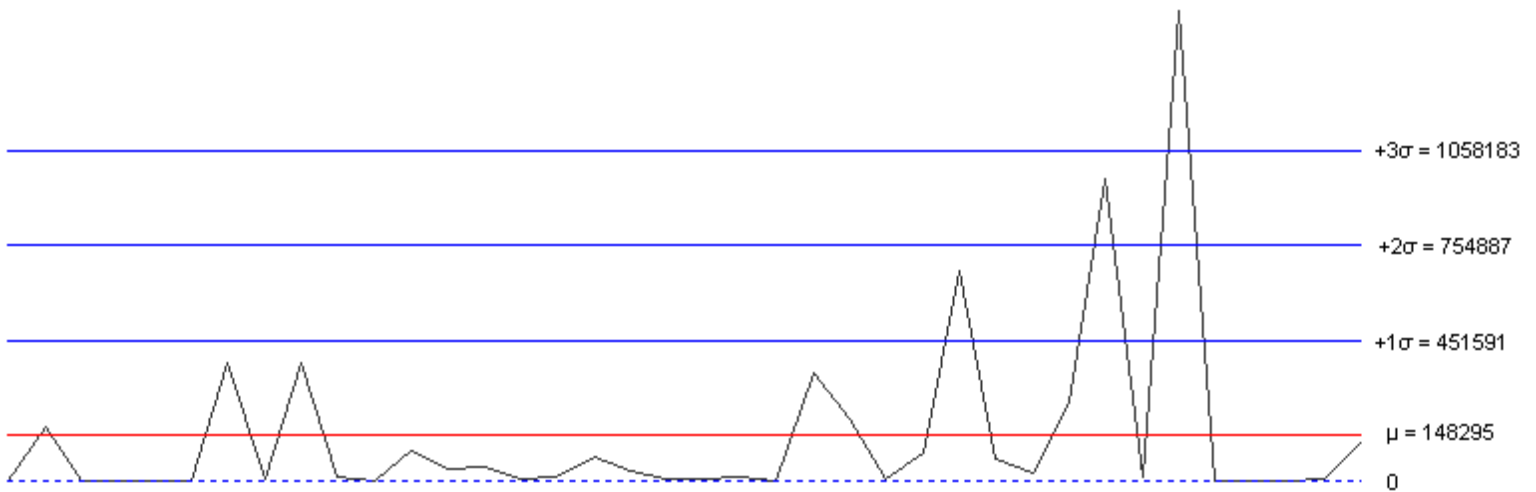


Figure 2 Control chart for number of units recalled for lead paint

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