Public Hearing
Children's Products Containing Lead: Technological Feasibility of 100 ppm for Lead Content

February 16, 2011

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Comments of Consumers Union of United States, Inc.
to the U.S. Consumer Product Safety Commission on

"Children's Products Containing Lead: Technological Feasibility of 100 ppm for Lead Content"

Presented by Donald Mays
On behalf of Consumers Union and Consumer Federation of America

February 16, 2011

Thank you for the opportunity to comment on the technological feasibility of 100 ppm for lead content in children's products. My name is Don Mays, Senior Director of Product Safety and Technical Policy for Consumers Union, the non-profit publisher of *Consumer Reports*. I offer my comments today on behalf of Consumers Union and Consumer Federation of America.

The scientific evidence is clear: There is no known safe level of lead exposure. Lead is a potent neurotoxin that can cause permanent, irreversible brain damage. Children are especially susceptible to its toxic effects. A child's exposure to lead can result in lifelong harms, such as reduced IQ, learning disabilities, aggressive behavior, and serious and long-lasting effects on heath and well-being. Cumulative lifetime exposure has also been linked to neurotoxicity and cardiovascular effects later in life. The health effects of lead exposure also pose a serious economic burden on American society and are costing us tens of billions of dollars. It is clear that we must do whatever we can to eliminate our children's exposure to this harmful toxin.

Unfortunately, lead is ubiquitous in our environment. Because lead has been used for years in paint, gasoline, and plumbing, it has now contaminated our soil, water, and air. Despite the fact that trace amounts of lead do reside in certain raw materials, we strongly believe that manufacturers can and should make children's products with very low levels of lead. In addition, we are staunchly opposed to the intentional addition of lead to children's products. Any such addition is completely unwarranted and should not be permitted.

Section 101(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires that, as of August 11, 2011, children's products may not contain more than 100 parts per million (ppm) total lead unless the Consumer Product Safety Commission (CPSC) determines that this standard is not technologically feasible. Our evidence proves that it is.

- In 2007, Consumer Reports tested a toy blood pressure cuff made by Fisher-Price that contained a high concentration of lead. One of several samples we tested measured as many as 10,000 ppm of lead. At the time it was sold, this toy was not in violation of any Federal regulations (since the CPSIA was not yet law). However, since that time, Fisher-Price has redesigned their blood pressure cuff. Subsequent tests have shown that a new model had only 47 ppm of lead.

- In 2006 we also found several children's vinyl lunch boxes that contained high levels of lead, ranging from about 4,600 to more than 11,000 ppm. Our tests proved that the lead in these bags could transfer to unwrapped foods. Now, many vinyl lunch boxes are labeled as 100% lead-free. Indeed, XRF screening tests of a few bags we recently purchased did not indicate the presence of lead.

- Just last year, our tests also uncovered a children's vinyl raincoat made by Kidorable's that contained in excess of 1,000 ppm lead – a level that exceeds CPSIA regulations. But when we purchased new samples of this same product, we found that they are now labeled as "lead free." Indeed, our tests of the new samples showed only trace amounts of lead in the new products, in the order of about 10 ppm. The manufacturer told us that it had reformulated its vinyl products to comply with the new provisions of the CPSIA.

These examples demonstrate that it is technologically feasible to make children's products with CPSIA-compliant levels of lead.

In addition, current regulations for paint set the limit for lead at 90 ppm. Before CPSIA, that limit was 600 ppm. The fact that paint companies are currently complying with the new standard shows that reducing lead in paint to under 90 ppm was technologically feasible.

Lowering the lead limit on children's products to100 ppm may require manufacturers that do not have good quality control practices to tighten up their processes. Manufacturers may need to more carefully select the materials used in their products, and test those materials before the product is manufactured. New limits may, for example, prevent the use of reground vinyl or electronic circuit boards in children's products. This would be a positive result, because reconstituted materials often contain other toxic substances such as cadmium, which is currently unregulated.

It has been argued that lead poses a hazard only when it is shown to be accessible and soluble in an acid solution that simulates saliva or stomach acid. We disagree. Since lead is not always molecularly bound to the material matrix or substrate in which it is used, it can be liberated as the product ages or is exposed to mechanical manipulation, environmental ozone, and ultraviolet light. That is why the CPSC worked with the Window Covering Safety Council more than 10 years ago to eliminate lead in vinyl window blinds, which were found to liberate lead dust as a result of exposure to sunlight and heat. In fact, of the many samples of Fisher-Price toy blood pressure cuffs we tested, the highest levels were found in one that had been in use for two years. In addition, extraction or solubility tests for heavy metals can be imprecise, having widely variable results due to the time required for extraction, agitation level, temperature, ambient light conditions, and solute to sample ratio. From a compliance and enforcement standpoint, it is far better to rely on the precise test results afforded by the current emission spectroscopy tests widely used for lead testing. Therefore, it is imperative that the regulation continue to rely on total lead content, not just lead that is accessible when the product is new.

In regard to detection limits and test precision, some argue that current test methods cannot accurately measure lead levels below or around 100 ppm. This argument is incorrect. Use of conventional emission spectrometry test methods such as atomic absorption (AA) or inductively coupled plasma (ICP) can detect lead in the parts per billion range – magnitudes lower than the proposed 100 parts per million limit. Those procedures generally have a precision range of about 1 to 5 percent. Therefore, with a sample that measures 100 ppm, for instance, one would expect to have no more than a standard deviation of plus or minus 5 ppm.

Another significant advantage of the current test method is its ability to measure the levels of several other elements – like other heavy metals – present in the product at the same time as measuring lead levels. In the future, should the CPSC write regulations for the use of total cadmium or other heavy metals used in children's products, the cost increment to conduct testing for those heavy metals would be negligible since the testing for those substances could be carried out simultaneously with the lead tests.

In regard to costs, reducing the lead limit to 100 ppm should not have an impact on the cost of testing. The list price for lead testing by independent labs in the U.S. is typically $60 to $90 per sample, and only $20 to $40 in Asia.

In conclusion, lead is an extremely potent neurotoxin that can cause irreversible brain damage to children. Reducing the level of lead in children's products to 100 ppm, as required by the CPSIA, is technologically feasible. Companies have already begun to comply with the statute's mandates, and our testing has shown that products previously containing high levels of lead have now been redesigned so that they contain less than 100 ppm of lead. The FJATA have also acknowledged the introduction of a CPSIA-compliant crystal into the market. In addition, the current testing method for evaluating lead levels is sufficiently precise, because it can detect lead in the parts per billion range. Consumers Union and Consumer Federation of America strongly believe that the 100 ppm lead limit is both reasonable and technologically feasible, and encourage the Commission to implement this requirement as soon as possible.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Wednesday, February 16, 2011

Testimony of
Dana Best, MD, MPH, FAAP

On behalf of the
American Academy of Pediatrics

Before the Consumer Product Safety Commission
"Children's Products Containing Lead: Technological Feasibility of 100ppm for Lead Content"

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Chairman Tenenbaum and Commissioners Adler, Moore, Nord and Northup, thank you for this opportunity to speak to you today. My name is Dana Best, MD, MPH, FAAP, and I am pleased to represent the American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. I am an Associate Professor of Pediatrics at George Washington University School of Medicine and an attending physician at Children's National Medical Center in Washington, D.C. I served for six years on the AAP's Committee on Environmental Health, which is the primary body within the AAP that handles lead and other environmental health issues.

Under the Consumer Product Safety Improvement Act of 2008 (CPSIA), the Consumer Product Safety Commission (CPSC) is directed to reduce to 100 parts per million (ppm) the allowable levels of lead in children's products in August 2011, "unless the Commission determines that a limit of 100 parts per million is not technologically feasible for a product or product category." The AAP appreciates the Commission's diligence in seeking public input about the public health and other impacts of reducing the permissible lead levels to 100ppm.

The Commission has undoubtedly received and reviewed a tremendous amount of material about the research behind lead exposure and its impact on child health. I will therefore give only a brief overview of the state of the science.

Lead Is a Known Neurotoxin

Lead has been recognized as a potent neurotoxin since the time of the Roman empire, although the mechanisms by which it inflicts brain damage have only been explored and understood in the past century. The brain damage caused by lead exposure is permanent and irreversible. Few options exist for treating lead exposure at high levels, and these treatments have potentially dangerous side effects. No options exist for treating lead exposure at low to moderate levels.

Exposure to lead is amply documented to cause the loss of intellectual capacity. On average, children whose blood lead levels (BLLs) rise from 10 to 20 micrograms per deciliter (mcg/dL) lose two to three IQ points. More recent studies have shown an even greater impact on IQ of BLLs under 10 mcg/dL. Key studies reported a loss of 4 to 7 IQ points in children whose lead levels rose from 1 mcg/dL to 10 mcg/dL. These studies suggest that "low" levels of exposure – meaning BLLs less than 10 mcg/dL – cause proportionately greater harm than higher levels.

In addition to these impacts on IQ, lead exposure has documented effects on behavior, with higher rates of behavioral problems reported in young children, teens and adults exposed to lead during childhood. Investigators have identified associations between lead exposure and increased aggression, commission of crime and antisocial or delinquent behaviors. Children with elevated lead are more likely to have problems with attention deficit, reading disabilities, and to fail to graduate from high school. Other effects include abnormal balance, poor eye-hand coordination, longer reaction times, and sleep disturbances.

With all of this information in mind, it is critically important to note that lead is bioaccumulative. A percentage of lead will be excreted by the body, and the rate of clearance is dependent on a number of factors, including nutritional status. But a percentage of lead is also stored in the body, primarily in bone. These body stores can persist over decades. When a woman becomes pregnant, her body draws upon its calcium stores to create her fetus's bone structure. If lead has been stored in the bone, the developing fetus will be exposed to doses of lead at points throughout pregnancy. Further, a women's blood lead in pregnancy puts her at higher risk for complications from high blood pressure. A recent study in Environmental Health Perspectives found blood pressure to be about 4-6 mmHg higher in women giving birth to infants with a cord blood lead level of 1-6 mcg/dL versus cord blood levels of $\leq$0.46 mcg/dL.

The costs associated with lead exposure are tremendous. Health economists estimate that every time average blood lead level increases by a small amount* across the children born in any given year, $7.5 billion is lost in potential earnings for those children. Other studies have estimated the annual cost of lead poisoning in American children at $43.4 billion. Costs are borne by our health care, education, and justice systems, among others.

Lead is naturally present in our environment at low levels. Human activities have raised those levels through contamination, whether by adding lead actively to products like paint or gasoline or producing it as a byproduct of activities like burning coal. Lead is present at low levels in our air, soil, and water, but often very difficult to remediate in those cases. It is therefore critical to restrict lead exposure in environments directly under our control, such as consumer products.

AAP's Role in the CPSIA

During the development of the CPSIA, the AAP was asked by Congress to recommend a limit for permissible levels of lead in children's products. The Academy engaged in a rigorous scientific process involving a review of the pertinent literature and ultimately recommended that lead be limited to 40ppm. AAP pediatric environmental health experts determined that, based on the most up-to-date science, an object with 77ppm lead would be capable of raising a child's blood lead level to a level that would result in the loss of one IQ point. Recognizing that most children are exposed to other sources of lead and that it is bioaccumulative, the AAP recommended a twofold margin of safety and reduced the recommendation from 77 to 40ppm. The level of 40ppm was also selected to fall above the naturally-occurring background levels of lead seen in various parts of the United States.

The AAP worked closely with Congress throughout the development of the CPSIA to provide access to pediatric environmental health experts and researchers, who consulted on various aspects of the legislation. The final bill represented a significant step toward reducing children's

* "Small amount" is defined here as 1 mcg/dL increase in blood lead level.

exposure to lead, particularly by setting limits where none had previously existed on materials other than surface coatings in children's products.

Health Effects of Reducing Lead Limits from 300 to 100ppm

In the January 26 *Federal Register* notice, "Children's Products Containing Lead; Technological Feasibility of 100 ppm for Lead Content," the CPSC requested public comment on several specific questions. The AAP would like to provide information on #6: "What health effects are associated with a reduction of the lead content limit from 300 ppm to 100 ppm? From 300 ppm to some other level above 100 ppm?"

Based on the AAP's previously-noted calculations, an object containing 77ppm of lead is capable of raising a child's blood lead level to a level that would result in the loss of one IQ point. Please note that this is not meant to be interpreted as a definitive statement for each exposed individual; rather, it is a public health statement representing what will be true for the majority of children. Individual children will have factors that either increase or decrease their vulnerability.

For the majority of children, ingestion of an item containing 300ppm of lead would result in the loss of almost 4 (3.9) IQ points. Ingestion of an object containing 100ppm lead would result in the loss of just over one (1.3) IQ points.

When averaged across even a modest population of children, the public health harm caused by lead is significant. Considering that there are about 75 million children in our nation, impacting one-half of one percent of all children would mean exposure of 3.75 million children. Respected economic studies estimate the loss of lifetime income at $8,346 (1995 dollars) for each loss of one IQ point. For 10,000 children, this equals approximately $83.4 million; for 100,000 children, it would be $834 million. For one million children, it would total over $8.3 *billion*.

Other Important Issues Related to Lead Exposure

The Commission has received numerous comments regarding the feasibility of reducing permissible lead levels from 300 to 100ppm. With those in mind, the AAP would urge the Commission to keep some additional points in mind.

Children must be protected from both acute and chronic exposure to lead. Cases where exposure to a single lead-laden object can cause severe or fatal lead poisoning are, happily, rare. The CPSIA focused on preventing the often-invisible but pernicious cases of silent lead poisoning, where parents or caregivers are unaware that lead exposure ever occurs. The Commission must remember that lead accumulates in the body and exposure can come from multiple sources, so exposure must be limited as much as possible from each individual product to avoid accumulation to dangerous levels.

Harm from lead is usually invisible. Most children are tested either once or twice for lead exposure, either around the ages of one or two years, or both. Exposures in infancy will not be detected until at least age one, and those that take place after the age of two years may never be detected. In some communities where the risk of lead poisoning from older housing stock is deemed low, testing for blood lead levels may not be performed at all. As a result, parents may never be aware of their child's elevated blood lead level or associated damage. Moreover, there is no way for parents to know if a given object contains lead, so they are powerless to control exposure or protect their children. It is the responsibility of the Commission to provide that protection for children and families.

Risk assessment of individual products or classes of products is impractical and subjective. Some have recommended that the CPSC engage in some form of risk assessment to determine the levels of lead permitted in children's products. From a medical perspective, the benefit of lead exposure is zero, and so the considerable risk will always outweigh the benefit of having lead in children's products. A risk assessment scheme would introduce tremendous levels of subjectivity into this process and remove any certainty for parents and caregivers about the safety of the items they purchase. In addition, the CPSC would shoulder an untenable burden in attempting to perform or confirm risk assessment on various products. For all of these reasons, the AAP urges you to reject calls for risk assessment related to individual products and the amount of lead that should be permitted in them.

Lead limits should be based on total, rather than accessible, lead levels. Congress thoroughly explored the issues related to accessible versus total lead and issued a clear statutory direction for the agency to regulate based on total lead. The variability among laboratory tests for accessible lead and the fact that accessibility can change over time (e.g. as certain materials degrade) led Congress to reject accessibility as the appropriate standard for regulation. In fact, Congress directed the CPSC to use total lead as a way to provide greater certainty and consistency, making it easier for companies to measure compliance reliably. Challenges with consistency among tests performed by laboratories should lead the CPSC to work more closely with those entities to ensure the appropriateness and consistency of protocols used. Laboratory issues do not, however, negate the validity of 100ppm as the appropriate standard protective of child health.

CPSC should collaborate closely with companies working to comply in good faith. The AAP appreciates that both the Commission and individual companies will undoubtedly face challenges related to compliance. In particular, very small producers may face difficulties related to the cost or complexity of testing. The AAP urges the CPSC to work closely with these entities to craft creative, flexible solutions that reduce the regulatory burden while also preserving child health and safety.

In conclusion, I appreciate this opportunity to offer comments on behalf of the American Academy of Pediatrics. The AAP urges the Commission to continue placing the highest priority on protecting children from lead exposure and its devastating consequences. Large numbers of children's products currently on the market already comply with lead limits; we encourage you

to work closely with those remaining companies who still face compliance challenges to identify solutions. In any small number of cases where the CPSC may determine that the 100ppm limit is not technologically feasible, the CPSC should use the flexibility granted by Congress under the CPSIA. The AAP stands ready to assist you in any way in this important undertaking. Please do not hesitate to call upon us.

ThermoFisher
SCIENTIFIC

Comments on "Technological feasibility of meeting the 100 ppm lead content limit for children's products"

***Dr. Stanislaw Piorek* and Mark Lessard**
Thermo Scientific Niton Analyzers

CPSC Public Hearing, 10 a.m. ET, February 16, 2011,
Bethesda, MY

The world leader in serving science

Meeting the 100 ppm Lead Level

- Handheld XRF is quite capable of analyzing lead to levels lower than the proposed 100 ppm limit; the Limits of Detection (LODs) achievable with HHXRF are typically at or below 10 ppm for most matrices (substrate materials) such as plastics, glass, ceramic and recycled materials.

- The LODs for metals are higher, at or below 100 ppm for most metal samples. A Sn based metal matrix can be difficult to analyze Pb at the100ppm level.

- HHXRF technology has already been embraced by many who are required to comply with the CPSIA. It is readily accessible, fast , nondestructive and it is very cost effective.

Cost Benefits of Screening with XRF

Analyzer Cost*	Samples per Day	Cost per Trigger Pull*
$25,000 (Niton XL2)	100	$0.33
	300	$0.11
	500	$0.06
$30,000 (Niton XL3t)	100	$0.40
	300	$0.13
	500	$0.08
$35,000 (Niton XL3t GOLDD)	100	$0.46
	300	$0.16
	500	$0.09

*Calculations are based on a 5-day week and 50-week year. Analyzer cost is approximate retail value.

Calculation details for complete elemental analysis profile – 100 samples/day ($25,000 analyzer):

100 x 5 x 50 = 25,000 trigger pulls annually
3 years = 75,000 trigger pulls
25,000 ÷ 75,000 = $.33

Cost Benefits of Screening with XRF – Lab v/s XRF

- Cost of a **single analysis** performed by a laboratory (ICP) may vary from $ 55 to $ 75.

- Typically, a toy or any child product will contain more than one component; ten to twenty different components is not unreasonable.

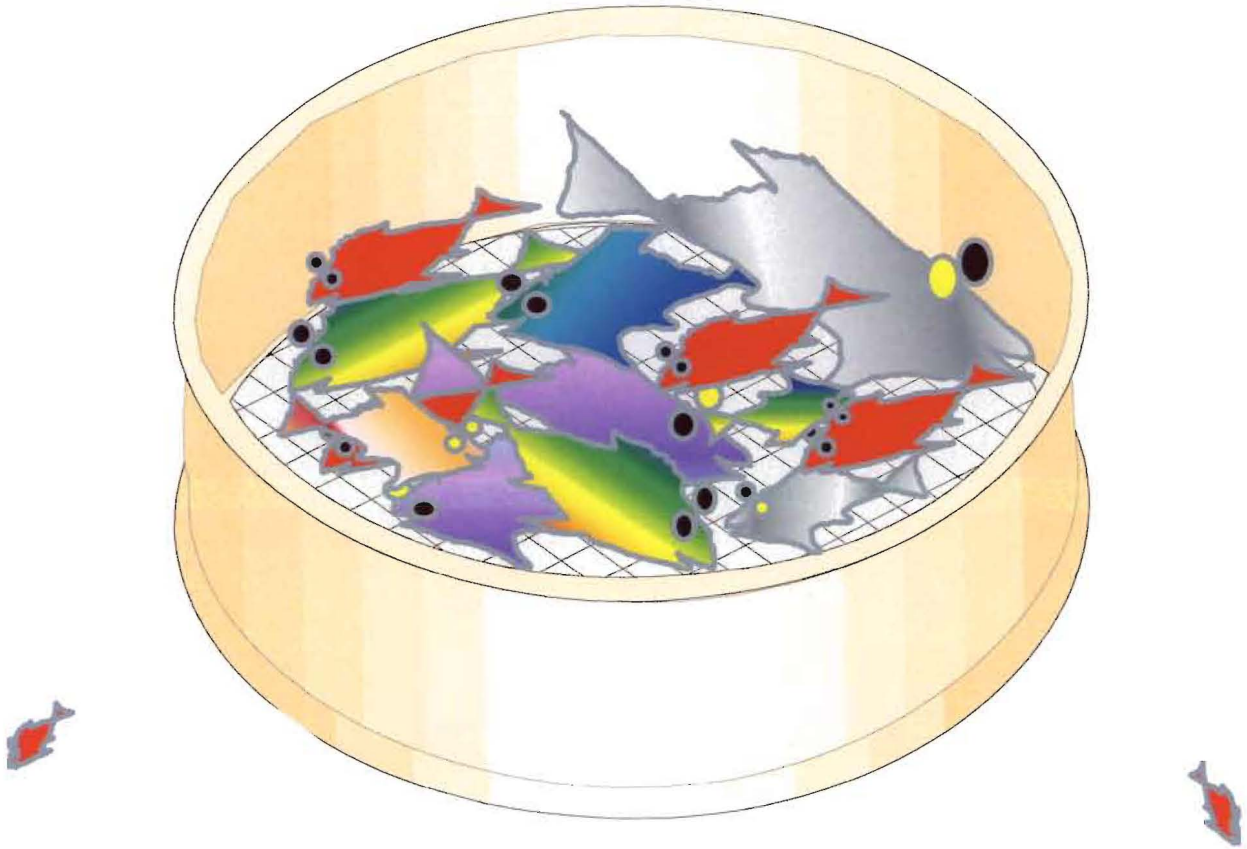
- The costs of testing add up very quickly
  - Assuming that object subject to test for compliance is composed of ten different materials each requiring testing at, say $55 per test, we end up with a bill for $550.
  - At this cost one could afford only 45 such tests, at a total of $25,000, the cost of an HHXRF Analyzer.

  - Note: XRF can provide the instantaneous analysis of up to 25 elements during a single measurement.

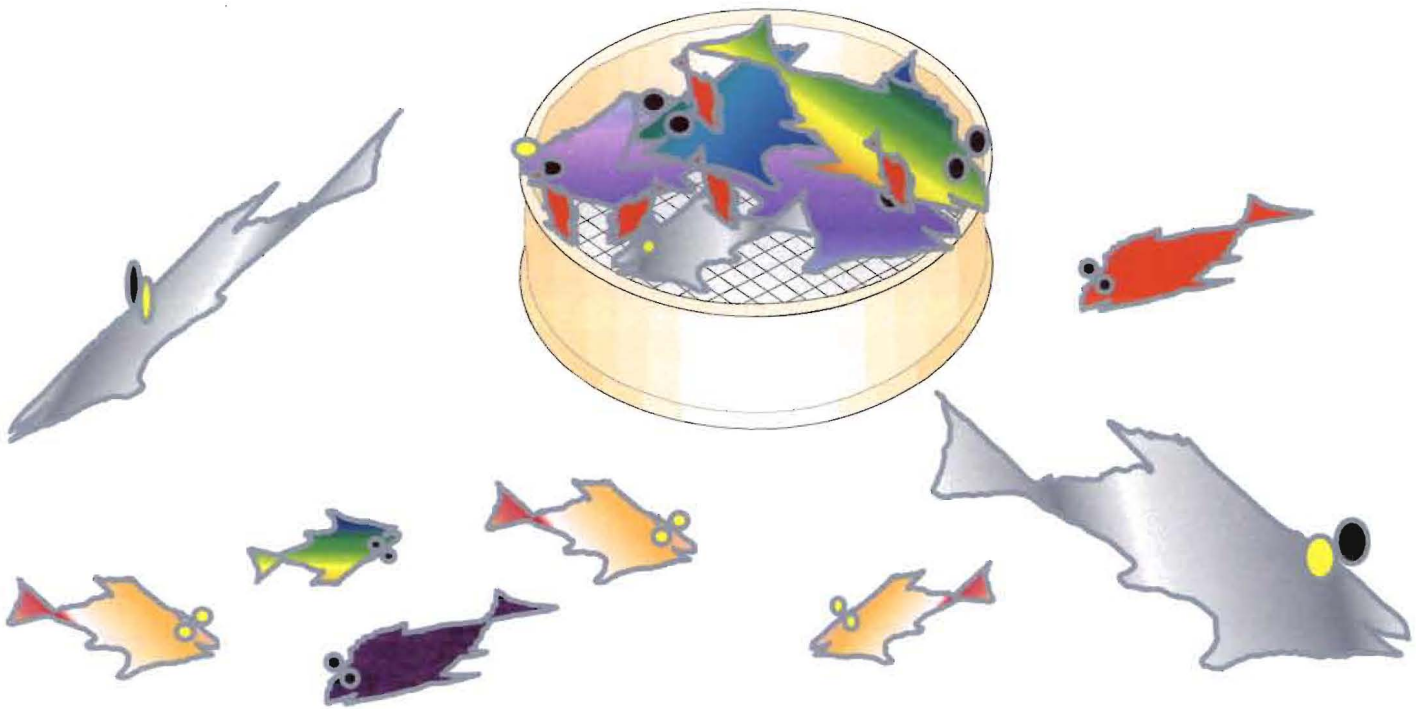
Cost Benefits of Screening with XRF - Fishing the Lead out

- Practice shows that majority (the estimates put number at 90 to 95 %) of noncompliant articles usually contain large quantities of lead, many times over the regulatory threshold, which are easily detected by HHXRF technology.
- Using the most sensitive laboratory methods to analyze major concentrations of elements is akin to catching sharks with a single fine mesh net while a large number of strong nets with not so fine mesh would be much more effective.
- HHXRF is an affordable, and very effective net to catch excessive levels of lead in products.
- Laboratory techniques with their better sensitivities represent a fine net but with limited reach with which to catch violations.
- HHXRF and laboratory methods are complementary and in tandem will provide for a higher level of compliance.

Casting a Coarse but Large Net



Casting a Fine but Small Net



Technological Feasibility of 100 ppm for Lead Content in Children's Products

CPSC Public Hearing
Bethesda, Maryland
February 16, 2011

Sanjeev Gandhi and Christina Crimi
Consumer Testing Services
SGS North America, Inc.
291 Fairfield Avenue
Fairfield, NJ 07004

WHEN YOU NEED TO BE SURE

SGS

THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY

- Founded in Rouen in 1878, under the name of Goldstück, Hainzé & Co. as a grain inspection company
- First registration as Société Générale de Surveillance in Geneva in 1919
- Listed publicly since 1985
- World's largest inspection, verification, testing and certification company
- A network of over 1,000 offices & laboratories with over 55,000 employees

100 PPM --Technological Feasibility
Lead Content in Children's Products

- SGS Comments on Technological Feasibility of 100 ppm limit
- Analytical techniques do exist to detect lead below 100 ppm across for most material types
  - There are some limitations of practical nature however (next slide)
- Statistical analysis of lead content testing data (90,000 points)
- Analysis covered major most types comprising children's products covered

Lead Content Variability – Data Limitations

- The lab does not have detailed BOM information ⇨ material types are only generically characterized
- Lack of electroplating information on metals can be a big factor
- The material is not purely homogeneous
- The digestion may not be complete
- Limitation of sample size (small quantity induces greater uncertainty)

100 PPM –Technological Feasibility
Source of Data

- Majority of data from SGS Shenzhen lab specializing in testing of children's toys and other children's products
- Analytical data stripped from customer information (name, contacts, product style #s etc. to preserve confidentiality)
- Data included in the study was collected over April-July 2010 period
- CPSIA limits of 90 ppm for lead in surface coating and 300 ppm for substrate already in effect

100 PPM – Technological Feasibility
Variety of Materials Examined

- Total of ~ 90, 000 data points included in the analysis
- Data came from testing of finished products
- 1.4 % of materials tested showed positive lead result (>40 ppm)

	Total Number of sample	Positive Sample	% Positive
Coating	33924	413	1.20%
Plastic	36602	247	0.70%
Metal	11605	440	3.80%
Glass/Ceramic	4464	118	2.60%
Others	2678	32	1.20%
Total	89273	1250	1.4%

Lead Content Distribution — Across Material Types

- Lead concentration levels (% data points) compared to lead limits

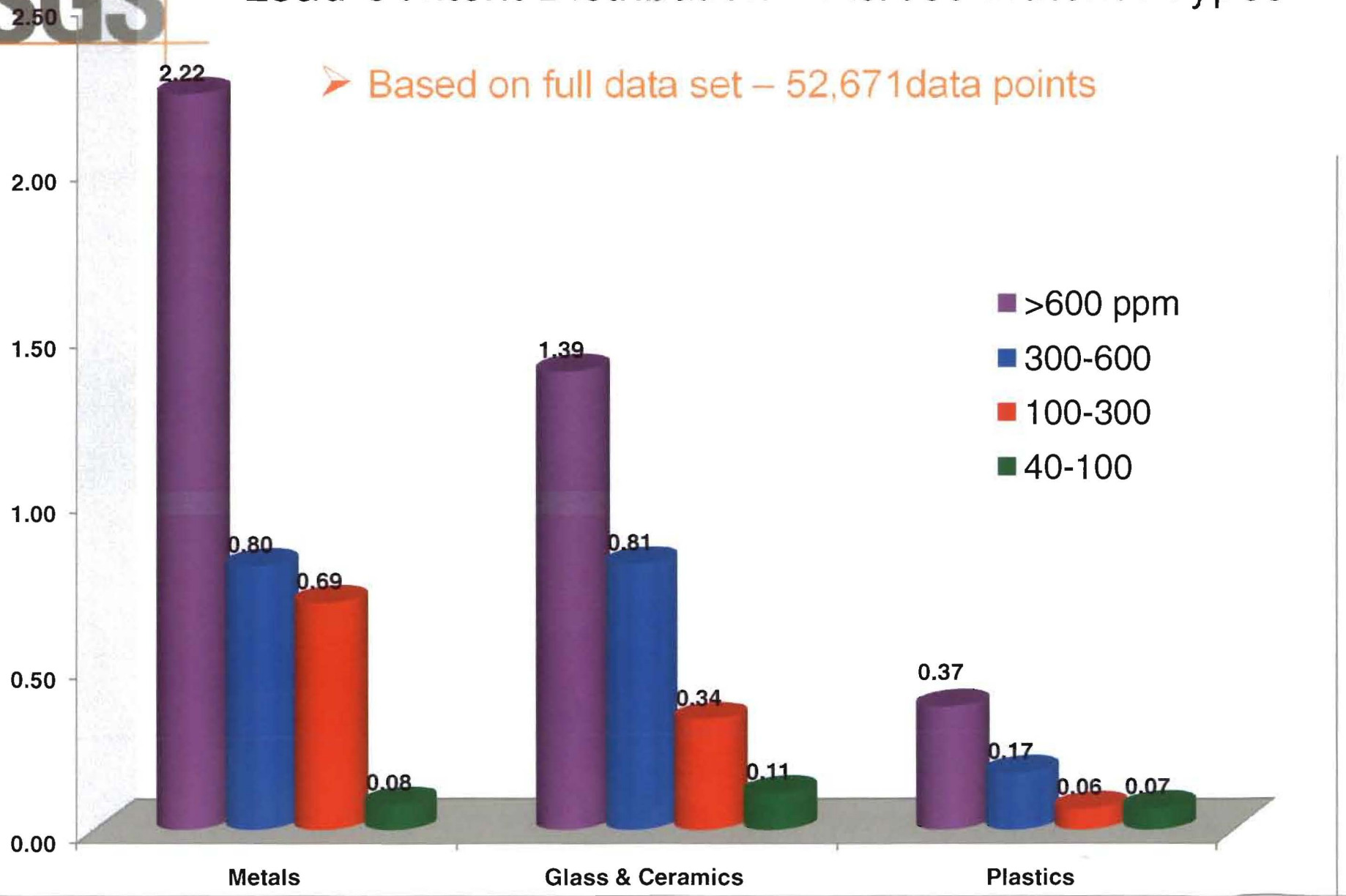
Lead Conc. (PPM)	Metals	Glass & Ceramics	Plastics
> 600	2.22	1.39	0.37
300-600	0.80	0.81	0.17
100-300	0.69	0.34	0.06
40-100	0.08	0.11	0.07

- Figure based on positive samples – 1250 data points

Lead Conc. (PPM)	Metals	Glass & Ceramics	Plastics
> 600	58.64	52.54	55.47
300 – 600	21.13	30.51	25.50
100 – 300	18.18	12.71	9.31
40 – 100	2.05	4.24	9.72

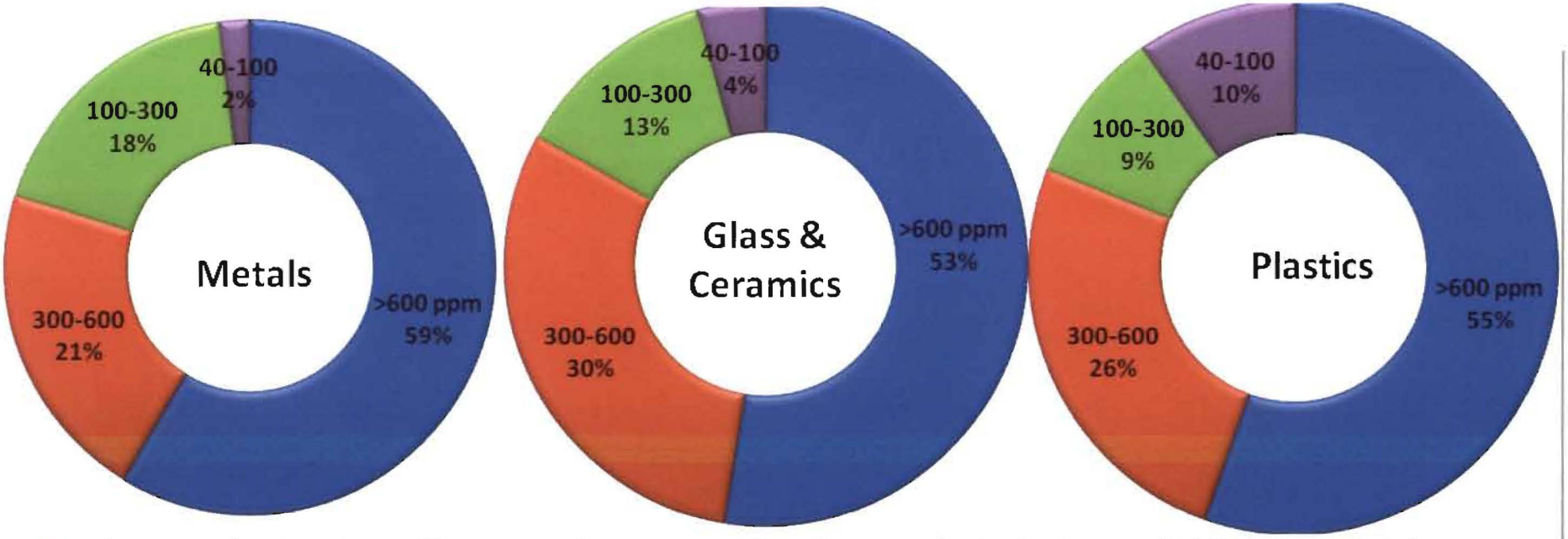
Lead Content Distribution – Across Material Types

- Based on full data set – 52,671data points



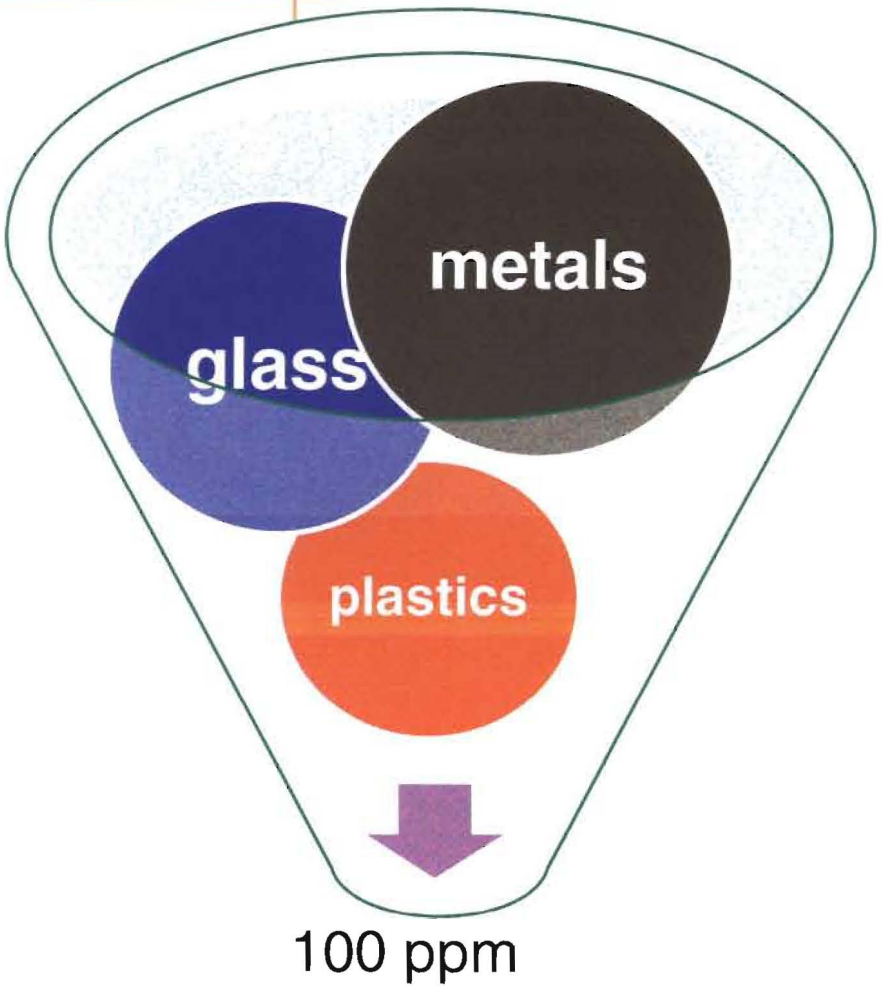
Lead Content Distribution – Across Material Types

- Figure based on positive samples – 805 data points



- Among the lead positive samples across the three substrate types (805 data points),
  - With 300 ppm limit, ~80 % materials fall outside the current acceptable level
  - With reduction in limit to100 ppm, ~90% of materials will fall outside the acceptable level
- Potentially with lower limits, across all tested samples
  - the lead positive materials can be reduced to 0.9 %

Lead Content Distribution – Across Material Types



- Overall observations
  - The highest variability in case of metals ranging from 100 to 10,000 ppm, factor of 100
  - The variability range for lead concentration in glass/ceramics and plastic much lower
  - Plastics: foam and rubber like materials show higher lead content compared to thermoplastics
  - The glass/ceramics sample, substrates with shiny texture have higher lead content due to type of coatings used
- General order of the materials that meet 100 ppm limits
  - Plastics<<glass<<ceramics<<metals

FINAL

Testimony of Mr. Milton Bush, Chief Executive Officer
American Council of Independent Laboratories

Before the

U.S. Consumer Product Safety Commission

"100 PPM—Technological Feasibility Public Hearing"

February 16, 2011

Good morning Madam Chairman; distinguished members of the Consumer Product Safety Commission:

I very much appreciate the opportunity to appear before you today to discuss the role of third party independent laboratories in the testing of consumer products under your jurisdiction, and specifically with regard to the technological feasibility of testing children's products for lead at current and potentially lower regulatory limits.

My name is Milton Bush and I am the Chief Executive Officer the American Council of Independent Laboratories (ACIL). I am also testifying on behalf of the International Federation of Inspection Agencies, Americas Committee (IFIA AC).

ACIL was founded in 1937 as the national trade association representing independent scientific laboratory testing. An independent laboratory is not affiliated with any institution, company or trade group that might affect its ability to conduct investigations, render reports, or give professional counsel objectively and without bias. ACIL's 150 member companies operate approximately 1000 facilities across the U.S. and abroad. They range from the one-person specialty laboratories to multi-disciplined, international corporations employing thousands of analysts, risk management specialists, consultants and support staff.

IFIA is the trade association for inspection agencies and conformity assessment organizations that provide inspection, testing, and certification services internationally. The promotion of integrity is one of the federation's top priorities. IFIA was founded in 1982 and Members and Associate Members include the leading testing and certification companies from around the world. They cover every field of inspection and related testing making IFIA's work and views truly representative of the profession. IFIA is a nonprofit organization. Its objectives are to review and, where possible, to improve the methods, standards, safety procedures and rules used and observed by Members for the benefit of Members and their clients. www.ifia-federation.org

IFIA and ACIL members are involved in virtually every aspect of public health and safety, from testing drinking water and food to make sure they are safe for consumption, to ensuring that our nation's armed forces have tools and weapons that will not fail when needed, and yes, making sure that consumer products are safe and compliant with federal and state standards.

IFIA and ACIL promote excellence, independence, professionalism, competency, and innovation within the testing and certification community. Toward that end, IFIA and ACIL both value effective and meaningful accreditation programs, as they are a key factor in ensuring technical competency of laboratories that ultimately lead to repeatable, reliable, and consistent test results.

The key distinction between IFIA and ACIL members and other conformity assessment bodies approved to perform third party testing by CPSC is independence. IFIA and ACIL members provide an objective review of product safety and performance free from both the economic demands of the marketplace and internal company pressures because they have no financial interest in the sale of products. This ensures that results of the evaluation of products to meet the specified requirements (relating to safety, health and the environment) are free from conflicts of interest and undue influence.

I would also recommend to the Commission's attention a review of the IFIA Guidelines, which outline the working procedures and professional standards normally used by IFIA members when providing testing, inspection and certification services. I have provided a link to those guidelines with my written testimony: http://www.ifia-federation.org/content/wp-content/uploads/2010/04/IFIA_Guidelines.pdf.

In addition to assuring that consumer products meet CPSC standards and are otherwise safe for consumer use, independent third party testing by qualified labs instills greater consumer confidence and results in ready market acceptance of those products. It is no accident, after all, that despite the fact that the CPSC has issued a "stay of enforcement" for the third party testing and certification of products to several CPSC standards (including most recently extending the stay for lead substrate in children's products) the majority of major retailers in the U.S. continue to require third party testing and certification in order to place products on their store shelves.

The focus of my testimony is limited to technological feasibility of consistently and reliably testing children's products to a 100 ppm substrate standard, a question on which IFIA and ACIL members have expertise.

The test method most commonly employed today to test for lead in the various substrates of consumer products, and that has been explicitly recognized and utilized by the CPSC, of course utilizes Inductively Coupled Plasma (ICP) technology, sometimes referred to as "wet chemistry."

ICP is an analytical technique used primarily for the detection of trace metals. The primary goal of ICP is to get elements to emit characteristic wavelength specific light, which can then be measured. ICP was first employed in the early 1960's and has since been refined and used in conjunction with other procedures for extremely precise quantitative analysis in a variety of commercial and scientific applications.

ICP is today employed as the "state of the art" in analytical measurement of heavy metals in a variety of contexts and is recognized as such by several federal agencies. These include the testing of environmental samples to EPA standards; for the evaluation of occupational hazards under NIOSH test methods; and for the measurement of lead and other trace elements in various metal alloys and fuels, according to numerous ASTM test methods. In short ICP is the most widely used and relied upon means of evaluating and guaranteeing the quality of a wide range of products and substances, well beyond just consumer products.

While there are several types of ICP analytical test methods, they all have been demonstrated, in various contexts and when properly performed, to achieve precision, reliability and repeatability capable of consistently determining lead levels at below 100 ppm in all widely used consumer product materials, including metal, plastic, glass and ceramic substrates. There have been several inter-laboratory studies, well known to the CPSC lab and other scientific staff that

have achieved analytical results of below 100 ppm for lead. These include the September 2008 "round robin" inter-lab study, "Results of Proficiency Test Metals in Plastics.

In addition to ICP, the CPSC has also recognized use of x-ray fluorescence (XRF) test methods to detect lead in plastic substrates of consumer products. The CPSC continues to review the expanded use of XRF to other substrate materials and surface coatings.

I would like to illustrate the importance of a solid framework on which repeatable, reliable, consistent test results are built. NIST's NVLAP accreditation program for energy efficiency of lighting products is a good example of an effective inter-laboratory comparison program, also referred to as proficiency testing. A single artifact, with known characteristics, is shared among all labs in the accreditation program for testing. A robust analysis of the results by the accreditors at NVLAP determine if a lab's results are outside of the expected results and if so, those labs are required to provide corrective actions. Key features of such a program include testing equipment calibration, standardized testing procedures, instructions, and uniform methods for reporting results. Such a framework enables the program administrators to determine the capability of laboratories in evaluation of products to test methods specified in the standards. Participation by laboratories in inter-laboratory testing, or proficiency testing, is a key requirement to maintain their accreditation.

When the CPSC determines the technologically feasibility for laboratories to test to the level of 100 ppm, it needs to rely on the laboratory accreditation and accreditation body recognition process to meet the sector-specific requirements under CPSC regulations. As we have commented previously, we also believe that while the ILAC-MRA is a reasonable place to start in determining which accreditation bodies are qualified to perform the necessary accreditations, it is very clear that there are still substantial differences between the accreditation bodies that are participating in this MRA. For example in China the accreditation body is controlled by the government, and the government also controls government owned labs. This is a potential conflict of interest. We believe that the CPSC needs to designate individual accreditation bodies based on specific criteria and that those bodies are periodically reviewed for competency.

The reliability, repeatability and consistency of test results is a by product of the proficiency testing framework used to determine the technological feasibility of the test methods and the laboratory accreditation process that assesses technical competency. IFIA and ACIL encourage

CPSC to consider how its current program may be further strengthened by adjustments in these two critical areas.

Thank you for the opportunity to testify before you here today. I would be happy to answer any questions you may have.

Testimony of Quin Dodd, Partner, Mintz Levin PC
and
Satbir Nayar, Director of Marketing, XOS Inc.

Before the

U.S. Consumer Product Safety Commission

"100 PPM—Technological Feasibility Public Hearing"

February 16, 2011

Good Morning Madam Chairman and Commissioners.

My name is Quin Dodd with the Washington office of the law firm of Mintz Levin. I am here today representing my client, XOS, Incorporated of East Greenbush, New York. Joining me today is my colleague, Satbir Nayar, Director of Marketing for XOS.

We both very much appreciate the opportunity to appear before you today.

I will be making some initial introductory remarks and then Satbir will address the technological capability of his company's technology and a new ASTM test method to reliably measure lead in consumer products well below 100 parts per million.

We have of course briefed you individually in the past about XOS' analyzer technology, called "HD XRF," as well as a new ASTM method, F-2853-10, that was recently published for the quantification of lead in paint and other surface coatings as well as substrates

First, Satbir and I would both like to thank the CPSC for your recent purchase of an HD Prime analyzer for the Gaithersburg Lab. I was out at the lab several weeks ago when the unit was installed and we're very pleased and proud that it is now being put to good use by Chemistry Division staff to help them fulfill their important mission. Although I will say I think the unit will look much better once it's in the new lab in Rockville!

If I may, then, I'd like to offer you a brief recap of where we are now with the technology and where we believe we are headed and then Satbir has a short Power Point presentation for you.

Since we briefed you personally just about a year ago, a lot has happened. XOS developed a new, transportable version of its analyzers, called "HD Equity" that is as precise and reliable as an HD Prime but smaller. Many more labs and manufacturers have acquired and installed XOS instruments and are now using them to test and/or verify testing for lead, cadmium and other heavy metals in a variety of substrate and surface coating materials.

Most importantly, though, as I mentioned and as Satbir will discuss in more detail, ASTM has reviewed, completed, and published the final version of a new standard test method for the quantification of lead in paint using "energy dispersive x-ray fluorescence spectrometry using multiple monochromatic excitation beams." (Now you see why Satbir is here with me!) We believe the finalization of this method, which was well over a year in development, paves the way for wider industry and regulatory acceptance of this alternative to traditional ICP for lead in paint, and ultimately for all regulated heavy metals in both paint and substrate materials.

As you all well know, Section 101 of the CPSIA both establishes very demanding new lead limits in children's products but also directly contemplates expanding the options manufacturers have to test to these tough new standards. While ICP or "wet chemistry" is currently the only specifically referenced CPSC test method for the quantification of lead in paint and most substrates, HD XRF can give this Commission and consumers at home the same or even greater level of confidence that products tested using it are indeed in compliance with these and possibly future heavy metals limits.

I would also like to state for the record that XOS is not now advocating and has never advocated for or against the 100 ppm lead standard called for by the CPSIA, or any other CPSC standard for that matter. Indeed, the company only entered this market space after enactment of the CPSIA, because it recognized the very limited options manufacturers and others had and, frankly, still have when it comes to testing for lead and other heavy metals in consumer products.

XOS has been a long time, world pioneer in the development of cutting-edge x-ray optic systems capable of screening out the background "noise" that limits the effectiveness of traditional XRF instruments. It commercialized this technology widely for the petroleum industry to measure the sulfur content of fuels in response to a broad (EPA) regulatory mandate at the time, and then began to expand upon the wider potential of this highly precise, non-destructive, affordable, and easy-to-use technology for other mandates around the world (e.g., CPSIA).

XOS is not asserting or anticipating that this technology will eliminate traditional test methods like ICP and XRF screening, but what it can do and is in fact currently doing at major labs and manufacturing facilities around the world is to provide an additional option to firms seeking to either verify their other testing programs or to test products in the first instance. In my view, this is exactly the kind of development that Congress envisioned and intended when it enacted the tough new standards of the CPSIA. Indeed, this type of approach—establishing a difficult regulatory standard and anticipating technological developments will rise up to meet it—has been repeated numerous times in the past. XOS and HD XRF represent an instance where it actually has worked.

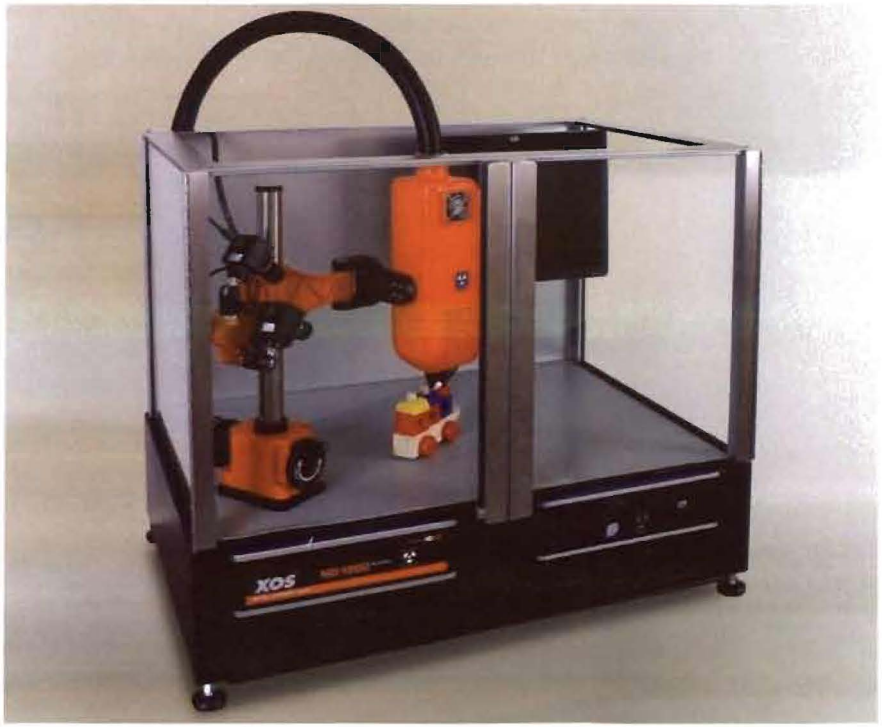
And if I may speculate, I believe it is the kind of development that you all would like to see as well: More testing options; cheaper, better, faster and non-destructive testing; and complete protection of consumers.

The phrase "win-win" is used a lot in this town, but I really can't think of a better application for it than with regard to HD XRF and its potential to enhance product safety.

Thank you again very much for your time and attention and now I would like to turn it over to my friend and colleague, Satbir Nayar, after which we would be happy to answer any questions you may have.

HDXRF

Quantification of Total Lead in Substrates at 100ppm limit – An alternative to wet chemistry



XOS®

Limits of Detection – HDXRF

HDXRF	Pb	Cd	Cr	As	Br	Sb	Se	Hg	Ba	Cl
Plastic Substrate	0.8	2	2	.8	1	5	1	1	50	100*
Metal Substrate	10	10	15	8	n/a	20*	5	10	200*	n/a

Plastic and PVC substrate measurements were for 2-3 minutes, paint on plastic and metal 4-6 minutes
Extending measurements would reduce these values
•Data reflects longer measurement times
Limits of Detection will vary dependent on specific type of matrix and combinations of elements present

ASTM Test Method F2853-10

" Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams "

- Published in August 2010
- Applicable for Pb concentrations of
  - >14 ppm for plastic and glass
  - >66 ppm for metals

XOS®

ASTM F2853-10 Substrate Precision - HDXRF

- Inter Lab Study completed in Sept 2009
- 9 labs, 34 samples, ~1000 measurements
  - Coated/uncoated, metal, plastic, glass, etc
- No bias

Repeatability (r) at 100ppm	
Uncoated Plastic/ Glass	Uncoated Metal
9ppm	33ppm

Reproducibility (R) at 100ppm	
Uncoated Plastic/ Glass	Uncoated Metal
23ppm	46ppm

XOS®

HDXRF - Precision today

- Standard Reference Materials –
  - Copper Alloy - Pb level certified at 58 ppm
    - r = 11 ppm
    - R = 14 ppm
  - Plastic - Pb level certified at 98 ppm
    - r = 6 ppm
    - R = 7 ppm
  - Plastic - Pb level certified at 13.6 ppm
    - r = 3 ppm
    - R = 4 ppm

XOS®

Thank you

For additional information

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qdodd@mintz.com

XOS

Presentation of Richard Woldenberg
100 ppm Lead Standard CPSC Hearing
February 16, 2011

I. Preliminary Comments

a. Posing a question with no answer or with an obvious (but unwelcome) answer.
b. Reduction of standard has little to do with health or safety.
c. Looks good on paper – but doesn't work in the real world.
d. Expense and disruption
e. Public fear factor. Arbitrary standard. PIRG quote.
f. Jobs will be lost – and so will cherished products
g. NO ONE WILL BE SAFER – but many people will be poorer.

I do not accept that CPSC is powerless to stop this change in standard.

II. What is being considered?

a. Reduction from 300 ppm in substrate to 100 ppm in substrate
b. Where does it end? Is 115 ppm dangerous but 100 ppm not?
c. "Technological Feasibility" – an utterly commercially-unrealistic standard – If Rolex CAN do it, Timex MUST do it.
d. Removes margin of error for low tech manufacturers.

III. Health Risks are Nil in this Region of Lead-in-Substrate Content

a. Historical CPSC Recall Statistics – all at higher levels of lead and all bio-accessible (soluble lead). The new standard is only applicable to INSOLUBLE LEAD.
b. Low injury instances makes proving effectiveness IMPOSSIBLE
c. No studies, **no causal link** to actual, documented injuries
d. Health risk is not just speculative – it is entirely HYPOTHETICAL.
e. Risk PALES in comparison to other risks (pools and spas, even pool drains)
f. Approved materials like approval of gold, platinum, silver, titanium, gemstones, surgical steel, palladium, rhodium, osmium, ruthenium and iridium for use in children's products.
g. End of use of recycled materials in children's products?

IV. Economics DO matter.

a. Cost versus Benefit. Benefit is zero – but cost is HUGE
b. Incentive to substitute components (low in utility (durability, quality, REAL safety). Think of metal grommets versus plastic. . . . [Raises question of ability to compete internationally.]
c. IMPOSSIBLE to manage risk to 1-2% of your activity if you can't identify WHICH 1-2% it is. Exit market versus gambling your net worth on a lab test report.
d. Examples of disruption
    i. Items slightly above 100 ppm in a single component
    ii. Complex items
    iii. Tight manufacturing tolerances lead to waste, rejected lots, shipping delays, penalties, randomized losses. Worst exposure on big, make-to-order shipments.
    iv. Failed component (safe but violative) can ruin an entire lot. Ex.: backpack with "bad" zipper. How to address "one" bad zipper?
    v. Variability in testing (report on tapes) leading to rejects. Up to 67% in the same lot. NO PATTERN. Surprising results in components not posing any conceivable poisoning risk (e.g., one piece of string tested ten times 239-275 ppm, one lot of yellow substrate in three tests varied from 23-139 ppm). **[Fear of 15 Month Rule on retesting.]**
    vi. Sharp increase in component surveillance costs. High cost to find few violative parts – often after the fact.
    vii. Expected loss of vendors and products. Expected exits at all levels of chain of commerce. Factory conditions akin to hospital ICU?
    viii. WE EXPECT 10-20% INCREASE IN COSTS FOR TIGHTER TOLERANCES. This exceeds our net profit margin.
    ix. Retesting costs expected to exceed $100,000 per annum. Stress and strain are an additional cost and consequence.
    x. New standard is an invitation to do-gooder and ambitious politicians to embarrass or destroy us. The new database also provides opportunities for competitors to attack our reputation.

V. Sourcing and Obtaining Components

a. There is much we don't know about how these components are sourced or obtained. These jobs are outsourced to trusted partners. Since there is no safety risk, we have NO REASON to know this answer. It's not our job.
b. Lead is in everything to one extent or another. Lead is an element and is found in nature. It's everywhere.

VI. The Decision Must be Pushed Out

a. Wal-Mart and others have their own 100 ppm standard already in place – in response to uncertainty and a distrust of this process
b. Regulatory compliance "exuberance". Consequences of Illinois' 40 ppm lead labeling law. [Recent incident involving Georgia mother.]
c. Retroactive or prospective?
d. How will the chain of commerce react? Will a new lower standard reduce demand for safe older stock that violates the standard?

VII. Near the Measurable Limit

a. Variability within a lot expected. Our test results: 1.7% passing tests between 100 – 300 ppm (46 out of 2701). CAN'T PREDICT WHICH 2% WILL BE BAD.
b. Wide variance in testing at same lab and between labs
c. Unpredictable results affected by tiny variances in procedure, staffing, mysterious factors – rule exposes us to UNCONTROLLABLE RANDOM EVENTS.

VIII. Diverted Business Purpose

a. Crisis of the day
b. Diversion of resources not productive and does not contribute to the greatest of the firm – will have an impact.
c. Boon for lawyers
d. Expected rising personnel turnover from wear and tear, particularly among team members charged with compliance activities.
e. Ruined business models. Who will stick around?

IX. Use of Compliant Material is No Answer

a. Educational products made of Ruthenium and Gold encrusted with diamonds and gemstones don't sell really well. We would be out of business.
b. Creating products that no one will buy is NO SOLUTION
c. Recycled materials are too risky under this inflexible rule. Must always use virgin materials.
d. We know of no means to always be compliant with this rule other than to be in a different business.

Stevenson, Todd

From: Kirsten@Kleynimals [kirsten@kleynimals.com]
Sent: Monday, February 14, 2011 1:16 PM
To: CPSC-OS
Subject: Presentation - Kirsten Chapman with Kleynimals

This is my presentation for the hearing on 100 PPM of lead in toys.

Thank you for allowing me to present to you today. I am a mother of two young boys and a recent entrepreneur. I have been working on a toy product for two years and just recently launched my toy for sales on December 1st 2010. The toy is a set of keys for babies six months and up that are made entirely of food grade stainless steel (stainless 304).

I want to give a little background on my motivation to create this toy prior to talking through the logistics of testing. Over the past six years, really since the birth of my first son, I have become more and more aware of the various toxins in our environment that I truly believe are leading to increased rates of illness in our population - whether that be developmental delays, autism or cancer. My evolution started with food, and then moved to cleaning supplies, skin/hair care products and eventually toys and consumer goods. I am not a scientist, so I am not here to present the facts behind how the various chemicals impact us, however, I am sure many of you have heard of the numerous studies - most recently about BPA and lead. I have become an incredibly skeptical consumer as a result, even if I don't always have a study that proves my suspicions. What I know is that I have a friend who told me that in one week recently she learned of 6 people between the ages of newborn to mid 30's who were diagnosed with cancer. I hear stories like this all too often and I think that we should all be alarmed enough to insist on changes.

The reality is that most kids put toys in their mouths. I was not as sensitive to this with my first son, who absolutely loved Thomas the train, but fortunately did not put them in his mouth. When many of the Thomas products were recalled because of lead in the paint, I sent all of the affected ones back to the company. But, I did not worry too much from a personal standpoint because my eldest did not put toys in his mouth. However, my second son has been a totally different story because he puts everything in his mouth. Therefore, as a consumer I find myself seeking toys that are from European companies because of the more stringent restrictions on toxic chemicals in their products (for instance, >90 PPM of lead in a solubility test). So, while I am particular about what I purchase for my kids, they also have generous grandparents who don't specifically seek out European restrictions. In fact, they more often purchase items from discount stores that come from China and that make me cringe when I see my youngest chomping on them.

Thus, when the idea struck me that the market needed a better toy key alternative, I was committed to designing something that was absolutely safe for all kids, because in the end, it's not just a personal thing - it's not just my child that matters. It's also not just about making money. It's about providing a product that hopefully is a winning business model, but that ultimately is safe for the individual kids enjoying it. It's a product that does not lead a parent to cringe when their child inevitably puts it in his mouth.

So, how did I get from that idea for a toy and commitment to safety to actually launching my product? I was lucky in that I knew I could make the product out of a safe material - something that we eat off of and cook with every day - food grade stainless steel. Honestly, the material itself was the motivating factor behind my idea. When it came to the logistics of getting the toy to market, beyond the obvious cost of manufacturing, the other costs I had to consider were testing the product for compliance and liability insurance. I never considered not testing, for that would have been a risk to my company for lawsuits and recalls. And back to individual children - it also would have meant risking their safety. I also never considered not doing the lead testing because I wanted to be able to assure parents that I was offering a completely safe product. From a consumer perspective, I know I want the assurances (again, back to my desire for European standards). When it came down to the expense of it all, the liability insurance was what nearly led me to give up on my dream of producing the keys. It was not the testing. Liability insurance for someone like me was over $8000. Testing, including additional testing for cadmium, lead and nickel, was still less than $1000.

Realistically, had the test results come back and were shown to have lead in the toy, I would have been rather devastated. However, I made it clear in my purchase order with the manufacturer that I wanted material certifications for the stainless steel, and specifically that it could not contain lead. This was not difficult to request, and it seems to me that all manufacturers could require material certification prior to purchasing the material used for the components of their toys.

If Europe is holding companies accountable to safeguard their citizens by having more stringent restrictions, what makes it so difficult to do here? Back to my story about Thomas the Train since that is the one that affected my family (and this is not to single them out, because I know it has happened to many companies, god forbid it happens to mine)…But, would that company not have saved money by
finding out before manufacturing their product what was in the paint?
Could we not take steps to ensure that components are safe before they are made into the final product? Ultimately, I have to believe that the cost of a recall - both from the practical expense of performing the recall, but also because of the detriment to the brand - has to cost more than ensuring components are safe from the beginning. And frankly, if it is a question of a company using a manufacturer who has misled them, a contract stipulating exactly what is expected as far as material should be part of the negotiations from the beginning. If the product does not meet the specified safety expectations, that contract should denote that the manufacturer needs to take the financial risk so that they are held accountable.

Why is it that we cannot offer the citizens of the US the same kind of safety protections as are afforded European citizens? I truly believe that a responsible company is one who is honest about the end result of their product on the individual - whether that be a direct impact through chemicals in the product or an indirect impact through deleterious effects on our environment (for example, water and air quality). In the end, what costs us more as a country is treating illnesses caused by the harmful effects of known toxins like lead, especially in the most vulnerable little bodies that are even more susceptible because of their small size. In the end, don't we all want our loved ones to be safe… and isn't everyone someone's loved one?

Kirsten Chapman
www.kleynimals.com
www.cleankeyanimals.com

CPSC

CPSIA: Technological Feasibility of 100ppm for Lead Content

February 16,2011

BPSA

Bicycle Products Supplier Association

BPSA President – John Nedeau

Mayer Brown – Erika Jones

Presented by: ACT Lab – John Bogler

Feasibility

- Technological
  - Material
  - Processes
- Economical
  - Material Costs
  - Manufacturing Costs

Testing

- ACT has tested over 2500 bicycles since the start of CPSIA and we have seen a tremendous improvement in product quality and substrate lead levels
- ACT Lab Tested Random Parts
- Tested same part in multiple areas with XRF and ICP (see spreadsheets and photos)

Seatpost Testing

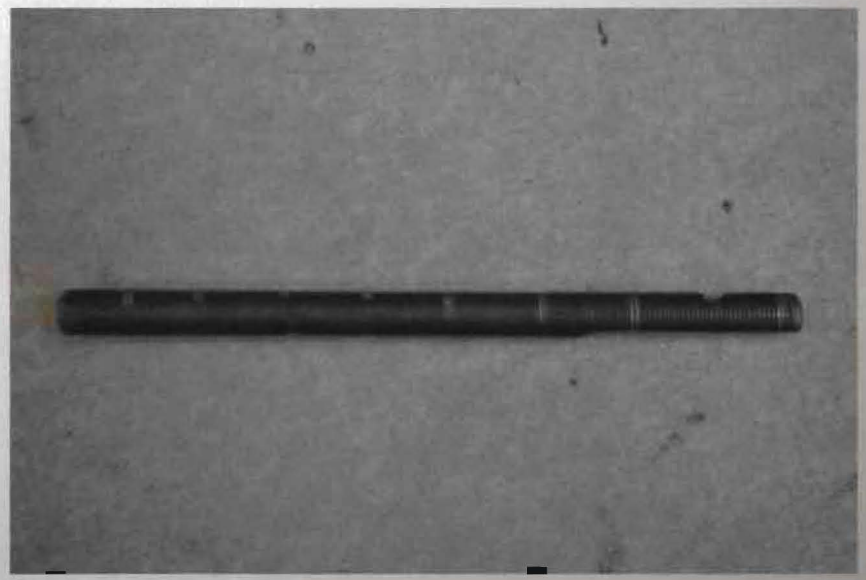
Component	Test #	Test Location	XRF-Content with Deviation	ICP Results (ppm)
Seat post - Black	1515	1	95	118
	1516	2	84	
	1517	3	60	
	1518	4	61	
	1519	5	45	58.62
	1520	6	87	
	1521	7	80	
	1522	8	86	
	1523	9	87	
	1524	10	66	99.82

Axle Testing

Component	Test #	Test Location	XRF-Content with Deviation	ICP Results (ppm)
Front Axle	1561	1	82	57.01
	1563	2	95	
	1564	3	90	
	1565	4	86	
	1566	5	108	64.99
	1567	6	86	
	1568	7	97	
	1569	8	101	
	1570	9	114	87.12
	1571	10	104	
	1572	11	99	
	1573	12	89	72.42

Axle Testing

Component	Test #	Test Location	XRF-Content with Deviation	ICP Results (ppm)
Front Axle	1479	1	87	
	1480	2	114	218.2
	1481	3	99	
	1482	4	82	
	1483	5	83	
	1484	6	106	94.15
	1485	7	68	56.1
	1486	8	69	
	1487	9	85	
	1488	10	96	83.59



Handlebar Testing

Component	Test #	Test Location	XRF-Content with Deviation	ICP Results (ppm)
Handlebar - Black	1574	1	74	62.7
	1575	2	91	
	1576	3	104	52.65
	1577	4	78	
	1578	5	76	
	1579	6	110	
	1580	7	87	60.58
	1581	8	71	
	1582	9	88	69.6
	1583	10	93	
	1584	11	90	
	1585	12	104	

Frame Testing

Component	Test #	Test Location	XRF-Content with Deviation	ICP Results (ppm)
Frame	1628	Seat Tube (Blue) - 10	118	50.79
	1629	Seat Stay (Blue) - 11	117	
	1630	Chain Stay (Blue) - 12	111	
	1631	Rear Dropout (Blue) - 13	106	43.82

Crank Testing

Component	Test #	Test Location	XRF-Content with Deviation	ICP Results (ppm)
Crank - Black	1586	Left - 1	85	62.3
	1587	Left - 2	106	
	1588	Left - 3	126	63.55
	1589	Left - 4	103	
	1590	Right - 1	117	
	1591	Right - 2	72	61.66
	1592	Right - 3	115	
	1593	Right - 4	126	53.64

Technological Process

- Purity and consistency of raw and recycled materials
- Cutting threads in materials without lead
- Testing equipment accuracy and preparation

Material Pricing and Practicality

- Pricing Differences
- Sourcing of material
- Availability of material
- Practicality of implementation

Results

- Testing showed that within the same piece of substrate, component results were +/- 50ppm
- Based on this testing of product it is not currently feasible to reduce the lead standard from 300 to 100 ppm
- Recycled steel and other materials will not meet the 100ppm standard through normal cost effective processes
- This will increase cost and be prohibitive for children's bicycles

Conclusion

- ACT has tested over 2500 bicycles since the CPSIA has been implemented and we have seen a tremendous improvement in overall product quality, including in the substrate lead levels
- ACT Lab and BPSA support testing requirements directed by CPSC when technologically feasible and when it increases safety for children
- Reduction from 300ppm to 100ppm is not technologically feasible
- Reduction from 300ppm to 100ppm has been discussed widely and the consensus is that this will not increase safety to consumers of bicycles

Written Comments Received in the Office of the Secretary as of February 10, 2011

Children's Products Containing Lead; Technological Feasibility of 100 ppm for Lead Content

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Stevenson, Todd

From: Information Center
Sent: Friday, January 28, 2011 5:30 PM
To: Stevenson, Todd
Cc: Wolfson, Scott; Filip, Alexander; Fleming, Nychelle
Subject: FW: Message from Email Form

Todd,

Please note the information below as comments.

Thank you,

Michael June

From: emailform@cpsc.gov [mailto:emailform@cpsc.gov]
Sent: Friday, January 28, 2011 2:23 PM
To: Information Center
Subject: Message from Email Form

01/28/2011 14:22:06

Name = TIna
Organization/Affiliation =
Daytime Phone = 309-695-5151
E-mail address = tinal@rkgrain.com

Message = Hi, I have been very concerned about the "safe" levels of lead in children's products. It is my understanding that currently that level is 300 ppm, but may be changing to 100 ppm. I've done some research and have learned that no level of lead is safe for young children. I am proposing that all products must have on their label how much ppm of lead it contains, so that way consumers are informed and it is to their discretion whether they want to purchase that product. When I see products on a store shelf, I shouldn't have to be questioning whether it is safe or not. It should disclaim all materials that make up that product, just as cigarettes & alcohol do, and say whether it "may" be harmful. Thank you.

Stevenson, Todd

From: Hampshire, Melissa
Sent: Thursday, February 03, 2011 12:02 PM
To: Stevenson, Todd
Subject: FW: MO AG recent toy testing - 100 ppm feasibility
Attachments: 2010 toy testing results - STAT Lab 12-10.pdf

From: Angle, Dave [mailto:dave.angle@ago.mo.gov]
Sent: Thursday, February 03, 2011 10:01 AM
To: Hampshire, Melissa
Subject: MO AG recent toy testing - 100 ppm feasibility

Hello:

We do testing every so often here in MO and I thought it would be helpful to let you know that in our latest round, each of the toys we tested came back less than 100 ppm for Pb and Cd. To me, that indicates that the 100 ppm standard is attainable and has been attained. The items tested include plastic substrate, surface coating, and metal.

Results are attached.

Dave Angle

David Angle
Assistant Attorney General
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Accreditation Numbers: IEPA ELAP 100445; ORELAP IL300001;AIHA 101160;NVLAP LabCode 101202-0

December 29, 2010

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Telephone: (573) 751-3376
Fax: (573) 751-2041

RE: Children's Toy Testing STAT Project No: 10120083

Dear Dave Angle:

STAT Analysis received 10 samples for the referenced project on 12/3/2010. The analytical results are presented in the following report.

All analyses were performed in accordance with methods as referenced on the analytical report. Those analytical results expressed on a dry weight basis are also noted on the analytical report.

Thank you for the opportunity to serve you and I look forward to working with you in the future. If you have any questions regarding the enclosed materials, please contact me at (312) 733-0551.

Sincerely,

Donald R. Cortes, Ph.D.
Laboratory Director

STAT Analysis Corporation

Date: *December 29, 2010*

CLIENT:	Attorney General of Missouri
Project:	Children's Toy Testing
Lab Order:	10120083

CASE NARRATIVE

For sample 10120083-004 (Client ID: Toy Story 3 Buzz Lightyear Figural Keyring), only the metal key ring was tested.
For sample 10120083-005 (Client ID: Toy Story 3 Buzz Lightyear Figural Keyring), only the keychain links were tested.
For sample 10120083-006 (Client ID: Disney Pooh & Friends Piglet Figurine), the red coating was primarily tested.
For sample 10120083-007 (Cliend ID: Mighty Beanz - Pirate Bean), only the plastic cover was tested.
For sample 10120083-008 (Cliend ID: Mighty Beanz - Pirate Bean), only the metal ball was tested.

The following samples were prepared using cyrogenic milling and microwave digestion as specified in Consumer Product Safety Comission method CPSC-CH-E1002-08.1:

10120083-006 (Client ID: Disney Pooh & Friends Piglet Figurine)
10120083-007 (Cliend ID: Mighty Beanz - Pirate Bean)
10120083-009 (Client ID: Creatures - Green Lizard)
10120083-010 (Client ID: Creatures - Red & Blue Lizard)

STAT Analysis Corporation
2242 West Harrison St., Suite 200, Chicago, IL 60612-3766
Tel: (312) 733-0551 Fax: (312) 733-2386 STATinfo@STATAnalysis.com
Accreditation Numbers: IEPA ELAP 100445; ORELAP 1L300001; AIHA 101160; NVLAP LabCode 101202-0

Report Date: December 29, 2010
Print Date: December 29, 2010

Client:	Attorney General of Missouri	**Client Sample ID**	Toy Story 3 Buzz Lightyear Figu
Lab Order:	10120083	**Tag Number:**	
Project:	Children's Toy Testing	**Collection Date**	
Lab ID:	10120083-004A	**Matrix:**	Product

Analyses	Result	RL	Qualifier	Units	DF	Date Analyzed
Metals by ICP/MS	**SW6020 (SW3050B)**			Prep Date: **12/20/2010**	Analyst: **JG**	
Cadmium	14	1		mg/Kg	10	12/21/2010
Lead	3.6	1		mg/Kg	10	12/21/2010

Qualifiers:

ND - Not Detected at the Reporting Limit
J - Analyte detected below quantitation limits
B - Analyte detected in the associated Method Blank
HT - Sample received past holding time
* - Non-accredited parameter
RL - Reporting / Quantitation Limit for the analysis
S - Spike Recovery outside accepted recovery limits
R - RPD outside accepted recovery limits
E - Value above quantitation range
H - Holding time exceeded

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Report Date: December 29, 2010
Print Date: December 29, 2010

Client:	Attorney General of Missouri	**Client Sample ID**	Toy Story 3 Buzz Lightyear Figu
Lab Order:	10120083	**Tag Number:**	
Project:	Children's Toy Testing	**Collection Date**	
Lab ID:	10120083-005A	**Matrix:**	Product

Analyses	Result	RL	Qualifier	Units	DF	Date Analyzed
Metals by ICP/MS	**SW6020 (SW3050B)**			Prep Date: **12/20/2010**	Analyst: **JG**	
Cadmium	ND	1.9		mg/Kg	10	12/21/2010
Lead	2.4	1.9		mg/Kg	10	12/21/2010

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Report Date: December 29, 2010
Print Date: December 29, 2010

Client:	Attorney General of Missouri	**Client Sample ID**	Disney Pooh & Friends Piglet Fi
Lab Order:	10120083	**Tag Number:**	
Project:	Children's Toy Testing	**Collection Date**	
Lab ID:	10120083-006A	**Matrix:**	Product

Analyses	Result	RL	Qualifier	Units	DF	Date Analyzed
Metals by ICP/MS	**SW6020 (SW3051A)**			Prep Date: **12/27/2010**		Analyst: **JG**
Cadmium	ND	2.2		mg/Kg	10	12/27/2010
Lead	ND	2.2		mg/Kg	10	12/27/2010

Qualifiers:

- ND - Not Detected at the Reporting Limit
- J - Analyte detected below quantitation limits
- B - Analyte detected in the associated Method Blank
- HT - Sample received past holding time
- * - Non-accredited parameter
- RL - Reporting / Quantitation Limit for the analysis
- S - Spike Recovery outside accepted recovery limits
- R - RPD outside accepted recovery limits
- E - Value above quantitation range
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Accreditation Numbers: IEPA ELAP 100445; ORELAP IL300001; AIHA 101160; NVLAP LabCode 101202-0

Report Date: December 29, 2010
Print Date: December 29, 2010

Client:	Attorney General of Missouri	**Client Sample ID**	Mighty Beanz - Pirate Bean
Lab Order:	10120083	**Tag Number:**	
Project:	Children's Toy Testing	**Collection Date**	
Lab ID:	10120083-007A	**Matrix:**	Product

Analyses	Result	RL	Qualifier	Units	DF	Date Analyzed
Metals by ICP/MS	**SW6020 (SW3051A)**			Prep Date: **12/27/2010**	Analyst: **JG**	
Cadmium	ND	2.6		mg/Kg	10	12/27/2010
Lead	ND	2.6		mg/Kg	10	12/27/2010

Qualifiers:

ND - Not Detected at the Reporting Limit
J - Analyte detected below quantitation limits
B - Analyte detected in the associated Method Blank
HT - Sample received past holding time
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RL - Reporting / Quantitation Limit for the analysis
S - Spike Recovery outside accepted recovery limits
R - RPD outside accepted recovery limits
E - Value above quantitation range
H - Holding time exceeded

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Accreditation Numbers: IEPA ELAP 100445; ORELAP IL300001; AIHA 101160; NVLAP LabCode 101202-0

Report Date: December 29, 2010
Print Date: December 29, 2010

Client:	Attorney General of Missouri	**Client Sample ID**	Mighty Beanz - Pirate Bean
Lab Order:	10120083	**Tag Number:**	
Project:	Children's Toy Testing	**Collection Date**	
Lab ID:	10120083-008A	**Matrix:**	Product

Analyses	Result	RL	Qualifier	Units	DF	Date Analyzed
Metals by ICP/MS	**SW6020 (SW3050B)**			Prep Date: **12/20/2010**	Analyst: **JG**	
Cadmium	ND	0.69		mg/Kg	100	12/22/2010
Lead	1.5	0.69		mg/Kg	100	12/22/2010

Qualifiers:
ND - Not Detected at the Reporting Limit
J - Analyte detected below quantitation limits
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HT - Sample received past holding time
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RL - Reporting / Quantitation Limit for the analysis
S - Spike Recovery outside accepted recovery limits
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Report Date: December 29, 2010
Print Date: December 29, 2010

Client:	Attorney General of Missouri	**Client Sample ID**	Creatures - Green Lizard
Lab Order:	10120083	**Tag Number:**	
Project:	Children's Toy Testing	**Collection Date**	
Lab ID:	10120083-009A	**Matrix:**	Product

Analyses	Result	RL	Qualifier	Units	DF	Date Analyzed
Metals by ICP/MS	**SW6020 (SW3051A)**			Prep Date: **12/27/2010**	Analyst: **JG**	
Cadmium	ND	3.8		mg/Kg	10	12/27/2010
Lead	ND	3.8		mg/Kg	10	12/27/2010

Qualifiers:

ND - Not Detected at the Reporting Limit
J - Analyte detected below quantitation limits
B - Analyte detected in the associated Method Blank
HT - Sample received past holding time
* - Non-accredited parameter
RL - Reporting / Quantitation Limit for the analysis
S - Spike Recovery outside accepted recovery limits
R - RPD outside accepted recovery limits
E - Value above quantitation range
H - Holding time exceeded

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Tel: (312) 733-0551 Fax: (312) 733-2386 STATinfo@STATAnalysis.com
Accreditation Numbers: IEPA ELAP 100445; ORELAP IL300001; AIHA 101160; NVLAP LabCode 101202-0

Report Date: December 29, 2010
Print Date: December 29, 2010

Client:	Attorney General of Missouri	**Client Sample ID**	Creatures - Red & Blue Lizard
Lab Order:	10120083	**Tag Number:**	
Project:	Children's Toy Testing	**Collection Date**	
Lab ID:	10120083-010A	**Matrix:**	Product

Analyses	Result	RL	Qualifier	Units	DF	Date Analyzed
Metals by ICP/MS	**SW6020 (SW3051A)**			Prep Date: **12/27/2010**	Analyst: **JG**	
Cadmium	ND	3.2		mg/Kg	10	12/27/2010
Lead	ND	3.2		mg/Kg	10	12/27/2010

Qualifiers:

ND - Not Detected at the Reporting Limit
J - Analyte detected below quantitation limits
B - Analyte detected in the associated Method Blank
HT - Sample received past holding time
* - Non-accredited parameter
RL - Reporting / Quantitation Limit for the analysis
S - Spike Recovery outside accepted recovery limits
R - RPD outside accepted recovery limits
E - Value above quantitation range
H - Holding time exceeded

ATTORNEY GENERAL OF MISSOURI

CHRIS KOSTER
ATTORNEY GENERAL

JEFFERSON CITY
65102

P.O. Box 899
(573) 751-3321

December 1, 2010

RE: MO AGO toy testing

Dr. Donald R. Cortes, Ph.D.
Laboratory Director
STAT Analysis Corporation
2242 West Harrison Street, Suite 200
Chicago, Illinois 60612

Dear Don:

Enclosed please find some items we would like tested for total lead and cadmium content. Please call me when the items arrive and we will discuss the particulars including surface coatings, substrates, and metals.

Thank you.

Sincerely,

David Angle
Assistant Attorney General

STAT Analysis Corporation
2242 W. Harrison Suite 200, Chicago, Illinois 60612 Phone: (312) 733-0551 Fax: (312) 733-2386
e-mail address: STATinfo@STATAnalysis.com AIHA, NVLAP and NELAP accredited

CHAIN OF CUSTODY RECORD

No.: Page: 1 of 1

Company: Missouri Attorney Generals Office
Project Number: Client Tracking No.:
Project Name:
Project Location:
Sampler(s):
Report To: Phone: (573) 751-3376
Fax: (573) 751-2041
QC Level: 1 2 3 4 e-mail: dave.angle@ago.mo.gov

P.O. No.:
Quote No.:
Turn Around:
Results Needed: / / am/pm

Client Sample Number/Description:	Date Taken	Time Taken	Matrix	Comp.	Grab	Preserv.	No. of Containers	Remarks	Lab No.:
Toy Story 3 Buzz Lightyear Figural Keyring.									
Disney Pooh & Friends Piglet figurine.									
Mighty Beanz - Pirate Bean									
Creatures - Green Lizard									
Creatures - Red & Blue Lizard									

Relinquished by: (Signature) Donica Dunkard Date/Time: 12/1/10 @ 3:30pm
Received by: (Signature) Date/Time: 12/3/10 3:15pm
Relinquished by: (Signature) Date/Time:
Received by: (Signature) Date/Time:
Relinquished by: (Signature) Date/Time:
Received by: (Signature) Date/Time:

Comments:

Preservation Code: A = None B = HNO_3 C = NaOH
D = H_2SO_4 E = HCl F = 5035/EnCore G = Other

Laboratory Work Order No.: 10120033
Received on Ice: Yes No
Temperature: °C

Don Cortes

From: Angle, Dave [dave.angle@ago.mo.gov]
Sent: Friday, December 03, 2010 6:05 PM
To: Don Cortes
Subject: Re: Test instructions

Hi Don:

Thanks for working late on this. The instructions are correct.

Hope you have a nice weekend.

Dave Angle

Sent from my BlackBerry

From: Don Cortes <DCortes@STATAnalysis.com>
To: Angle, Dave
Sent: Fri Dec 03 17:45:34 2010
Subject: Test instructions

Dave,

Since the specifics instructions were not on the COC or included in the package, would you email them to me, if correct:

ClientSampID	Comments	Test
Toy Story 3 Buzz Lightyear Figural Keyring	Test green surface coating if sufficient	Total Pb, Cd
Toy Story 3 Buzz Lightyear Figural Keyring	Test purple surface coating if sufficient	Total Pb, Cd
Toy Story 3 Buzz Lightyear Figural Keyring	Test grey substrate only	Total Pb, Cd
Toy Story 3 Buzz Lightyear Figural Keyring	Test metal keyring only	Total Pb, Cd
Toy Story 3 Buzz Lightyear Figural Keyring	Test keychain links only	Total Pb, Cd
Disney Pooh & Friends Piglet Figurine	Test pink surface coating if sufficient	Total Pb, Cd
Mighty Beanz - Pirate Bean	Test outer plastic only	Total Pb, Cd
Mighty Beanz - Pirate Bean	Test metal ball only	Total Pb, Cd
Creatures - Green Lizard	Test green substrate only	Total Pb, Cd
Creatures - Red & Blue Lizard	Test red substrate only	Total Pb, Cd

What you email me will become part of the report (with the COC and evidential record).

Thanks.

Sincerely,

Donald R. Cortes, Ph.D.
Laboratory Director

STAT Analysis Corporation

Stevenson, Todd

From: Handmade Toy Alliance [savehandmadetoys@gmail.com]
Sent: Thursday, February 10, 2011 12:16 PM
To: CPSC-OS
Cc: Nord, Nancy; Adler, Robert; Tenenbaum, Inez; Moore, Thomas; Northup, Anne; Howsare, Matt; Falvey, Cheryl; Martyak, Joseph
Subject: HTA Letter re: 100 PPM—Technological Feasibility Public Hearing
Attachments: HTA Letter for 100ppm hearing.pdf

[FORMATTED LETTER ATTACHED]

February 10, 2011

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway,
Bethesda, Maryland, 20814
cpsc-os@cpsc.gov

Re: 100 PPM—Technological Feasibility Public Hearing

Dear Mr. Stevenson:

On behalf of the Handmade Toy Alliance, an alliance now numbering 620 toy stores, toymakers and children's product manufacturers from across the country who want to preserve unique handmade toys, clothes, and children's goods in the USA, we respectfully submit the following comments for consideration during the Commission's hearing on the feasibility of imposing a 100ppm lead content limit on children's products.

To begin with, we would like to refer the Commission to our earlier letter on the subject, dated September 27, 2010. A copy can be found at http://handmadetoyalliance.blogspot.com/2010/09/hta-comments-on-technological.html . We would like to reiterate that letter's conclusion, which stated:

"As small manufacturers, we lack the wherewithal to demand consistent compliance to such a low standard from our component suppliers, many of whom do not specifically manufacture for children's products. We lack the resources to test repeatedly to ensure that any given test's results are actually within a 100ppm limit given the tests' margins of error. And, in an environment where the Commission blurs bright lines, we lack the patience for such a low limit that has no impact on human health but could well jeopardize our family businesses."

After reading the other responses to the Commission's initial requests for comments on the feasibility of a 100ppm standard, we were struck by the near unanimity among manufacturers and trade groups representing manufacturers. Almost all these respondents agreed with us that a 100ppm would be difficult to achieve consistently, would be difficult to measure, would add unnecessary and untenable compliance costs, and would not directly correspond with any health risks associated with lead content in different materials.

Now, we are being asked to clarify our position regarding how the feasibility of a 100ppm standard would vary according to the type of material and the extent to which 100ppm-compliant components are "commercially available".

Unfortunately, none of our members are chemists or materials scientists. Nor do we posses the resources to engage a scientific study of the vast myriad of products our members produce in order to fully answer these questions. The best we can do is describe our businesses and the difficulties we would encounter if we were required to meet a 100ppm lead standard.

For this hearing, the Commission asked, "What factors or considerations should we evaluate in deciding whether a product complying with the limit is 'commercially available?'" Unlike mass market manufacturers, we do not always begin our production with raw materials. We frequently purchase component goods like zippers and buttons from Jo-Ann Fabrics, beads and polyfill from Michael's, and screws and hinges from Home Depot.

These components have not been tested by a CPSC-accredited third party lab and do not indicate their lead content. Nor do the manufacturers of these components make any claim or guarantee regarding the consistency of materials used that would suggest that a hinge or button purchased in June would have the same lead content as the same item purchased in August. Indeed, many of these component parts are sold by distributors such as Dritz Notions or Stanley Hardware and bear no indication of the company which actually manufactured the part in the first place.

So, before the CPSC decides the extent to which 100ppm-compliant components are "commercially available", we ask that the Commission should first conduct a thorough survey of the lead content of the component parts on sale at Jo-Ann Fabrics, Michaels, and Home Depot (or other comparable retailers). We urge the Commission to test a few dozen screws, buttons, zippers, and hinges—and then do the same test again in a month. This would be the best and only way determine the commercial availability of 100ppm-compliant parts for our members.

Unfortunately, we were not able to initiate such a study in the 15 days from when the Commission posted notice of this hearing and the date our comments were due. Nonetheless, the difficulty and expense of conducting such a survey is the exact same difficulty and expense small batch manufacturers will be facing if they would be required to comply with a 100ppm lead content standard.

While we recognize that it would be problematic for larger companies as well, we believe that small batch manufacturers, who have little or no negotiating power with their component suppliers, would be most adversely affected by a 100ppm standard. Much as we'd like to see the development of marketplace of pre-tested component parts, the truth is that, in most cases, this marketplace has so far failed to materialize. The burden of compliance, therefore, remains almost exclusively with the end-product manufacturer. A 100ppm standard would vastly aggravate this burden.

We believe the Commission can and should consider the economic feasibility of a 100ppm standard. And, we believe that any such consideration of the economic impact would logically lead to the conclusion that a 100ppm standard is not, in fact, feasible.

Finally, as discussed in our previous letter, we believe that a 100ppm total lead limit which does not take bioavailability into account is an inappropriate standard for measuring the health risk of a children's product. We have read the comments by consumer groups which reiterate the facts that lead accumulates in a child's body over time and that there is no safe amount of lead exposure. And, while we agree with these assertions, we can not find any logic which would justify a blanket 100ppm limit for all types of materials in all children's products.

It simply does not make sense to us that the lead content in brass, steel, plastic, vinyl, or glass should all be subject to the same limit, since each material behaves differently when exposed to human skin or sylvia. Nor does it make sense to us that a baby rattle, puzzle, football, or bicycle should pose the same risks of lead ingestion or that these various products should all be subject to the same 100ppm standard.

We therefore urge the Commission to conclude, as we have, that a 100ppm lead standard is not technologically feasible; that 100ppm compliant component parts are not commercially available, especially for small batch manufacturers; and that a 100ppm standard would not relate to the risk of lead exposure as it varies from one material to another and from one type of product to another.

Our members are personally dedicated to making safe, quality products.
We represent centuries of American craftsmanship which has nourished generations of American children.

Please consider the impact of 100ppm on our member businesses. Please do not allow the perfect to be the enemy of the good.

Thank you again for taking the time to read and consider our comments.

Respectfully Submitted,

The Handmade Toy Alliance

A listing of all 620 business members of the Handmade Toy Alliance is available at http://www.handmadetoyalliance.org/AllianceInfo/OurMembers.aspx
.

February 10, 2011

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway,
Bethesda, Maryland, 20814
cpsc-os@cpsc.gov

Re: 100 PPM—Technological Feasibility Public Hearing

Dear Mr. Stevenson:

On behalf of the Handmade Toy Alliance, an alliance now numbering 620 toy stores, toymakers and children's product manufacturers from across the country who want to preserve unique handmade toys, clothes, and children's goods in the USA, we respectfully submit the following comments for consideration during the Commission's hearing on the feasibility of imposing a 100ppm lead content limit on children's products.

To begin with, we would like to refer the Commission to our earlier letter on the subject, dated September 27, 2010. A copy can be found at http://handmadetoyalliance.blogspot.com/2010/09/hta-comments-on-technological.html . We would like to reiterate that letter's conclusion, which stated:

> *As small manufacturers, we lack the wherewithal to demand consistent compliance to such a low standard from our component suppliers, many of whom do not specifically manufacture for children's products. We lack the resources to test repeatedly to ensure that any given test's results are actually within a 100ppm limit given the tests' margins of error. And, in an environment where the Commission blurs bright lines, we lack the patience for such a low limit that has no impact on human health but could well jeopardize our family businesses.*

After reading the other responses to the Commission's initial requests for comments on the feasibility of a 100ppm standard, we were struck by the near unanimity among manufacturers and trade groups representing manufacturers. Almost all these respondents agreed with us that a 100ppm would be difficult to achieve consistently, would be difficult to measure, would add unnecessary and untenable compliance costs, and would not

directly correspond with any health risks associated with lead content in different materials.

Now, we are being asked to clarify our position regarding how the feasibility of a 100ppm standard would vary according to the type of material and the extent to which 100ppm-compliant components are "commercially available".

Unfortunately, none of our members are chemists or materials scientists. Nor do we posses the resources to engage a scientific study of the vast myriad of products our members produce in order to fully answer these questions. The best we can do is describe our businesses and the difficulties we would encounter if we were required to meet a 100ppm lead standard.

For this hearing, the Commission asked, "What factors or considerations should we evaluate in deciding whether a product complying with the limit is 'commercially available?'" Unlike mass market manufacturers, we do not always begin our production with raw materials. We frequently purchase component goods like zippers and buttons from Jo-Ann Fabrics, beads and polyfill from Michael's, and screws and hinges from Home Depot.

These components have not been tested by a CPSC-accredited third party lab and do not indicate their lead content. Nor do the manufacturers of these components make any claim or guarantee regarding the consistency of materials used that would suggest that a hinge or button purchased in June would have the same lead content as the same item purchased in August. Indeed, many of these component parts are sold by distributors such as Dritz Notions or Stanley Hardware and bear no indication of the company which actually manufactured the part in the first place.

So, before the CPSC decides the extent to which 100ppm-compliant components are "commercially available", we ask that the Commission should first conduct a thorough survey of the lead content of the component parts on sale at Jo-Ann Fabrics, Michaels, and Home Depot (or other comparable retailers). We urge the Commission to test a few dozen screws, buttons, zippers, and hinges—and then do the same test again in a month. This would be the best and only way determine the commercial availability of 100ppm-compliant parts for our members.

Unfortunately, we were not able to initiate such a study in the 15 days from when the Commission posted notice of this hearing and the date our comments were due. Nonetheless, the difficulty and expense of conducting such a survey is the exact same difficulty and expense small batch manufacturers will be facing if they would be required to comply with a 100ppm lead content standard.

While we recognize that it would be problematic for larger companies as well, we believe that small batch manufacturers, who have little or no negotiating power with their component suppliers, would be most adversely affected by a 100ppm standard. Much as we'd like to see the development of marketplace of pre-tested component parts, the truth is that, in most cases, this marketplace has so far failed to materialize. The burden of compliance, therefore, remains almost exclusively with the end-product manufacturer. A 100ppm standard would vastly aggravate this burden.

We believe the Commission can and should consider the economic feasibility of a 100ppm standard. And, we believe that any such consideration of the economic impact would logically lead to the conclusion that a 100ppm standard is not, in fact, feasible.

Finally, as discussed in our previous letter, we believe that a 100ppm total lead limit which does not take bioavailability into account is an inappropriate standard for measuring the health risk of a children's product. We have read the comments by consumer groups which reiterate the facts that lead accumulates in a child's body over time and that there is no safe amount of lead exposure. And, while we agree with these assertions, we can not find any logic which would justify a blanket 100ppm limit for all types of materials in all children's products.

It simply does not make sense to us that the lead content in brass, steel, plastic, vinyl, or glass should all be subject to the same limit, since each material behaves differently when exposed to human skin or sylvia. Nor does it make sense to us that a baby rattle, puzzle, football, or bicycle should pose the same risks of lead ingestion or that these various products should all be subject to the same 100ppm standard.

We therefore urge the Commission to conclude, as we have, that a 100ppm lead standard is not technologically feasible; that 100ppm compliant component parts are not commercially available, especially for small batch manufacturers; and that a 100ppm standard would not relate to the risk of lead exposure as it varies from one material to another and from one type of product to another.

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Please consider the impact of 100ppm on our member businesses. Please do not allow the perfect to be the enemy of the good.

Thank you again for taking the time to read and consider our comments.

Respectfully Submitted,

The Handmade Toy Alliance

A listing of all 620 business members of the Handmade Toy Alliance is available at http://www.handmadetoyalliance.org/AllianceInfo/OurMembers.aspx .

Handmade Toy Alliance Blog

Working to save small batch producers of children's products from the CPSIA. Read more at www.handmadetoyalliance.org.

SUNDAY, SEPTEMBER 26, 2010

HTA Comments on the Technological Feasibility of Lowering CPSIA Lead Limits to 100ppm

September 27, 2010

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway,
Bethesda, Maryland, 20814

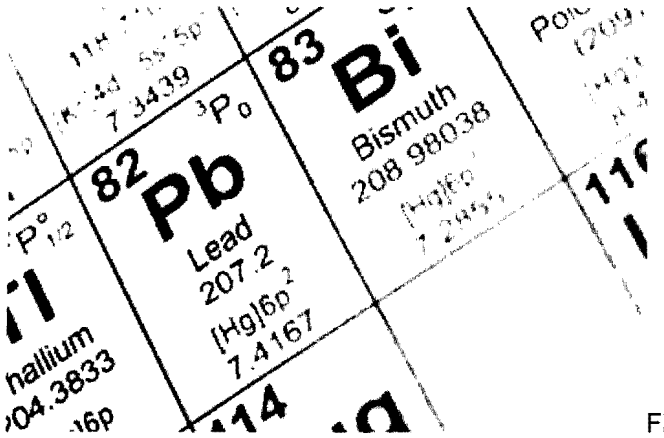
Re: Comments Regarding the Technological Feasibility of 100ppm for Lead Content Under the Consumer Product Safety Improvement Act (CPSIA) [Docket No. CPSC-2010-0080]

Dear Mr. Stevenson:

On behalf of the Handmade Toy Alliance, an alliance now numbering 548 toy stores, toymakers and children's product manufacturers from across the country who want to preserve unique handmade toys, clothes, and children's goods in the USA, we respectfully submit the following comments regarding the technological feasibility of a 100ppm lead content limit.

We wish to reiterate that the CPSC and the Congressional leadership from both parties have openly acknowledged that the broad sweep of the CPSIA has created unintended consequences for products and industries which had nothing to do with the toy and jewelry safety scare of 2007. In light of the fact that Congressional Democrats and Republicans have so far been unable to work together to craft a solution for the small businesses we represent, it remains up to the Commission to promulgate rules that serve to help businesses large and small to understand what is needed to comply with the CPSIA.

As with the rulemaking process regarding the definition of a children's product, we believe that Congress has given the Commission an important opportunity to avoid further unintended consequences by ruling that the 100ppm limit on lead in substrates is not a feasible standard.



First and foremost, we believe that total lead is not a reasonable standard for evaluating the risk of lead poisoning from a consumer product. Whether the limit is 300ppm or 100ppm, a total lead standard is a purely political, not a scientific, assessment of risk. Despite the fact that no scientific study directly correlates total lead content with the risk of lead poisoning, consumer groups insisted during the drafting of the CPSIA that a "bright line" total limit, which was easier to measure, enforce, and explain to the public, was preferable to a soluble standard which more accurately reflects risk.

This key difference has unnecessarily set the US market apart from other markets, in particular the European Union, and has cost millions of dollars worth of redundant testing.

We have been arguing for two years that the US should adopt the European Union's method of evaluating the risk of lead exposure by measuring the bioavalibility of soluble lead in substrates. By defining the limits based on total lead, the CPSIA has effectively outlawed materials such as brass, crystal, and rhinestones which are perfectly safe biologically yet violate the CPSIA's limits on total lead.

Now we are being asked to comment on whether a 100ppm standard would be "technologically feasible". Most of the comments the commission will receive on this issue will likely focus on the word "feasible". We, however, would like to argue that a 100ppm limit is not technological.

The simplest definition we found of the word "technology" is: *The practical application of science to commerce or industry.*

Because science shows that a total lead limit does not actually measure the risk of lead poisoning, such a limit, whether it is 300ppm or 100ppm, cannot be described as the application of science to commerce or industry. It may represent the application of political expediency or good intentions, but it is not an application of science. Therefore, reducing the limit from 300ppm to 100ppm would merely be compounding and increasing the side-effects of an unscientific principle. Whether or not 100ppm is feasible, it is not technological.

We agree that consumer products should be regulated by "bright line" standards, but these should be based on science and common sense. For example, we had hoped that the Commission would adopt clear and and easy to understand standards when it recently considered the definition of a children's product. Instead, our comments seeking clear standards were ignored, as were the comments of many other stakeholders. The Commission staff chose to issue a 63 page definition which provides no bright lines and no clear definition. HTA member Sarah Natividad, the owner Curious Workmanship, a home-based business in Utah, observed:
[The CPSC] could have saved hard drive space, several forests of trees, and a lot of time and effort by just making the rule say "It's a children's product if we say it is, so just ask us and if we feel like it, we'll decide for you." Because that's what it boils down to. Now, besides the fuzzy line between kids and adults, we also have the fuzzy line between infants and kids and whether a child might reasonably be assumed to touch and use a lamp or a piece of furniture. Why on earth did they think TWO fuzzy lines constituted clarification?

Indeed, in the weeks since the final draft of the definition was published, the CPSC has illogically re-defined the intended age of at least two products so that it could initiate recall procedures. The first was a recall of Click Armband Bracelets by Fun Stuff, Inc., which were clearly marked as designed for ages 3 and over. Despite the fact that no responsible parent would give these throwaway plastic toys to a toddler, the Commission chose to initiate recall proceedings by redesignating them as toddler toys.

In the second recent case, a line of mood rings were reclassified by the Commission as a children's product despite the fact that they were clearly labelled with sexually suggestive language which was specifically designed to appeal to teenagers and adults, not children.

By issuing an obfuscating definition of a children's product and by creatively reclassifying products so that it can force recalls, the Commission is doing everything except promulgating bright line standards. These actions do not go unnoticed. They tell children's product manufacturers both large and small only one message: there are no bright line standards, only the will of Commission.

The end result of this uncertainty is a growing realization that any children's product business, no matter how responsible or how ethical, is just one incident report away from terrible penalties and overwhelming legal fees. Small businesses like our members lack the resources to defend themselves from the Commission's unilateral actions and are increasingly choosing to exit the children's' product marketplace altogether.

So, in this environment, is a 100ppm limit feasible? Consider the analysis by Sarah Natividad, who is also a former mathematics professor. She concludes that the more we test and the stricter we make our standards, the more impossible it is to comply with the law. She writes:
It is mathematically impossible to find all defective objects without going to the expense of testing them ALL. And that's assuming testing is 100% accurate, which it's not. And to add insult to injury, the more zealously you test by sampling, the more confused you will be about the safety of your product. CPSIA was supposed to reduce confusion about product safety, but now you have mathematical proof that it does exactly the opposite.
This mathematical paradox will be dramatically aggravated by lowering lead limits to 100ppm--a limit which makes sampling errors, random chance, and the accuracy of testing equipment much more likely to play a decisive role in the outcome of both pre- and post-market product safety evaluations. Testing costs will increase, uncertainty will increase, risk of destroying finished inventory will increase, and the number of CPSC recalls will increase. The result will be weakened businesses, undermined consumer confidence, and a public even more inured to the product recall process.

As small manufacturers, we lack the wherewithal to demand consistent compliance to such a low

standard from our component suppliers, many of whom do not specifically manufacture for children's products. We lack the resources to test repeatedly to ensure that any given tests results are actually within a 100ppm limit given the tests' margins of error. And, in an environment where the Commission blurs bright lines, we lack the patience for such a low limit that has no impact on human health but could well jeopardize our family businesses.

Thank you again for taking the time to read and consider our comments.

Respectfully Submitted,

The Handmade Toy Alliance

A listing of all 548 business members of the Handmade Toy Alliance is available at .
http://www.handmadetoyalliance.org/AiliianceInfo/OurMembers.aspx

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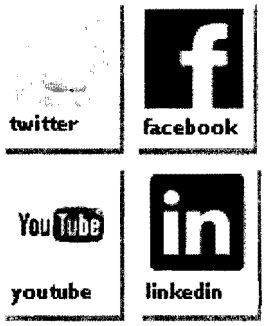

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