UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

**Memorandum**

Date: February 11, 2009

TO : Office of the General Counsel
Office of Hazard Identification and Reduction
Office of Compliance and Field Operations

FROM : Todd A. Stevenson, Director,
Office of the Secretary

SUBJECT : Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Lead Content in Children's **Metal Jewelry** as Established by the Consumer Product Safety Improvement Act of 2008
Published in the *Federal Register* December 22, 2008
Comments due by January 21, 2009

| COMMENT | DATE | SIGNED BY | AFFILIATION |
|---|---|---|---|
| 1 | 1/13/09 | John Gaspari<br>Vice President | ESS Laboratory<br>185 Frances Avenue<br>Cranston, RI 02910 |
| 2 | 1/14/09 | Dr. Richard Medina<br>Quality Assurance Officer | Environmental Testing and Consulting, Inc.<br>2790 Whitten Road<br>Memphis, TN 38133 |
| 3 | 1/14/09 | Dan Scott | Treehouse in the Glen, LLC<br>Toys Kids Love Naturally<br>dan@treehouseintheglen.com |
| 4 | 1/20/09 | Linda Kessler | lkcreation@yahoo.com |

| COMMENT | DATE | SIGNED BY | AFFILIATION |
|---|---|---|---|
| 5 | 1/20/09 | Gustavo A. Delgado, Ph.D.<br>CEO | Forensic Analytical Laboratories, Inc.<br>3777 Depot Road, Suite 409<br>Hayward, CA 94545-2761<br>gdelgado@forensica.com |
| 6 | 1/21/09 | Sheila A. Millar<br>On behalf of Fashion Jewelry Trade Association | Keller and Heckman LLP<br>1001 G Street, N.W.<br>Suite 500 West<br>Washington, DC 20001 |
| 7 | 1/21/09 | Donald L. Mays<br>Senior Director, Product Safety & Technical Public Policy | Consumers Union |
| | | Janell Mayo Duncan<br>Senior Counsel | Consumers Union |
| | | Rachel Weintraub<br>Director of Product Safety and Senior Counsel | Consumer Federation of America |
| | | Nancy A. Cowles<br>Executive Director | Kids in Danger |
| | | Christine Hines<br>Consumer and Civil Justice Counsel | Public Citizen's Congress |
| | | Ed Mierzwinski<br>Federal Consumer Program Director | U.S. Public Interest Research Group |
| | | Elizabeth Hitchcock<br>Public Health Advocate | U.S. Public Interest Research Group |
| 8 | 1/21/09 | Susan Templeton | st22@cfl.rr.com |

| COMMENT | DATE | SIGNED BY | AFFILIATION |
|---|---|---|---|
| 9 | 1/13/09 | Nathan A. Pera, IV<br>Chairman/Executive VP | Environmental Testing & Consulting, Inc.<br>2790 Whitten Road<br>Memphis, TN 38133 |
| 10 | 1/26/09 | Jennifer Johnson<br>Owner | Mama's Magic Studio<br>327 Mayellen Avenue<br>San Jose, CA 95126 |

## Stevenson, Todd

**From:** Richard Medina [rmedina@etcmemphis.com]
**Sent:** Wednesday, January 14, 2009 3:22 PM
**To:** Accreditation for Children's Metal Jewelry
**Cc:** Nathan Pera
**Subject:** Fwd: ILAC and NELAC Recognition

Dr. Richard Medina
Quality Assurance Officer

>>> Richard Medina 1/13/2009 8:04 AM >>>
**Office of the Secretary**

**Laboratory Accreditation Process for the Testing of Lead Content in Children's Metal Jewelry**

This email is in response to the 'Request for Comments' found in the December 22, 2008 Federal Register.

This comment is a request to the Commission that in addition to ILAC-MRA signatories, it consider accepting laboratory accreditation by NELAC (National Environmental Laboratory Accreditation.)

This is a national recognized accreditation program that follows the requirements of the ISO 17025 laboratory accreditation standard. This organization is similar to the A2LA (American Association for Laboratory Accreditation) which is listed as a ILCA-MRA signatory accrediting body.

Thank you for your consideration of this request.

Dr. Richard Medina

Dr. Richard Medina
Quality Assurance Officer
Environmental Testing and Consulting, Inc.
2790 Whitten Road Memphis, TN 38133
901-213-2447

# ESS Laboratory

*Division of Thielsch Engineering, Inc.*
185 Frances Avenue, Cranston, RI 02910


January 13, 2009

Office of the Secretary
Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Laboratory Accreditation Process for Testing
for Lead Content in Children's Metal Jewelry

The December 22, 2008 Federal Register, vol. 73 No 246, outlined "Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Lead Content in Children's Metal Jewelry as Established by the Consumer Product Safety Improvement Act of 2008.

The regulation states, that the baseline accreditation for laboratories is to ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories" is required; and the accreditation must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA).

**ESS Laboratory is a National Environmental Laboratory Accreditation Program (NELAP) accredited laboratory in conformance with the National Environmental Laboratory Accreditation Conference (NELAC) Standards; and is certified for numerous analytical methods in addition to the digestion and analysis of solid, wipes and paint samples for lead determinations.**

**The NELAC Standards are organized according to the structure of ISO/ICE 17025, and where deemed necessary specific areas of the NELAC Standards contain more specific information then specified by ISC/ICE 17025. The NELAC, Quality Systems Chapter 5 references various ISO standard and organizations, including the International Laboratory Accreditation Cooperation (ILAC).**

**NELAC Standards require that a Laboratory must have written Standard Operating Procedures for all Administrative, Calibration, Quality Control/Quality Assurance, Document Control and Testing procedures in addition to; documented demonstration of competency for each test an analyst performs. Periodic NELAP laboratory audits, including proficiency sample analysis, are required to maintain accreditation.**

**The goal of NELAC is to foster the generation of environmental laboratory data of known and acceptable quality on which to base public health and environmental management decisions.**

The following is a brief description of both NELAC and NELAP:

The National Environmental Laboratory Accreditation Conference **(NELAC)** is a cooperative association of States and Federal Agencies, formed to establish and promote mutually acceptable performance standards for the operation of environmental laboratories. The standards cover both analytical testing of environmental samples and the laboratory accreditation process. Private sector input to the process is obtained through a variety of mechanisms including open semiannual meetings, participation in NELAC committees, and through the Environmental Laboratory Advisory Board (ELAB), a federally chartered advisory committee with a balanced representation of the private sector, that provides advice to EPA and NELAC.

The National Environmental Laboratory Accreditation Program **(NELAP)** is the program that implements the NELAC standards. States and Federal agencies serve as Accrediting Authorities with coordination facilitated by EPA to assure uniformity. Accreditation by one NELAP Accrediting Authority is mutually recognized by the other State and Federal

ESS performs the Lead analysis on Children's Metal Jewelry for many of the leading Jewelry Manufactures and Associations, in strict conformance to the CPSC-CH-E1001-08 December 4, 2008 and NELAC Quality requirements. The CPSC testing procedures reference EPA SW 846 testing methods. The NELAC/NELAP includes SW 846 methods as part of its certification/accreditation process.

Unfortunately the NELAC/NELAP accreditation bodies are not signatories to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA). However their accreditation requirements meet and are some instances exceed the ILAC-MRA requirements and are recognized by various States and Federal Agencies

We respectfully request that NELAC/NELAP accreditation by acceptable to CPSC as and accreditation body.

Should you have any questions or require additional information, please do not hesitate to contact me.


John Gaspari

Vice President
(401) 461- 7181 ext 3099
jgaspari@thielsch.com

## Stevenson, Todd

**From:** John Gaspari [JGaspari@thielsch.com]
**Sent:** Tuesday, January 13, 2009 1:58 PM
**To:** Accreditation for Children's Metal Jewelry
**Subject:** Laboratory Accreditation Process for Testing Lead Content in Children's Metal Jewelry
**Attachments:** ESS Comments RE CPSC Accreditation Process.pdf

Office of the Secretary:

Enclosed is a copy of ESS Laboratory's comments in response to the Dec 22, 2008 Federal Register (Vol. 73, No. 246), regarding the
Laboratory Accreditation Process for Testing Lead Content in Children's Metal Jewelry.

Regards,

John Gaspari
Vice President
ESS Laboratory
Tel: (401) 461 7181 ext 3099
Fax: (401) 461 4486
Cell: (401) 474 0282
jgaspari@thielsch.com

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## Stevenson, Todd

**From:** Dan Scott [dan@treehouseintheglen.com]
**Sent:** Wednesday, January 14, 2009 9:34 PM
**To:** Accreditation for Children's Metal Jewelry
**Subject:** Laboratory Accreditation Process for Testing for Lead Content in Children's Metal Jewelry

*Leadaccredjewelry@cpsc.gov*

It doesn't stand a test of logic that an accreditation is needed to detect levels of lead that are not in compliance with the CPSCIA. Gross screening using XRF must be allowed as the costs and time required to perform digestions and Mass-Spec [or other regime] on every sample is not realistic and the accuracy in every case is not warranted.

If a measurement is close to a specification and needs to be refereed, then a more exhaustive regime could be justified, but for most materials and applications the expected amount of lead measured is at background levels.

It would be more appropriate for CPSC to standardize methods for testing toys using XRF, including calibration procedures and guidelines for referee points based on detection methods. It is impossible to exert "undue influence" on a calibrated tool.

Please consider the advantages of more data, instantaneously derived and the protection of consumers. Not only can an entire warehouse can be screened using this method, but more samples can be affordably taken on more parts of a toys and jewelry.

Above and beyond the requirements of CPSCIA, we all want to find lead and track it back to the source. XRF is the only realistic way to achieve this.

Thank you for your consideration of this matter.

Dan Scott
Treehouse in the Glen, LLC
Toys Kids Love Naturally
408.396.0070

4

**Stevenson, Todd**

**From:** LINDA KESSLER [lkcreation@yahoo.com]
**Sent:** Tuesday, January 20, 2009 8:10 AM
**To:** Accreditation for Children's Metal Jewelry
**Subject:** Laboratory Accreditation Process for Testing for Lead Content in Children's Metal Jewelry

Hi, I am writing in regards to testing childrens jewelry for lead content. I handcraft childrens jewelry, mostly beaded jewelry. Name bracelets designed with sterling silver letters and sterling silver charms, clasps and spacers, which I understand sterling silver is exempt now. Also used are freshwater pearls, which are exempt. I also use glass beads and cats eye beads and plastic flower beads, a lot of supplies come from www.czechbeads.com all of which are lead free. I also use swarovski crystals in my creations of childrens jewelry, which swarovski has already done testing on their crystals and determined that they do not pose a hazard to children. In fact, they won a lawsuit against California and even California, in their lead in Children's jewelry law, allows the use of 1 gram of swarovski crystals in their children's jewelry. We are not talking about "metal" when it comes to handcrafters designing quality childrens jewelry. Also, many supplies are purcahsed from http://www.rings-things.com/ which classifies all it's materials as to whether they contain lead, so designers can be in compliance with supplier certification. Handcrafted jewelry cannot be tested in a CPSC lab, because it is created at the time a customer orders it, they are one of a kind designs and would be dissolved in acid and the materials would be destroyed in testing.

What I am recommending to the CPSC is that they enact a law similar to what California has, a lead in children's jewelry law with classes of materials that are approved for use in handcrafted children's jewelry. I am all for the safety of children, but you cannot test handcrafted children's jewelry in a CPSC lab, number one it is cost prohibitive and number two it would destroy the product that you are testing.

Forensic Analytical

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2009 JAN 21 P 1:20

RE: Laboratory Accreditation Process for Testing for Lead Content in Children's Metal Jewelry

Ms. Nancy A. Nord, Acting Chairman
Consumer Product Safety Commission

Dear Ms. Nord,

In response to the request for comments in the notice published on page 78332 of the Federal Register, Vol. 73, No. 246, December 22, 2008, in regards to the Accreditation Requirements for Third Party Conformity Assessment Bodies To Test To the Requirements for Lead Content in Children's Metal Jewelry as Established by the Consumer Product Safety Improvement Act of 2008, Public Law 110-314, Forensic Analytical Laboratories, Inc. respectfully requests that you consider the following comment:

The US Environmental Protection Agency (US EPA) currently has an ISO/IEC 17025:2005 compliant program in place for accrediting laboratories that perform testing for lead content in paint, soil and settled dust in support of childhood lead poisoning prevention. The National Lead Laboratory Accreditation Program (NLLAP) is administered by the EPA through a Memorandum of Understanding (MOU) with two accrediting bodies; the American Industrial Hygiene Association (AIHA) and the American Association for Laboratory Accreditation (A2LA). Both of these accrediting bodies are themselves accredited to ISO 17011 by recognized certification bodies; A2LA under the International Laboratory Accreditation Cooperation (ILAC) and AIHA under the National Cooperation for Laboratory Accreditation (NACLA). In addition, AIHA has submitted applications for full recognition to the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Inter-American Accreditation Cooperation (IAAC), both ILAC signatories.

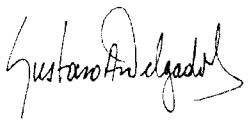
We fail to understand why Section II A of CPSIA 110-314 was written in a manner that did not recognize the National Lead Laboratory Accreditation Program that was already in place for accrediting laboratories to support lead-based paint risk assessment. Furthermore, the specification that only accrediting bodies that are recognized by ILAC is a fairly transparent end-around on the other premier accrediting body of lead laboratories, the AIHA. It is particularly troubling to note that this exclusion disqualified the majority of laboratories that are accredited under the NLLAP, as most of these laboratories are accredited by the AIHA. This puts the list of currently qualified laboratories at only 20 in the United States, which is not sufficient to handle testing for the new requirements under the CPSIA. At the very least, it places a restraint of trade on a large cross-section of smaller, qualified laboratories in the United States.

4332 Depot Road, Suite 404 Hayward, California 94545-2761 • Telephone: 510/887-8828 800/827-FASI Fax: 510/887-4218

We are concerned that the Consumer Product Safety Improvement Act and CPSC requirements were issued in a way that did not allow AIHA or AIHA-accredited labs to comment on these requirements. Had a comment and review period been included in the process, AIHA and its accredited laboratories would have been given a chance to demonstrate why AIHA lead laboratories should be listed as third party CPSC labs.

A solution to the problem would be to allow AIHA specifically, or any laboratory that is accredited by a signatory of the NLLAP and/or NACLA to qualify for participation under this Act. This relatively simple solution to the problem would reverse the financially disadvantaged position that this rulemaking has forced us into. We urge you to quickly enact this change to the rule to not only allow the best laboratories to vie for the work but for the smaller companies to maintain competitive viability.

Respectfully yours,



Gustavo A. Delgado, Ph.D., CEO
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Cc: **The Honorable Daniel K. Inouye**, Chairman, Senate Committee on Commerce, Science, and Transportation
**The Honorable Barbara Boxer**, Member, Senate Committee on Commerce, Science and Transportation
**Mr. Thomas Hill Moore**, CPSC Commissioner
**Mr. Robert "Jay" Howell**, Acting Assistant, Executive Director for Hazard Identification and Reduction, CPSC

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Writer's Direct Access
Sheila A. Millar
(202) 434-4143
millar@khlaw.com

January 21, 2009

**Via Electronic Mail:**

Todd A. Stevenson
Director, Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East-West Highway
Room 502
Bethesda, MD 20814

**Re: Laboratory Accreditation Process for Testing for Lead Content in Children's Metal Jewelry**

Dear Mr. Stevenson:

On behalf of the Fashion Jewelry Trade Association (FJTA) and Manufacturing Jewelers and Suppliers Association (MJSA), we appreciate this opportunity to submit these comments in response to the Consumer Product Safety Commission's ("CPSC" or "Commission") Request for Comments and Information entitled Accreditation Requirements for Third Party Conformity Assessment Bodes to Test to the Requirements for Lead Content in Children's Metal Jewelry as Established by the Consumer Product Safety Improvement Act of 2008 ("CPSIA").[1] FJTA represents makers of fashion or costume jewelry in the U.S. MJSA represents makers of parts and components used in fashion and fine jewelry. Generally FJTA and MJSA members do not produce vending machine, premium or novelty items. The combined membership of both organizations represent over 2,000 companies affected by the CPSIA.[2] U.S. retail sales of jewelry, including fine jewelry, fashion jewelry and watches, is estimated at almost $66 billion in 2008. Approximately 62,000 people are employed in the jewelry industry; many are self-employed and most are small businesses. FJTA and MJSA respond to this request for comments on the proposed accreditation standards for metal jewelry, offer these thoughts on the proposal, and suggest some clarifications to the referenced test method.

The jewelry industry is pleased that the CPSC Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (including Children's Metal Jewelry), CPSC-CH-E1001-08 (hereafter "CPSC Metal Jewelry SOP"), recognizes both the CPSC metal

[1] 73 Fed. Reg. 78331 (December 22, 2008). See http://www.cpsc.gov/businfo/frnotices/fr09/metaljewelry.pdf.

[2] Pub. L. No: 110-314, 122 Stat. 3,016 (August 14, 2008).

jewelry total lead procedure and a modified Environmental Protection Agency (EPA) procedure, EPA 3051(A), can be used. Several states have adopted requirements applicable to jewelry which specify testing via the EPA method, including California, which has also submitted a request that the CPSC recognize its requirements are not preempted. We are pleased that the Commission has also recognized that Inductively-Coupled Plasma-Mass Spectrometry (ICP-MS), Flame Atomic Absorption Spectroscopy (FLAA) and Graphic Furnace Atomic Absorption Spectroscopy (GFAA) may be used as alternatives to Inductively-Coupled Plasma-Optical Emission Spectroscopy (ICP-OES), using applicable recognized analytical techniques. This should allow additional laboratories who may not have ICP-OES equipment to be accredited and increase competition among accredited laboratories. These changes respond to prior comments on these aspects of the test procedure (see attachment A).

There are two aspects of the procedure, however, that should be revised. First, under the CPSIA, any material that is not paint or surface coating as defined under the CPSC's regulations at 16 CFR Part 1303 is a substrate material. Those regulations specifically exclude printing inks "or those materials which actually become part of the substrate, such as...those materials which are actually bonded to the substrate, such as by electroplating or ceramic glazing."[3] While existing CPSC regulations make explicitly clear that there are other types of coatings in addition to electroplated coatings that become part of the substrate, the CPSC test procedure requires that the test sample include "any electroplated coating which is considered to be part of the substrate."[4]

Second, the CPSC has proposed, and both FJTA and MJSA support, exclusion of precious metals, among other materials, from the test requirements. Thus, excluded materials such as sterling silver or karat gold that might be used in electroplated coatings do not have to be tested.

To avoid confusion by accredited laboratories that will result in unnecessary added expense in testing, the procedure should be revised to clarify that other types of coatings or finishes besides electroplated coatings may actually be part of the substrate, and that testing on metals that are excluded from testing (including where used as electroplated coatings) is not required. This procedures A.2. and B.2. should be revised, in pertinent part, as follows:

> Component parts of children's products including metal jewelry items generally weigh several grams or more, and an aliquot (with no paint or similar surface coating, but

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[3] 16 CFR §1303.2(b)(1).

[4] See CPSC Metal Jewelry SOP Hot Block sample preparation description at A.2., Microwave Method sample preparation description at B.2, p. 4.

including any electroplated or other coating which is considered to be part of the substrate, excluding precious or other metals exempt from testing) will have to be obtained.

Component or raw material testing is another major concern. Jewelry industry members report that test costs may exceed $1,000 per item, depending on the number of components used, recognizing that many jewelry items feature use of mixed materials. Allowing for reasonable component testing is a critical need to avoid a crushing financial burden on small businesses. This is an issue on which the jewelry industry associations will submit separate comments in response to the CPSC's Request for Comments and Information on third-party testing of component parts.

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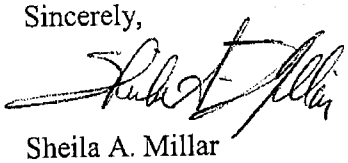
FJTA and MJSA appreciate the opportunity to submit these views and, as always, would be happy to provide additional information or respond to questions.

Sincerely,



Sheila A. Millar

Enclosure: Attachment A

cc: Michael Gale
James K. McCarty

# Attachment A

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October 31, 2008

Todd A. Stevenson
Director, Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East-West Highway
Room 502
Bethesda, MD 20814

**Re: Comments on CPSIA Section 101: Lead in Children's Products**

Dear Mr. Stevenson:

On behalf of the Fashion Jewelry Trade Association (FJTA), we appreciate this opportunity to submit these comments in response to the Consumer Product Safety Commission's (CPSC) Request for Comments and Information entitled *Children's Products Containing Lead: Lead Paint Rule Section 101 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)*.[1] FJTA represents makers of fashion or costume jewelry in the U.S. who are affected by the CPSIA.[2] Generally FJTA members do not produce vending machine, premium or novelty items. The fashion jewelry industry is about a $9 billion industry in the U.S.; many industry members are small businesses. FJTA wishes to focus these comments on testing requirements for lead, and exceptions from lead substrate limits.

## I. Testing

Fashion jewelry is noted for its use of a wide variety of materials. Plastic, wood, paint, crystal, metal, enameling, epoxies, gemstones – all may be used in fashion jewelry designed or intended primarily for children 12 and under. There are a variety of procedures that can be used to test products or materials used in jewelry for total or accessible lead. Within 120 days after enactment, the CPSC must issue requirements for accreditation of third party conformity assessment bodies to assess conformity with lead limits as to metal jewelry.

Several test procedures are recognized for determining the presence of lead in metal although not all have been peer-reviewed or standardized. They include tests for total lead, tests for extractable lead (mimicking ingestion scenarios), saline tests (mimicking mouthing

[1] http://www.cpsc.gov/about/cpsia/101rfc.pdf.

[2] Pub. L. No: 110-314, 122 Stat. 3,016 (August 14, 2008).

scenarios), wipe tests (principally used for products that might create lead dust), and surface lead screening tests, such as using X-ray fluorescence (XRF) technology. In Section 101(f)(3) of the CPSIA, Congress specifically recognized XRF technology as suitable lead screening tool, but only for paint or other surface coatings covering a surface area no larger than 1 square centimeter. The suitability of using XRF technology on larger areas is to be assessed by the Commission no later than one year after enactment of the CPSIA.[3] At least for now, XRF technology is not suitable as a compliance test in most cases but has gained increasing use as a screening tool. Accordingly, laboratory testing for total lead will generally be required, so the most relevant methods for assessing compliance with the lead limits established by the CPSIA must be identified.

Laboratory test methods for measuring total lead typically involve use of a strong acid that dissolves most metals and other materials and, consequently, lead present in the substance. The Association of Official Analytical Chemists (AOAC) Official Method 974.02, *Lead in Paint: Atomic Absorption Spectrophotometric Method*, sets out a procedure for determining the total concentration of lead in paint, but the CPSC determined this method might not to fully dissolve metal alloys. The CPSC therefore devised its own metal jewelry procedure, which includes separate methods of testing for total lead as well as a method for testing for accessible lead. These methods are set out in *Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry*, which accompanies the *Commission's Interim Enforcement Policy for Children's Metal Jewelry Containing Lead.* The CPSC's total lead testing method for metal jewelry requires grinding the material into small particles. The CPSC methods for total lead and for accessible lead in metal jewelry both require an Inductively Coupled Plasma (ICP) mass spectrometer. For its part, the Environmental Protection Agency (EPA) uses several methods to test for metals, including lead. Two EPA standards, EPA methods 3050B (Acid Digestion of Sediments, Sludges or Solids) and EPA Method 3051 (Microwave Assisted Digestion/Sludges, Solids), are specified in California and Minnesota legislation, and in a Proposition 65 consent agreement. Analysis can be done by Atomic Absorption (AA) or ICP.

FJTA members are complying with California and Minnesota jewelry requirements, but have experience in testing using the CPSC procedure as well. FJTA is concerned that relatively few laboratories may have ICP equipment, a major potential issue in connection with accrediting laboratories. We urge the Commission to consider, in identifying a suitable method or methods for lead in metal jewelry and for other lead testing, suitability and accuracy of tests, relative costs, inter-laboratory variability, and the number of laboratories capable of conducting the tests. In addition, since children's jewelry includes a variety of materials that have to be tested, attention must be paid to appropriate methods and standards for accrediting laboratories capable

[3] CPSIA § 101(f) (4).

of conducting tests not only on metal, but also on the variety of other materials that might be used in jewelry that will be subject to regulation. Calibration procedures for all types of lead testing and procedures must be well understood.

We note that within the jewelry industry some rare examples of inter-laboratory variability in test results have arisen, suggesting the possible need for additional guidance on this point. Given the very tight limits on lead content established by the CPSIA, even slight variations in test procedures, equipment or calibrations may mean the difference between passing and failing.

It is common for children's jewelry to use identical but assorted components made from different materials, like plastic, elastic, metal, wood, and paint, combined in different ways, to make different styles of jewelry. For example, with a bracelet and a necklace containing identical colored plastic and painted wooden beads strung on an elastic band with a plated metal clasp, each substrate item must meet the lead substrate limits. Plated metal, or metal coated with epoxy or other material that bonds to the substrate, must be tested in a composite manner to meet the lead limits. Surface coatings, like the paint on the wooden beads in this hypothetical example, are subject to the separate limits on paint. Paint used in jewelry is often used in very tiny amounts; the only practical way to assure that the paint meets lead paint standards is to test the paint, since it would destroy an enormous number of items to scrape enough material from painted jewelry to obtain an adequate sample size, although XRF may be an option in this scenario. FJTA members report that testing costs can be in the $1,000 range per item. We urge the Commission to clarify how compliance with the relevant lead standards can be demonstrated through testing of identical components that might be used in different products.

FJTA urges the Commission to recognize reasonable component or raw material testing as the basis for certifications required under the CPSIA. FJTA members understand the need for robust quality control to assure that components or raw materials meet required specifications and have implemented quality control procedures to assure that they do. The industry looks forward to working with the Commission on clarifying testing and related technical issues

## II. Exceptions

The Commission has requested comments on whether components in children's products contain lead, whether any such components are inaccessible, whether test methods are available to assess the accessibility of component parts under Section 101(b)(2) and (4), and current compliance or possibility of compliance with regulations, such as the European Directive . In Europe, lead crystal is subject to Directive 69/493/EEC, which establishes requirements on the total quantity of lead in crystal, including *minimum* lead content. Higher lead content connotes higher quality in many instances. Lead crystal is exempt from the Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) pursuant to

Commission decision 2006/690/EC. This decision added to the Annex of 2002/95/EC "Lead bound in crystal glass."

In addition to addressing inaccessible component parts and electronics, FJTA also suggests that the Commission consider the policy framework for granting exceptions for materials or products that do not pose a risk under Section 101(b)(1) of the Act.

The Commission has authority to exclude specific products or materials if it determines that lead in such product or material will neither result in the absorption of any lead into the body, taking into account normal and reasonably foreseeable use and abuse, nor have any other adverse impact on public health or safety. Under the total lead content limit approach adopted in the CPSIA, Congress understood that children could be exposed to some lead through reasonably foreseeable handling, use and abuse, such as swallowing or mouthing, even where products meet the lowest limits established in the Act. Consequently, we believe the intent of Section 101(b)(1) is to offer a means for the Commission to grant health- and risk-based exceptions for products or materials whose use or misuse by children will not result in adverse health effects when the product, material or component is used or misused. During the legislative discussions, lead crystal was identified as a primary candidate for an exemption under this provision, but FJTA believes that there may be a variety of materials that would meet the statutory criteria.

Various sources establish the safety of certain materials or products that should be excluded under this provision. For example, through a consensus process that included scientists, toxicologists, scientists and others, the jewelry settlement agreement under Proposition 65 excluded from regulation precious metals, stainless steel, most gemstones, and crystal on grounds that they do not pose a risk to human health. One category of exempt materials includes materials that have no or trace amounts of lead, like gems or precious metals (in the case of precious metals, the inclusion of lead at more than very low parts per million levels can alter properties and violates standards that apply to the metals). The second category includes crystal and glass. Lead crystal, by definition, may include 24 – 35% lead, but lead is physically bound in the matrix of the crystal. Lead content in crystal is not deemed accessible to children in a manner that results in a health risk (A third category, less relevant to the jewelry industry, might be materials that require lead to impart strength or performance (like steel or other metals), including where such product or material relates to a safety-critical aspect of the end product.)

There is no evidence in the peer-reviewed scientific literature that any of the materials exempt from the California or Minnesota requirements used in jewelry, considering reasonable use and abuse scenarios, will be harmful to the health of children or other consumers.

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FJTA appreciates the opportunity to submit these views and, as always, would be happy to provide additional information or respond to questions.

Sincerely,

Sheila A. Millar

cc: Michael Gale

## Stevenson, Todd

**From:** Millar, Sheila A. [Millar@khlaw.com]
**Sent:** Wednesday, January 21, 2009 4:26 PM
**To:** Accreditation for Children's Metal Jewelry
**Cc:** Howell, Robert; Falvey, Cheryl; gmullan@cpsc.gov; FJTA@aol.com; James McCarty
**Subject:** Laboratory Accreditation Process for Testing for Lead Content of Metal Children's Jewelry
**Attachments:** 2009_01_21 FJTA_MJSA Lead Accrued Comments Final.pdf

Attached please find comments on the above-referenced matter on behalf of the Fashion Jewelry Trade Association and Manufacturing Jewelers and Suppliers Association.

Sheila A. Millar
tel: 202.434.4143 | fax: 202.434.4646 |
millar@khlaw.com
1001 G Street, N.W., Suite 500 West |
Washington, D.C. 20001

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***Consumers Union * Consumer Federation of America***
*** Kids in Danger * Public Citizen ***
*** U.S. Public Interest Research Group ***

January 21, 2008

Office of the Secretary
Consumer Product Safety Commission
4330 East-West Highway
Bethesda, Maryland 20814
Via e-mail: Leadaccredjewelry@cpsc.gov
Facsimile (301) 504-0127

**Comments of Consumers Union, Consumer Federation of America, Kids in Danger, Public Citizen and the U.S. Public Interest Research Group to the U.S. Consumer Product Safety Commission on "Laboratory Accreditation Process for Testing Lead Content in Children's Metal Jewelry"**

## Introduction

Consumers Union of U.S., Inc. (CU), Consumer Federation of America (CFA), Kids in Danger, Public Citizen and the U.S. Public Interest Research Group (jointly "We") submit the following comments in response to the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") in the above-referenced matter ("Notice of Requirements" or "Notice").[1] The CPSC has published this Notice of Requirements in order to implement section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008, Public Law 110-314, ("CPSIA") which amends the Consumer Product Safety Act. In this Notice, the CPSC publishes the "criteria and process for Commission acceptance of accreditation of 'third party' laboratories for testing to the 600 ppm and 300 ppm

[1] "Accreditation Requirements for Third Party Conformity Assessment Bodies to test to the Requirements for Lead Content in Children's Metal Jewelry as Established by the Consumer Product Safety Improvement Act of 2008," 73 Fed. Reg. 78331 (December 22, 2008).

lead content limits...."[2] We submit these comments in response to the CPSC's Notice of Requirements.

## Background

Section 102(a)(2) of the CPSIA requires the CPSC to publish a "notice of requirements for accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which such children's product is subject." See CPSIA § 102(a)(3)(A), as codified at 15 U.S.C. 14(a)(3)(A). Within 120 days after the date of enactment, the Commission must publish notice of the requirements for accreditation of third party conformity assessment bodies that will assess conformity with the lead limit requirements of section 101(a)(2) as it relates to children's metal jewelry.[3]

In this case, the requirements are stated to be effective on December 22, 2008, the date of publication. However, the Commission seeks comments "on the accreditation procedures as they apply to that testing and on the accreditation approach in general, since the Commission must publish additional testing laboratory procedures over the coming months."[4]

## Recommendations

We urge the CPSC to adopt the following recommendations in its implementation the accreditation of third party conformity assessment bodies.

We support the requirements (described in section II.B. of the Notice) for "firewalled laboratories" seeking accreditation status to submit copies of their training materials to the Commission for review "showing how employees are trained to notify the Commission immediately and confidentially of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue

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[2] Id. at 78332.
[3] See CPSIA § 102(a)(3)(B)(iv), as codified at 15 U.S.C. 14(a)(3)(B)(iv).
[4] 73 Fed. Reg. at 71332.

influence over the laboratory's test results."[5] These additional requirements are designed to prevent undue influence by manufacturers or private labelers who own the testing laboratory used, and apply to any laboratory for which a manufacturer or private labeler of the children's product to be tested holds an interest of 10 percent or more.

We are concerned, however, that the Commission declined to address situations where the manufacturer or private labeler is owned by the same parent company that owns the laboratory. We believe that the same or similar undue influence could arise from a parent company that owns both the laboratory and the manufacturer. For this reason we urge the CPSC to extend the document submission requirements for "firewalled laboratories" to situations of common parentage -- where the manufacturer or private labeler is owned by the same parent as the laboratory.

The definition of firewalled laboratories should be expanded beyond those labs where manufacturers or private labelers own more than a ten percent interest. To prevent potential conflicts of interest, the extra requirements for proving impartiality must also be applied to any independent lab that does 50 percent or more of their business with a single manufacturer or private labeler of children's products.

It is important that the Commission apply rigorous standards to ensure that impartiality is maintained within firewalled laboratories. We support the requirement that these laboratories submit copies of their training documents to the Commission for review showing how employees are trained to notify the Commission immediately and confidentially of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over the laboratory's test results. However, the Commission should develop a stringent standard for such training documents to meet. Standards for impartiality are addressed in ISO/IEC Guide 65 - General Requirements for Bodies Operating Product Certification Systems, which could, as a starting place, be applied for this purpose. This standard requires a documented structure designed to

[5] Id. at 78333.

safeguard impartiality, including provisions to ensure the impartiality of the operations of the certification body. Other standards or best practices that are more protective of laboratory and test result integrity should also be considered for the development of a training document standard. As part of the accreditation process, the laboratory should be required to show proof of its compliance with the ISO/IEC Guide 65 or the stringent standard regarding impartiality protections developed by the CPSC.

The Commission should also conduct periodic reviews and revise accreditation requirements to ensure that the highest standards for laboratory accreditation are being followed. For example, if the ISO/IEC 17025 : 2005 – General Requirements for Competence of Testing and Calibration Laboratories is superseded by a more stringent accreditation standard, then the Commission should, at minimum, adopt the more stringent standard.

The Commission should establish a defined system for de-listing an accredited laboratory for just cause. Examples of reasons for delisting and accredited lab might include, but are not limited to:

- evidence of conflict-of-interest or where there is undue influence by a manufacturer, a common parent company, or other party that could have affected test results;
- a laboratory has been found to be incompetent to conduct required testing due to personnel or laboratory equipment changes; or
- a laboratory has a record of repeatedly certifying products that are later identified as non-compliant.

## Conclusion

For the foregoing reasons, we urge the Commission to adopt these recommendations in its implementation of section 102(a) of the CPSIA.

Respectfully submitted,

Donald L. Mays
Senior Director, Product Safety & Technical Public Policy
Consumers Union

Janell Mayo Duncan
Senior Counsel
Consumers Union

Rachel Weintraub
Director of Product Safety and Senior Counsel
Consumer Federation of America

Nancy A. Cowles
Executive Director
Kids in Danger

Christine Hines
Consumer and Civil Justice Counsel
Public Citizen's Congress Watch

Ed Mierzwinski
Federal Consumer Program Director
U.S. PIRG

Elizabeth Hitchcock
Public Health Advocate
U.S. PIRG

## Stevenson, Todd

**From:** Giddings-Jonas, Lynette [GiddLy@consumer.org]
**Sent:** Wednesday, January 21, 2009 5:41 PM
**To:** Accreditation for Children's Metal Jewelry
**Subject:** Comments on Lab Accreditation for Children's Jewelry
**Attachments:** Comments on Lab Accreditation for Children's Jewelry.pdf

Attached below are comments on Lab Accreditation for Children's Jewelry:

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## Stevenson, Todd

**From:** st22@cfl.rr.com
**Sent:** Wednesday, January 21, 2009 6:06 PM
**To:** Accreditation for Children's Metal Jewelry
**Subject:** Lab Accreditation Process for Testing for Lead Content in Children's Metal Jewlery

To whom it may concern:
I understand this new regulation is designed for the safety of children, however, there are sellers on www.etsy.com who design and sell top quality lead free children's jewelry. The costs of testing would simply put them out of business. I am one of them. I only purchase sterling silver and other materials from reputable dealers in the United States. Are there exceptions to this new regulation? This regulation is not fair and should not be allowed to pass. Please know there are many in opposition to this regulation as it penalizes small, reputable businesses.
--
Susan Templeton
www.ElephantTalesUsa.com
"stuff for you & the little members of your herd"

ETC Environmental Testing & Consulting, Inc.

www.etcmemphis.com 2790 Whitten Road Memphis, Tennessee 38133 main (901) 213-2400 fax (901) 213-2440
A Laboratory Management Partner

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January 13, 2009

Office of the Secretary
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MA 20814

REF: Laboratory Accreditation Process for Testing for Lead Content in Children's Metal Jewelry

Office of the Secretary:

This letter is in response to the December 22, 2008 Federal Register notice regarding the above referenced laboratory accreditation process.

This comment is a request to the Commission that in addition to ILAC-MRA signatories, it consider accepting laboratory accreditation by NELAC (National Environmental Laboratory Accreditation.)

This is a national recognized accreditation program that follows the requirements of the ISO 17025 laboratory accreditation standard. This organization is similar to the A2LA (American Association for Laboratory Accreditation) which is listed as a ILCA-MRA signatory accrediting body.

Our laboratory has been providing analytical testing services since 1972. Our laboratory is very well qualified to provide the testing services as required by the Consumer Protection Safety Act of 2008.

I can be reached at (901) 213-2446 or via email at nathan.pera@etcmemphis.com.

Thank you for your consideration of this request.

Sincerely,

Nathan A. Pera, IV
Chairman/Executive Vice-President
Environmental Testing & Consulting, Inc.

Jewelry
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December 9, 2008



Jennifer Johnson
327 Mayellen Ave.
San Jose, CA 95126
jen@mamasmagicstudio.com
(408) 297-0895

Small Business Ombudsman
U.S. CPSC
Washington, D.C. 20207

Dear Sir or Madam:

On February 10th, 2008, unless you can help, hundreds of thousands of small businesses like mine are going to be forced to close. I am the sole proprietor of a new small business. I am also the mother of two young children, and it is from both of these perspectives that I write to you to express my concerns about the new Consumer Product Safety Improvement Act.

I am very much in favor of reasonable efforts to protect children from toxic products, but I cannot support the CPSIA as it now stands. As I understand it, this legislation in its current form is not good for consumers or for businesses, especially small businesses like mine. It is well intentioned, but the testing requirements will decrease consumer options for children's goods, increase price significantly, and put me – and many other handcraft artists like myself – out of business.

In my little handcraft business, Mama's Magic Studio, my primary product is Baby Friendly Beads breastfeeding jewelry. Each of my beaded jewelry designs is one of a kind, because I enjoy the creative process and because my customers like having unique creations. Additionally, when I opened my business this year, I planned eventually to branch out into making jewelry, dolls, and other items for children.

The CPSIA will have dramatic consequences for businesses like mine. My main concern is the requirement that all *units* of children's items be tested for lead content and phthalates. The problem, as I understand it, is that every "unit" created must be independently tested by the manufacturer, the artist making the item. It is not sufficient to rely on testing done by suppliers, and there are no exceptions or considerations made for smaller "micro" manufacturers like myself. For artists like me who make small runs or one of a kind items, the testing required by this legislation is simply not economically possible.

Neither should it be necessary. Almost all the handcraft artists I know use commercially available supplies to create their products or work with materials that are inherently nontoxic. Do

beads suddenly contain lead because I have strung them together on cord? Does a baby blanket mysteriously turn toxic because I've knitted the yarn into a different shape? Of course not. If the materials were safe before I worked my "magic" on them, they should still be safe once my product has been finished. Why require an additional round of redundant testing on the finished item, at a cost of hundreds of dollars per item? All of my products cost less than $50 retail. Most of them are one of a kind. This is the case with many of the handcraft artists I know: moms trying to make a little extra grocery money, grandmas knitting for the church bazaar, proud-but-small businesses trying to make the world a little more beautiful while making a living. How on earth can we test our products as required by the CPSIA and remain profitable?

While my jewelry is **not** a toy, and is intended as costume jewelry to be worn by adults, I am very concerned that the new CPSIA regulations might apply to my product because it could be interpreted as something that is "used" by children under 12 (namely, babies grasping the jewelry while nursing, instead of pulling at mama's hair). I have submitted a question to the CPSIA website asking for clarification on this, but I have not yet received a reply. Even if my product is found to be exempt, however, I cannot support the testing requirements as stated in the law. Because of these requirements, I have put on hold all plans to start making any children's items, because it seems impossible for a small handcraft business like mine to comply with this law. Essentially, my business plan for future growth has been entirely undermined because of this legislation.

It has been challenging enough, as a new business owner, to deal with with the California Lead in Jewelry Law. Of course, being a mother myself, I absolutely understand the need for safe children's items – and to date I have erred on the side of caution and considered breastfeeding jewelry to fall under the category of children's items in terms of compliance with the law. I have made every effort to use only nontoxic materials that are lead-free and to take safety into account with my designs, even though my jewelry is technically costume jewelry for adults. So I sympathize with the CA law, the efforts to keep children safe, and I am doing my best to comply.

As I understand it, the CA law allows the manufacturer some wiggle room to use information from suppliers in order to be in compliance with the law. (From the online FAQ: "Although the law does not specifically require a person to conduct compliance testing, the only way to know for certain if an item is in compliance with the law is to have it analyzed by a laboratory using the methods specified in the law (EPA Methods 3050B or 3051). DTSC highly encourages businesses to obtain certificates of compliance and other detailed information about the composition of materials purchased from jewelry component suppliers. The law specifies various factors that will be considered when assessing penalties for violations including whether good faith measures were taken to comply with the law and the time these measures were taken." http://www.dtsc.ca.gov/LeadInJewelry.cfm.) This seems to be a reasonable approach. To me, it makes a lot more sense to require a supplier of materials to do testing and certify the safety of their materials, and I appreciate knowing exactly what I'm using in my jewelry. However, once this testing has been done by my supplier, I do not see a need for additional testing. I find it baffling that the CPSIA would not allow for a similar approach to the CA law, especially where small businesses and handcraft artists are concerned.

As a mother of two young children, I am well aware of the need to protect children from toxic substances. I also cherish the wide range of choices and the entrepreneurial spirit provided by the handmade community. I have befriended several handcraft artists in my shopping for my children, and it is such a joy to see my kids using and wearing items made with love by someone that I know. While well intentioned, the CPSIA goes about protecting children in the wrong way. The testing requirements place an unjust and unnecessary burden on small business and handcraft artists. I fear that the if the CPSIA goes into effect as written, the only ones who will be able to legally sell their stuff for kids are large businesses, places like Target and Walmart, places selling mass-produced goods from manufacturers that can afford the testing. And it's likely that their costs will be passed on to consumers, so we will all be paying more for less. How sad that would be!

In a time of economic crisis, the last thing I want my government to do is make it more difficult for me (and small businesses like me) to survive. But that's exactly what will happen once the CPSIA goes into effect. As you may be aware, more and more people are expressing concern about all this, and a movement is beginning. "National Bankruptcy Day" has been declared for February 10th and the regulations going into effect: http://nationalbankruptcyday.com/.

I certainly don't want to close my doors as of February 10th. However, given the way the Act is written, and the broadness of its scope, I fear that it may come to that. I *know* that it will come to that for many of my colleagues in the handmade community. Surely this is not what the CPSIA was intended to do.

Here are my specific suggestions for amending the legislation:

- Waive the testing requirements entirely for small volume manufacturers, those of us in the small handcraft businesses especially. The Handmade Toy Alliance has suggested businesses with revenue less than 1 million dollars in the USA should be exempt. Requiring this testing really will put us all out of business.
- If a waiver is not possible, the CPSC should provide free testing to small businesses that produce children's products.
- If the CPSC does not have the means or inclination to offer free testing, the burden of testing should be borne by the manufacturers of materials used in handcraft businesses (fabrics, beads, paints, etc.). If their product could potentially be used to make something used by a child under the age of 12, the manufacturer of those *materials* should certify them as lead and phthalate free. The manufacturer should then make those certifications available to their customers. Shouldn't these folks be making safe products anyway?
- Allow third party certifications from the supplier as sufficient proof of items being lead and phthalate free. If the beads in my necklaces have been tested and certified by the company from which I purchase them, I should be able to obtain those certifications and not have to re-test those same beads simply because I put them on a piece of string. Same goes for somebody making children's textiles: if the fabric and thread are certified as safe, why must they be tested again simply because they've been rearranged?

In my experience, it has been very difficult to obtain any "certificates of compliance" from suppliers (as suggested by the CA law) most likely because of their own concerns about liability. So if the CPSIA were to take this approach, more would need to be done on a national basis to require suppliers of materials to provide those certificates to us so that we can be fully informed about the materials we use in our own products. In the case of handcraft artisans and small businesses like myself, it is our suppliers who have financial capital for these tests, access to the material in bulk (so that only a relatively small portion of the material needs to be tested; in comparison, with my small inventory, a very large percentage would be required for testing purposes, creating another financial hardship). It is simply unreasonable to put the burden of testing on small businesses like mine. Additionally, even if I had the money (which I certainly don't), how would I find a lab to do the testing, and will they have the capacity to meet my needs? It really puts a small business owner in a bind.

I am just one of hundreds of thousands of small businesspeople in the US who will be adversely affected by the testing provisions of the Act. I know that the Act was conceived as a well-intentioned effort to safeguard children against lead and other contaminants in toys, primarily from overseas. Unfortunately, the way it's written, the Act will simply drive American small manufacturers of children's goods out of business, thereby increasing our reliance on imported toys and goods. Is this really the best way to ensure our children's safety? No. Is this a good idea in these times of economic crisis? Absolutely not. Unless it is changed to address the concerns I have outlined, the Act will not help and will certainly do harm in our economy – the last thing it needs at this time. Please help make sure that February 10th, 2009, does not become "National Bankruptcy Day" for myself and countless others like me.

I am not a lawyer, nor does my very small business budget include enough extra money to pay for legal counsel, so I have come to my understanding of these issues by doing my own research, reading the text of the law, and talking with other handcraft artists. Folks are in a panic about this. Perhaps I have misunderstood how this law will affect me and the hundreds of thousands of other business owners like me; if so, I would be delighted to know and I will certainly spread the word. I look forward to your timely reply so I can make educated decisions about whether or not I can comply with the new standards.

Without your help, my choice come February 10th will be to close up shop, continue business illegally, or radically change my business by ceasing production of any and all items for children or related to children's needs. I sincerely hope you and your colleagues will work together so that folks like me don't have to choose between closing shop and becoming a criminal.

Sincerely,

Jennifer Johnson

Jennifer Johnson
Owner, Mama's Magic Studio