

THE VISION COUNCIL VOLUNTARY LEAD GUIDELINES

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THE **VISION**COUNCIL

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EXECUTIVE SUMMARY

During 2007 the public became aware that some toys contain excessive amounts of lead, a regulated substance. Soon many products, including some eyeglass frames, were found to contain lead above allowable limits. This guideline provides an overview of the lead regulations and its impact on eyeglass frames and sunglasses.

For years, the federal regulation limiting lead content, 16 C.F.R. 1303, required that paint or other surface coatings on toys and children's products contain no more than 0.06% lead or, 600 parts per million (PPM) by weight. This 600 PPM threshold had been adopted in the regulation of lead in children's jewelry, including glaze coatings, ceramic glaze and printing ink that may be used on that jewelry. The regulation set allowable lead levels, but did not identify safe lead levels.

However, as a result of the recently enacted Consumer Product Safety Improvement Act of 2008, (hereafter the CPSIA) the maximum limit of lead in toys and children's products is to be reduced to 300 PPM beginning one year after enactment of the CPSIA (August 14, 2009), and then to 100 PPM three years from the enactment date (August 14, 2011) unless the Consumer Products Safety Commission (CPSC) determines that such a threshold is not technically feasible. In addition, the lead requirements are being expanded beyond simply lead in the paint or surface coating to include lead in other parts of the product under certain circumstances. New third-party testing and labeling requirements for children's products have also been created to promote safety. Furthermore, the CPSIA defines any children's product as primarily for children 12 years of age or younger. This landmark legislation will likely influence how CPSC enforces existing laws as well.

The Vision Council's belief is that eyeglass frames and sunglasses, even if sold into the children's market, are outside the scope of the CPSIA's new restrictions on lead and testing requirements for children's products. Members' products are considered medical devices and are regulated by the Food and Drug Administration. However, the Federal Hazardous Substances Act, which sets standards for toxic and hazardous substances, still applies to our frames and sunwear. The CPSC requires that products found to contain lead exceeding the allowed level must be promptly reported

to the CPSC and other governmental bodies. For additional information on this topic, member companies can contact The Vision Council.

If you chose to test, and your frames or sunwear are found to comply with the lead requirements, care should be exercised in regards to written and verbal claims. False or misleading claims are prohibited by federal regulation. It is recommended that companies use accurate language in labeling regarding lead content and avoid the use of the terms such:

- Lead Free
- Lead Safe
- Complies with all Federal and State Requirements on Lead Content
- Warranty, Guarantee, and similar, used in describing lead content

QUESTIONS AND ANSWERS

Q: Does the CPSIA require me to test?

A: No. As discussed above, frames and sunwear are regulated as medical devices by the U.S. Food and Drug Administration, and therefore are not within the scope of the CPSIA, so third party testing for lead is not mandated. However, because the CPSC has enforcement authority over products sold in the United States with lead levels in excess of the statutory maximum; you could be subject to recalls and monetary penalties if your products were to exceed those levels. Thus, testing is an option for assuring that your frames or sunwear do not contain excessive lead levels.

Q: How much should this cost?

A: The cost for screening tests is as low as \$30.00 as of January 2008. You need only test samples from production, how many is up to you, and there is the option to batch test groups of frames as a screening control. Should a test of a group of frames come back positive for lead, tests on individual frames can then be accomplished.

Q: Are there different types of tests?

A: Yes. Several tests can identify lead. Lead concentration

above the 600 PPM limit is easy to detect and so less expensive test methods are useful as a screening tool. Positive results can then be retested with more sensitive methods.

Q: Of the possible tests for lead content, which is better?

A: Although there are ASTM defined methods for testing other product including toys, there are no defined lead testing methods for eyeglass frames or sunwear. Using a certified testing company is the first step in determining which testing options are available, at what cost, and at what level of sensitivity. Appendix C contains a list of testing laboratories known to The Vision Council member companies.

Q: Should I get a lawyer involved?

A: Engaging an attorney is not essential but you may want to do so if there a possibility of non-conforming product.

Q: How can The Vision Council help me?

A: The Vision Council technical and legal staff is at your service. This guideline document is a first step.

FORWARD

This member-driven document is intended as an informative overview for The Vision Council member companies that import, buy, sell or distribute eyeglass frames and sunwear in the United States.

Use of the guidelines contained herein is voluntary, and by no means ensures that all hazards, liabilities or current laws are mitigated through its use. There may be practices, standards and or regulatory requirements applicable to your operations that exceed the recommendations in this document. Because federal and state regulations are frequently not aligned, and subject to change, consulting all sources of information from federal, state, regional and city authorities is recommended. Please see Appendix A for additional minimum recommended reading, as well as Appendix B for definitions.

This guideline does not purport to address all of the safety concerns associated with the presence of lead in eyewear. It is the responsibility of the reader to establish appropriate safety and health practices and determine the applicability of the various regulations.

Because the federal lead paint laws set an upper limit, and do not give a safe lead level, any and all levels of lead should be considered hazardous in varying degrees, and the industry should strive to reduce all possible exposure.

The Vision Council does not guarantee, promise or warrant that the information in this document will meet the legal or liability needs of manufacturing operations, purchasers or sellers of eyeglass frames or sunwear. This is a determination that your business must make and for which The Vision Council is not responsible.

Comments or suggested changes to this document should be sent to:

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SCOPE

This document is intended to inform and outline the topic of federal lead paint regulation as it applies to eyeglasses or sunwear , and includes general guidelines and good practices for those members of The Vision Council that are involved in that segment of the industry.

INTRODUCTION

Over the course of years and as new information continues to emerge about the toxicity of lead, the Center for Disease Control and Prevention (CDC) has continuously lowered the allowable level of lead exposure to coincide with measured levels of lead in children's blood.

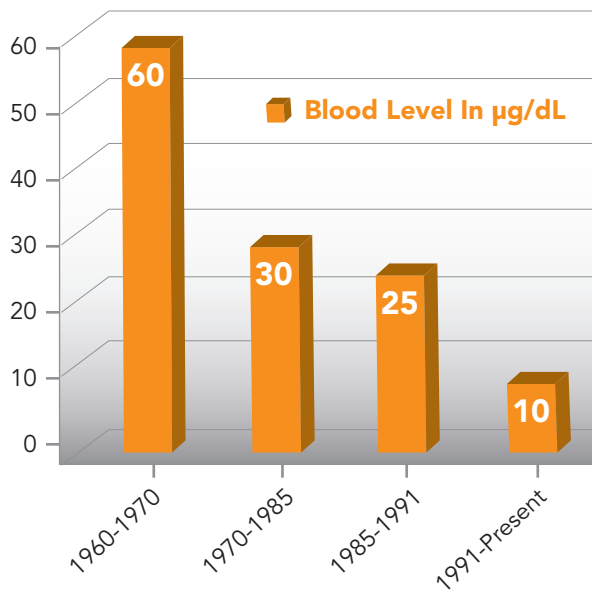


Figure 1: Lowering of CDC-recommended action level for blood lead in children over time.

In 1991, the CDC recommended adoption of 10 µg/dL (micrograms/deciliter) biological exposure index as an action level for children, and as an advisory level for environmental and educational intervention. As a direct result, the 600 PPM standard for paint and children’s jewelry, and similar environmental factors, has been enacted in order to promote lead levels below the CDC case management guidelines. This threshold, as discussed above, will be graduated first to 300 PPM and then to 100 PPM for children’s products. It should be noted that none of the federal laws or regulations attempt to establish a “safe” level of lead in any product, and no acceptable safe blood lead threshold has been identified for children, but instead the regulations seek to set allowable maximum levels that are deemed acceptable.

This information has provoked various agencies, U.S. states and municipalities to propose regulations seeking to reduce levels of lead in children’s blood lower than the CDC guidelines, through control of the environment and objects to which children could be exposed. These environmental factors include the monitoring by various bodies such as lead content by weight or part per million for; ambient air (gasoline), drinking water, soil in play and non-play areas, food, jewelry and paint.

Because of the wide number of bodies and entities concerned with lead, it is incumbent on companies and individuals to remain vigilant at all times for new regulations

and guidelines. Due to the prominence of lead as a public health concern, several federal agencies have issued advisory standards or enforceable regulations that have become law. The governmental agencies that monitor lead include:

- CDC – Centers for Disease Control and Prevention
- OSHA – Occupational Safety and Health Administration
- ACGIH – American Conference of Governmental Industrial Hygienists
- NIOSH – National Institute for Occupational Safety and Health
- EPA –Environmental Protection Agency
- CPSC –Consumer Product Safety Commission
- FDA –Food and Drug Administration

Of those agencies listed above, the most applicable to eyewear and sunwear intended for use by children is the CPSC. The relevant regulations enforced by the CPSC are found at 16 C.F.R. § 1303 and 16 C.F.R. § 1500. These regulations do not set safe lead levels, but instead seek to set a level at which lead content is considered excessive and likely to induce, through direct contact or ingestion, lead blood levels in excess of 10 micrograms per deciliter. This is reflected in the current regulations that require that paint or other surface coating not contain more than 0.06% lead or, 600 PPM by weight.

Interestingly the same threshold has been adopted in the regulation of lead in children’s jewelry, glaze coatings, ceramic glaze and printing ink that may be used on that jewelry.

TESTING REQUIREMENTS

An appropriate testing method would allow an operator to reasonably ascertain that a frame meets the federal lead paint regulation, and is not limited to current testing as performed in industry. The regulation does not limit new technologies or alternative methods. It is reasonable to presume that any new or cutting edge methodologies should be scientifically based, repeatable and economically feasible.

According to CPSC guidelines, excessive lead test results for product that has already been released into the market must be reported to the CPSC and other governmental bodies per federal and state laws, regulations, and guidelines; and reported within various time periods. Please see Appendix C for a list of testing laboratories.

ON-GOING TEST STRATEGIES

In line with any good manufacturing practice and normal process control, product should be continually tested on a regular basis and at regular intervals. A typical test regime that could reasonably ensure compliant product is going to market would include these features:

- Products would be tested prior to release in the market.
- Products would be retested on a regular basis, including upon change of supplier, change in components, or changes in specifications as well as other factors.
- Laboratories chosen for this work should be certified by and accredited by bodies such as NADCAP, ASTM and others.
- Test results should be maintained for several years per applicable regulations for that state and locality.

In an effort to make the testing uniform, and subsequently the test results over the course of time, and in the case that multiple testing laboratories might be used, the following general recommendations can be made for good practices in testing for the presence of lead on eyewear and sunwear coatings:

- The testing methodology should have a minimum test sensitivity of +/-35 PPM, where-in results of the presence of lead less than 35ppm could be considered residual noise in the process.
- Coating test results approaching the current 600 PPM upper limit (for example a result of 585 PPM with a sensitivity of +/-35ppm yielding a possible result of 620ppm) and within the minimum sensitivity should be repeated with more accurate methodologies.
- Collection of samples from each frame should be taken from every major surface area on all parts of the frame including both sides of temples, bridges and other components.
- Collection of coating samples of markings from every group of printed alphanumeric characters should occur; this would include printing on the inside of temples, bridges, logos and other areas excepting demo lenses.
- As appropriate, samples should be taken from frames that include metal adornments that are not fully covered and encapsulated by any surface coating and could touch the skin of the wearer. Inaccessible components that are not physically exposed because they are sealed or encased and which will not become physically exposed through normal and reasonably foreseeable use of the product are exempt from testing.

In order to properly control test results, it is key that the samples collected are uniform across a family of tested of product. For this reason it is recommended that a strict procedure be maintained for the collection of each sample, a test sample gathering procedure document be written and enforced and individual records for each test sample be maintained for every sample collected. These individual sample collecting records should be unique to each test result, and this information available with any eventual testing results, which would be available for future joint review.

CLAIMS AND ADVERTISING

Claims as to the percentage of lead found in the construction of an eyeglass or sunwear frames should be consistent with its actual make-up.

As noted in the section *A Brief History: U.S. Regulatory Philosophy*, one reason why the U.S. self-regulating system works is that there are a number of federal and state laws and regulations that prohibit the use of false or misleading labeling or advertising of products or services sold in the United States. In some cases, U. S. laws and regulations not only prohibit false or misleading labeling or advertising, but also mandate that information regarding certain characteristics of a product or service be disclosed to buyers. At the federal level, one of the most important laws in this area, and one which is enforced by the Federal Trade Commission (FTC), is The Fair Packaging and Labeling Act. This act requires consumer commodities to be accurately labeled regarding the description of the product's identity and net quantity.

While the FTC is not authorized to resolve individual consumer complaints (although most states have established offices for this purpose) letters from consumers can trigger investigations of an industry or of a specific company. If, during an investigation, the FTC staff find reason to believe that a company has violated the law, and if the case is not settled by a formal agreement with the company (known as a Consent Order), the FTC can decide to sue the company. Depending on circumstances, the case may be tried before an administrative law judge or in federal court. The FTC may seek an order against the company to cease and desist, a preliminary or permanent injunction against the sale of the product, consumer redress or other appropriate relief.

BACKGROUND: CODE OF FEDERAL REGULATIONS

The Code of Federal Regulations (C.F.R.) are the general and permanent rules published in the Federal Register by the executive branch and agencies of the federal government. The Federal Register is divided into 50 Titles that represent various areas subject to federal regulation. Every volume of the C.F.R. is updated once each calendar year, and is issued or reissued on a quarterly basis.

- Titles 1-16 are updated as of January 1
- Titles 17-27 are updated as of April 1
- Titles 28-41 are updated as of July 1
- Titles 42-50 are updated as of October 1

All Titles are divided into chapters, usually bearing the name of the agency issuing the Title. Each chapter is further subdivided into parts that cover specific regulatory areas. All parts are organized in sections, and most citations in the C.F.R. are provided at the section level. A list of issuing agencies and where they appear in a C.F.R. may be found in Appendix C of the U.S. Government Manual.

In addition, the Code of Federal Regulations are also available online through the National Archives and Records Administration's (NARA) Office of the Federal Register (OFR) and the Government Printing Office.

Please note that the relevant CPSC regulations, 16 C.F.R. § 1303 and 16 C.F.R. § 1500 et seq. will be undergoing amendment in order to implement the CPSIA. Therefore, it is suggested that you contact The Vision Council if questions arise as to whether or not you are reviewing the most current version of the regulations.

A BRIEF HISTORY: U.S. REGULATORY PHILOSOPHY

It is useful to know something about the U.S. regulatory philosophy to understand when federal or state government agencies are likely to become involved in conformity assessment. U.S. regulatory philosophy relies heavily on a manufacturer's declaration of conformity (or self-certification) wherever possible. Manufacturers' declaration of conformity is one of the oldest and simplest forms of certification. The vast majority of U.S. marketplace transactions

involve only the buyer and the seller – without intervention by any third party, whether government or the private sector. There are a number of reasons why this approach is successful in the United States. These include: (1) the sometimes severe penalties imposed by the U.S. legal and judicial system on products proven to be defective or hazardous to the public safety or environment; (2) the increasing access that the U.S. consumer has to information about poor quality or hazardous and defective products through various news and publications media; (3) the size of the U.S. marketplace and the ability of the U.S. consumer to switch to a competing product if dissatisfied; and (4) U.S. laws and regulations regarding truth in labeling and advertising. The last three serve to increase consumer protection by enabling U.S. consumers to make better informed decisions regarding the products they purchase and to switch brands if dissatisfied.

APPENDIX A

Referenced Documents and Recommended Reading for Ophthalmic Professionals

16 C.F.R. 1303 Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead Containing Pain

16 C.F.R. 1500 Federal Hazardous Substances Act Regulations, including sections:

16 C.F.R. 1500.50 Test Methods for Simulating Use and Abuse of Toys and Other Articles Intended for Use by Children

16 C.F.R. 1500.51 Test Methods for Simulating Use and Abuse of Toys and Other Articles Intended for Use by Children 18 Months of Age or Less

As mentioned above, please note that the relevant CPSC regulations, 16 C.F.R. § 1303 and 16 C.F.R. § 1500 et seq. will be undergoing amendments in order to implement the CPSIA. Therefore, it is suggested that you contact The Vision Council if questions arise as to whether or not you are reviewing the most current version of the regulations.

ISO 10993 Biocompatibility Standards

Consumer Product Safety Act

APPENDIX B - DEFINITIONS

Unless otherwise listed below this document uses those terms in the manner listed in the document ISO TC172 - PDAM 13666

Biological Exposure Index (BEI) – A guidance value for assessing biological monitoring results. The BEI for blood lead is 30 µg/dL. (ACGIH 2005)

Eyewear – A broad category of spectacles worn external to the body (i.e. does not include contact lenses). This family of devices consists of frames bearing lenses, worn in front of the eyes, typically supported by the nose and two temple pieces which are placed over the ears. Also known as glasses, eyeglasses, sunwear, sunglasses, and readers, these devices are most often worn for vision correction, eye protection or as a fashion accessory. Toy and novelty items are not included in this category.

Frame – Those parts of eyewear other than the optical lenses that allow the lenses to be worn.

Lacquer Paint – Coatings and other similar surface-coating materials means a fluid, semi-fluid or other material, with or without a suspension of finely divided coloring matter, which changes to a solid film when a thin layer is applied to a metal, wood, stone, paper, leather, cloth, plastic or other surface. This term does not include printing inks or those materials which actually become a part of the substrate, such as the pigment in a plastic article, or those materials which are actually bonded to the substrate, such as by electroplating or ceramic glazing.

Lead – This includes all forms of lead including but not limited to; lead compounds, lead oxides and other lead-heavy metal combinations naturally found in the environment.

Lead Containing – Lead-containing paint means paint or other similar surface coating materials containing lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 0.06 percent by weight of the total nonvolatile content of the paint or the weight of the dried paint film.

Paint – Those coatings and other similar surface-coating materials meaning a fluid, semi-fluid or other material, with or without a suspension of finely divided coloring matter, which changes to a solid film when a thin layer is applied to a metal, wood, stone, paper, leather, cloth, plastic or other surface. This term does not include printing inks or those materials which actually become a part of the substrate, such as the pigment in a plastic article, or those materials which are actually bonded to the substrate, such as by electroplating or ceramic glazing.

Toy – Toys and other articles intended for use by children means those toys and other articles which are intended to be entrusted to or for use by children. This would not include all articles to which children might have access simply because they are present in a household.

APPENDIX C - TESTING LABORATORIES

For a list of testing laboratories known to member companies please contact The Vision Council.

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APPENDIX D – COPY 16 C.F.R. 1303.1-5

As mentioned above, these regulations will be undergoing revision in order to implement the CPSIA. Please ensure that you are reviewing the most up-to-date version. Contact The Vision Council if you have questions as to whether or not you are reviewing the most current version of the regulations.