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

This document has been electronically approved and signed.

BALLOT VOTE SHEET

Date: January 13, 2011

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM : Philip Chao, Assistant General Counsel
Hyun S. Kim, Attorney

SUBJECT : Notice of Public Hearing – Technological Feasibility of 100 ppm

BALLOT VOTE Due: January 20, 2011

Attached is a draft *Federal Register* notice of public hearing on the technological feasibility of meeting the 100 parts per million (ppm) lead content limit and associated public health considerations for children's products.

Please indicate your vote on the following options.

I. Approve the publication of the draft notice in the *Federal Register*.

_____ _____
(Signature) (Date)

II. Approve the publication of the draft notice in the *Federal Register* with changes. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve the publication of the draft notice in the *Federal Register.*

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* notice of public hearing.

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

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

[Docket No. CPSC-2010-0080]

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of public hearing.

SUMMARY: Section 101(a) of the Consumer Product Safety Improvement Act ("CPSIA") provides that, as of August 14, 2011, children's products may not contain more than 100 parts per million ("ppm") of lead unless the Consumer Product Safety Commission ("CPSC," "Commission," or "we") determines that such a limit is not technologically feasible. The Commission may make such a determination only after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products. Through this notice, the Commission is announcing that it will conduct a public hearing to receive views from all interested parties about the technological feasibility of meeting the 100 ppm lead content limit for children's products and associated public health considerations.

DATES: The public hearing will begin at 10 a.m. EST on February 17, 2011, and conclude the same day.

ADDRESSES: The public hearing will be held in the Hearing Room, 4th Floor of the Bethesda Towers Building, 4330 East West Highway, Bethesda, MD 20814.

ONLINE REGISTRATION AND WEBCAST: Members of the public who wish to attend the public hearing are requested to preregister online at http://www.cpsc.gov/_____. You may register until 5 p.m. EST on February 16, 2011. This public hearing also will be available live

via webcast on February 17, 2011, at http://www.cpsc.gov/webcast. Registration is not necessary to view the webcast. A transcript will be made of the proceedings of the public hearing.

ORAL PRESENTATIONS AND WRITTEN COMMENTS: To make oral presentations, participants must preregister online. Presenters must also submit a request to make an oral presentation, and the written text of such comments captioned "100 PPM–Technological Feasibility Public Hearing" by electronic mail (email) to *cpsc-os@cpsc.gov*, or mailed or delivered to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, no later than 5 p.m. EST on February 11, 2011. Commenters should limit their presentations to approximately 15 minutes, exclusive of any periods of questioning by the Commissioners or CPSC staff. We may limit further the time for any presentation and impose restrictions to avoid excessive duplication of presentations.

Participants who are unable to make an oral presentation may submit written comments regarding the issues outlined under Supplementary Information captioned "100 PPM–Technological Feasibility Public Hearing" by electronic mail (email) to *cpsc-os@cpsc.gov*, or mailed or delivered to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, no later than 5 p.m. EST on February 11, 2011. Any information submitted in writing and orally to the CPSC at the public hearing will become part of the public record.

FOR FURTHER INFORMATION CONTACT: Concerning requests and procedures for oral presentations of comments: Rockelle Hammond, Consumer Product Safety Commission, Bethesda, MD 20814; telephone: (301) 504–6833; email: cpscos@cpsc.gov. For all other

matters: Dominique Williams, Consumer Product Safety Commission, Bethesda, MD 20814; telephone: (301) 504–7597; email: dwilliams@cpsc.gov.

SUPPLEMENTARY INFORMATION: Section 101(a)(2)(C) of the CPSIA (15 U.S.C. 1278a(a)(2)(C)) provides that, as of August 14, 2011, children's products may not contain more than 100 parts per million (ppm) of lead unless the Commission determines that such a limit is not technologically feasible. The Commission may make this determination only after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products. Section 101(d) of the CPSIA (15 U.S.C. 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

> (1) a product that complies with the limit is commercially available in the product category;
>
> (2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;
>
> (3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
>
> (4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

If the Commission determines that the 100 ppm lead content limit is not technologically feasible for a product or product category, section 101(a)(2)(D) of the CPSIA requires the Commission, by regulation, to establish the lowest amount below 300 ppm that it determines is technologically feasible. On July 27, 2010, we published a notice in the *Federal Register* (75 FR 43942) requesting comments and information regarding the technological feasibility for manufacturers to meet the 100 ppm lead content limits. We received comments from consumer groups, manufacturers, retailers, associations, and laboratories regarding the technological feasibility of meeting the 100 ppm lead content limit. A number of commenters stated that some classes of materials will have difficulty meeting the 100 ppm lead content limit, including metal components and some glass and ceramic components. According to the commenters, source materials, including recycled materials for metal alloys, cannot comply consistently due to the variability of the materials. A few commenters contended that other materials, such as plastics, could comply if only virgin plastics are used. However, some commenters stated that for all materials, there is significant variability among test results, even for identical products, due to variations in testing methodology and procedures, and that inter- and intra- laboratory variability must be addressed. Several commenters also stated that there are no demonstrable health benefits of reducing lead limits from 300 ppm to 100 ppm in light of the relative inaccessibility of lead that is bound in plastic or metal. Other commenters stated that there are children's products in the market now that meet the 100 ppm lead content limits, and that it is not only possible, but also essential for the public health, to reduce lead in consumer products—particularly children's products—to the lowest levels that are technologically feasible. We are still reviewing the comments and will consider them along with the additional information

presented at the hearing. Participants should not resubmit their comments, which were submitted in response to the July 27, 2010 notice. The Commission is seeking new or additional information that specifically addresses the issues outlined below in the public hearing that were not addressed in the earlier comments:

(1) Please identify any product or product category that already complies with the 100 ppm limit and describe the extent to which such product(s) or product categories are commercially available in the United States. We are interested especially in:

(a) metal components in children's products, how such metal components are sourced or obtained, and the extent to which lead is found in metals alloys even when it is not introduced intentionally;

(b) plastic and non-metal materials in children's products, how such plastic and non-metal materials are sourced or obtained, and the extent to which lead is found in such materials even when it is not introduced intentionally;

(c) glass and ceramic materials in children's products, how such glass and ceramic materials are sourced or obtained, and the extent to which lead is found in such materials even when it is not introduced intentionally; and

(d) what factors or considerations should we evaluate in deciding whether a product complying with the limit is "commercially available?"

(2) What technologies exist that would enable manufacturers to comply with the 100 ppm limit? In responding to this question, please describe the technology or technologies and the product or product category that would benefit.

(a) Please describe the extent to which the technology or technologies is commercially available or otherwise available to manufacturers.

(b) Section 101(d)(2) of the CPSIA states that the technology to comply with the limit is "commercially available to manufacturers or is otherwise available within the common meaning of the term." What factors or considerations should we evaluate in deciding whether a technology is "commercially available" or "otherwise available within the common meaning of the term?"

(3) What industrial strategies or devices have been developed that are capable or will be capable of achieving a lead limit of 100 ppm by August, 2011?

(a) What barriers, if any, exist to prevent a company from adopting such an industrial strategy or device to achieve the desired limit?

(b) How might CPSC determine whether companies are acting in "good faith" as to their capabilities in adopting a particular industrial strategy or device?

(4) What alternative practices, best practices, or other operational changes exist that would allow the manufacturer to comply with the 100 ppm lead limit? What factors or considerations might encourage or deter manufacturers from adopting such practices or operational changes?

(5) What data on inter- and intra- laboratory variability and inter- and intra- lot variability exists? In responding to this question, it would be very helpful if the basis for such variability can be explained. For example, the sensitivity of a particular piece of laboratory equipment or the use of a particular test method might lead to some variation in results.

(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? In responding to these questions, published scientific or medical articles will be helpful.

Any information submitted in writing and orally to the CPSC at the public hearing will become part of the public record. The public hearing will begin at 10 a.m. EST on February 17, 2011, and will conclude the same day. This public hearing will also be available live via webcast on February 17, 2011, at http://www.cpsc.gov/webcast. Requests to present oral comments must be submitted to the Office of the Secretary no later than 5:00 p.m. EST on February 11, 2011. Written comments, or a written copy of the text of the oral comments, must be received no later than 5:00 p.m. EST on February 11, 2011. Commenters should limit their presentations to approximately 15 minutes, exclusive of any periods of questioning by the Commissioners or the CPSC staff. We may limit further the time for any presentation and impose restrictions to avoid excessive duplication of presentations. A transcript will be made of the proceedings of the public hearing. Access to the docket to read background documents, including a transcript of the public meeting, or comments received, will be made available at http://www.regulations.gov under Docket No. CPSC-2010-0080.

Dated:_____

_____
Todd A. Stevenson, Secretary
Consumer Product Safety Commission

Staff Briefing Package

Staff Recommendation for a Public Hearing on the Technological Feasibility of 100 ppm Total Lead Content in Children's Products

01/13/2011

Dominique J. Williams, Toxicologist
Directorate for Health Sciences
Phone: 301-504-7597
Email: dwilliams@cpsc.gov

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Briefing Memo

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

This document has been electronically approved and signed.

Memorandum

January 13, 2011

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction
Dominique J. Williams, Toxicologist, Directorate for Health Sciences

SUBJECT : Consumer Product Safety Improvement Act of 2008 (CPSIA) – Staff Recommendation for a Public Hearing on the Technological Feasibility of 100 ppm Total Lead Content in Children's Products

Introduction

Section 101(a) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") provides that, as of August 11, 2011, children's products may not contain more than 100 parts per million ("ppm") of lead, unless the Consumer Product Safety Commission ("CPSC" or "Commission"), determines that it is not technologically feasible, after notice and a hearing, and after analyzing the public health protections associated with substantially reducing lead in children's products. Section 101(d) of the CPSIA (15 U.S.C 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

> (1) a product that complies with the limit is commercially available in the product category;
>
> (2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;
>
> (3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
>
> (4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

On July 27, 2010, a notice was published in the *Federal Register* requesting comments and information regarding the technological feasibility of manufacturers meeting the 100 ppm lead content limit. A total of 24 comments were received from consumer groups, manufacturers, retailers, associations, and laboratories regarding the technological feasibility of meeting the 100 ppm lead content limit. The main categories of discussion were: test result variability due to

material composition; variability in test results between different laboratories; public health protectiveness of 100 ppm; economic burden; available of compliant materials in the manufacturing supply chain; and 100 ppm lead is technologically feasible.

The purpose of this staff briefing package is: (1) to convey to the Commission a summary of the comments received in response to the July 27, 2010 Federal Register Notice seeking comments on the technological feasibility of 100 ppm for lead content, and (2) to recommend that the Commission hold a public hearing to obtain additional information that the Commission can consider in determining the technological feasibility of 100 ppm for lead content. Staff has reviewed the public comments received and believes that specific information is lacking as to whether a lead content limit of 100 ppm is indeed technologically feasible and the public health significance of reducing lead content in children's products to such a limit. The staff's recommendation of a public hearing is based on the belief that a public hearing will provide the Commission with additional information it can consider in determining the commercial availability to children's product manufacturers of the materials and products needed to comply with the reduced lead content limit.

Discussion

A. Summary of Comments

Tab A is a staff memo summarizing the comments received in response to the FR notice. The actual comments received can be viewed at www.regulations.gov/search/Regs/home.html#docketDetail?R=CPSC-2010-0080. A number of commenters stated that some classes of materials will have difficulty meeting the 100 ppm lead content limit, including metal components, and some glass and ceramic components. According to the commenters, source materials, including recycled materials for metal alloys, cannot comply consistently due to the variability of the materials. A few commenters contend that other materials, such as plastics, could comply, provided that only virgin plastics are used. However, for all materials, commenters stated that there is significant variability among test results, even for identical products, due to variations in testing methodology and procedures, and that inter- and intra- laboratory variability must be addressed. Several commenters also stated that there are no demonstrable health benefits of reducing lead limits from 300 ppm to 100 ppm in light of the relative inaccessibility of lead that is bound in plastic or metal. Other commenters stated that there are children's products currently on the market that meet the 100 ppm lead content limits, and that it is not only possible, but also essential for the public health, to reduce lead in consumer products to the lowest levels that are technologically feasible, particularly in children's products. A detailed description of the comments can be found in Tab A.

B. Additional Information Needed

CPSC staff believes that additional information is needed in the areas of: (1) commercial availability of raw materials and components for use by children's manufacturers in the production of components and/or finished children's products; (2) data related to the public health effects associated with a reduction of lead content limit from 300 ppm to 100 ppm; and (3) specific data on inter- and intra- laboratory variability and inter- and intra- lot variability. Given that a large number of commenters suggested that metal products, or products containing metal components, are not able to comply consistently with a 100 ppm lead content limit, CPSC staff

would request specific data related to metal products or metal-containing products. One-third of the commenters stated that their suppliers do not exclusively supply children's product manufacturers, and therefore, are unable to consistently obtain compliant materials. At this time, CPSC staff does not have information on the current supply chain and material specifications for the children's products industry. In addition, one-third of the commenters also expressed concern over testing variability. It is unclear to CPSC staff whether the variability described by commenters is related to inter- or intra-laboratory variability, or whether it is related to inter- or intra-lot variability. Currently, CPSC staff does not have public health-effects data related to small shifts at the lower levels of lead content. In an effort to continue assessing the health protectiveness of lowering the lead content limit from 300 ppm to 100 ppm, specific data on incremental changes in total lead content and the health effects associated with these changes are needed.

C. Public Hearing

CPSC staff believes that the most effective and efficient way to obtain information and address the public comments is through a public hearing on the abovementioned topics. Commission staff will continue to review the comments received in response to the July 27, 2010 FR notice and will consider them along with other information presented at the hearing.

Options

CPSC staff provides three options to the Commission: (1) hold a public hearing on the above topics; (2) do not hold a public hearing; or (3) other action.

Conclusions and Recommendations

CPSC staff believes that additional information is needed in the areas of: (1) commercial availability of raw materials and components for use by children's manufacturers in the production of components and/or finished children's products; (2) data related to the public health effects associated with a reduction of lead content limit from 300 ppm to 100 ppm; and (3) specific data on inter- and intra- laboratory variability and inter- and intra- lot variability. The most effective and efficient way to obtain information and address public comments is through a public hearing on the topics mentioned above. Therefore, CPSC staff recommends a public hearing on the specified topics noted above.

TAB A: Public Comments Summary

TAB A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: 1/12/2011

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for Health Sciences

FROM : Dominique J. Williams, Toxicologist, Directorate for Health Sciences

SUBJECT : Summary of Public Comments: Technological Feasibility of 100 ppm Total Lead Content in Children's Products

Introduction

Section 101(a) of the Consumer Product Safety Improvement Act ("CPSIA") provides that, as of August 11, 2011, children's products may not contain more than 100 parts per million ("ppm") of lead, unless the Consumer Product Safety Commission ("CPSC" or "Commission") determines that it is not technologically feasible, after notice and a hearing, and after analyzing the public health protections associated with substantially reducing lead in children's products. Section 101(d) of the CPSIA (15 U.S.C 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

> (1) a product that complies with the limit is commercially available in the product category;
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> (2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;
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> (3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
>
> (4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

On July 27, 2010, a notice was published in the *Federal Register* requesting comments and information regarding the technological feasibility of manufacturers meeting the 100 ppm lead content limits. A total of 24 comments were received from consumer groups, manufacturers, retailers, associations, and laboratories regarding the technological feasibility of meeting the 100 ppm lead content limit. The main categories of discussion were: test result variability due to

material composition; variability in test results between different laboratories; public health protectiveness of 100 ppm; economic burden; available of compliant materials in the manufacturing supply chain; and 100 ppm lead is technologically feasible. The following are summaries of the comments submitted.

Discussion

Variability

Material Composition

Comments

Commenters expressed concern that due to inherent background levels of lead in some materials, especially metallic materials, 100 percent compliance with a 100 ppm lead limit would be difficult if not impossible to achieve. Although some metallic materials will comply, not all metallic materials will comply. In addition, those metallic materials that might comply, may not comply all the time.

Commenters believe that the mixing of metals to make alloys, and the use of recycled materials to make common alloys, such as brass, also make it difficult to fully comply with the reduced lead substrate limit due to the nature of metals. One commenter in particular mentioned that the inability for some metal components to comply appears to reflect the requirement for high concentrations of lead in materials intended to be cast, machined, and formed.

Another reason commenters said it would be difficult to comply with a 100 ppm lead content is the multistage process of finishing a product, which includes layering other metals or finishes that have trace amounts of lead. In addition, two commenters stated that there is a limit to which an element can be removed from an alloy; thus, they argued, even lead free metals can be contaminated.

Laboratory Testing

Comments

Some commenters claim that the degree of variability in the results from lead testing within labs and between labs qualifies the limit of 100 ppm as technologically infeasible. Many commented on the data published by YKK, a zipper manufacturer, which suggests a high degree of testing variability that could cause inconsistent compliance for some products. In an article published in the *Product Safety Letter* of July 19, 2010, YKK discussed that of 20 known test laboratories receiving samples, half returned results that were within 10 percent of the approximate 71 ppm known target. Some commenters reported their own test data also showed some variability, with one commenter saying that the failures are found in many different materials they use, and no pattern has been found.

One commenter stated that "it is vitally important that third party test results be both accurate and consistent," so that inaccurate tests will not create an economic burden on businesses. One commenter stated that a failed result under these conditions would drive the company to solve a "high lead" problem that may not exist and result in an increase in costs and a reduction in trust in the test results. Another commenter stated that lab testing variability could cause a component

with a true lead level of less than 100 ppm to fail and that a difference in 30 percent has been seen in intra-laboratory testing.

Two commenters indicated that when mixed metals, such as steel, are tested, there could be difficulties extracting the suspect metal, such as lead, as well as errors in measuring it. These commenters report that metallurgists and chemists indicate that this is due to the readings from the primary metal interfering with the results of the other metals present.

One commenter suggested that the "... averaging of results of a sample or application of a statistical measure like Z-score to the results" could address issues with laboratory variability.

One commenter confirmed that the limit of detection for a handheld x-ray fluorescence (XRF) analyzer is below the 100 ppm for lead. The commenter believes XRF is cost-effective, easy to operate, non-destructive, and provides reliable and quick extensive analyses of a significant number of products and component parts. The commenter provided data to counter concerns that XRF cannot detect 100 ppm lead consistently.

Public Health Protectiveness

Comments

As noted by commenters, section 101 of the CPSIA requires the CPSC to assess the pubic health protectiveness of dramatically reducing lead levels in children's products. Some commenters urged the CPSC to consider exposure from background levels and the lack of exposure due to lead being trapped in the matrix of the product. Taking these points into consideration, commenters contend that the CPSC should determine that a reduction of lead limit from 300 ppm to 100 ppm, or any level in between, does not substantially increase the level of protectiveness and that there is no basis to further reduce the lead limit. One commenter noted that the two main sources of lead are in the home from old lead-containing paint, and from soil contaminated by the use of lead-containing gasoline. One commenter stated that the real question should be: "[What is] the potential amount of lead that can be released from a children's product?"

In addition, another commenter claimed that a total lead standard is not a reasonable way to evaluate risk of poisoning and that there were no scientific studies directly correlating total lead content to the risk of lead poisoning. The commenter argued that a total lead standard is not a scientific assessment and asserted that reducing the limit to 100 ppm would "merely be compounding and increasing the side effects of an unscientific principle."

Citing their in-house testing results, commenters stated that there is an extremely low risk of exposure to lead in their products, with two reporting that wipe sampling and saline extraction test data show that there are no health risks for representative components containing lead concentrations higher than 100 ppm after XRF and ICP-MS analysis. According to one commenter, there is no evidence of injury due to lead levels between 100 ppm and 300 ppm in the substrate. The same commenter reviewed the CPSC recall data from 1999 to 2010 and found one death and three unverified lead injuries; making the injuries "the statistical equivalent of no injuries. Thus, ... impossible to prove statistically that any reduction in injuries flows from the change in standard."

Additionally, one commenter said that the current limit of 300 ppm total lead in children's components represents a high margin of safety; and that the exposure scenarios now have been radically reduced compared to those when total lead content was unregulated.

However, other commenters stated that there is no safe level of lead and expressed that any reduction in allowable lead levels in children's product increases health protectiveness. One commenter reminded the CPSC that significant health problems in children have been associated with blood lead concentrations in the 5–10 microgram per deciliter range and possibly less; and that lead exposure has been shown to have neurocognitive effects even at low levels.

Extension of Current Stay of Enforcement

Comments

Two commenters expressed a desire for the requests for extension (due by 12/2/2010) of the existing stay of enforcement, covering the 300 ppm requirement on youth recreational vehicles, also cover requirements to comply with the 100 ppm limit.

Global Harmonization

Comments

Two commenters expressed a desire to have section 101 of the CPSIA harmonized to the European solubility standard for lead, which evaluates the risk of lead exposure through measuring the bioavailability of soluble lead in substrate. They contended that because supplier factories are already producing products to the European Union's standard, a move toward a global standard would reduce testing costs and the time needed to do multiple tests under different standards.

One commenter recommended that the CPSC retain the 300 ppm lead in the substrate standard and establish a voluntary leachable lead standard.

CPSC Enforcement Discretion

Comments

Some commenters discussed the CPSC using enforcement discretion if it is determined that 100 ppm lead in the substrate is technologically feasible. It was stated that due to variability in testing products and the potential for environmental contamination of the tested product, a margin of error should be recognized through enforcement discretion.

100 ppm Lead in Substrate Is Technologically Feasible

Comments

Most products already comply

Several commenters mentioned that most products on the market already have levels at or below 100 ppm. One commenter referenced a 2009 study presented on HealthyStuff.org where, out of 669 children's toys and products, lead was detected in 18 percent; and seven percent of the products were over the American Academy of Pediatrics (AAP) recommended lead level of 40 ppm. Some of the commenters also provided data of their own to support the contradiction that the 100 ppm total lead content limit is feasible and that technology already exists for manufacturers to reformulate non-compliant products to comply.

However, for manufacturers, the concern is meeting a 100 ppm total lead content level consistently. One commenter said that in general, "products produced to this stricter standard are compliant." However, there is still a small, "but statistically relevant percentage," failure rate of 0.46 percent. Another commenter reported that less than two percent of their testing line falls between 100 ppm and 300 ppm.

Non-metal Materials Can Comply

Comments

Some commenters contended that nonmetal materials – specifically glass, paper, stone, ink, and plastics – could comply consistently with the 100 ppm total lead limit. However, there were some commenters who showed concern that enamel-glazed ceramics and glass that are either colored, require machining, polishing, or specific optical characteristics, would not be able to comply.

It was noted by two commenters that most plastic components can be made to comply with the 100 ppm total lead content limit consistently, but to do so would require the use of virgin materials. One commenter stated that certain materials used in children's jewelry, such as plastic beads, currently meet a 200 ppm lead limit under laws enacted in California and Minnesota. In addition, it was noted that there is now a CPSIA-compliant crystal, with properties similar to leaded crystal, that meets the 100 ppm limit.

Economic Burden

Comments

Several commenters stated that a further reduction in the total lead limit to 100 ppm would increase the cost of production, increase cost to consumers, and impose economic hardship on businesses. A commenter contended that small businesses lack the business resources to repeatedly test to make sure their results are actually within the 100 ppm limit.

One commenter concerned about the impact of the change in lead limits on the costs of promotional products reported that the incremental cost of compliance with the lower lead substrate limit could, in some cases, result in an increase in promotional product costs from about $1 to $13, and that this could result in some companies closing. In some instances, according to another commenter, compliance can be achieved through the use of virgin raw material, but the cost would increase by as much as 28 percent and lead to a substantial increase in the price of the finished product, which will continue to increase over time due to the limited supply of the raw materials. Additionally, one commenter projected a 10–20 percent increase in cost for finished goods subject to the new standard, and commented that "purer" materials can be used, but they are not practical or economic.

Some commenters questioned whether the economic impact of a 100 ppm limit is justified by the benefits associated with it. While there may be some additives, such as bismuth, which can be used instead of lead for its machining properties, the process for this is proprietary, making it more costly.

Current Product Supply Chain

Comments

Many commenters claimed that reducing the lead content limit from 300 ppm to 100 ppm is not technologically feasible due to suppliers not manufacturing specifically for children's products and not providing a consistent supply of compliant products. One commenter stated that in order to achieve lead limits below 200 ppm, stricter controls need to be implemented in the supply chain; but this would likely reduce the number of suppliers and increase the cost of production.

Some commenters claimed that it is difficult to demand consistent compliance to such a low standard, and asserted that suppliers may reject their small requests to avoid the risk of not complying with the standard.

Two commenters stated that test failures occur "because certain metal components comprised of general use fasteners and other metal parts, which may be used in toys, cannot practically be produced in a controlled fashion without a globally sanitized supply chain."

Other

Comments

There were two commenters who referred to regulations for a 40 ppm lead limit, one referring to the State of Illinois lead labeling law, and the other referring to the consent judgment for Dollar Tree on their children's ponchos.

Comment

One commenter specifically was concerned that the decals they manufacture for use on glass and ceramic substrates would not be able to comply with the 100 ppm total lead limit. The commenter further explained the process by which the decals are attached to the substrate through vitrification.

Comment

There was one commenter who requested that the August 14, 2011 date for 100 ppm total lead limit compliance be a manufactured by date and not apply to products currently on shelves.

*Actual comments can be found at:
www.regulations.gov/search/Regs/home.html#docketDetail?R=CPSC-2010-0080.