



Department of Health and Human Services

Maine People Living Safe, Healthy and Productive Lives

John E. Baldacci, Governor

Brenda M. Harvey, Commissioner

## **Report Pursuant to:**

## Public Law 2007, Chapter 604

- Developments on the federal level and in other states with regard to protecting children from lead poisoning from children's toys and products;
- Thresholds for lead in children's toys and products; and
- A summary of literature on lead poisoning from children's toys and products.

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**Prepared by:** 

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### Introduction

Public Law 2007, Chapter 604 of the 123<sup>rd</sup> Maine Legislature, amended Maine's Lead Poisoning Control Act (22 MRSA Chapter 252) to establish restrictions on lead-containing children's products. Section 2 of this public law directed the Department of Health and Human Services (DHHS) to report by January 15, 2010, to the Joint Standing Committee of the Legislature having jurisdiction over health and human services regarding lead in children's toys and products. The report must include developments on the federal level and in other states with regard to protecting children from lead poisoning from children's toys and products, thresholds for lead in children's toys and products. The joint standing committee may submit a bill to the Second Regular Session of the 124th Legislature based on the report.

This report is organized into four sections. The first section is a brief review of the requirements of Maine's new law establishing limits on lead in children's toys and products. The second section is a review of developments on the federal level with regard to protecting children from lead poisoning from children's toys and products. This section focuses on the Consumer Product Safety Commission Improvement Act of 2008 (CPSIA). The CPSIA establishes new federal thresholds for lead in children's toys and products. The third section discusses the issue of federal pre-emption of Maine law that was anticipated as a possibility in crafting the Maine act. The final section will provide a brief summary of the literature on lead poisoning from children's products and toys.

This report was prepared with assistance from the Attorney General's Office.<sup>1</sup> An updated legal analysis of the federal preemption of Maine's Act is pending. Because of the way Maine's act was crafted, combined with what appears to be a more deferential approach to state consumer product safety standards by the Consumer Product Safety Improvement Act, federal preemption is not viewed by the Department as having any significant adverse impact on Maine Law.

### A. Maine's Law Establishing Limits on Lead in Children's Toys and Products

Maine Law. Public Law 2007, c. 604 amended Maine's Lead Poisoning Control Act (22 MRSA c. 252) to prohibit the manufacture, sale or distribution of a "lead-containing children's product" in Maine after July 1, 2009.<sup>2</sup> The term lead containing children's product was defined to include products marketed for children 12 years of age or under, including toys, child care articles, children's lunch boxes and children's jewelry, which:

(1) contained lead in the aggregate, excluding lead in a paint or surface coating, at more than .009 percent of the total product weight, except that if the product lead level is preempted by federal law then the federal standard for lead level governs;<sup>3</sup> or

<sup>&</sup>lt;sup>1</sup> State of Maine Office of Attorney General Memorandum to Andrew Smith, State Toxicologist, from N. Paul Gauvreau, AAG. October 20, 2008. Potential Federal Preemption of Maine Lead Content Prohibitions in Children's Products.

<sup>&</sup>lt;sup>2</sup> <u>http://www.mainelegislature.org/ros/LOM/LOM123rd/123S1/PUBLIC604.asp</u>

<sup>&</sup>lt;sup>3</sup> Note that Maine laws expresses lead limits as a percent by mass (e.g., 0.009%), whereas federal law expresses lead limits in parts lead per million parts of some substance on a mass basis (e.g., 90 parts per million, abbreviated as ppm). On a mass basis, a ppm is equivalent to a milligram lead per kilogram of mass of the containing substance. These units can be converted from one to the other. For example, 90 ppm is equivalent to 0.009%, 300 ppm is equivalent to 0.03%.

(2) is coated with a paint or surface coating with a lead content which exceeded the Consumer Product Safety Commission (CPSC) standard as established in 16 C.F.R. Part 1303,<sup>4</sup> as amended.

The Maine statute specifically exempted certain consumer electronic products in which the leadcontaining component was inaccessible to children. The lead in aggregate limits for products was linked to any preempting federal limits in anticipation that pending federal legislation would establish national lead limits on product content. Federal limits on lead in paint and surface coatings were already in existence (0.06%) at the time the Maine act was crafted and were viewed as preempting. Consequently, Maine's lead limits on paint and surface coatings were linked to the existing federal limits, as amended.

The Maine statutory sales ban could be enforced by a civil action initiated by the Attorney General under the Maine Unfair Trade Practices Act. Initial violations by manufacturers with 25 or fewer employees were to result only in warnings. Other violations would result in graduated financial sanctions, ranging from not more than \$5,000 per violation for initial offenses to penalties not to exceed \$50,000 for third or subsequent violations, provided the Court could waive financial penalties if it determined the manufacturer or retailer had acted in good faith. Penalties collected under this section must be paid to the Lead Poisoning Prevention Fund established pursuant to section 1322-E. No resources were provided to support an inspection program to discover violations of the provisions of the Maine act.

# **B.** Developments on the federal level in regard to protecting children from lead poisoning from children's toys and products

<u>Federal Law.</u> On August 14, 2008, President Bush signed into law the Consumer Product Safety Improvement Act of 2008 (CPSIA). The wide ranging legislation significantly enhanced the Consumer Product Safety Commission (CPSC) regulation of lead content (as well as for phthalates<sup>5</sup>) in children's toys and products, restructured the CPSC regulatory approach to children's toy and product safety standards, augmented the CPSC staff to provide expanded regulatory oversight, and provided for greater federal and state coordination in regulating children's toys and products for excess lead (and phthalate) content. Among the major provisions of this new legislation are:

- (a) A provision which considered any children's product as defined in the CPSA (15 U.S.C. §2052(a) (16)) containing excess lead content to be treated as a banned hazardous substance under the Federal Hazardous Substances Act (15. U.S.C §§1261 et. seq.);
- (b) A provision establishing new limits on lead content for children's products, excluding paint and surface coatings. By February 10, 2009, products designed or

<sup>&</sup>lt;sup>4</sup> <u>http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title16/16cfr1303\_main\_02.tpl</u>

<sup>&</sup>lt;sup>5</sup> The term "Phthalates" refers to a group of chemical compounds which are heavily produced and widely used in plastics found in numerous consumer products. Often phthalates are used to increase the flexibility of polyvinyl chloride (PVC) and polyvinylidene chloride (PVDC) polymers. Phthalates are released over time, dispersed into the air, water, soil or living organisms. In general the potential adverse effects of phthalates are less understood than is exposure to lead in children's products. *See Phthalates in Plastics and Possible Human Health Effects*, CRS RL34572, 7/29/08, p. 1.The CPSIA banned three phthalates (DEHP, DBP and BBP) in toys or child care articles which contain in excess of .01 percent, and would prohibit on an interim basis the sale of children's toys or child care articles containing concentrations in excess of 0.1 percent of the phthalates DINP, DIDP or DnOP until a scientific review is conducted.

intended primarily for children 12 and younger may not contain lead in aggregate of more than 0.06 percent by weight; within 1 year of the enactment date (August 14, 2009), the lead content threshold is to be reduced to 0.03 percent; and within 3 years of enactment (August 14, 2011), the maximum content is to be reduced to 0.01 percent unless the Commission determines, after public hearings, that such a standard is not technologically feasible for a child product or child product category;

- A provision establishing lower limits on lead in paint and surface coatings. By August 14, 2009, the Act provides that paint and similar surface-coating materials for consumer products must be reduced from 0.06 percent to 0.009 percent by weight;
- (d) A provision requiring manufacturers, prior to importing any children's toy or product, to have the product tested by an accredited third party certified by the CPSC for compliance with child safety standards;
- (e) A provision requiring the manufacturer of a children's product to label the product and its packaging to identify the product's location and date of manufacture;
- (f) A provision requiring the CPSC, when notified of any voluntary corrective action by a manufacturer or retailer, or when it issued any order relating to substantial product hazards, to notify state health departments;
- (g) A provision requiring the CPSC, subject to appropriations, to establish and maintain a consumer product safety database available through its website;
- (h) A provision expanding the authority of the CPSC to prohibit the stockpiling of any product for the purpose of circumventing a consumer product safety rule;
- A provision authorizing the CPSC, upon the determination that a substantial product hazard exists, to order the manufacturer, distributor or retailer to cease product distribution; notify state and local health officials, post a notice of the hazard on its website and publicize the substantial product hazard to interested parties;
- (j) A provision increasing the maximum civil and criminal penalties regarding violations of the CPSA and the Federal Hazardous Substance Act.
- (k) A waiver provision which allows the CPSC, upon application by a State or other political subdivision, to consider a rulemaking to exempt provisions of section 26(a) of the CPSA (15 U.S.C. §2075) relating to children's toy and product lead content safety standards if the Commission finds (1) the State or political subdivision standard provides a significantly higher degree of protection from a risk of injury than does the CPSC consumer product safety standard; and (2) the State or political subdivision safety standard does not unduly burden interstate commerce.<sup>6</sup>
- (1) A provision to allow states to avoid preemption of existing state laws by federal law, by allowing a State or other political subdivision to continue in effect a safety requirement applicable to a toy or children's product that is designed to deal with the

<sup>&</sup>lt;sup>6</sup> In making its determinations regarding undue burden on interstate commerce, the Commission is to determine the technological and economic feasibility of compliance, the geographic distribution of the product in question, and the probability other states would apply for a similar safety standard exemption.

same risk of injury as the [CPSC] standards... and that is in effect on the day before the enactment [of the CPSIA], if such State or political subdivision has filed such requirement with the CPSC within 90 days after the enactment of the CPSIA in such form and manner as the Commission shall require.

(m) A provision amending the CPSA to accord State Attorneys General the right to seek injunctive relief for violations of the CPSIA, provided the State notify the CPSC at least 30 days in advance, or at such earlier time as the CPSC may approve, and allow the State Attorneys General to file for immediate injunctive relief if the State determined such action is required to protect its residents from a substantial product hazard.

<u>Comparison of new federal and state lead thresholds for children's products</u>: The provisions enumerated as items (b) and (c) above describe the new limits on lead in children's products established by the CPSIA. Assuming it is technologically feasible, the CPSC will adopt a limit of 0.01 percent lead content limit by August 14<sup>th</sup> 2011. This limit is nearly the same as Maine's limit of 0.009 percent, which became effective July 1, 2009. The current federal limit on lead on content in products is 0.03 percent.

The new federal limit on lead in paint or surface coatings of 0.009 percent represents a significant reduction over the prior federal limit of 0.06 percent. Maine law references the federal limit on lead in paint and surface coatings. The new federal limits are compared with Maine's new limits on children's toys and products in the table below.

| Thresholds for Lead in Children's Toys and Products                 |                         |                          |
|---|-------------------------|--------------------------|
| Lead Limit Category   | Federal Limits          | Maine Limits             |
| Lead Content in Products<br>excluding Paint and Surface<br>Coatings | 0.060 % as of 2/10/2009 | 0.000 % 6.7/1/2000       |
|   | 0.030 % as of 8/14/2009 | 0.009 % as of 7/1/2009   |
|   | 0.010 % as of 8/14/2011 |                          |
| Lead in Paint and Surface<br>Coatings                               | 0.009% as of 8/14/2009  | Linked to Federal Limits |

### C. Federal Preemption of Maine's Act

The Consumer Product Safety Act partially preempts contrary state law in the area of consumer product safety. The Maine Legislature crafted its legislation with a view towards averting federal preemption by incorporating existing and potential future federal limits on lead in children's toys and products. The CPSC had previously adopted safety standards regarding a limit on lead content in paint and surface coatings of children's toys and products. As these federal limits were viewed as preempting, the Maine act expressly references this federal limit, as amended.<sup>7</sup> Federal limits on lead in product content were under consideration by the U.S. Congress at the time the Maine act was under consideration. The Maine Legislature defined lead content limits for children's product as defaulting to any federal limits that would preempt the new state limit of 0.009%.

<sup>&</sup>lt;sup>7</sup> 22 MRSA §1316-A.1.F.(2)

The CPSIA of 2008 newly enacted Section 106(h)(2) provides that the Consumer Product Safety Act will not preempt a State safety standard applicable to toys or other children's products designed to address the same risk of injury as the corollary CPSC safety standard, provided the State safety standard were in effect at the time of the adoption of the CPSIA and the State duly notified the Consumer Product Safety Commission within 90 days of the enactment of the CPSIA. In this regard, the CPSIA provision allows a State to continue to enforce a children's toy or product safety standard designed to deal with the same risk of injury as the CPSC safety standards even if the State standards are more restrictive, provided that the State has filed its safety standard with the CPSC within 90 days of the enactment of the CPSIA. Since the Maine statute went into effect on April 14, 2008, four months before President Bush signed the CPSIA into law, it appears the Maine safety standard would not be subject to CPSA preemption if the Department properly notified the CPSA of its new child product lead content safety standard.

The Department did not act to register Maine's Act with the CPSC for the following reasons:

- Maine law already references federal limits for lead in paint and surface coatings applied to children's toys and products. Thus these limits remain unchanged regardless of whether the Maine act is registered.
- The new federal limits for permissible lead content of children's toys and products in aggregate likely to go into effect in August 2011 will be very close to those established in Maine Law (i.e., 0.01 % versus 0.009 %). Should these lower federal limits not go into effect, the CPSIA includes a provision under which Maine may seek a waiver to enforce its lower limits.<sup>8</sup>
- The resources of the federal government to conduct product testing at the national level prior to a product entering the market are clearly superior to Maine's capacity to accomplish the same. In fact, Maine's enforcement would be largely limited to discovery of lead containing children's products after the product has entered the market. Since resources to support an inspection program were not provided, Maine would largely be in a reactive posture, contemplating enforcement action only when lead containing products were identified by CPSC recalls.
- The CPSIA of 2008 includes a provision to accord State Attorneys General the right to seek injunctive relief for violations of the CPSIA, provided the State notify the CPSC at least 30 days in advance, or at such earlier time as the CPSC may approve, and allow the State Attorneys-General to file for immediate injunctive relief if the State determined such action is required to protect its residents from a substantial product hazard. Previously State Attorneys-General had a similar right to file for injunctive relief to enforce Federal Hazardous Substance Act violations, but did not enjoy the right to seek injunctive relief to enforce CPSA violations. Thus, even without registering Maine's act, it appears Maine still has the ability to take enforcement action on any lead containing children's toys and products determined to be sold in Maine.
- It was the Department's understanding (through participating in the legislative deliberations) that one of the primary objectives of the Maine Act was to promote the

<sup>&</sup>lt;sup>8</sup> Section 106(h)(1) of the CPSIA amended 15 U.S.C. §2075(a) of the Consumer Product Safety Act to allow States to apply for CPSA waivers in the event of more restrictive state consumer product safety standards, provided the state regulations do not impose an undue restraint upon interstate commerce.

passage of new federal limits on lead in children's products that could be more successfully applied nationally and prior to products entering the market.

By not seeking registration of Maine's act with the CPSC, the provisions of the definition of a lead containing children's toy or product referencing federal limits are now in effect. That is, the current limit on lead content excluding paint and surface coatings is the new federal limit of 0.03 percent (due to be lowered in 2011 to 0.01 % assuming technologically feasible) and the limit on lead in paint and surface coatings is the new federal limit of 0.009 %.

### D. Summary of Literature on Lead Poisoning from Children's Products and Toys

Two severe cases of lead poisoning of children from lead containing products were known at the time the Maine act was under consideration. One case was the severe lead poisoning of a 4-year old child in Oregon resulting from ingestion of a toy necklace. This case ultimately resulted in a nationwide recall of 150 million pieces of imported metallic toy jewelry sold in vending machines.<sup>9</sup> The second case was the death of a child in Minnesota after ingestion of a heart-shaped metallic charm that had been attached to a metal bracelet as a free gift with the purchase of shoes. This incident resulted in the voluntary recall of 300,000 of these items by the CPSC and Reebok.

A systematic review of atypical sources of childhood lead poisoning in the United States between 1966 and 2006 has been recently published.<sup>10</sup> Atypical sources refers to causes of lead poisoning excluding the well-established lead paint ingestions and exposure in occupational settings. The authors of this report systematically retrieved and reviewed reports of childhood lead poisoning in the U.S. from atypical sources by searching various web-based databases with titles and abstracts of scientific journals (e.g., Medline), websites of state lead poisoning prevention programs, and the CPSC database for poisoning reports from January 1966 to December 2006.

The authors were able to retrieve 28 reports, documenting a total of 82 incidents nationwide of childhood lead poisoning from atypical sources. These 82 incidents were grouped by the authors into the following categories.

| Atypical Source Category  | Number of incidents |
|---|---------------------|
| Folk remedies   | 47                  |
| Leaded fashion accessories, recreational items, pellets and bullets | 13                  |
| Imported condiments and candies                                     | 9                   |
| Lead-tainted ethnic cosmetics                                       | 8                   |
| Dinnerware and ceramics   | 4                   |
| Bullet fragments  | 1                   |

By far the most number of reported cases was from folk remedies. Most of these were attributable to use of two remedies used for treatment of abdominal symptoms, *azarcon* and *greta*. *Azarcon* consists of lead tetraoxide, and is mixed with oil, milk or sugar and incorporated

<sup>&</sup>lt;sup>9</sup> MMWR. 2004. Brief Report: Lead poisoning from ingestion of a toy necklace – Oregon, 2003. Morbidity and Mortality Week Report, U.S. Centers for Disease Control and Prevention. 53(23):509-511.

<sup>&</sup>lt;sup>10</sup> Gorospe, EC and Gersterberger, SL. 2008. Atypical sources of childhood lead poisoning in the United Sates: A systematic review from 1966 to 2006. Clinical Toxicology 46:728-737.

in the child's milk or tortilla meal. *Greta* consists of lead monoxide administered in the same manner as *azarcon*. Both are most commonly used within the Hispanic community.

A review of the Maine Center for Disease Control's Maine Childhood Lead Poisoning and Prevention database for case reports of children with elevated blood lead levels covering the years 2000 through 2007 did not identify a single case where a toy or children's product was identified as the primary or contributing factor for having an elevated blood lead level.

#### SUMMARY

Public Law 2007, c. 604 amended Maine's Lead Poisoning Control Act (22 MRSA c. 252) to prohibit the manufacture, sale or distribution of a "lead-containing children's product" in Maine after July 1, 2009. The Maine Legislature crafted its legislation with a view towards averting federal preemption of thresholds for lead in children's products by referencing existing and potential future federal limits on lead in children's toys and products. On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was signed into law. This wide ranging federal legislation significantly enhanced the Consumer Product Safety Commission (CPSC) regulation of lead content in children's toys and products, restructured the CPSC regulatory approach to children's toy and product safety standards, augmented the CPSC staff to provide expanded regulatory oversight, and provided for greater federal and state coordination in regulatory children's toys and products for excess lead content. The CPSIA included a provision to allow states to avoid preemption of existing state laws by federal law, provided states properly register their laws within 90-days of the enactment of the CPSIA. The Department chose not to register Maine's act because: 1) Maine's threshold limit for lead in paint and surfaces coatings is already tied to the federal limit; 2) new federal limits for lead in product aggregate will by 2011 likely be essentially the same as Maine's; and 3) a new provision in the CPSIA provides State Attorneys General the right to seek injunctive relief for violations of the CPSIA. Current threshold limits for lead in children's toys and products are 0.009 percent by weight for paint and surface coatings, and 0.03 percent by weight (to be lowered to 0.01% by 2011 if technological feasible) for content excluding paint and surface coatings.

A systematic review of atypical sources of childhood lead poisoning in the United States between 1966 and 2006 has been recently published. Atypical source refers to causes of lead poisoning excluding the well-established lead paint ingestions and exposure in occupational settings. The authors were able to document a total of 82 incidents nationwide of childhood lead poisoning from atypical sources. By far the most number of reported cases was from folk remedies containing lead. The second most common category of atypical sources was a grouping included fashion accessories, recreational items, and various leaded pellets and bullets. A review of the Maine Center for Disease Control's Maine Childhood Lead Poisoning and Prevention database for case reports of children with elevated blood lead levels covering the years 2000 through 2007 did not identify a single case where a toy or children's product was identified as the primary or contributing factor for having an elevated blood lead level.