The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Environmental Health
250 Washington St., 7th Floor, Boston, MA 02108-4619
Phone: 617-624-5757 Fax: 617-624-5777
TTY: 617-624-5286

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, M.D.
SECRETARY

JOHN AUERBACH
COMMISSIONER

# DETAILED RESPONSE TO COMMENTS RECEIVED DURING PUBLIC COMMENT PERIOD ON PROPOSED AMENDMENTS TO BAN LEADED CHILDREN'S JEWELRY UNDER 105 CMR 650.000: HAZARDOUS SUBSTANCE REGULATIONS

March 12, 2008

COMMENT: Many spoke to the scientific literature on the health effects associated with blood lead levels less than 10 µg/dL; that children are particularly vulnerable to health effects from lead exposure; that many factors contribute to a child's development but lead exposure is completely preventable; that lead is a cumulative toxin and hence exposures to multiple sources of lead (e.g., in consumer products intended for children) should be reduced or eliminated; lead is not completely eliminated from the body once absorbed; and that there is no safe threshold for exposure to lead. (Shannon, Palfrey, Weltman, Graef, Ketelson, Woolf, Link, Rabin, Saunders, Wolbarst, Rosenberg, Lawrence, Lauenstein, Katz, Rainer, Rowland)

RESPONSE: MDPH agrees that a threshold below which no adverse effects are observed has not been demonstrated; that health effects of lead are due in part to the persistent nature of lead in the body; and that children are particularly vulnerable to the toxic effects of lead.

Recently, the U.S. Centers for Disease Control and Prevention reported (CDC 2007) on the growing literature demonstrating an inverse relationship between blood lead levels less than 10 µg/dL and developmental outcomes. For example, one study in Rochester, NY, observed a decrease in IQ of more than 7 points over the first 10 µg/dL increase in lifetime average blood lead concentrations (Canfield et al. 2003). A more recent study reaffirmed an inverse association between lead at low levels and IQ (Lanphear et al. 2005). In this study, the authors reported a decrease in IQ of 3.9 points from an increase in blood lead levels from 2.4 to 10 µg/dL, and concluded that children with maximal blood lead levels less than 7.5 µg/dL are associated with intellectual deficits (Lanphear et al. 2005).

COMMENT: MDPH should expand the proposed regulation to ban the sale of all products intended for use by or in connection with children; data of testing with XRF of other children's products were submitted in support of a broader ban; some specified that limits should be applied to all components of a product, as well as the total product; others pointed to certain products in

particular, such as lunch boxes, bibs, backpacks, and car seats; one commenter wanted lead banned from all products (Weltman, Graef, Ketelson, Palfrey, Shannon, Link, Montana, Rabin, Saunders, Wolbarst, Katz, Steinberg, Chan, Rainer, Rosenberg, Lawrence, Brindisi, Spark, Lauenstein, Rowland, Jones, Wheeler).

RESPONSE: MDPH will further evaluate lead in other children's products and consider additional regulatory action. We are in the process of gathering available information, including any testing data, on other children's products, and have submitted Freedom of Information Act requests to the U.S. Consumer Product Safety Commission (CPSC) to help gather data for this effort (e.g., for CPSC testing data on bibs, lunch boxes, plastic toys). We are also aware of a recent final rule promulgated by the U.S. Environmental Protection Agency requiring certain manufacturers, including importers, of consumer products intended for use by children to submit unpublished health and safety information on the lead content of children's products (Federal Register 2008). [EPA has reported that the deadline for these submissions is April 28, 2008, and that the information submitted should be available several months later.] Under the Hazardous Substances regulation, we must demonstrate that reasonably foreseeable uses of the product could result in an exposure risk to lead on or in the product.

To aid in this effort, MDPH will conduct testing of various children's products for both total lead content and accessible lead. The results of this testing will provide additional supporting data to broaden the scope of the proposed ban on lead in children's jewelry.

The MDPH proposed regulations reference CPSC analytical methods for analysis of children's jewelry for total lead content and accessible lead using an acid extraction method. The CPSC methods, described in CPSC's Standard Operating Procedure for Determining Lead and Its Availability in Children's Metal Jewelry (February 3, 2005) define "item" as follows: "Individual sub-sample within the total sample, such as a necklace, a ring or a bracelet, that can be subjected to lead testing. Ideally, the sample should contain only identical items, not a mix of several different items. An item, such as a bracelet, may be broken into its component parts. such as bead, hook pendant, with those components parts individually analyzed." This is further clarified by CPSC analytic chemists (CPSC 2006) who note that "Distinct metal component items within a jewelry sample, such as pendant, hooks, or beads, are tested separately for total and accessible lead. " Thus, the referenced method in MDPH's proposed regulations allow for component testing to determine compliance. MDPH will provide further details on testing requirements in its guidance document.

COMMENT: Several comments urged that the total lead content standard of children's products, including jewelry, be limited to 40 ppm or trace amounts (Shannon, Woolf, Ketelson, Palfrey, Link, Montana, Rabin, Saunders, Wolbarst, Katz, Steinberg, Rainer, Spark, Laurenstein). Support for 40 ppm as trace definition included noting that 40 ppm is considered lead-contaminated soil (Ketelson, Shannon) or background levels of lead in soil (Rainer, Rowland). Supports Academy of Pediatrics efforts, which includes support of limit of lead in products intended for children to trace amounts, or 40 ppm (Graef, Woolf, Ketelson, Palfrey, Shannon).

RESPONSE: MDPH recognizes that there are published articles regarding background concentrations of lead in soil, including the one cited to support the 40 ppm value (Friedland and Johnson, 1985), showing soil lead concentrations in areas not affected by historical or current lead deposition (e.g., rural agricultural soils, more remote forest lands) in the range of 40 ppm.

Likewise, lead concentrations in soil in many urban areas, including in Massachusetts, are considerably higher due to historical (e.g., vehicle traffic) or current deposition of lead (e.g., from municipal waste incinerators). For example, the Massachusetts Department of Environmental Protection (MDEP) considers background representative of typical concentrations found in areas with fill materials (e.g., urban areas) in Massachusetts to be 600 ppm (MDEP 2002).

It is perhaps most important, however, to focus on the dual standard proposed by MDPH for lead in children's jewelry. We examined CPSC testing data for children's jewelry and found that approximately one-third of those items less than 40 ppm total lead would NOT have met our requirement of 15 µg/d accessible lead. Thus, we believe the dual standards are more protective than proposing a single requirement of 40 ppm total lead content.

We note that some comments suggested that 40 ppm is considered by EPA as "lead-contaminated soil." The 40 ppm value discussed above relates to comments on soil background levels of lead. We believe that the comments suggesting 40 ppm is considered by EPA to be "lead contaminated soil" referred to EPA's definition of lead contaminated dust, which is 40 µg/ft2; the units of µg/ft2 are not parts per million (ppm).

COMMENT: Legal interpretations were made related to the Department's authority, under Chapter 94B, to ban all children's products if they contain more than trace amounts of lead (defined as between 10-40 ppm). The specific regulatory language suggested was "Products marketed to or intended for use by children that contain more than trace amounts of lead, including the manufacture, shipping, or sale of such products, at retail or wholesale, indoors or outdoors, over the internet, or through catalogs." (Rainer). Other commenters suggested that MDPH should not have to demonstrate that any one particular item containing lead would cause health damage in order to ban it (Ketelson, Saunders).

RESPONSE: Under M.G.L. c. 94B, §2, a "banned hazardous substance" is defined as "any toy or article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance susceptible of access to a child…" A "hazardous substance" includes, among others, any substance which is "toxic" and may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonable foreseeable ingestion by children…" The definition for "toxic" is "any substance, other than a radioactive substance, which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface."

A substance is not toxic if reasonably foreseeable uses of the substance do not present an exposure risk that could result in harm (i.e., if the toxin is not "accessible," then no exposure/health risk exists). If a substance is not toxic, then it is not a hazardous substance subject to a ban under M.G.L. c. 94B, §2. To ban a product containing lead, MDPH, at a minimum, must show not only that lead is toxic but that reasonably foreseeable uses of the product could result in an exposure risk to lead on or in the product.

It should also be noted that under current state law, G.L.c.111, s.194, the application of lead-based paint, glaze or other substance to any toy, furniture, cooking, drinking, or eating utensil is prohibited. Lead-based paint, glaze, paint or other substance is defined by the statute as more than 600 ppm of lead by weight. Since this standard for lead-based paint/glaze or other applied

substance is defined by statute, the Department cannot alter this standard by regulation under 105 CMR 650.000.

COMMENT: "Children" should be defined. Some commenters suggested a definition of 12 years of age or younger (Shannon, Palfrey, Woolf, Ketelson, Link, Ketelson, Montana, Rabin, Saunders, Wolbarst, Spark, Steinberg, Brindisi, Larence, Lauenstein, Katz), while others suggested less than 7 years of age (Gale, Rennie, Barber). One commenter who suggested less than 7 years of age said that this definition would prevent major economic impact (Barber).

RESPONSE: Virtually all commenters asked that "children" be defined. It has been documented that young children can accidentally ingest jewelry meant for older children or adults (e.g., the 4-year old fatally poisoned Minnesota child ingested an item part of a shoe promotion aimed at children up to about 12 years of age). In addition, young children (e.g., less than 7 years of age) frequently emulate their older siblings and may find sibling jewelry attractive. MDPH is proposing that "children" be defined as less than 14 years of age.

COMMENT: Massachusetts needs to be proactive because the federal government is not doing enough (Montana, Rowland, Roper)

RESPONSE: MDPH is being proactive on lead in children's jewelry and we hope other states and the federal government will follow suit. As mentioned previously, we will be further evaluating the potential to ban other children's products.

COMMENT: The proposed standards of 600 ppm and 15 µg/day do not go far enough (Woolf, Lawrence, Steinberg).

RESPONSE: The proposed regulation requires that jewelry be less than 600 ppm *and* contain less than 15 µg/day of accessible lead as determined by an acid extraction test. As we explained earlier, the criterion of 15 µg/day is actually more protective than a limit of 40 ppm as a single criterion because jewelry containing 40 ppm or less total lead can still violate the 15 µg/day criterion. The quantity of lead that could become accessible in the acid environment of the stomach after accidental ingestion cannot always be predicted based on the total lead content of the item, which is why we proposed the dual criteria.

COMMENT: Comments were submitted about the nature of different types of jewelry and differences in accessibility of lead in some types:

- Toy jewelry is made for a child to dress a doll or something very small (Gale)
- The Fashion Jewelry Trade Association does not add lead to metal used to manufacture children's jewelry (Gale)
- "Fashion jewelry" is not a toy and is not vending machine jewelry (Gale)
- Metal used in fashion jewelry is plated (Gale). Another manufacturer spoke of jewelry that is plated with three different layers, which prevents leaching if ingested (Barber). One comment cited laboratory testing data that demonstrated that plated jewelry will not leach lead (Exponent).
- Lead in glass crystal is not accessible (Gale)

RESPONSE: MDPH agrees that "toy" jewelry is too restrictive and has revised the proposed regulations to a more simple "children's leaded jewelry." This is also consistent with CPSC, which includes toy jewelry in the broader category of children's jewelry.

It is MDPH's understanding from the industry comments that certain types of jewelry that may fall under "children's jewelry" do not leach lead, even if the lead content is above 600 ppm (and hence, would not meet our dual standards). In support of this, industry representatives submitted test results of plated jewelry. Acid extraction results of six plated jewelry items containing up to 60,000 ppm total lead resulted in accessible lead from <0.05 to 75.6 µg over 6hours. The latter item would not have met the MDPH 15 µg/d criterion, and indeed, this item could pose a serious exposure risk to children if ingested.

It should also be noted that CPSC reported on limited testing of eight metal jewelry items (not specified whether the items were plated). All items had total lead content greater than 45 percent (or 450,000 ppm). After the six-hour acid extraction test, none of the samples exceeded the then-CPSC criterion of 175 µg lead, but after 24-168 hours, all samples had exponential increases in the amount of lead extracted (up to 661,626 µg lead). For that reason, we believe that all children's jewelry must meet the 600 ppm limit to prevent these types of exposure risks.

COMMENT: Several comments spoke to the desire for a national standard (Gale, Rennie, Barber); these included comments that different standards (e.g., 15 µg/day versus 175 µg/6 hours) confuse small businesses (Green).

RESPONSE: MDPH proposes to adopt the 600 ppm standard for total lead content, which has been adopted by several states and CPSC. However, an additional standard for accessible lead is required under this proposed regulation. MDPH hopes other states and CPSC will consider adopting our accessibility standard. We are in the process of formulating a guidance document that will clearly state how to maintain compliance with the regulation.

COMMENT: Research shows that children over 4 years of age do not usually swallow things (Barber).

RESPONSE: Items clearly not intended for this age group are commonly ingested, such as coins, jewelry, and batteries. The case of the fatal ingestion of the Reebok charm illustrated the fact that lead content in jewelry that may not be intended for use by children under 6 year old must also be considered. Several parents testified at the public hearings about the difficulty in ensuring that younger children do not access the toys and belongings of older siblings.

In addition, the CPSC reported results of a review of the National Electronic Injury Surveillance System (NEISS) database on emergency room treated injuries associated with ingestion of consumer products by children. Their review revealed that during the period 2000-2005, an estimated 302,687 emergency room (ER) treated injuries occurred, nearly 80 percent of which were children under age seven years. The remaining 20 percent of the estimated injuries were reported in youths aged seven to 18 years. The objects most commonly swallowed were coins, accounting for nearly half of ingestions, followed by jewelry (about 6.6 percent of the total). These data indicate that swallowing items is NOT unusual, even in the 7-18 year age category.

COMMENT: Several comments spoke in support of California law, which was adopted by Minnesota and Illinois (Gale, Barber, Poirier), which includes the following stipulations:

- Defines "children" as ≤ 6 years of age
- Defines "classes" of items that can be sold in California after March 1, 2008: Class 1 items have no lead limit and include sterling silver, pearls, certain gemstones, stainless steel, and other items; Class 2 are items with lead limits, e.g., electroplated metal less than 60,000 ppm, unplated metal less than 15,000 ppm, plastics less than 200 ppm lead, and surface coatings less than 600 ppm; Class 3 are any items that are NOT Class 1 or 2 and have less than 600 ppm lead.

RESPONSE: For reasons that have already been described, we do not believe that setting one standard based on total lead content (e.g., 600 ppm) is sufficiently protective. In fact, CPSC data indicate that over 40 percent of jewelry samples with less than 600 ppm total lead content contained more than 15 µg/day of accessible lead. Thus, these items would present serious exposure risks to children who ingest them.

It is our understanding that the California law was enacted based on stipulations of the California Proposition 65, which only takes into account average exposures of toxins. Swallowing a piece of jewelry could not be considered when the California law for lead in jewelry was enacted, presumably because it was not considered an "average" exposure. The MDPH proposed regulations are purposefully designed to protect against the scenario of swallowing leaded jewelry.

COMMENT: We do not want Massachusetts to have a stricter standard than elsewhere that could be unattainable from a manufacturing perspective (Rennie).

RESPONSE: In reviewing CPSC sampling data of more than 400 jewelry items, one quarter of the tested items (nearly all of which were metal) would meet the dual standards proposed under MDPH regulations. Thus, in the absence of any data to the contrary, we believe these standards are achievable for children's jewelry.

COMMENT: CDC said that "in some areas of the U.S. as many as 35 percent of children with elevated BLL are reported to have been exposed to items decorated or made with lead. In most cases, the hazardous product is only identified after a child is lead poisoned." There is basis for strong regulations (Wolbarst).

RESPONSE: We have explained in response to earlier comments our plans to further evaluate other children's consumer products for exposure risks to lead. With respect to children's jewelry, we are moving forward with the most protective regulations in the country. In addition, Massachusetts is the only state to take this action through the regulatory process rather than through statute.

COMMENT: There is lead in coins and in playground soils (Gale).

RESPONSE: As noted previously, CPSC reported that after coins, jewelry was the next most common ingested item in children up to aged 18 years (CPSC 2006). Thus, the issue of

children's leaded jewelry is not trivial and cannot be ignored. Standards for lead in soil are under the regulatory jurisdiction of the U.S. Environmental Protection Agency or the Massachusetts Department of Environmental Protection, while regulatory jurisdiction for lead in consumer products, such as children's jewelry, is with MDPH. Thus, we have the authority and are moving forward with our proposed regulations.

COMMENT: Did DPH sample products of modern, lead-safe manufacturing or were they older, after sitting on the shelves? (Green)

RESPONSE: Previous MDPH sample collection efforts involved spot sample collection at retail stores throughout the state. MDPH staff took samples from vending machines, in toy stores, in displays designed to appeal to children, and other settings. The purpose of the collection was not to assess age of the product but simply to collect samples clearly targeted to children and then determine whether they contained lead. The important point here is that we found samples with high levels of accessible lead, and they were being sold in Massachusetts regardless of their age, origin, or any other characteristic of the item.

COMMENT: Retailers and small businesses would have to rely on the supply chain for authentic documentation. There is a need for provisions to protect those down the line from the testing procedures to protect against liability or class-action law suits (Rennie).

RESPONSE: MDPH will provide a guidance document that will assist all parts of the supply chain in maintaining compliance with the regulation. MDPH intends to provide this guidance document to the industry for review and comment.

COMMENT: We would like Massachusetts to adopt the California exemption for lead crystal in rhinestone since the lead is not accessible; if no exemption is granted, this would cause much financial damage to the industry by eliminating rhinestones (Green). The economic impacts may be much more than expected or severe (Barber), especially if there is no exemption related to rhinestones (Green).

RESPONSE: MDPH did not receive any data on the economic impact of the proposed regulations or about lead crystal in rhinestone. In the absence of these data and based on responses to many previous and related comments, MDPH is still proposing to require both a 600 ppm total lead content and 15 µg/d accessible lead criteria.

COMMENT: Because Massachusetts is proposing a different standard than in other states, it becomes impossible for an American manufacturer to do business in the state (Green).

RESPONSE: As noted earlier, CPSC data demonstrate that children's jewelry can meet the dual criteria being proposed by Massachusetts. We did not receive any data on economic impacts of the proposed legislation. In addition, it is possible that because of these regulations, consumers may be more apt to purchase children's jewelry in Massachusetts because they know the jewelry is required to meet the proposed criteria.

COMMENT: MDPH should set up a department to inspect products and send inspectors to the places that make these items; this could become an industry for the state (Roper); test each batch of imports for lead (XRF?) (Barber)

RESPONSE: MDPH plans to conduct routine and regular spot inspections across the state after the regulations go into effect. The inspections will include determining whether retail establishments selling children's jewelry have proper documentation demonstrating compliance and also will include periodic collection of samples for subsequent analysis for total lead and accessible lead.

COMMENT: Massachusetts should consider using XRF to test toys in Massachusetts (McIssac, Wolbarst)

RESPONSE: MDPH has not found that XRF analyzers are reliable in determining whether lead in a product poses an exposure risk to a child. The XRF results will detect the presence of lead in a product (most reliable for homogeneous items) but cannot determine if lead is accessible to a child. In addition, the accuracy of an XRF reading depends on a variety of factors (e.g., the time the instrument is on a product and whether the instrument is lying flat on a product) such that most government agencies (e.g., CPSC, National Center for Healthy Housing) or manufacturers (e.g., Niton) recommend that XRF measurements be taken only by professionals. Most importantly, however, we believe that the XRF is not necessarily predictive of what a child would actually be exposed to.

COMMENT: MDPH should lower the "lead action level" in accordance with current medical science. "Lead Poisoned" should be defined as greater than 10 µg/dL (Lawrence).

RESPONSE: MDPH is evaluating several actions associated with the lead regulations, including the re-establishment of the Governor's Advisory Council on lead poisoning prevention. The proposal to ban lead in jewelry intended for use by children is being promulgated using the Hazardous Substance regulation (105 CMR 650.000). This regulation is distinct from the Massachusetts Lead Law (MGL c.111, sections 189A-199B) and its applicable regulations (105 CMR 460.000), which defines the childhood lead poisoning threshold that triggers mandatory residential lead inspection and that the property be appropriately abated and brought into compliance.

COMMENT: Some comments were submitted relating to the technical analysis conducted by MDPH to derive the proposed standards, particularly the 15 µg/day accessibility standard. Specific technical comments included the following:

- While in extreme cases, jewelry could stay lodged in the stomach for a week or more, one has to be careful about statements that lead stays in the stomach for a long period of time. The residence half-life of ingested material within the stomach compartment is only about 1.2 hours during childhood. After that it passes from the stomach to the lower gastrointestinal tract, where it is mostly likely to be excreted from the body rather than absorbed.

- Even a 175 µg exposure (CPSC guidance) would not result in blood lead levels greater than 10 µg/dL.
- Conclusions above were based on using a different pharmacokinetic model called the Leggett model, than used by CPSC or MDPH. The Leggett model includes some key differences in assumptions (e.g., half-life of lead in blood (15-40 days by Leggette vs. 10 months by CPSC).

RESPONSE: The retention of foreign bodies in the stomach is not an uncommon event. There are multiple accounts in the scientific literature showing foreign body ingestion followed by retention in the stomach for longer than the time it takes for food to pass (Butterworth 2007, ASGE 2002, Mowad 1998, Paul 1993, Litovitz 1992). One author found that more than 33 percent of ingested coins are retained in the stomach for two weeks (Arana 2001). Additionally, in a study of button battery ingestions, the larger the ingested item, the less likely it would pass through the stomach (Litovitz 1992). Specifically, these authors found that batteries larger than 15 to 23 mm (about 0.6 to 0.9 inches; for comparison, the diameter of a US quarter is approximately one inch) lodged only in the stomach. Batteries measuring 11.6 mm (about 0.46 inches) arrested equally in the stomach and the more distal bowels. Batteries smaller than 7.9 mm (about 0.3 inches; for comparison, a US penny is about 0.75 inch in diameter) never arrested in the stomach.

A 4 year old child in Minnesota ingested a heart shaped charm about the size of two quarters stacked on each other and attached to an 8 inch chain that was a promotional item included in the purchase of girls' shoes. This item remained in this child's stomach for approximately 10-14 days before he died from the effects of lead toxicity (CDC 2006). A 4 year old child in Oregon suffered severe lead poisoning after the accidental ingestion of medallion which measured 7/8$^{th}$ of an inch and was purchased from a vending machine. This item remained in the child's stomach for approximately 3 weeks and required endoscopic removal (CDC 2004). Between case reports and literature on stomach retention times of ingested objects, we believe it is a reasonable assumption that these objects may remain in a child's stomach for weeks.

With respect to the use of a different pharmacokinetic model used by an industry consultant (Exponent) versus the widely used U.S. EPA Integrated Expsosur Uptake and Biokinetic model (IEUBK), one key assumption likely contributed to the lower industry predictions of impact of ingested leaded jewelry. Exponent assumed a half-life of lead in blood of 15-40 days, while the IEUBK model assumes a half-life of three months. Given the extensive and long history of use and peer review of the EPA IEUBK model, we believe this model was appropriately chosen for derivations of our accessibility criteria. We consulted with EPA scientists on how best to use the model for a scenario of ingesting a leaded jewelry item, which is detailed in our technical memo dated August 2007.

In addition, it is important to note that once absorbed, lead is never completely excreted from the body. It is largely stored in bone tissue and small amounts are retained in the brain, kidney, and liver. The bone pool of lead in children is much more labile than the bone pool in adults (EPA 2007), and hence lead in bone serves as a source of lead to the blood as continual reapportionment occurs, particularly in childhood. For that reason, EPA and many others believe a more appropriate half-life of lead in blood (due to movement between blood and bone) is approximately three months. In addition, regardless of the half-life of lead in blood, because it is retained in other body tissues, it can continue to exert its toxic effects.

COMMENT: Multiple standards proposed by different states and CPSC make it difficult for manufacturers to maintain compliance. Which one is safe? (Greene)

RESPONSE: As discussed in responses to previous comments above, MDPH believes that our proposed dual standards will protect children from dangerous levels of lead exposures. We are adopting the widely used limit of 600 ppm total lead content, but we do not support the CPSC 2005 interim guidance of 175 µg accessible lead. (It is important to note that it appears that the latest CPSC proposal (CPSC 2006) is considering only a total lead content limit (600 ppm) as the agency proceeds with proposed rulemaking.) The 175 µg guidance is not protective because (1) it assumes only 6 hours of exposure, and there is ample evidence both in case reports and the scientific literature that ingested foreign objects can remain in the stomach for much longer periods of time; and (2) it appears that the guidance is designed to achieve an average blood lead level of 10 µg/dL among a population of children exposed to lead in jewelry. The latter means that approximately 50 percent of children with this exposure would exceed a blood lead level of 10 µg/dL, which is problematic for MDPH.

COMMENT: Parent comments included the following:

- Parents need help in keeping children's products containing lead away from their children (Blasi).
- The state should do testing for lead in children's products and should make XRF available to parents so they can test products in their home (Query)
- Parents can't steer children away from hazards all the time, including outside the home or from products used by their older siblings (Spark, Montana)
- Lower income families do not have the resources required to protect their children (Montana)
- There is an unfair and unnecessary burden on parents (Rowland), who spend an inordinate amount of time trying to identify non-toxic items for their children (Montana)

RESPONSE: MDPH will conduct random spot checks of children's jewelry to ensure that retailers are in compliance with the proposed regulation. Retailers are subject to penalties for the sale of banned hazardous substances. MDPH is evaluating the potential for harm to children from exposures to lead from other children's products. MDPH may move forward with additional regulations based on these evaluations. Finally, as noted previously, MDPH has not found that XRF is reliable in determining whether lead in a product poses an exposure risk to a child. The XRF will only detect the presence of lead in a product and cannot determine if lead is accessible to a child.

COMMENTERS:

Keith Barber, Jewelry Manufacturer
Leon Bethune and Thomas Plant, Boston Public Health Commission
Zuaka Blasi, Parent
Derek Brindisi, City of Worcester, Department of Health and Human Services
Becky Chan, Parent
Exponent, consultants to the industry
Michael Gale, Fashion Jewelry Trade Association
John Graef, M.D., Children's Hospital, Boston
Alan Green, Manufacturer
John Jones, Department of Public Health, Worcester
Nancy Katz, Parent
Lee Ketelson, Alliance for a Healthy Tomorrow, Clean Water Action
Paul Laurenstein
Eloise Lawrence, Esq., Conservation Law Foundation
Zena Link, Healthy Environment Leadership Project, Clean Water Action
John McIssac, ASAP Environmental
Jennifer Montana, Parent
Aloris Query, Parent
Sean Palfrey, M.D., Boston Medical Center
Elizabeth Poirier, State Representative (Attleboro)
Richard Rabin, Lead Action Collaborative
Andrew Rainer, Attorney in support of Alliance for a Healthy Tomorrow
William Rennie, Retailers Association of Massachusetts
Jean Roper
Beth Rosenberg, Tufts University School of Medicine
Erin Rowland, Parent
Elizabeth Saunders
Michael Shannon, M.D., Children's Hospital, Harvard Medical School
Laura Spark, Parent
Pamela Steinberg
Eric Weltman, Massachusetts Public Health Association
Joanne Wheeler
Lynn Wolbarst, League of Women Voters of Massachusett
Alan Woolf, M.D., Children's Hospital, Harvard Medical Schoo

REFERENCES

Agency for Toxic Substance and Disease Registry. *Toxicological Profile for Lead.* 09/2005.

American Society for Gastrointestinal Endoscopy. "Guidelines for the Management of Ingested Foreign Bodies." *Gastrointestinal Endoscopy.* 2002, 55;7; pp. 802-806.

Arana A, Hauser B, Hachimi-Idrissi S, Vandenplas Y. "Management of Ingested Foreign Bodies in Childhood and Review of the Literature." *European Journal of Pediatrics.* 2001, 160; pp. 468-472.

Bellinger, DC and Needleman HL. "Intellectual Impairment and Blood Lead Levels." *The New England Journal of Medicine.* July 2003, 349;5, correspondence; pp. 500.

Butterworth J and Feltis B. "Toy Magnet Ingestion in Children: Revising the Algoristhm." *Journal of Pediatric Surgery.* 2007, 42; E3-E5.

Canfield R, Henderson C, Cory-Slechta D, Cox C, Jusko T, Lanphear B. "Intellectual Impairment in Children with Blood Lead Concentrations below 10 µg per Deciliter." *The New England Journal of Medicine.* April 2003, 348,16; pp. 1517-1526.

Federal Register. "Health and Safety Data Reporting; Addition of Certain Chemicals." *Federal Register.* Vol. 73, No. 19, Tuesday, January 29, 2008; pp. 5109-5115.

Gwiazda R, Campbell C, Smith D. "A Noninvasive Isotopic Approach to Estimate the Bone Lead Contribution to Blood in Children: Implications for Assessing the Efficacy of Lead Abatement." *Environmental Health Perspectives.* January 2005, 113;1; pp.104-110.

Holmgren G.G.S, Meyer, M.W., Chaney R.L., Daniels R.B. "Cadmium, lead, zinc, copper, and nickel in agricultural soils of the United States of America." *Journal of Environmental Quality.*. Apr/June 1993, 22;2; pp. 335-348.

Hu H, Rabinowitz M, Smith D. "Bone Lead as a Biological Marker in Epidemiologic Studies of Chronic Toxicity: Conceptual Paradigms. *Environmental Health Perspectives.* January 1998, 106;6; pp. 1-8.

Jospeph DiGangi, Greenpeace USA. *Lead and Cadmium in Vinyl Consumer Products, A Greenpeace Expose.* October 1997.

Jusco TA, Henderson CR, Lanphear BP, Cory-Slechta DA, Parsons PJ, Canfield RL. "Blood Lead Concentrations < 10 µg/dL and Child Intelligence at 6 Years of Age." *Environmental Health Perspectives*. February 2008, 116;2; pp. 243-248.

Kordas K, Canfield RL, Lopez P, Rosado JL, Vargas-Garcia G, Cebrian ME, Alatorre-Ricco J, Ronquillo D, Stoltzfus RJ. "Deficits in Cognitive Function and Achievement in Mexican Fist-graders with Low Blood Lead Concentrations." *Environmental Research.* 2006, 100; pp. 371-386.

Lanphear B, Dietrich K, Auinger P, Cox C. "Cognitive Deficits Associated with Blood Lead Concentrations <10 µg/dL in US Children and Adolescents." *Public Health Reports.* November/December 2000; 115; pp. 521-529.

Lanphear B, Hornung R, Khoury J, Yolton K, Baghurst P, Bellinger D, Canfield R, Kietrich K, Bornschein R, Greene T, Rothenberg J, Needleman H, Schnaas L, Wasserman G, Graziano J, Roberts R. "Low-Level Environmental Lead Exposure and Children's Intellectual Funtion: An INternation Pooled Analysis." *Environmental Health Perspectives*. July 2005; 117,7; pp. 894-899.

Litovitz T and Schmitz BF. "Ingestion of Cylindrical and Button Batteries: An Analysis of 2382 Cases." *Pediatrics.* April 1992, 89;4; pp.747-757.

Massachusetts Department of Environmental Protection. *Background Levels of Polycyclic Aromatic Hydrocarbons and Metals in Soil.* May 2002. http://www.mass.gov/dep/cleanup/laws/backtu.doc

Massachusetts Department of Environmental Protection. *Guidance for Disposal Site Risk Characterization, In support of the Massachusetts Contingency Plan.* Interim Final Policy WSC/ORS-95-141. July 1995.

Mowad E, Haddad I, Gemmel D. "Management of Lead Poisoning From Ingested Fishing Sinkers." *Archives of Pediatric and Adolescent Medicine.* 1998; 152; pp. 485-488.

Paul RI, Kaufer-Chrstoffel K, Binns HJ, Jaffe DM, Pediatric Practice Research Group. "Foreign Body Ingestions in Children: Risk of Complication Varies With Site of Initial Health Care Contact." *Pediatrics.* January 1993, 91;1; pp. 121-127.

Rust SW, Kumar P, Burgoon DA, Niemuth NA, Schultz BD. "Influence of Bone-Lead Stores on the Observed Effectiveness of Lead Hazard Intervention." *Environmental Research, Section A.* 1999, 81; pp. 175-184.

Shacklette HT and Boerngen JG. "Elemental Concentrations in Soils and Other Surficial Materials of the Conterminous United States*" U.S. Geological Survey Professional Paper.* 1270. Washington, 1984.

Tellez-Rojo MM, Bellinger DC, Arroyo-Quiroz C, Lamadrid-Figueroa H, Mercado-Garcia A, Schnaas-Arrieta L, Wright RO, Hernandez-Avila M, Hu H. "Longitudinal Associations Between Blood Lead Concentrations Lower than 10 µg/dL and Neurobehavioral Development in Environmentally Exposed Children in Mexico City." *Pediatrics.* 2006; 118, pp. 323-330.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55d323a1.htm#fig 2006

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5323a5.htm#fig 2004

U.S. Consumer Product Safety Commission. *CPSC Staff Report on Lead and Cadmium in Children's Polyvinyl Chloride (PVC) Products.* November 21, 1997.

U.S. Consumer Product Safety Commission. *Petition for Ban on Lead Toy Jewelry, Petition HP 06-1*. December 4, 2006. http://www.cpsc.gov/LIBRARY/FOIA/foia07/brief/LeadToyJewelry.pdf

U.S. Consumer Product Safety Commission. "Revision of the CPSC 0.06% Lead in Paint Standard (16 CFR Titel II Part 1303)." June 22, 1990.

U.S. Environmental Protection Agency. *Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of Scientific and Technical Information*. EPA-452/R-07-013. November 2007.

U.S. Environmental Protection Agency. *Residential Lead Hazard Standards - TSCA Section 403.* 40 CFR Part 745. January 2001. http://www.epa.gov/lead/pubs/leadhaz.htm

U.S. Environmental Protection Agency. *Guidance Manual for the IEUBK Model for Lead in Childre*WER #9285.7-**15-1, February 1994.**