

Testimony of Barbara D. Beck, Ph.D, DABT

Regarding the Consumer Product Safety Improvement Act:

The Need for a Risk-Based Approach

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Executive Summary

The lead limits recently stipulated by the Consumer Product Safety Improvement Act (CPSIA) of 2008 have forced many manufacturers to stop selling their products, because the products contain components exceeding the 600 ppm total lead standard of the Act. The difficulty with this approach to regulating lead in products is that it does not consider the *actual* exposure of children to lead. If the exposure to lead is very small, there will not be any health effects. Unfortunately, as presently interpreted, the CPSIA does not support consideration of exposure. Risk-based analyses that take into consideration exposure frequency and duration, exposure route, and dose represent a scientifically supportable approach to determining compliance with the lead standard, as well as to supporting exclusions from the lead standard. I recommend that that such risk-based analyses be allowed under the auspices of the Act.

Introduction

Good morning and thank you for this opportunity to testify regarding the CPSIA and the need for a risk-based approach for lead in children's products. I am Barbara D. Beck, Ph.D., diplomate of the American Board of Toxicology, and fellow of the Academy of Toxicological Sciences. For 22 years I have been a toxicologist and Principal with Gradient Corporation, a firm specializing in human health exposure and risk assessment, and located in Cambridge, Massachusetts. Prior to Gradient, I held positions at the Harvard School of Public Health, US EPA Region I, and Tufts University School of Medicine. I am currently president-elect of the Academy of Toxicologists, and have been a diplomate of the American Board of Toxicology (DABT) for 20 years.

Over my 30+ year career in toxicology and public health, I have worked extensively on projects involving lead. More than 20 years ago, while at US EPA Region I, I developed the first target action level for lead in soil. During my tenure at Gradient, I have worked on many projects involving lead exposure, toxicology and risk. These projects have involved refinery and mining sites, children's toys, consumer products, and automotive vehicles. I was also significantly involved in providing regulatory comment for the lead National Air Quality Standard (NAAQS).

I would like to emphasize that I am presenting my testimony this morning as an independent scientist. While my travel costs have been paid, I am here today on my own time, and I am not being compensated for any of the time I have spent preparing for today's testimony.

1 Consumer Product Safety Improvement Act (CPSIA) of 2008

The Consumer Product Safety Improvement Act (CPSIA) of 2008 stipulates that, as of February 10, 2009, children's products that contain more than 600 ppm (mg/kg) lead may no longer be sold in the United States (US Congress, Pub. L. No. 110-314, § 101(a)(2)). The limit will be reduced to 300 ppm after August 14, 2009 and then to 100 ppm on August 14, 2011, unless the Commission determines that this lower limit is not technically feasible. While manufacturers may petition for exclusion from these standards, exclusions are allowed only if the manufacturers can demonstrate that no lead can be absorbed by children.

The scientific community understands that, based on multiple lead-related recalls occurring in 2007, Congress was motivated to write the Act to be protective of our children's health, and, in the case of lead, to eliminate lead risk to children. However, there have been untoward consequences of the Act, as some manufacturers and businesses have suspended sales of their existing inventory. This is a result of certain individual components in the products (*e.g.*, valve stems in bikes and All Terrain Vehicles (ATVs)) exceeding the current lead standard – even though exposure to lead in those components is unlikely, and would not result in health effects.

A risk-based exposure analysis is the solution to this problem. A risk-based approach would focus on *actual* exposure and the health significance of that exposure. Such an approach can be extremely effective in protecting a child's health. Consider, for example how average blood lead levels in children have been reduced by nearly 10-fold, from 15 µg/dL in 1976 to 1.6 µg/dl in 2004 (US EPA, 2008), an important public health success story. This was accomplished by focusing on *important* sources of lead exposure, specifically lead in air (from leaded gasoline), in food (primarily from lead solder), and in paint, to the general population of children. Indeed, risk-based approaches are widely used and considered appropriate in other sectors, for example, in human health risk assessment for lead in soil performed for Superfund sites (US EPA, 1997).

2 Exclusions from the CPSIA

Although the Act and subsequent published Federal Register guidance include provisions for groups of manufacturers to petition for an exclusion from the lead standards, the statute does not currently allow manufacturers and companies to present risk-based evaluations of their products or components in support of an exclusion. The Act states the Consumer Product Safety Commission (CPSC) may exclude a specific product or material from the lead content limits if they are provided "the best available, objective, peer reviewed scientific evidence...demonstrating that the normal and reasonably foreseeable use and abuse activity by a child (including swallowing, mouthing, breaking, or other children's activities) and the aging of the material or product for which exclusion is sought will not result in the absorption of *any* lead into the body, nor have any other adverse impact on health or safety" (US Congress, 2008; CPSC, 2009a). As currently interpreted, it has become clear that the use of the word "any" does not support a risk based approach.

By totally ignoring exposure and risk, the Act affords an uncertain public health benefit. As the CPSC has noted, in the case of ATVs, "the possibility that children will suffer significant lead exposures from these classes of vehicles is remote, at best" (CPSC, 2009b). This conclusion is consistent with our own analysis of ATVs, described later in these comments. Therefore, I recommend that a risk-based approach be allowed for standard compliance and for exclusion petitions, as a scientifically appropriate way to determine whether lead in a product will actually pose harm to children. In the letter to Representative John Dingell, CPSC agrees with this approach, and states that "Congress could modify this exclusion criterion to allow *de minimis* levels of absorption or to change the focus to preventing any significant increase in blood lead levels of a child, particularly for children who are of the age of the intended user" (CPSC, 2009b). CPSC also recommends that Congress give the Commission "more discretion to grant exclusions from the lead and phthalate limits" (CPSC, 2009b).

3 Consideration of Exposure: Risk-Based Approach

The mere presence of lead in a children's product or component does not mean that there is an exposure hazard to a child. Several factors, described below, must be considered to determine whether the lead in a particular product constitutes a health risk to a child contacting that product.

3.1 Dose Response

The most fundamental concept in toxicology is the dose-response relationship, commonly summarized as "the dose makes the poison" (Eaton and Gilbert, 2008). All substances show a dose-response relationship. For example, small amounts of salt may be consumed without adverse effects, but ingestion of much larger quantities can result in adverse effects, such as elevated blood pressure (Braunwald *et al.*, 2001). As another example, at the recommended dose of two tablets, aspirin yields pain relief from headaches or other minor aches, and even lower doses can be used to prevent and manage cardiovascular disease. However, taking more than the recommended dose can lead to increasing levels of toxicity, including death (Hardman *et al.*, 2001). Similarly, lead exhibits a dose-response relationship, with the likelihood and nature of effects being greater with increasing dose, typically expressed as blood lead levels.

3.2 Exposure Duration and Frequency

The dose of a chemical is affected by a number of factors. For example, how long and how often someone comes into contact with a chemical will affect the dose. In the case of a children's consumer product, it is important to know whether the child comes into contact with the product every day, or only occasionally. It is also important to know how many hours or minutes of each day a child contacts the product. With less time of contact, the dose will be less.

3.3 Exposure Route

The way that a person comes into contact with the chemical (for example, through the skin *versus* taking the chemical in through the mouth) is also important. While some chemicals can be taken in through the skin, others are not taken in through the skin very well, if at all. In the case of a children's products, a child might possibly chip or bite paint off a painted product, or, if the paint is loose, take paint off by sucking on the children's product. If the paint contains lead, these activities could result in some lead taken into the body through the mouth; this is termed "ingestion." Because lead is not taken up through the skin, just handling the children's product will not result in a dose of lead.

3.4 Lead Intake *versus* Uptake

Intake is generally expressed as the amount of a chemical at the skin, lungs, gastro-intestinal tract that is available for absorption. Intake, while necessary to yield a "dose", is not equivalent to absorbed dose (uptake), the amount of a chemical absorbed into the blood stream. Lead intake (particularly from children's products) is primarily through ingestion (*e.g.*, through direct mouthing of a children's product or through hand-to-mouth contact).

How much lead a child actually absorbs, after lead is ingested, is an important consideration in a risk-based approach. Bioavailability (*i.e.*, the fraction of ingested lead that is solubilized in the gastro-intestinal tract) determines the amount of lead that can be absorbed into the body (uptake). Bioavailability must be considered when evaluating exposure using a risk-based approach. The bioavailability of lead in the digestive tract depends on the physical (*i.e.*, particle size) and chemical form of lead, and can vary by more than 10-fold. This is clearly an important determinant of the amount of lead uptake into the body.

3.5 Blood Lead Modeling

In order to evaluate the impact of lead exposure to the body, the amount of lead absorbed must be converted to a blood lead value. Models such as the *Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children* (US EPA, 1994), or the O'Flaherty model (1997) are widely accepted risk-based approaches that have been used in a number of circumstances to quantify the impact of lead uptake on blood lead. These models can be and have been applied in risk-based approaches to evaluate the impact on blood lead of different types of exposures of lead, from soil, air and products.

3.6 Consideration of Age of Child

The Act considers products manufactured for children up to age 12. However, there is a significant difference between a 2-3 year old toddler and a 12 year old, and how they will interact with a children's product. The 2-3 year old will have much more frequent hand to mouth contact than the 12 year-old. Moreover, the 2-3 year old will not contact products in the same manner as a twelve year old (*i.e.*, a toddler will not fill the air in a bicycle tire). In the CPSC's letter to Representative John Dingell, the Commission suggests that, since ATVs are designed for children ages 6 and older, "these children are far less likely to ingest or mouth components of a motorized vehicle – even those that are physically exposed – than something that fits readily in the mouth, such as a jewelry chain or a charm" (CPSC, 2009b). Clearly, a risk-based approach is critical to understanding how age affects exposure. CPSC also agrees; in their response to Representative Dingell they state, "For example, toxic limits are better regulated based on the possibility of exposure in relation to age. Foreseeable use data, combined with mouthing and ingestion data at various ages, would define the group at risk for any given product" (CPSC, 2009b).

4 Risk-Based Approach Example – ATVs and Bikes

As an example of how a risk based approach can be used to evaluate whether lead in components poses an exposure hazard to children, I recently evaluated exposures to ATV and bike components made from lead-containing alloys (specifically, valve stems and brake handles); some of these components exceed the current lead standard (Polaris Industries *et al.*, 2009). I performed an exposure analysis of these components using scientifically accepted exposure assessment procedures and worst-case exposure scenarios that, while plausible, were likely to overestimate exposures for most children. I determined that estimated lead intakes from ATV and bike components are well below typical daily intakes of lead from food and water, and that such estimated intakes would not result in a measurable impact on blood lead levels in children. Thus, the components should not be considered an exposure hazard. This analysis represents a model for the risk-based approach, an approach that is not currently supported by the Act.

Figure 1 summarizes our analysis for valve stems, comparing typical blood lead in a 6 year old. The contribution of lead from the valve stem is indiscernible as the blood level remains the same.

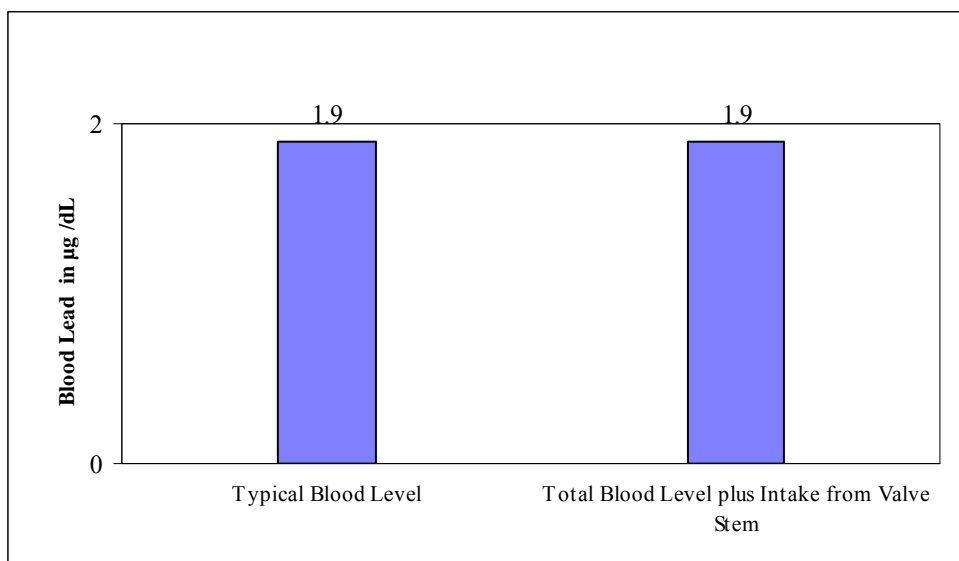


Figure 1. Comparison of Blood Lead Levels in µg/dL for a 6 Year-Old Child, with and without Consideration of Lead Intake from a Valve Stem

5 "No" versus "De minimis" Lead Absorption

I recognize that the statute refers to no lead absorption in the body; however, as a scientific matter, the concept of "no lead absorption" would be reasonably interpreted to mean no measurable impact on blood lead. This is consistent with the fact that, even at the permitted concentrations of lead in products (*i.e.*, 600 ppm at the first threshold), one cannot assume that the impact on lead uptake into the body is zero. For our analysis, as presented in Figure 1, the estimated impact of lead from the valve stems on blood lead would not be discernible. "No lead absorption" under the Act has, unfortunately, been interpreted to mean zero, even if the amount a child might ingest is infinitesimally small with no measurable impact on blood lead; thus, a component product, such as the valve stems described in the preceding analysis, could be concluded as not meeting the standard. This is clearly unreasonable. A

product that has no significant impact should not be considered to have "failed" the standard. Quantifying and interpreting the impact to blood lead is the scientifically appropriate and health protective approach.

6 Recommendation

In conclusion, in order to appropriately evaluate lead in children's products, I recommend use of a risk-based approach, with emphasis on prevention of significant increases to blood lead. Such an approach would be protective of children's health, while allowing for a reasonable and scientific evaluation of potential exposure hazards. I urge Congress and CPSC consider a risk-based approach as permissible under the CPSIA.

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