Staff Report*

CPSIA Section 101(b): Functional Purpose Exception from Lead Content Limit for Children's Products for a Specific Product, Class of Product, Material, or Component Part

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I. Introduction

The Consumer Product Safety Improvement Act of 2008 (CPSIA) provides specific limits for lead in children's products. Section 101(a) of the CPSIA requires that as of February 10, 2009 (180 days after the date of enactment of the Act), products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. The Act specifies that as of August 14, 2009 (1 year after the date of enactment of the Act), the limit will be reduced to 300 ppm, and that as of August 14, 2011 (3 years after the date of enactment of the Act), the limit will be reduced further to 100 ppm, unless the Commission determines that such a limit is not technologically feasible for a product or product category. The CPSIA provides a definition of "technological feasibility," which includes commercial availability of products, available industrial strategies, or alternative practices or operational changes that would allow compliance with the limit. Because the Commission did not find that it is not technologically feasible to have the lower limit, children's products and component parts of children's products manufactured after August 14, 2011, with a few exceptions, must comply with the 100 ppm limit.[1]

Section 101(b) of the CPSIA, as amended by Public Law No. 112-28 (excerpts at Appendix A), allows for exceptions to the lead content requirement for children's products, based on certain criteria. The Commission may grant an exception for a specific product, class of product, material, or component part, if it determines that it is not practicable or technologically feasible to manufacture the product by removing the excess lead or making the lead inaccessible; the product or part is not likely to be placed in the mouth or ingested; and the exception will have "no measurable adverse effect on public health or safety." The statute further provides that there is no measureable adverse effect if the exception "will result in no measurable increase in blood lead levels of a child."

Section 101(b) originally provided that the Commission may exclude a specific product or material from the lead limits established for children's products if the Commission determines that lead in such product or material will neither: (a) result in the absorption[2] of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.[3]

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[1]   See the Record of Commission Action at: http://www.cpsc.gov/library/foia/ballot/ballot11/100ppmlead.pdf. Also see *Federal Register* notice, 76 FR 44463, concerning the effective date of the lower lead limit available at: http://www.cpsc.gov/businfo/frnotices/fr11/leadeffdate.pdf.

[2] In toxicology, "absorption" refers to the transfer of a chemical into the systemic circulation from the site of exposure, primarily through the skin, respiratory tract, and gastrointestinal tract (Gregus, 2008).

[3] In 2009, the Commission received several requests from manufacturers and trade organizations seeking exclusions from the lead limits for certain products. The requests were accompanied by data or other analyses, which indicated that exposures to lead from the products would be very low and would not pose a danger to children who used the products. Because the information submitted in each case concluded that children's contact with the product could result in absorption of lead, however small the

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Congress subsequently enacted Public Law 112-28, which amended the CPSIA, changing the standard for exclusions in section 101(b).

This document addresses the third of the three criteria for consideration of an exception from the lead content requirement for children's products. This criterion provides that the exception will have "no measurable adverse effect on public health or safety," based on a determination that the exception "will result in no measurable increase in blood lead levels of a child."

The purpose of this document is not to provide a detailed analysis of the toxicology of lead. Recent work by the U.S. Centers for Disease Control and Prevention (CDC), U.S. Environmental Protection Agency (EPA), California Environmental Protection Agency Office of Environmental Health Hazard Assessment (OEHHA), and others has documented extensively the large body of research into the effects of lead (see, for example, CDC, 2005; EPA, 2006; OEHHA, 2007). Rather, this document provides a brief review of lead toxicology and discusses staff's current thinking about the relationship between the level of lead exposure and the adverse health outcomes associated with exposure.

II. <u>Discussion</u>

A. Exposure to Lead, Blood Lead Levels, and Adverse Health Effects

The adverse health effects associated with lead exposure in children are well documented and may have long-lasting or permanent consequences. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and the subsequent risk of adverse health effects.

These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, neurocognitive deficits, and hearing problems. Studies have shown associations between lead exposure and increased risk of health effects involving organ systems, such as the cardiovascular system and kidneys, as well as neurocognitive effects. At lower levels of exposure, the effects of lead may be subtle. At relatively high exposures, children may suffer severe abdominal pain, vomiting, anemia, fatigue, behavioral changes, and encephalopathy, which can result in death.

Young children are at greater risk from exposure to lead than adults because their bodies and central nervous systems are still developing, they engage in activities that increase their exposure (hand-to-mouth activities), and they absorb and retain a larger percentage of ingested lead per unit of body weight.

The amount of lead in the blood generally indicates recent or continuing exposure to lead.[4] The higher a blood lead level (BLL) is, the more serious the potential health effects are. No "safe" level of lead in the blood has been identified.

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amount absorbed, staff concluded that the statutory standard had not been met. In each case, the Commission agreed with staff and denied the request for exclusion.

[4] Lead is a natural constituent of the environment, and centuries of human uses of lead continue to contribute to exposure. Currently, the geometric mean blood lead level (BLL) in U.S. children aged 1–5 years is about 1.5 micrograms lead per deciliter of blood (µg/dL) (CDC, 2012).

In practice, BLL may be considered a "snapshot" of a child's exposure to lead from all sources, generally relatively recent exposures. BLL measurements are routinely conducted in young children, especially in certain communities with known or expected lead hazards, such as older housing with lead-based paint. Measurement for changes in BLL, *i.e.*, two or more measurements over time, may be done for various purposes but is especially useful for identification of a suspected new significant exposure, such as recent industrial activity or home renovation work, or to monitor decreases from a high, dangerous BLL to lower levels due to treatment and actions to reduce or remove lead hazards from a child's environment.

Perhaps the best-characterized adverse effects of lead exposure are the neurocognitive effects, including intelligence, as measured by the intelligence quotient (IQ). The relationship between lead exposure, as measured by BLL, and reduction in IQ in children is the subject of a number of epidemiological studies conducted over many years in several countries around the world (see detailed reviews in EPA, 2006; OEHHA, 2007).

Included in these reviews is a publication by Lanphear and colleagues (Lanphear *et al.*, 2005) of an analysis of several of the most relevant studies to describe quantitatively the dose-response relationship between lead exposure and IQ in children. This key study specifically considered the lower levels of lead exposures; *i.e.*, BLLs in the range of 2.4 µg/dL to 30 µg/dL. Lanphear *et al.* (2005) showed that the relationship between increasing lead exposure and changes in IQ is not linear and depends on the level of children's exposure. That is, increasing lead exposure in children who have lower levels of exposure (*e.g.*, <7.5 µg/dL or <10 µg/dL) has a larger effect on IQ than increasing exposure in children who already have higher levels of exposure to lead.

The most recent national data, collected in 2007–2008 (CDC, 2012), show that the median BLL in children ages 1–5 years is 1.4 µg/dL, and the 95th percentile is 4.1 µg/dL.[5] Some children are still at risk for lead exposure, although the numbers of affected children (and the percentage of the population that is affected) have been declining because of efforts by government and the public health community to reduce lead exposure wherever possible. Thus, during 1999–2004, 1.4 percent of children ages 1–5 years had blood lead levels at least 10 µg/dL; during 1988–1994, the percentage of children with at least this level was 4.4 percent (CDC, 2009).

Therefore, most children currently have lead exposures in the lower end of the ranges of BLLs evaluated by researchers such as Lanphear *et al.* (2005).

The quantitative analysis by Lanphear *et al.* (2005) resulted in a log-linear model with a reasonable fit to the data that describes the relationship between IQ and BLL, measured concurrently.[6] With adjustment for covariates, this relationship is presented as:

$$\text{Change in IQ} = \ln(\text{BLL}) * (-2.7).$$

Staff notes that the relationship between BLL and IQ, as a nonlinear function, varies depending on the range of BLL under consideration. Because of the infinite number of individual BLL levels or BLL ranges that could be considered for purposes of developing information that can be applied to children or groups of children with unknown BLLs, staff believes that it is appropriate

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[5] The median, also called the 50th percentile is the midpoint of the BLL measurements. Fifty percent of the values are lower than the median; 50 percent are higher. At the 95th percentile, 95 percent of the values are lower, and 5 percent are higher.

[6] Concurrent measurement of BLL and IQ means that researchers obtained blood samples for BLL measurement at the same time they administered the IQ test to the individual children in the study.

to consider the average change in IQ over a specified range of BLLs. Staff also believes that it is appropriate to focus on the 1 μg/dL to 10 μg/dL BLL range because most U.S. children have BLLs within this range. While an even more narrow range could be selected, staff believes that it is appropriate to use the range that includes most children, including the upper end of the distribution of current BLLs. Staff also believes that the wider range is appropriate because of the limitations of the quantitative analysis, including uncertainties associated with the analysis and underlying data.

Therefore, for an increase in BLL from 1 μg/dL to 10 μg/dL, the model estimates a loss of IQ of 6.2 points. Averaging this IQ loss over the BLL range results in an estimated average loss of 0.69 IQ points per increase in BLL of 1 μg/dL.[7]

The width of the 95 percent confidence interval (-3.74, -1.66) for the model's coefficient (-2.7), as published by Lanphear *et al.* (2005), indicates the uncertainty in this estimate. The upper end of the interval (-1.66) indicates that the effect of lead on IQ could be lower than the point estimate derived from the model. Using this value rather than the point estimate (-2.7) results in an estimated loss of 3.8 IQ points associated with an increase in BLL from 1 μg/dL to 10 μg/dL (an average of 0.42 points per increase in BLL of 1 μg/dL in this BLL range). Using the lower end of this interval (*i.e.*, -3.74, which represents larger changes in IQ associated with increasing lead exposure) shows that IQ loss for an increase in BLL from 1 μg/dL to 10 μg/dL could be 8.6 points (an average of 0.96 points per 1 μg/dL BLL increase in this BLL range).

In summary, the purpose of the discussion in this section was to describe the relationship between levels of exposure to lead and the adverse effect of lead exposure, measured as the change in IQ. Numerous studies have shown that lead exposure in young children is associated with reduced IQ. Lanphear *et al.* (2005) analyzed these studies to derive quantitative estimates of the exposure-effect relationship. The analysis showed that the relationship is complicated, and depends on the level of exposure. Staff chose to consider the information concerning lead exposures that are currently typical of most children. Staff also considered the uncertainty in the estimate that means that the effect of lead could be more or less pronounced than a central estimate (*e.g.*, median or average) might indicate.

For the purposes of evaluating children's exposure to consumer products, staff chose to consider the upper end of the range of the quantitative estimates of the relationship between lead exposure and IQ loss, as the more health protective option. Therefore, staff concludes that evaluation of children's products should be based on the average relationship between exposure and effect for BLLs between 1 μg/dL and 10 μg/dL, using the upper bound of the 95 percent confidence interval of the Lanphear *et al.* (2005) quantitative estimate. Thus, staff recommends that evaluation of children's products should be based on the estimated 0.96 IQ points lost per increase in BLL of 1 μg/dL.

B. Measurement of Blood Lead Levels

The wording of the statute concerning "measurable increase in blood lead levels of a child" addresses the ability to discern a difference between two measurements. In this case, the two

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[7] The analysis by California's Office of Environmental Health Hazard Assessment (OEHHA, 2007), and the published report of the agency's findings (Carlisle *et al.*, 2009) also is based on the models developed by Lanphear *et al.* (2005). The California reports include a more detailed discussion of the available information and conclusions about the estimates than is presented here.

measurements are: (1) the BLL of a child without exposure to the product under consideration for an exception to the lead content requirements for children's products, and (2) the BLL of a child after or during use of the product in which component parts may contain lead in excess of the established limits. Measurement is always associated with some level of uncertainty. Because each measurement has an associated uncertainty, and the "true" values are unknown, one value can only be said to be increased compared to another, if the difference is large enough to be outside the estimates of the range of uncertainty of both measurements.

Uncertainty in measurement is a function of random and non-random variability in laboratory-related performance, for example, performance by different laboratory staff, instruments used, samples preparation, and times of measurement. Uncertainty can be quantified, such as the precision[8] related to repeated measurement of a specific sample using a specified method within a period of time. Precision related to use of different methods in different laboratories can also be quantified under stated conditions.

Furthermore, laboratory-related performance is not the only determinant of precision and accuracy in testing biological samples. The concentration of lead in a blood sample depends on the characteristics of the lead exposure, such as the source of the lead, and factors affecting absorption of lead after ingestion. Day-to-day variation, and even with-in day variation in exposure to lead will affect BLL measurements. Moreover, blood volume, diet, micronutrient status (*e.g.*, calcium, iron), and metabolic processes will affect the presence and concentration of lead in blood. For example, dehydration results in reduced fluid in blood, and an apparent increase in concentration for the other substances found in blood, including lead. Staff has not located studies specifically on BLL variability; but one study on iron shows substantial variation in serum iron levels within individuals over a single day (Dale *et al.*, 2002). Thus, the BLL of an individual, even over a relatively short period of time could vary substantially. This variability is in addition to that of laboratory-related performance and will affect the ability to discern whether two or more measurements are different.

BLL measurements are conducted using standardized procedures and methods for collecting and processing blood samples, as well as using laboratory analytical instruments to detect and quantify the lead that is present in the sample.

In practice, measured blood lead levels are generally reported as micrograms of lead per deciliter (one deciliter is equivalent to 100 milliliters) of blood, or µg/dL. BLL values are often reported as whole numbers (*e.g.*, 5 µg/dL or 9 µg/dL), or with a single digit after the decimal point (*e.g.*, 2.1 µg/dL or 7.6 µg/dL). Rarely are values reported with additional digits after the decimal place because a higher level of precision is not usually possible based on the capabilities of the test method and instrumentation. Furthermore, higher levels of precision are not required for decisions involving follow-up monitoring of blood lead levels, initiation of treatment, environmental testing, or remediation and mitigation activities.

With respect to laboratory-related performance, uncertainty in routine measurement of BLL can be relatively high. Current federal criteria for acceptable performance for laboratories that perform blood lead testing allow an error of ±4 µg/dL or ±10%, whichever is greater, for samples

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[8] In measurement, precision refers to the ability of the test to achieve the same result from several measurements of the same sample. A related concept is accuracy, which refers to the closeness of the measurement to the "true" value.

with lead concentrations within a clinically relevant range of values[9] (42 CFR section 493.937). However, many laboratories can readily perform within ±2 μg/dL (CDC, 2007). In fact, the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP), which advises the secretary of the U.S. Department of Health and Human Services (HHS) and the director of the Centers for Disease Control and Prevention (CDC), has voted unanimously to send a letter to the HHS secretary, the CDC Clinical Laboratory Improvement Advisory Committee, and others, recommending that the performance criteria for BLL measurement be tightened to ±2 μg/dL or ±10%.[10]

Performance criteria allow evaluation of laboratories seeking certification to perform the specified testing. The criteria reflect that even if methods and procedures are optimized to reduce testing error, a certain level of variability in the reported values is still expected. While certification criteria indicate performance in terms of precision and accuracy that is acceptable for clinical testing purposes, such criteria do not necessarily define achievable performance.

Several methods are currently available for analysis of lead in blood, using different types of laboratory instruments. The scientific literature includes evaluations of such methods for characteristics such as limit of detection, accuracy, and precision. Recent studies conducted to characterize lead-containing blood samples and methods (Murphy *et al.*, 2009; Sobin *et al.*, 2011) show that high levels of precision are possible when analyses are conducted by expert laboratories using the most modern and sophisticated methods and instrumentation. Generally, between-laboratory measures of uncertainty are larger than within-laboratory estimates, especially when different methods are used (Parsons *et al.*, 2001).

Because sources of variation and uncertainty other than measurement-related factors, such as the intrinsic variability among biological samples, cannot readily be quantified, staff believes that a practical way to deal with the unknown factors affecting measurement precision in the before-exposure and after-exposure scenario is to base the approach to addressing a "measurable increase in blood lead levels of a child" on estimates that include between-laboratory performance. That is, staff believes that a "measurable increase" in BLL is more appropriately described by estimates of variability and uncertainty between methods and analysts, not by the high levels of precision that may be demonstrated by repeat measurements of a well-characterized sample by an expert analyst.

Thus, staff chose not to consider the studies showing achievement of the highest levels of precision (*i.e.*, lowest variability among results) by repeated measurements by a single analyst, but instead chose to focus on studies that included multiple measurements of specified blood samples using multiple laboratories and methods. Staff believes that the study by Parsons *et al.* (2001) reasonably accounts for multiple sources of variability in BLL measurements and is appropriate for use in defining a practical "measurable increase in blood lead levels of a child."

The study by Parsons and colleagues (Parsons *et al.*, 2001) described the certification of a number of clinical reference materials for the determination of lead in blood. This

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[9] Clinically relevant BLLs range between approximately 1 μg/dL to >80 μg/dL. Thus, the blood lead testing performance criteria allow up to a 4 μg/dL deviation from the target value for samples with lead concentrations up to 40 μg/dL; for samples containing more than 40 μg/dL, the allowance is 10 percent of the target value.

[10] Meeting of the Advisory Committee on Childhood Lead Poisoning Prevention, November 16–18, 2010, Atlanta, Georgia. Record of the proceedings available at: http://www.cdc.gov/nceh/lead/ACCLPP/Meetings/Minutes/2010NovMinutes.pdf.

interlaboratory study[11] analyzed candidate blood lead reference materials using currently available modern analytical methods and instruments. Based on this analysis, the four samples were certified as 5.9±0.4 µg/dL, 14.5±0.6 µg/dL, 42.2±1.8 µg/dL, and 76.0±2.2 µg/dL (all-method mean; between-laboratory standard deviation).[12]

As discussed above, blood lead levels of most children in the United States are currently less than 5 µg/dL (the 95th percentile is 4.1 µg/dL). The lowest blood lead concentration in the Parsons *et al.* (2001) study was 5.9±0.4 µg/dL.[13] While the mean value of this sample is higher than the BLLs of most U.S. children, it is in the range of "lower" BLL values studied by Lanphear *et al.* (2005) and others with respect to intellectual deficits associated with lower lead exposures.

If we assume that a reasonable estimate of measurement precision for well-conducted testing for lead in blood samples can be described by the overall standard deviation of the lowest blood lead sample in the Parsons *et al.* (2001) analysis, then a measurement could be as much as 0.4 µg/dL higher or lower than the estimate of the "true" value.

Staff notes that the range described by the standard deviation contains approximately 68 percent of the results of the measurements performed on the sample. That is, the range accounts for a bit more than two-thirds of the measurements, but not for all of the measurement outcomes.

However, staff further notes that evaluations of lead-containing children's products will not be based on actual measurements of BLLs in children after contact with products, but instead will consist of laboratory testing of products and expert evaluation of the potential for lead exposure from children's use of the products. Thus, staff believes that using the standard deviation from the Parsons *et al.* (2001) study to formulate an interpretation of "a measurable increase in blood lead levels" reasonably accounts for both the reality of uncertainty and variability in laboratory testing and the possibility of high levels of performance in testing blood samples, should testing actually be carried out. On the other hand, the findings of the Parsons *et al.* study do not account for the possible additional uncertainty due to biological variability of blood samples collected at different times—uncertainty that has not been quantified.

To illustrate the application of a precision estimate, such as the standard deviation, consider the following hypothetical case involving blood samples similar in all respects except lead concentration. With a testing precision of ±0.4 µg/dL, a sample with a "true" BLL of 2.7 µg/dL reasonably could be measured as 2.3 µg/dL; and a sample with a "true" 1.9 µg/dL BLL also could result in a measurement of 2.3 µg/dL. Thus, the difference between such samples could be 0.8 µg/dL, yet the two samples would appear to have the same concentration. If the two samples have BLLs that are farther apart, then the tests could discern that they are different. Therefore, a

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[11] Eight laboratories were selected from a pool that serve as referee laboratories in the New York State Department of Health proficiency testing program for blood lead. Among the eight laboratories, three different analytical methods were used to generate nine datasets.

[12] Staff notes that these reported values for the four samples are based on repeated measurements of reference materials; they do not represent different samples of blood taken from one individual at different times.

[13] All-method mean ± between-laboratory standard deviation.

measurable difference between two such samples could be defined as approximately two times the precision of the analytical method—approximately 0.8 μg/dL in this case.[14]

C. Theoretical BLL Estimates

Another way to assess lead exposures in children is through theoretical quantitative analyses based on knowledge of the fate of lead in a child's body after an exposure has occurred. Extensive scientific literature and several physiologic models exist that describe the relationship between exposure and BLL. Thus, with a given exposure scenario, one can use a model to estimate the expected change in the BLLs of an affected individual or population. Models allow scientists and public health practitioners to evaluate possible exposures and to relate estimated lead exposures to expected adverse health effects through the BLL estimates. The EPA's Integrated Exposure Uptake BioKinetic Model for Lead in Children (IEUBK) is one such model.[15]

The IEUBK is a computer-based model that incorporates current data and information about the characteristics of lead exposure, uptake into the body, biokinetics of lead in the body, and probability distributions to estimate BLLs in children exposed to lead-contaminated media, such as air, water, food, and soil. The model allows other potential sources of lead to be considered, as well, making it useful for considering the possible effects of exposure to lead from children's products. The program estimates the geometric mean (GM) (50th percentile) of the BLL distribution for a hypothetical child or population of children. The user can specify certain model inputs, such as the level of lead in the exposure media or daily intake of lead from another source, as well as the ages of children being considered (from all or part of the age range 0–84 months.

As discussed above, in practice, a measureable increase in BLL could be defined as approximately 0.8 μg/dL, based on an interlaboratory study of blood samples. Thus, staff used the IEUBK model to explore the effect of a hypothetical children's product as an additional source of lead, by specifying various values for additional daily exposure to identify the level of exposure that would be associated with an increase in BLL of 0.8 μg/dL.

In addition to specifying the additional daily intake of lead, the user of the model must specify the proportion of the lead that is absorbed into the body after ingestion. The model's default absorption of ingested lead is 50 percent from diet and water and 30 percent for soil and dust. Staff chose "50 percent" for absorption of lead from use of a lead-containing toy or other children's product because the potential absorption of lead from children's products is unknown and because this value is the more conservative (health-protective) choice. With the exception of the optional alternative source input and the associated absorption rate, staff ran the model using the default inputs for the age range 0–84 months.

Staff believes that it is appropriate to consider the upper end of the distribution because of the variety of factors that influence the BLLs that result from lead exposure in different children.

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[14] Staff has simplified the discussion of the applicable statistical concepts. The statistics of measurements, which are actually based on distributions of measurements, do not support exactly two times the precision as the measurable difference; it is more accurate to say the differences in measurements would be discernible at somewhat less than two times the precision.

[15] Integrated Exposure Uptake Biokinetic Model for Lead in Children, Windows® version (IEUBKwin v1.1 build 11) (February, 2010) 32-bit version. Available at: http://www.epa.gov/superfund/health/contaminants/lead/products.htm.

Because the model produces the geometric mean of the distribution with a specified (or default) geometric standard deviation (GSD), the BLLs that correspond to different percentiles of the distribution can be calculated using the definition of a z-score for the standardized log-normal distribution. Thus, $z = (\ln[BLL]-\ln[GM])/(\ln[GSD])$. Or, after rearranging and exponentiating, $BLL = GM*GSD^{Z}$.

Using all default inputs with no additional lead exposure source, the model results in a geometric mean of 2.730 μg/dL, with a calculated 95th percentile of 5.915 μg/dL.[16] The model with an additional lead exposure of 2.2 μg/day results in a geometric mean of 3.088 μg/dL, with a 95th percentile of 6.690 μg/dL. Thus, 2.2 μg/day is the level of exposure that results in a BLL increase at the 95th percentile of approximately 0.8 μg/dL–the increase in BLL, as discussed above, that could be considered to be a measureable increase. Therefore, a lead exposure of less than 2.2 μg/day would not result in a measureable increase in the BLL of a child, if a measurable increase in BLL is defined as at least 0.8 μg/dL. Staff notes that while the model considers lead exposures that occur daily through several years of early childhood, increased exposure to lead over much shorter time periods also will result in BLL increases, as absorbed lead will remain in the blood for several weeks before being stored in other parts of the body, such as bone, or eliminated from the body. Lead that is stored in bone or other tissues will continue to contribute to BLLs due to the dynamic nature of lead storage and distribution within the body.

III. Public Health Protection

While the statute defines "no adverse effect on public health or safety" as "no measurable increase in blood lead levels," staff notes that the limitations of measurement of chemicals in biological samples, in some cases, may fail to detect what may be significant exposures with respect to potential health outcomes. This is not necessarily the case with measurements of lead in blood, but the following is a discussion of the potential health effects that may be associated with increased lead exposure within the limits of measurement.

As discussed above, uncertainty in laboratory measurement of lead in blood limits the ability to discern small BLL changes or small differences in BLL among different samples. Based on the results of an interlaboratory study of lead in blood reference samples, a measureable increase is perhaps 0.8 μg/dL. Because most children in the United States now have a BLL of less than 10 μg/dL, staff believes that it is appropriate to consider the adverse health effects of changes in BLL in the lower range of BLL, *i.e.*, between 1 and 10 μg/dL.

As discussed above, the work by Lanphear *et al.* (2005) describes quantitatively the relationship between BLL and IQ loss using a log-linear model. Based on this model, an increase in BLL from 1 μg/dL to 10 μg/dL is associated with an IQ loss of 6.2 points (0.69 points per increase in BLL of 1 μg/dL), or 8.6 points, using the upper bound of the 95 percent confidence interval (0.96 points decrease per increase in BLL of 1 μg/dL).

Thus, an increase in BLL of 0.8 μg/dL may be associated with an IQ loss of approximately 0.6 points, based on an estimated loss of 0.69 IQ points per increase in BLL of 1 μg/dL. Because quantitative assessments like this are associated with uncertainty, just like laboratory methods discussed above, it is appropriate to consider that the level of possible IQ loss associated with

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[16] The model's default GSD is 1.6. For the 95th percentile, z=1.6449.

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increasing BLL may be larger than indicated by the single quantitative estimate. Therefore, a BLL increase of 0.8 μg/dL may be associated with an IQ loss of approximately 0.8 points, based on the upper bound estimate of loss of 0.96 points per increase in BLL of 1 μg/dL.

Staff believes that the health implications of a loss of IQ of this level in an individual can be considered to be minimal because this outcome would not be observable in an individual, given the complexities of human development, behavior, and performance, as well as the expected variation in IQ among people; and it is not clinically relevant because no particular illness or injury results that would require treatment or care.

On the other hand, even small changes in a measure, such as IQ in a large population, may be significant with respect to public health because a downward shift in IQ in a population would be associated with an increase in the numbers of children in the lower range of IQ that is associated with cognitive impairment and disability, as well as a decrease in the numbers of children in the higher IQ range.

Others, including the EPA and California's OEHHA, have recently considered potential lead exposure and the implications for public health. Staff notes that the reasons for the actions by these agencies are specific to their needs and regulatory authorities. In both of these examples, the focus is on environmental sources of lead. Decisions about these sources are expected to be based on different criteria than decisions concerning toys and other children's products. However, the analyses of available data in each of these cases require consideration of public health protection.

For example, the EPA, within the authority and requirements of the Clean Air Act, conducted an extensive review and analysis of the available data related to lead exposure and adverse health effects (EPA, 2006). This analysis supported the subsequent revision of the national ambient air quality standards (NAAQS) for lead, which are intended to improve health protection for at-risk groups, especially children (EPA, 2008). The analysis of the data resulted in the selection of neurotoxicity as the best characterized effect of lower-level lead exposure, and a quantitative estimate of the relationship between BLL and IQ in the lower range of blood lead levels currently found in the United States, focusing on possible small changes in IQ in exposed children.

In a comment on the proposed NAAQS rule for lead (Henderson, 2008), members of the EPA's Clean Air Scientific Advisory Committee expressed concern that the proposed standards for lead were based not on protection of a substantial portion of the population, but on the average impact on the IQ of the population. The advisory committee emphasized that "a population loss of 1–2 IQ points is highly significant from a public health perspective," and that the standard should protect 99.5 percent of the population from exceeding that level of IQ loss, a conclusion that previously had been expressed in the committee's review of EPA staff draft documents (Henderson, 2007). The EPA agreed with this position (EPA, 2008; 73 FR 67000). The EPA explained that the approach to revising the lead standard considers a subset of children—those living near sources of lead, and therefore, more likely to be exposed to lead in air at the limit of the standard—and does not reflect average exposure for all children in the United States. The EPA concluded that "a standard based on consideration of this framework would provide the same or greater protection from estimated air-related IQ loss for a high, albeit unquantifiable, percentage of the entire population of U.S. children." The EPA pointed out that it "is not determining a specific quantitative public health policy goal in terms of an air-related IQ loss

that is acceptable or unacceptable in the U.S. population *per se*, but instead is determining what magnitude of estimated air-related IQ loss should be used in conjunction with the specific air-related IQ loss evidence-based framework being applied" in the review (EPA, 2008; 73 FR 67000). Based on its review, EPA concluded that "an air-related IQ loss of 2 points should be used in conjunction with the evidence-based framework in selecting an appropriate level for the standard" (EPA, 2008; 73 FR 67005). Again, the framework focused on a subset of children—those more likely to be exposed to lead in air at the limit of the standard, not all children in the United States.

As mentioned previously, scientists with the California Office of Environmental Health Hazard Assessment developed a benchmark BLL for assessing risks to children in certain exposure scenarios, relying largely on the analysis by Lanphear *et al.* (2005), and made recommendations regarding *de minimus* effects of lead exposure (Carlisle *et al.*, 2009; OEHHA, 2007). This group's two publications presented somewhat different conclusions. Carlisle *et al.*, (2009) concluded that an **IQ loss** of one point is a *de minimus* change. The OEHHA (2007) report indicated that an **increase in BLL of 1 µg/dL** is a *de minimus* change. In this case, the distinction is not critical because the authors' analysis of the data shows that a 1 µg/dL increase in BLL is associated with a loss of 1 IQ point (*i.e.*, 1 µg/dL increase in BLL = 1 IQ point loss = *de minimus* change).

The OEHHA (2007) report also concluded: "[c]hanges in blood lead less than the adopted [1 µg/dL change] are expected to cause ***no measurable adverse effect***, although a very small adverse effect theoretically does occur at the [change] [emphasis added]."

Staff notes this particular conclusion because the emphasized wording is identical to a portion of the statutory requirements for exceptions to the lead content requirements for children's products in CPSIA section 101(b)(1)(a)(iii).[17] Staff believes that the use of this wording in the statute may not be coincidental, and that the California findings should be considered in the present proceeding.

Staff acknowledges that the purposes and required findings for different regulatory proceedings are not identical. However, consideration of public health protection is an element in each one. While judgments about adequate levels of protection may differ in different exposure and regulatory contexts, CPSC, EPA, and OEHHA are all interested in protecting children from lead exposure. Staff also notes that while lead neurotoxicity is well studied and the effects of lower lead exposures on IQ have been quantified, lead is associated with other adverse health effects in children. Staff believes that neurotoxicity is likely the most sensitive health endpoint, and that steps taken to avoid exposures that are associated with neurotoxicity will also protect against other lead-related effects.

From the analyses presented above, staff estimates that a measureable increase in BLL is approximately 0.8 µg/dL, excluding explicit consideration of biological variability, and that such an increase may be associated with a loss of IQ of about 0.8 IQ points. This level of IQ loss is similar to the levels of effect determined by OEHHA to be *de minimus* (1 IQ point loss) and by

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[17] "[A]n exception for the product, class of product, material, or component part will have ***no measurable adverse effect*** on public health or safety, taking into account normal and reasonably foreseeable use and abuse. CPSIA §101(b)(1)(a)(iii) [emphasis added].

EPA (2 IQ point loss) as appropriate for consideration in the evidence-based framework for the air quality standard.

IV. Conclusion

The statutory criteria for an exception from the lead content requirements include consideration of measureable changes in BLL. Staff concludes from the available data that a measureable change in BLL is approximately 0.8 µg/dL.[18] A change in BLL of less than this level is not measurable in practice because of the limitations and variability inherent in measuring lead in blood in a clinical laboratory. Additionally, staff recognizes that biological variability in BLL over time in an individual further limits the ability to measure a change in BLL attributable to lead exposure. Furthermore, staff finds from the available data that an increase in BLL of about 0.8 µg/dL may be associated with an IQ loss of about 0.8 IQ points, a level of change in IQ that would not be observable in an individual. Therefore, staff concludes that a BLL increase of 0.8 µg/dL in a child will have no measurable effect on public health or safety.

A person's BLL changes in response to changes in exposure, and theoretical biokinetic models allow estimation of the BLL under various exposure conditions. Staff used the EPA's IEUBK model to assess the impact of lead exposure on BLL to estimate the level of daily exposure to lead that would not result in a measurable increase in BLL. As discussed above, a lead exposure of less than 2.2 µg/day would not result in a measureable increase in BLL of a child, if a measurable increase in BLL is defined as 0.8 µg/dL. While the model used in this analysis considers daily lead exposures over several years in early childhood, *i.e.*, chronic exposure, lead exposures over much shorter time periods also result in BLL increases. Historically, staff has considered exposure of at least 15–30 days to be a chronic exposure because anecdotal information has shown that BLL increased in children within 1 month of exposure to residential lead hazards.

CPSC staff believes that only a subset of children would have access to an excepted product or component part of a product that contains more than 100 ppm lead. Staff expects that a relatively small number of children's products will ever be granted an exception by the Commission from the 100 ppm statutory limit because of the strict conditions for such exceptions provided in the amended CPSIA. Furthermore, the use of lead in children's products at concentrations significantly greater than 100 ppm is not widespread currently, as demonstrated by results of product testing presented during the Commission's proceeding on the issue of technological feasibility of the 100 ppm lead limit.

Possible exposure to lead in products depends upon a child's interaction with a product and certain behaviors that are not uniformly practiced by all children. One of the conditions for an exception is that "the product is not likely to be placed in the mouth or ingested." Thus, products or component parts of products that are likely to be placed in the mouth or ingested, two important possible routes of exposure to lead, are not eligible for an exception from the lead content requirement.

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[18] Staff notes that an increase of 0.8 µg/dL could represent a substantial increase in a child's BLL, given that the most recent national estimates show that the median BLL in children ages 1–5 years is 1.4 µg/dL (CDC, 2012).

Possible remaining pathways for exposure are: (1) transfer of lead to the hands or fingers during touching or handling the product, and subsequent ingestion of lead from transfer of lead to the mouth from normal hand-to-mouth contact; and (2) inhalation of lead that is released from a product into the air. Staff believes that the latter route of exposure is an uncommon situation for lead exposure from children's products because lead and lead compounds most commonly used in consumer products are not volatile, and significant releases of lead-containing particles from products into the air is not expected for most products during normal use or misuse. Nonetheless, the potential for exposure to lead due to release of lead-containing particles into the air should be assessed during the case-by-case evaluations of products, component parts, or materials for possible exceptions to the lead content requirement for children's products.

Based on the information previously submitted to the Commission concerning possible exclusions from lead limits (*e.g.*, bicycles, motor sports equipment, brass part on tractor toy), staff believes that the actual lead exposure from potentially excepted products will be considerably less than the 2.2 µg/day level of exposure that staff estimates as a level that would not result in a measureable increase in BLL of a child, although the potential for lead exposure must be assessed for each product.

V. Staff Recommendation

CPSC staff recommends to the Commission, for the purposes of evaluating children's products for an exception from the CPSIA lead limit, that the statutory condition that a product "will have no measurable adverse effect on public health or safety" is met if a potential exposure to lead from the product is estimated to result in an increase in a child's blood lead level of less than 0.8 µg/dL. The level of exposure that would be associated with such an increase is about 2.2 µg per day.

Evaluation of products for potential exception to the lead content requirement should be based on estimates of exposure from expected use, including normal and reasonably foreseeable use and abuse. In the laboratory, "wipe-sampling" is used to estimate the potential transfer of lead from the surface of the product to a child's hands. Lead that could transfer to a child's hands during use of the product could then be transferred to the child's mouth and ingested. Case-by-case evaluations of products should also include other routes of possible exposure, as appropriate, including assessment of possible release of lead-containing particles from a product into the air, where they could be inhaled and absorbed into the blood through the lungs.

Staff notes that these conclusions and recommendations are subject to change, to the extent that new information and understanding about potential lead exposures from products and the effects of lead exposure become available.

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Public Law No. 112-28 [1] [excerpt]

SECTION 1. LIMITATION ON LEAD IN CHILDREN'S PRODUCTS.

(b) ALTERNATIVE LIMITS AND EXCEPTIONS.—Section 101(b) of such Act (15 U.S.C. 1278a(b)(1)) is amended—

(1) by striking paragraph (1) and inserting the following:

''(1) FUNCTIONAL PURPOSE EXCEPTION.—

''(A) IN GENERAL.—The Commission, on its own initiative or upon petition by an interested party, shall grant an exception to the limit in subsection (a) for a specific product, class of product, material, or component part if the Commission, after notice and a hearing, determines that—

''(i) the product, class of product, material, or component part requires the inclusion of lead because it is not practicable or not technologically feasible to manufacture such product, class of product, material, or component part, as the case may be, in accordance with subsection (a) by removing the excessive lead or by making the lead inaccessible;

''(ii) the product, class of product, material, or component part is not likely to be placed in the mouth or ingested, taking into account normal and reasonably foreseeable use and abuse of such product, class of product, material, or component part by a child; and

''(iii) an exception for the product, class of product, material, or component part will have no measurable adverse effect on public health or safety, taking into account normal and reasonably foreseeable use and abuse.

''(B) MEASUREMENT.—For purposes of subparagraph (A)(iii), there is no measurable adverse effect on public health or safety if the exception described in subparagraph (A) will result in no measurable increase in blood lead levels of a child. The Commission may adopt an alternative method of measurement other than blood lead levels if it determines, after notice and a hearing, that such alternative method is a better scientific method for measuring adverse effect on public health and safety.

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[1] Public law 112-28 is available at: http://www.gpo.gov/fdsys/pkg/PLAW-112publ28/pdf/PLAW-112publ28.pdf.

Appendix B

External Peer Review

In January 2012, CPSC staff sought external scientific peer review of staff's draft document, "CPSIA Section 101(b): Functional Purpose Exception from Lead Content Limit for Children's Products for a Specific Product, Class of Product, Material, or Component Part." Comments from the five reviewers were received by staff in March 2012. Staff revised the draft document based on the peer reviewers' comments.

This appendix contains the charge questions provided to the peer reviewers, a summary of the peer review comments, and staff's responses to the comments.

Peer Review Charge Questions

Please provide complete written answers to the following list of charge questions. We would appreciate if you would use this Word file and enter your responses below each question. If you reference additional literature, please provide a complete citation and a copy if possible. Please comment on any and all aspects of the discussion, conclusions, and recommendations related to evaluating children's products for possible exception to lead content limits.

1) Is the brief presentation of the current knowledge on blood lead levels, adverse effects, and public health protection accurate and sufficiently complete? Is there anything more that you think should be added, given the purpose and context of this staff paper?

2) Is the approach to evaluating the potential lead exposures from children's products or component parts of products in the context of the statutory requirements for possible exceptions appropriate?

3) Overall, are the conclusions and recommendations reasonable and supported by available information?

4) Please provide any additional issues, questions, or comments you have on the draft staff paper.

Summary of Peer Reviewer Comments and Staff Responses

Comment[1]	Comment	Staff Response
2.1.1	"small changes," "small" should be defined	Revised text
2.1.2	Referring to a specific passages on page 4: questions about de minimus change	Staff draft text is actually referring to OEHHA report; revised text around the discussion
	Questions lack of standard definition for "no measurable effect on public health or safety"	Clarified text—no scientific standard, although policies have been adopted; lead context
	Precision defines "no measurable increase in blood lead level"	Section added for this topic, separate from discussion of BLL
	What's the point of page 4/5 spanning paragraph?	Address the health outcome of IQ deficit as significant public health concern

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[1] The peer review comments are numbered according to the following scheme: the first of the three numbers represents the section of the final peer review report that contains the reviewers' comments (*i.e.*, section 2); the second number designates the charge question being addressed in the comment (1–4); and the third number identifies the peer reviewer (1–5).

2.1.3	Brief presentation is not adequate	Clarified intent of staff report; staff did not repeat the detailed analyses that are already available
	Reference to proficiency testing requirements—unclear relevance	Addresses current expectations of measurement precision and accuracy
	Key issue—precision of measurement methods; references Parsons et al. 2001; Sobin et al., 2011	Added text to discuss studies, including Parsons et al., 2001, concerning preparation and validation of clinical reference materials by expert labs
	Correct text about lead in blood being recent or ongoing exposures to lead; an increase in BLL is recent or ongoing exposure	Revised to clarify
	Expand discussion of adverse health effects; EPA 2006; address non-linear concentration-response (steeper slope at lower BLL)	Added text, but staff did not repeat the detailed analyses that are available
	Issues with discussion of Cal OEHHA: incorrect reference to de minimus change in IQ (should be change in BLL)	OEHHA report referred to de minimus change in BLL; Carlisle paper, as cited by staff, refers to change in IQ—unclear why authors of the two docs (mostly same people) changed the emphasis and wording
	Move discussion of OEHHA work to "Public Health Protection"	Re-organized text
	Differentiate IQ in individuals vs. populations	Addressed individual vs. population
	Inaccurate discussion of EPA regulatory action:	Staff revised and clarified text; intent was to express (although more briefly) the information provided by this reviewer
	Incorrectly indicated that EPA characterized a "relatively small subset of children"	While this text is not a quote of EPA, staff is referring to 73 FR 67000 where EPA indicates their focus on a high percentile (unquantifiable)
	Incorrectly indicated that EPA "cannot quantitatively describe this group"	73 FR 67000 describes the unquantifiable subgroup in terms of size of the group; staff did not intend to imply that EPA did not describe a quantitative estimate for IQ loss in the subgroup; text was revised
	Inaccurate conclusions about EPA's response to the CASAC comment; reviewer states, "In response, EPA stated that they agree that NAAQS should prevent air-related IQ loss of a significant magnitude in all but a small percentile of the population…."	Staff intended to express exactly the information discussed in this comment—that EPA agreed with the CASAC's view, and that the framework considers air-related IQ loss in a high percentage of the population; text was clarified
	Report needs to include the context for CPSC: children's products, and magnitude of current BLLs	Included context of the discussion—children's products that may be considered for exception to the lead content limits under certain conditions

2.1.4	Inaccuracies in health effects summary: use of primary target, ongoing; non-linear concentration-response	Revised text
	Distinguish population and individual risk; confusion in concepts related to measurable increase in BLL and concepts related to measurable adverse effects on public health	Revised text to address increased BLL (as indicated in the statute); clarified in context of public health—wording of the statute complicates this; addressed that measurable change in BLL needs to be considered in the context of public health, not just in terms of measurement (because one might think of a situation involving adverse effect on public health at exposure levels that would be within the ability to measure)
	Misleading description of EPA focus on air-related lead exposure (not just breathing)	Clarified inaccurate text
2.1.5	Distinguish population and individual predictions or measurements of BLL; IEUBK is populations, and can indicate incremental change in BLL with relatively small changes in intake, and can predict small shifts in BLL population distribution	Clarified text
	For the proposed criteria: clarify intake vs. uptake of lead; clarify averaging time for modeling; clarify parameter of the distribution	Mean intake and BLL increase was used in draft
2.2.1	What is the technical rationale that products at 100 ppm will not exceed the proposed increase in BLL?	The lead content requirement is by statute; staff has not evaluated potential exposure from complying products
	Need to account for aging and deterioration of the product in determining migration potential.	This issue is part of testing of products, but not directly part of the public health exception criterion; results of testing will be evaluated in the context of the criterion.
	Wipe methodology seems reasonable; references needed.	This was provided for convenience, but is not directly tied to the development of the public health exception criterion; deleted
2.2.2	Unclear if linear regression is basis of health endpoint; need discussion of mode of action to support.	There is evidence for a non-linear association between BLL and IQ deficit; revised text to discuss, focus on lower concentration range (applicable to most of the population)

2.2.3	The report seems to conclude that the measurable increase in BLL is not useful	This implication is not intended; while the Act specifies the definition of no measureable adverse effect public health, staff intended to supply some context to this by including implications of lead exposure that are not tied to the practical nature of measurement abilities; *i.e.* staff sought to demonstrate that decisions made about measurable increase in BLL are consistent with public health protection
	Report needs to indicate why OEHHA characterization is relevant.	While the contexts are different, analyses and conclusions of others related to lead exposure (and defining and preventing excess exposure) can help support CPSC conclusions
	Report seems to address IQ effects in only the children playing with the specific product in concluding no effect on public health, and implies (incorrectly) that support is provided by EPA's statements; further, the reviewer indicates that EPA must consider protection of any (sensitive) subgroup of the population	Staff's discussion of EPA findings unintentionally oversimplified a complicated analysis. Staff specifically included statements by the advisory committee (and EPA's agreement) about the implications of population-wide decreases in IQ to address the question of measurable adverse effects on public health or safety; EPA's framework included loss of 1–2 IQ points; subsequently, advisory committee members cautioned that "a population loss of 1–2 IQ points is highly significant from a public health perspective," and that this level of effect should be "prevented in all but a small percentile of the population;" because EPA ultimately chose loss of 2 IQ points for consideration in the framework, staff concluded that (at least for this specific proceeding) EPA considered that up to a 2 point IQ loss was protective of even the sensitive subgroup of the population
	Suggests CPSC consider the adversity of effect on the most exposed subgroup (those with full-time contact with the product), and consider impacts of the full lifecycle of the products on public health or safety	Staff analyses may tend to be conservative, but not necessarily worst case; lifecycle of the product can be considered in the case-by-case product testing and evaluations part of an assessment
	Footnote: the protection of public health includes the exposed subgroup of children	Staff agrees, but did not clearly express that a specified level of IQ loss in a population can be significant to public health, but not significant for individual health; small change (1-2 points) in IQ is not meaningful in the individual (and would not necessarily be discernible in the individual); however, public health also may deal with situations of varying levels of risk in a population, where a small percentile may experience adverse health outcomes (*e.g.*, 1 per million as acceptable level of cancer risk in a population)
	Consider current distribution of BLLs in children, as an increase in 1 µg/dL is substantial increase in a median-level child (2007-2008 about 1.4 µg/dL)	Added text to discuss current BLL information

2.2.4	Mouthing/ingestion seem reasonable as dominant pathways of exposure; other pathways may be relevant	The statute does not provide for an exception in the case that the product or component is likely to be mouthed to ingested; therefore, products will be assessed on whether those pathways are likely, and, if not, the other possible routes of exposure, such as hand-to-mouth transfer
2.2.5	Ambiguities in the association of intake and BLL need to be clarified: baseline conditions, shape of distribution (GSD), percentile (using IEUBK, as an example) The period of exposure is important in considering the magnitude of BLL, but is not an issue for the change in BLL with respect to narrower age ranges	Clarified model inputs Staff agrees; while different ages have different exposures and BLLs, a change in BLL with a specific exposure is not very sensitive to the different age ranges
2.3.1	Address the concerns given above, and conclusions and recommendations appear to be supported	Reviewer comments carefully considered
2.3.2	Expand on mode of action	Staff did not repeat the detailed analyses recently completed by others; analysis draws on previous extensive work
2.3.3	Report doesn't have clear rationale for conclusion about the change in BLL with measurable effect on public health No rationale for focus on OEHHA's judgment in their own exposure circumstance, and claims about no measurable effect if the affected group is small, public health protection should include affected children Conclusion about 1 µg/dL increase in BLL as not measurable is not supported	Revised text to better support conclusions Clarified that the affected population is expected to be small <u>and</u> that the potential for harm for the affected individuals is insignificant Text focuses on the measurement and precision; conclusions are also supported with public health info; *i.e.*, even increases that cannot be measured could be associated with unacceptable risk, but that is not the case here

2.3.4	Conclusions not in line with recent ACCLPP position to reduce all lead exposure to the extent feasible; staff indicated that Commission did not find that it is not technically feasible to meet 100 ppm limit	Staff disagrees that the draft's conclusions are at odds with ACCLPP position; further, CPSC statute provides for exceptions to the lead content requirements for children's products only under strict criteria that severely limit the products granted an exception; criteria include practicability and feasibility, and exposure and health; technological feasibility has a specific statutory meaning, the criteria for exception also includes practicability which addresses whether compliance is possible in practice
	In large population studies, difference in BLL less than 1 µg/dL are discernible	Staff agrees that an exception should not result in population changes in BLL, but also believes that exceptions will not affect large populations because of the strict criteria for exception, and the expected very small potential exposure from exceptions (very much less than the figures discussed in the report)
2.3.5	This comment discusses the distribution of BLLs, and the effect of an increase in exposure with the upper percentile estimated as increases in 1.5-2 µg/dL in the 97–99th percentiles	Staff draft had considered the central part of the distribution in which a 6 µg/day increased intake would increase BLL about 1 µg/dL; revised to consider the distribution and implications for highest percentile
2.4.1	None	
2.4.2	Use of negligible and exposure in disingenuous in a no-threshold situation; should use *de minimus*, and define the *de minimus* risk level	The difficulty is in the language, not the concept; "*de minimus*" is a term with legal connotations, and staff tries to avoid using it; insignificant may be more useful in this context, because staff believes that the actual exposures from excepted products, and the effect of the exposures, will likely be far less (perhaps orders of magnitude) than the figures discussed in the draft, *i.e.*, 6 µg/day increased exposure, 1 µg/dL increased BLL, 1-2 point IQ loss; the report focuses on the measurement issue per the Act, and support the conclusion with the public health implications
	The association between 6 µg/day increased exposure and 1 µg/dL increased BLL is not obvious	Clarified the use of biokinetic models
	Discuss mode of action	Staff did not repeat the detailed analyses recently completed by others; analysis draws on previous extensive work

2.4.3	What is the point of discussion of BLL changes smaller than 0.1 µg/dL?	This information is discussed prior to the draft conclusion about 1 µg/dL change to provide another angle to the discussion of significant and relevant changes in BLL
	Why are the models informative? Also include information about distributions.	Draft report focused on the measurement issue per the Act; supported the conclusion with public health discussion; the utility of the models is to provide estimates of the level of exposure that would result in the measurable increase in BLL; important for evaluation of the product and potential for exposure to the lead in the product
	May need to consider influence of age on BLL.	Yes, but age may not be a key consideration in changes in BLL
	Incorrect characterization of EPA action as focusing on breathing.	Characterization of EPA action corrected; intent was to discuss that EPA's mandate involves a more pervasive type of exposure that consumers do not control, while the children's product exposures are important only for children who use the particular products (expected to be a small proportion of products)
	Unclear source for the association between 6 µg/day increased exposure and 1 µg/dL increased BLL.	Clarified use of biokinetic models
2.4.4	None	
2.4.5	Reviewer can provide Excel file with IEUBK model runs	Staff used IEUBK to explore BLL model results