



U.S. CONSUMER PRODUCT SAFETY COMMISSION

4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814-4408

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Chairman Inez M. Tenenbaum
 Commissioner Nancy A. Nord
 Commissioner Anne M. Northup
 Commissioner Robert S. Adler

ITEM:

Petition Requesting Exception from Lead Content Limits; Notice Granting Exception
(Briefing package dated March 21, 2012)

DECISION:

The Commission voted unanimously (4-0) to approve publication of the draft notice with changes in the *Federal Register* granting an exception on a petition submitted by Joseph L. Ertl, Inc., Corporate office of divisions: Scale Models and Dyersville Die Cast for its die-cast, ride-on pedal tractors under section 101(b) of the Consumer Product Safety Improvement Act, as amended by Public Law 112-28. Chairman Tenenbaum and Commissioners Nord, Northup and Adler issued the attached statements regarding this matter.

For the Commission:

A handwritten signature in black ink, appearing to read "Todd A. Stevenson".

Todd A. Stevenson
Secretary

* Ballot vote due March 30, 2012
(Chairman Tenenbaum extended the due date from March 27, 2012.)

Attachment: Statement of Chairman Tenenbaum
 Statement of Commissioner Nord
 Statement of Commissioner Northup
 Statement of Commissioner Adler



**U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814**

CHAIRMAN INEZ M. TENENBAUM

**STATEMENT OF CHAIRMAN INEZ M. TENENBAUM ON THE PETITION
OF JOSEPH ERTL, INC. FOR AN EXEMPTION FROM THE LEAD CONTENT LIMITS
FOR CERTAIN COMPONENTS OF ITS RIDE-ON PEDAL TRACTORS**

April 27, 2012

I join my colleagues in applauding the Commission's unanimous vote to grant the petition of Joseph Ertl, Inc. for an exception from the lead content limit of 100 parts per million (ppm) for certain aluminum alloy components of its die-cast, ride-on pedal tractors. This outcome is not only a demonstration of my commitment to common sense application of the lead content limits when necessary, but also a vindication of the "functional purpose" exception itself.

Background of the Functional Purpose Exception

On September 10, 2009, just two short months after becoming Chairman, I testified at my first U.S. House of Representatives Committee on Energy and Commerce oversight hearing and was asked whether the U.S. Consumer Product Safety Commission (CPSC) needed additional flexibility with the lead content limits established by the Consumer Product Safety Improvement Act of 2008 (CPSIA). This line of questioning stemmed from the fact that the CPSIA, as originally enacted, contained only two exemptions from the lead content limits that provided relief for certain components of children's products. Those two provisions established exclusions for certain electronic devices and inaccessible component parts of children's products. A third exemption in the law, commonly referred to as the "any lead" exclusion, proved too inflexible to provide relief, resulting in some legitimate concerns about the lack of a meaningful exemption provision in the law for components of products that did not fit within the first two exemptions.

The "Any Lead" Exemption

In order to grant an exclusion using the "any lead" exemption, the Commission was required by statute to determine, by regulation, that the lead in the product would "neither result in the absorption of any lead into the human body . . . nor have any other adverse impact on public health or safety." Starting in 2008, before my tenure as Chairman even started, the Commission denied each petition seeking an exemption under the "any lead" exclusion because, in each petition submitted, the manufacturer admitted that a small amount of lead was present in the product that could be handled by the child and result in the hand to mouth ingestion of minuscule amounts of lead in a child's body. In considering these petitions, the Commission correctly interpreted the plain words "any lead" to mean just what the statute said—*any lead*—which resulted in the denial of those petitions.

Some critics contended that the Commission's interpretation of the "any lead" exclusion was more inflexible than Congress intended, and the language could have been interpreted to grant exclusions where children could not ingest the lead in an amount that would lead to "a meaningful increase in blood lead levels." However, neither the CPSC staff, nor four of the five Commissioners serving during the time when these petitions were considered, accepted this broader interpretation of the plain statutory language.

The Renewal of Functional Purpose

Following the September 2009 CPSC oversight hearing, I received a written question from then Subcommittee on Commerce, Trade, and Consumer Protection Ranking Member George Radanovich, who asked me about my support for potential statutory exclusions for certain products from the lead content limits. In response to this question, I convened a meeting with CPSC's toxic metals experts in which we discussed the concept of a functional purpose exception to the lead content limits. CPSC staff was already very familiar with this type of condition for an exemption because the Commission had already adopted a similar requirement as a part of its interpretive rule on exclusions from the lead limits for certain electronic devices. Under this rule, exemptions for certain electronic devices are allowed only where "*the use of lead is necessary for the proper electronic functioning of the component part* and it is not technologically feasible for the component part to meet the lead content limits."¹

Additionally, the agency had long recognized the functional purpose provision of the Federal Hazardous Substances Act (FHSA), which gave the Commission the ability to exempt "articles, such as chemical sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved" from consideration as a banned hazardous substance.² Although this functional purpose provision of the FHSA was superseded by the requirements of Section 101 of the CPSIA as it relates to lead content in children's products, the new functional purpose provision in PL 112-28 restores the same basic principle it embodied.

After exploring the concept of this exception within the agency and growing comfortable with it personally, I sent Mr. Radanovich a response to his question on October 16, 2009, that outlined a functional purpose exception.³ In the twenty-two months that followed, I continually advocated for a functional purpose exception to the lead content limits.

The Functional Purpose Exception: The Right Approach

During Congressional consideration of various options to add some additional flexibility to the Section 101 lead limits, the functional purpose concept was subject to a number of exaggerated criticisms by those who sought much larger exceptions or wholesale repeal of the landmark

¹ 16 CFR §1500.88(c)

² 15 U.S.C. § 1261 (q)(1)(B)(i)

³ In response to then Ranking Member Radanovich's question, I stated: "[I]t would be helpful to have a narrow exception to the overall Section 101 lead prohibition in cases where a component with lead is required for a functional purpose, contact with the lead is infrequent, and the elimination of such component part is impracticable or impossible based on available scientific and technical information."

Section 101 lead limits. My support of the requirement for a petitioner to meet the basic functional purpose criteria to obtain an exception to the lead content limits has remained consistent and is based on the fact that lead is a powerful neurotoxin and virtually all experts have concluded that there is “no known safe level of lead.”⁴ In the end, I was gratified that Congress almost unanimously supported this approach as the only health-protective, workable option.

The Commission’s unanimous vote on the Ertl Petition shows that the functional purpose exception was the appropriate legislative solution. The decision also puts to rest the major criticisms of the functional purpose exception, including claims that:

- The exception will only apply to a “null” set of products.

While this vote does not guarantee how the Commission will handle future petitions from manufacturers of different products, I believe it is particularly noteworthy that the very first petitioner was able to successfully obtain an exception for their products. Using a totality of factors approach that took into account each of the considerations surrounding the statutory criteria, staff was able to analyze this petition carefully and come to a recommendation that the Commission grant the exception.

- Exceptions granted under this type of provision cannot be extended to a product class and every individual company within a product category will have to individually petition the agency to receive relief.

For this petition, staff was able to survey the relatively small market for ride-on toys and therefore confidently recommend that an extension of the same exceptions granted to the petitioner was suitable for the entire class of these particular products. The Commission accepted staff’s recommendation, meaning no other companies manufacturing these types of ride-on toys must seek the same exception.

- The functional purpose exemption will only benefit very large businesses with the resources needed to incur the expenses associated with consulting the legal and scientific experts required to put together a petition.

This petitioner was financially constrained but able to submit a substantive petition, albeit missing a few data points, and receive an exception under the functional purpose provision.⁵ While I share Commissioner Adler’s concern for the somewhat incomplete nature of the petition and his appreciation of the extra steps that staff undertook to handle those missing data points, I note that this is the first petition we have received. It is my hope that any future petitions will contain the data needed for staff to more easily make a recommendation to the Commission.

⁴ <http://www.cpsc.gov/pr/tenenbaum01152010.pdf> at 3; Commissioner Adler has also provided some background on this point in his statement on this vote (<http://www.cpsc.gov/pr/adler04252012.pdf> at 1, 2).

⁵ <http://www.cpsc.gov/pr/adler04252012.pdf> at 4, 5.

- The provision requiring petitioners to show the need for an exception on a component basis is unworkable.

The petitioner was able to specifically identify and tailor the request to only those components for which an exception was needed. I was especially comforted by the fact that the petitioner tailored this request in the same manner that Congress wrote the statutory provision allowing for a 300ppm lead content limit for just those components of bicycles that could not meet the 100ppm limit.

- Companies would flood the agency with requests for functional purpose exceptions, thereby diverting valuable agency resources away from more pressing safety issues.

Unsurprisingly, the agency has received only one functional purpose petition in the seven months since the functional purpose exception became law, and our staff was able to consider it with an immaterial impact on agency resources. The existence of only one functional purpose petition and lack of any petitions concerning the technological feasibility of the 100ppm lead content limit further evidences that the Commission made the right decision regarding the technological feasibility of the 100ppm lead content limit.

- The Commission's ability to, after granting an exception, require an alternative lead content limit higher than the 100ppm limit would reduce the appeal to manufacturers of submitting a petition seeking an exception.

Not only was this petitioner undeterred from submitting a petition to the agency, the petitioner did not even seek a complete exemption from the lead content limits. Instead, the petitioner only sought an increase in the permissible lead content limits up to 300ppm and submitted extensive test results showing it could meet the 300ppm limit for its products. This petitioner has set an excellent precedent that I strongly encourage and will expect any future petitioners to follow.

- The likelihood of a petitioner successfully obtaining a functional purpose exception is low given the membership of the Commission.

I am pleased that the Commission unanimously granted this petition, and I look forward to working with my fellow Commissioners on any future petitions.

Moving Forward

I would like to echo the sentiment of my colleagues cheering the unanimity of this decision and express my shared desire to work together on any future petitions. I also want to thank our professional staff for their excellent work dating back to the first consideration of a functional purpose exception all the way forward to the approval of CPSC's first functional purpose petition over two years later. Working together, we as an agency can utilize this new tool to provide common sense relief from the lead content limits where it is warranted.



**U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814**

COMMISSIONER NANCY A. NORD

**Statement on the Commission's decision to approve
the petition of Joseph L. Ertl, Inc., requesting an exception from
the lead content limits for children's products**

April 9, 2012

For the first time since Congress passed the Consumer Product Safety Improvement Act of 2008 (CPSIA), the Consumer Product Safety Commission has granted a petition for exception from the statutory limit on lead content allowable in children's products. I was pleased to join my colleagues in unanimously granting the petition. The petitioner's product met all the statutory requirements for obtaining an exception, which included demonstrating to the Commission's satisfaction that reasonably foreseeable use and misuse of the product will not have an adverse effect on public health or safety. I hope that the analysis the Commission approved will provide guidance to the public—and to the staff—on effectively using the exception process to obtain relief from an onerous requirement that does not necessarily increase public safety.

Background

In the CPSIA, Congress mandated that the permissible lead content for children's products be lowered to 100 parts per million (ppm) in 2011 unless the Commission determined that this level was not technologically feasible. By a divided vote, the Commission determined that it could not find the lower limit technologically infeasible, and thus the 100 ppm cap became law.

After the CPSIA was passed, Congress was deluged with complaints about the draconian nature of the law and its lead limits. Businesses small and large, consumers, and groups ranging from libraries to secondhand shops pointed out that many provisions of the CPSIA were not necessary to protect public health and that many aspects of the legislation would have devastating unintended consequences. The Commission learned of many businesses which were closed because of the inflexible nature of the law, including the lead content limits. As a result, Congress amended the CPSIA, fixing some of the glaring inequities in the law and creating a special process for the Commission to use to exempt certain products from the stringent lead limits.

Pursuant to this process, Joseph L. Ertl, Inc., filed a petition seeking exception for the company's scale-model farm tractors and trailers—ride-on toys for children ages 3 to 10—whose components cannot meet the 100 ppm limit. The components are made from

aluminum alloys that contain trace amounts of lead. The Commission staff analyzed the petition and recommended granting an exception. The Commission did so unanimously.

The Commission's—and the staff's—analysis shows the path ahead.

The Commission's staff conducted a thorough, holistic analysis of the Ertl petition in light of the statutory requirements, summarized here:

In response to a petition for an exception for a product or product category from the lead limits of CPSIA § 101(a), or on its own, the Commission *must* grant an exception to lead limit if

- removing the lead is not practicable or technologically feasible,
- the product will not be mouthed or ingested in normal use or misuse, and
- public health and safety will not be negatively affected because children's blood lead levels will not measurably increase.¹

The analysis rests on several determinations and assumptions that can serve as a guide to future applicants for exceptions.

Practicability

First, staff found that it was impracticable for Ertl to remove or reduce the lead content in its toys to meet the 100 ppm limit, even though it was technologically feasible (following from the Commission's unfortunate July 2011 determination). For example, to meet the 100 ppm limit, Ertl would have to purchase a minimum of 7 years' worth of material at a cost of 15% of the company's annual sales. Further, among the aluminum alloys that could satisfy a higher lead limit, one could consistently satisfy a 300 ppm cap, while another alloy could satisfy a 200 ppm cap. We did not, however, think it necessary for the company to use the second alloy because it was more expensive and less available than the alloy that could meet a 300 ppm cap. Thus, the Commission took market conditions into account in acknowledging that meeting the 100 ppm limit was impracticable, and—considering the exposure analysis discussed below—determined that the company could use a material more available in the market to achieve a less-stringent limit than could be reached with a rarer, more expensive material.

We also relied on other factors to conclude that eliminating or reducing the lead content to meet the 100 ppm limit was not practicable: other potential avenues of eliminating lead were unwieldy because they would have required substantial retooling

¹ CPSIA § 101(b)(1), Pub. L. 110-314, 122 Stat. 3016 (Aug. 14, 2008), as amended by Pub. L. 112-28 § 1, 125 Stat. 273 (Aug. 12, 2011).

of the company's manufacturing process, because they would have prevented the company from achieving the aesthetic standard that the company and its customers desired (that is, accurately mimicking the appearance of full-size farm equipment), and because they would have rendered the toys unfit for their intended use, perhaps driving the company from the scale-model ride-on toy market. This analysis demonstrates that these factors in combination—costs, market conditions, the manufacturing process, and company and consumer preferences—are relevant to a determination of practicability. This broad conception of practicability takes into account the realities of the modern manufacturing and supply chain, and balances exceedingly low risks against disproportionate costs. This allows the Commission to make the smart regulatory choice that protects consumers' safety and choice.

Mouthing & ingestion unlikely

Second, children are unlikely to mouth or ingest the lead-containing components on Ertl's ride-on toys. Users would be at least 3 years old, above the age where mouthing occurs most frequently. Indeed, mouthing was not a great concern, given that the product's design prevented children's mouths from reaching the lead-containing components during normal use. And the components could not fit in a child's mouth anyway. Additionally, the toy's powder-coat finish made the actual transfer of lead from a component to a child's hand (the most likely method of lead ingestion being hand-to-mouth movement) exceedingly unlikely. This was so even though use of the finish could not render lead content inaccessible (as a matter of law), because the coating would prevent a child from accessing the lead except in cases where wear and tear removed some or all of the finish. (Again, this judgment was affected by the exposure analysis discussed below.)

No adverse effect on public health or safety

Finally, the staff determined that the requested exception would not have an adverse effect on public health or safety, in light of reasonably foreseeable use and abuse of Ertl's toys. This determination was made on the basis of the statutory requirement that the "exception . . . result in no measurable increase in the blood lead levels of a child."² To make this determination, staff took the position that the most likely method by which lead would enter a child's blood was by hand-to-mouth contact after the child touched a lead-containing component. Staff then determined, by reference to studies of exposure from other products, that—under conditions close to the worst case scenario—a child's actual ingestion of lead could be 0.6 micrograms (μg) per day of use. Theoretically calculated, this exposure could result in a 0.1 μg per deciliter increase in blood lead

² *Id.* § 101(b)(1)(B).

levels. This degree of increase is not measurable using current tools and methods. Staff did not find it necessary to perform any testing on the product here. The analysis indicates that when actual exposure is so minute as to make a theoretical blood lead level increase undetectable and essentially speculative, then we will not find an adverse effect on public health or safety.

The petition was correctly granted.

Based on the analysis presented to us by our staff, we must conclude that the Ertl Company's ride-on tractors and trailers have no adverse effect on public health or safety, and must grant the petition. Importantly, in the analysis, we did not see fit to micromanage Ertl's manufacturing process. Instead, we considered the product, the market, and the risks in a rigorous manner that took into account the world as it is. It is, therefore, fitting that we acknowledged that similar component parts in ride-on toys pose equally low risks, and that we extended the exception to them.

The Commission's decision is smart regulatory action. Now that the Ertl Company has gone through this process, I hope that other, equally deserving manufacturers will use this process to seek relief from the 100 ppm lead limit. Potential applicants should take note: If a petition meets the statutory requirements, the Commission *must* approve it. Congress did not give the Commission discretion to do otherwise. What is more, the Commission has the power to grant exceptions without waiting for a petition. I hope the Commission will proactively use this authority to relieve the regulatory burden of the 100 ppm cap.

Finally, I would be remiss if I did not acknowledge the unanimity of this decision. I am pleased that my colleagues and I could work together on this issue. After a time when agreement among the Commissioners was rare, agreement on a matter as important as this suggests that Commissioners are finding ways to bridge their differences.



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

COMMISSIONER ANNE M. NORTHUP

STATEMENT OF COMMISSIONER ANNE M. NORTHUP ON THE PETITION
REQUESTING AN EXCEPTION FROM THE LEAD CONTENT LIMITS: ERTL SCALE
MODELS AND DYERSVILLE DIE CAST

April 5, 2012

I write to applaud the unanimous vote to grant an exception to the 100 ppm lead content limit for certain children's ride-on pedal tractor component parts made with aluminum alloys. The vote represents a watershed moment in the Consumer Product Safety Commission's approach to the regulation of lead in the metal substrate of children's products. It establishes for the first time bipartisan acceptance, based on the expert advice of CPSC's professional staff, of the principles that (1) lead in children's products presents a risk of harm only to the extent that children are exposed to the lead; and (2) metal substrate containing 300 ppm of lead that is not likely to be placed in the mouth, ingested, or *extensively* contacted by children does not present a health risk, because it does not measurably increase blood lead levels. Based on these conclusions, I believe a wide range of additional products should be similarly excepted from the 100 ppm lead content limit. I therefore encourage product manufacturers to petition for relief, and urge my fellow Commissioners to support me in exercising our authority to initiate additional exceptions as appropriate.

Staff's determination that no measurable increase in blood lead level would result from a child's exposure to certain aluminum alloy components of a ride on tractor containing 300 ppm of lead was not a close call. Staff has conducted extensive wipe-testing of metal jewelry items and vinyl bibs containing far more lead – up to 100,000 ppm (equivalent to 10 percent lead), and these tests resulted in average lead transfers per wipe of less than 0.02 micrograms of lead. *See* Staff Briefing Package: Request for Exception from CPSIA Section 101(a) lead content limit for Pedal Tractors from Joseph L. Ertl, Inc., Scale Models of Dyersville Die Cast Divisions (March 21, 2001) (“Ertl Briefing Package”) at 30. Based on “[e]xtensive scientific literature and several physiologic models” describing the relationship between exposure and blood lead level, staff estimated that even exposure to as much as 1.2 micrograms per day, in *addition* to default inputs for lead from sources such as diet and soil, does not result in a measurable increase in the blood lead level of children ages 3-7 years. *Id.* at 31. Staff further estimated that a child could have between no contacts and several contacts with a ride on pedal tractor on any given day. *Id.* at 31-32. Thus, even using an average per wipe exposure of materials having far more lead than the component parts at issue here, and the relatively high number of 60 contacts per day ($1.2/.02 = 60$), there would still be no measurable increase in blood lead levels, and therefore no adverse impact on public health or safety.

Notably, Ertl also satisfied the other criteria for the grant of an exception to the 100 ppm lead content limit, based on circumstances that are likely present in connection with many other products containing lead in metal substrate. The CPSC has authority to except from the 100 ppm lead content limit a product, class of product, material, or component part that, in addition to not resulting in a measurable increase in the blood lead level of a child: (1) requires the inclusion of lead because it is not *practicable* or not technologically feasible to manufacture it by removing excessive lead or by making the lead inaccessible; and (2) is not likely to be placed in the mouth or ingested. 15 U.S.C. § 1278a(b)(1)(A)(i)-(iii).

Practicability is evaluated on a case-by-case basis taking into account a number of factors, including the utility of the substitute material, the availability of materials with less than 100 ppm lead, relative cost, inaccessibility considerations, conformity assurance and technological feasibility. Ertl Briefing Package at 2, n. 1. The CPSC concluded that it was not practicable for Ertl to manufacture the pedal tractor components using aluminum alloy with 100 ppm of lead, in part because the minimum quantity available for purchase represented a seven year supply at Ertl's rate of manufacture, and would require about 15% of the company's yearly sales to purchase it. Ertl Briefing Package at 13. Other materials, such as plastic, zinc or steel were determined not to be practicable, because they would either change the "appearance" of the product, result in a much heavier product, or require Ertl to invest in new metal stamping technology and training, which would increase the per unit production cost. Ertl Briefing Package at 3. Staff had a choice between recommending that Ertl be required to use aluminum alloy containing 200 ppm or 300 ppm of lead, both of which were equally attainable in the quantities needed. Staff concluded that 300 ppm was practicable, because the 200 ppm alloy would increase manufacturing costs by 1% over that of the 300 ppm alloy. *Id.* Making the aluminum alloy inaccessible by introducing a covering was deemed not practicable because it "would represent a change in [the] current manufacturing process." *Id.*

While practicability must be assessed on a case-by-case basis, several important principals can be gleaned from staff's approach to the Ertl petition. First, a petitioner may be entitled to retain the current appearance of a product for "aesthetic" reasons, i.e., metal vs. plastic, if its customers prefer it. *Id.* Indeed, significant differences in "general appeal to consumers" can support considering a model made with a different material to be a "different product." *Id.* at 20. In addition, a petitioner need not undermine the functionality of the product in order to reduce its lead content, by, for instance, increasing its weight to an extent that impedes maneuverability. The Ertl case also highlights the importance of cost differentials. The fact that introduction of a new material would increase the cost of manufacture by necessitating a change in the manufacturing process was a factor in favor of granting the petition. Indeed, even a 1% increase in total manufacturing cost justified favoring aluminum alloy with 300 ppm of lead over aluminum alloy with 200 ppm of lead. The accessibility of an alternative with less lead is also key, and in that regard, the mere fact that a market exists does not warrant a finding of practicability. As the Ertl case demonstrates, the need to warehouse amounts in excess of that needed for ongoing manufacturing purposes also weighs against a finding of practicability.

With regard to the likelihood that a component will be placed in the mouth or ingested, the size and location of the component are central considerations. So long as the component is too large to be ingested or placed in the mouth, the only route of lead exposure is through hand to mouth activity. And as staff's health sciences experts concluded, components containing 300 ppm of lead in metal substrate that are not "extensively contacted by children" do not expose children to sufficient lead through hand to mouth contact to measurably increase blood lead levels. *See Draft Federal Register Notice – Petition Requesting Exception from Lead Content Limits; Notice Granting Exception (as amended March 30, 2012) at 5.* Notably, in the case of the Ertl ride on tractor, this included the main body casting, which CPSC's human factors experts determined was the component most likely to be touched by a child playing on the tractor. Ertl Briefing Package at 26.

Based on staff's analysis of the Ertl petition and the principles that can be derived from it, there are other candidates for potential exception. These include: tricycles, scooters, certain sporting equipment, hobby horses, pogo sticks, and skate boards, just to name a few that come readily to mind.

While I am pleased that the functional purpose exception included with the 2011 amendments to the Consumer Product Safety Improvement Act may have greater utility than I feared, recognition of these principles comes too late and at far greater cost than was necessary. As originally enacted, the CPSIA permitted the Commission to exclude from the reduced lead limits products that would neither "result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child," nor have any other adverse impact on health or safety. CPSIA § 101(b)(1). It is clear from staff's conclusion in the Ertl case that many product components containing 300 ppm – or even 600 ppm -- of lead in metal substrate that are too large to be ingested or placed in the mouth would not result in the *measurable* absorption of any lead. Yet the Commission determined in 2008 that the absorbability exclusion could never be satisfied by any material, product or component. During the succeeding three years, many businesses that might satisfy the criteria applied in Ertl under the new functional purpose exception have closed, substantially reduced their product line, or compromised the durability or functionality of their products, because they could not practicably reduce the lead in their products, despite the fact that the products presented no risk of meaningful lead exposure.

The Ertl petition vote similarly highlights the unnecessary economic harm caused by the Commission's party-line vote to reduce the lead standard to 100 ppm based on the questionable conclusion that there is no product, class of products, materials or components for which it is not "technologically feasible" to do so. Most obviously, the conclusion was reached for aluminum alloy, which we now know does not present a risk of harm to children at 300 ppm of lead when used in larger component parts. The testing that underlies staff's conclusion that such aluminum alloy is not a health risk could support the same finding for other metal substrate containing 300 ppm of lead when used in a component that is not ingestible or able to be placed in the mouth. But instead of

adopting a blanket exception, the Commission has left it to individual manufacturers to bear the expense and delay of petitioning the Commission for relief.

In conclusion, I applaud the Commission's decision to finally recognize that certain components of children's products containing 300 ppm of lead in metal substrate do not present a risk of harm because they do not *expose* children to sufficient lead to measurably increase blood lead levels. I hope that this milestone decision invites additional petitions and inspires the Commission to independently consider other opportunities to alleviate the unnecessary economic harm caused by its 100 ppm decision. I only wish the rational approach represented by the Commission's adoption of staff's analysis of the Ertl petition had prevailed sooner.



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

**Statement of Commissioner Robert S. Adler
Regarding the Petition of Joseph Ertl, Inc., for an Exemption From the Lead
Content Limits for Certain Components of Its Ride-On Pedal Tractors**

April 25, 2012

On March 27, 2012, the Consumer Product Safety Commission unanimously voted to grant an exception¹ from our lead content limit of 100 parts per million (ppm) to Joseph L. Ertl, Inc., (hereinafter, “Ertl” or “petitioner”) for the aluminum alloy parts of its die-cast, ride-on pedal tractors. I was pleased to join in this vote, which I believe represented a thoughtful and measured approach to implementing the statutory mandate that governs the Commission’s regulation of lead. That said, I feel it useful to add a few words to explain what I think our vote represents and what it does not.

Background

Lead is a powerful neurotoxin that accumulates over time. Even low levels of lead are widely associated with learning disabilities, decreased growth, hyperactivity, impaired hearing and brain damage. The regulation of lead has been a controversial topic almost since the day the Consumer Product Safety Commission began operations. Over the years, the Commission has struggled with lead issues, including lead in paint, lead in candles, and lead in children’s products. And, as safety studies have become more refined, our understanding of lead’s hazards has expanded, leading to greater restrictions on its use.

In fact, the history of lead regulation has consistently shown that each time a standard for lead has been set, new evidence has surfaced that demonstrates that even lower levels of lead can harm consumers, especially young children. Children have proven to be more vulnerable to lead’s effects than adults for several reasons: they tend to mouth things in

¹ I shall use the terms “exception” and “exemption” interchangeably throughout this statement.

the environment, their gastrointestinal tracts tend to absorb more chemicals than adults, and their developing nervous systems are thought to be more vulnerable to lead than adult systems.² In fact, virtually all experts have concluded that there is no known “safe” level of lead. The most that can be said is that below certain lead levels, science currently cannot measure adverse health effects. The lack of measurable adverse effects at these low exposure levels, however, does not mean that no such effects occur.

More broadly, one should note that lead hazards continue to plague our society. Despite major strides towards reducing lead exposure in young children in recent years, the United States still has an unacceptably large number of children with elevated blood lead levels.³ To be sure, most of the problem relates to matters outside of the CPSC’s jurisdiction, such as lead paint in older houses and apartments, or toxic dirt in inner city playgrounds and neighborhoods. But, the CPSC still bears a significant measure of responsibility given the ubiquity of children’s products and the fact that even small amounts of lead add to the total lead load in children’s bodies.

Based on the most current evidence available at the time, Congress, in the Consumer Product Safety Improvement Act of 2008 (CPSIA), took the regulation of lead to perhaps its most stringent level. In section 101(a) of the CPSIA, Congress set progressively lower lead limits in children’s products from 600 ppm to 300 ppm by statute. Congress then lowered the lead content in children’s products to no more than 100 ppm unless the Commission determined that such a limit was not “technologically feasible.” After analyzing the available economic data and providing an open hearing for members of the public, the Commission staff determined that most manufacturers would find it technologically feasible to meet this standard. Accordingly, the Commission, by majority vote on July 13, 2011, approved the staff’s determination, thereby complying with the statute’s direction to lower the lead limit to 100 ppm.

Exemptions from the Lead Limits

When Congress debated the CPSIA in 2008, a number of manufacturers insisted that they would have great difficulty meeting the new lead limits. In response, Congress first gave manufacturers a six-month grace period before requiring a 600 ppm lead limit for children’s products and then an additional six-month period before moving the limit to 300 ppm. In addition, Congress provided statutory exemptions from the lead requirements for certain children’s electronic devices and for inaccessible component parts of children’s products. Finally, Congress wrote an exclusion provision for products

² For an expanded discussion of lead hazards, I refer the reader to my statement on lead, *Statement on Lead Regulation Under the CPSIA* at <http://www.cpsc.gov/pr/adler01222010.pdf> (January 22, 2010).

³ See, e.g., Los Angeles Times, “Unsafe Levels of Lead Still Found in California Youths,” <http://articles.latimes.com/2012/feb/19/local/la-me-lead-poisoning-20120219>; Environmental Protection Agency, “Basic Information on Lead,” <http://www.epa.gov/lead/pubs/leadinfo.htm>; and “Lead Poisoning,” http://en.wikipedia.org/wiki/Lead_poisoning.

where the Commission determined such products would not produce “any” absorption of lead into the human body nor have any other adverse impact on public health or safety.⁴

In fact, the latter exemption proved too stringent to accommodate the legitimate concerns of some manufacturers. As CPSC staff repeatedly pointed out when the Commission considered various requests by manufacturers for exemptions from the lead standard, virtually all products that contain lead leach some of this heavy metal, even if only infinitesimal amounts, that could be absorbed by a human body. In short, the universe of products eligible for an exemption under this section probably constituted a null set. Needless to say, this caused a number of manufacturers to voice objections to the lack of a meaningful exemption provision in the law.

Congress acknowledged these concerns when it amended the CPSIA by enacting Public Law (P.L.) 112-28. Under this new law, Congress added a “functional purpose” test for exempting products containing lead. As a long-time supporter of such a test, I welcomed Congress’s action. Although I have some misgivings about the precise language in the functional purpose test of P.L. 112-28,⁵ I consider it generally to be a thoughtful and balanced approach to regulating lead. Under this test, the Commission must make three findings in order to grant an exemption from the lead content limit to a children’s product:

- (1) The product requires the inclusion of lead because it is not practicable or technologically feasible to manufacture the product by removing the lead or by making it inaccessible,
- (2) The product is not likely to be placed in a child’s mouth or ingested under reasonably foreseeable use and abuse of the product, and

⁴ Specifically, Congress, in section 101(b) of CPSIA, provided that:

- (1) The Commission may, by regulation, exclude a specific product or material from the [banned lead levels] if the Commission, after notice and a hearing, determines on the basis of the best-available objective, peer-reviewed, scientific evidence that lead in such product or material will neither –
 - A. Result in the absorption 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.

⁵ What causes my misgivings is how Congress defined the term “no measurable adverse effect on public health or safety.” For purposes of our granting exemptions under the new law, the term means that there can be “no measurable increase in the blood lead levels of a child” from exposure to the product. Although I see no particular problem with this standard given the current state of science, I fear two possible unintended outcomes in the future. First, but quite unlikely, it is conceivable that small scientifically unmeasurable amounts of lead might one day be found to produce harmful health effects in children. In such a case, the test would be too lax. Second, and more likely, there may come a time when infinitesimally small changes in blood lead levels carrying no negative health effects might be measurable in a child, thereby triggering an unnecessary rejection of a manufacturer’s request for a product’s exemption from the lead standard.

- (3) An exception for the product will have no measurable adverse effect on public health or safety, taking into account reasonably foreseeable use and abuse of the product.⁶

The Ertl Petition

On September 29, 2011, under the newly-enacted functional purpose test, Ertl requested an exemption from the 100 ppm lead content limit for children's products for its die-cast ride-on pedal tractors. The firm claimed that it was not practicable for it to meet the lead content limit of 100 ppm for the aluminum alloy components of these tractors. As a small manufacturer with 2011 sales of approximately \$1 million, Ertl argued that being forced to purchase complying alloyed metals would, in effect, force it to exit the farm toy business.⁷ The company claimed, however, that it could meet an upper limit of 300 ppm through careful monitoring of its purchases.

With respect to the second prong of the functional purpose test, based on its experience with its customers, the company claimed that a child would be unlikely to extensively touch the areas of the tractor with the metal casting. Rather, the child would typically sit on the seat and hold the plastic steering wheel, neither of which would expose the child to the metal casting. Moreover, although not arguing that the powder coating surface on the metal casting would render the tractor compliant with the lead standard,⁸ the company noted that the coating would tend to reduce contact between the metal casting and the child, thereby lessening the child's exposure to the metal alloy.

Finally, with respect to the question of whether the metal alloys in its products would have a measurable adverse public health effect, the company pleaded lack of financial resources to provide an answer with scientific certainty. Instead, the company referenced the testing that it had subjected its products to over the years – and which it would use for future production – to demonstrate that it could consistently meet an upper limit of 300 ppm.

Staff Analysis of the Ertl Petition

Although the company did not submit extensive human factors data nor any significant scientific data regarding the health risks of its product, CPSC staff did its best to fill in the gaps in the company's exemption request. Frankly, these gaps concern me and make me reluctant to support similar requests from companies with the financial resources to

⁶ Section 101(b)(1)(A)(i)-(iii) of P.L. 112-28.

⁷ In particular, the company indicated that aluminum alloys with less than 100 ppm would entail its having to purchase special "heat batch" materials, with a minimum order size of 120,000 pounds, or roughly seven years worth of material, requiring about 15 percent of its yearly sales just to purchase the materials.

⁸ Section 101(b)(3) of the CPSIA, as a matter of law, bars consideration of paint as a barrier that would render lead in the substrate of a product inaccessible to a child.

provide better data. That said, I applaud the proactive staff steps to deal with the request from this financially-limited company.

Based on its analysis, staff concluded that, although it was technologically feasible for Ertl to make tractors to the 100 ppm standard, the added costs the company would face in doing so made it impracticable to meet the standard. Accordingly, staff concluded that Ertl met (or “failed,” depending on one’s perspective) the practicability requirements for an exemption.

With respect to the issue of a child mouthing or ingesting lead from the component parts in question, staff agreed with the petitioner’s claim that, notwithstanding occasional behaviors that might result in a child’s exposure to the lead-containing components, these parts are too large for a child to place in his or her mouth. Moreover, based on staff’s analysis, they agreed with the company’s claim that users of the tractors are of an age whereby few of them would be likely to engage in mouthing behaviors for the toys they use.

Staff’s consideration of the last finding required in P.L. 112-28 – whether there would be a measurable adverse effect on public health – gives me some concern, although, on balance, I accept their judgment. I start with the fact that the company submitted no evidence regarding whether there would be any measurable adverse effect on public health. I further note that staff never acquired an Ertl tractor for testing to confirm that a child’s exposure to the product would result in no measurable increase in the child’s blood lead level.

What staff did instead was to look to past studies of wipe tests on other products with lead content more than 100 ppm. In particular, staff pointed to data from previous agency tests on metal jewelry and polyvinyl chloride products where lead contents ranged from 100 ppm up to 100,000 ppm (equivalent to 10 percent of the metal in the product). According to staff, even extremely high levels of lead showed transfers from a wipe test (the test that staff would use on an Ertl tractor) that averaged less than 0.02 micrograms (μg) per test. Accordingly, staff concluded that a similarly small amount of lead would be transferred from one of petitioner’s products in such a test. Staff then cited a model from the Environmental Protection Agency (EPA) known as the “Integrated Exposure Uptake BioKinetic Model for Lead in Children” (IEUBK), to predict the likely added exposure to lead resulting from a child’s playing with a tractor every day over a fairly long period of time. In applying the IEUBK model to the Ertl tractor, staff, to be conservative, assumed a higher exposure to lead than 0.02 micrograms:

Staff includes the estimate of the effect on the blood level of daily exposure to 0.6 $\mu\text{g}/\text{day}$ to provide quantitative context to this analysis. If staff were to use the assumption that about half of the lead that might collect on the hands during the day would be transferred to the child’s mouth during the day, it would follow that

about 1.2 µg of lead could collect on a child's hands (*i.e.*, 0.6 µg/ day transferred to the mouth), resulting in the theoretical change in blood lead level of 0.1 µg/dL, a change that is not a measurable increase in the blood lead level.

Staff further stated that it expected that possible daily exposure to lead from the pedal tractor “would be very low, perhaps even nondetectable, using standard laboratory techniques.” Based on this analysis, staff concluded that the total exposure would be so small that it would have no measurable adverse effect on public health.

Finally, staff pointed out that the tractors for which Ertl sought an exemption are similar to off-highway vehicles which Congress, in P.L. 112-28, exempted from the 100 ppm lead content limit and to bicycles and similar products for which Congress set a 300 ppm lead limit for their metal components, such as pedals. Given the similarities of products and the similarities of risk, it is, therefore, a short step to consider treating the petitioner's product in a similar fashion. Accordingly, staff recommended approval of the Ertl petition.

My Vote

Having consulted with CPSC staff on the matter and having carefully read the briefing package, I voted to approve the recommendation to grant this exemption request. I did so with some concern.

My concern is that staff's conclusion that exposure to the lead in an Ertl tractor might in theory be detectable raises the question whether future petitioners should submit actual test reports to demonstrate that no such result would occur. I say this because past petitioners for exemptions, for the most part, have provided such test reports⁹ and, as I understand it, there are a number of labs and toxicology consulting firms that can assist in providing such information at a relatively low cost. I strongly urge future petitioners to submit not just information regarding the amount of lead in their children's products, but also the exposure to this lead that children would likely face when using such products.

⁹ See, e.g., *Petition for Temporary Final Rule to Exclude a Class of Materials Under Section 101(b) of the Consumer Product Safety Improvement Act*, by Polaris Industries, American Suzuki Motor Corporation, Arctic Act, Inc. Kawasaki Motors Corp, U.S.S. American Honda Motor Co, Inc., and Yamaha Motor Corporation (January 27, 2009); *Petition for Temporary Final Rule to Exclude a Class of Materials Under Section 101(b) of the Consumer Product Safety Improvement Act*, by Motorcycle Industry Council (MIC) (January 28, 2009); *Petition for Temporary Final Rule to Exclude a Class of Materials Under Section 101(b) of the Consumer Product Safety Improvement Act* by Bicycle Product Suppliers Association (BPSA) (May 6, 2009); *Section 101 Request for Lead Content Exclusion for Pen Part Components* by David Baker, LLC, for the Writing Instrument Manufacturers Association (February 9, 2009); and *Section 101 Request for Exclusion of a Material or Product; Request to Exempt Crystal Beads and Rhinestones* by Jewelry Producers and Retailers, Fashion Jewelry Trade Association (FJTA), Manufacturing Jewelers and Suppliers of America (MJSA), Footwear Distributors and Retailers of America (FDRA), National Retail Federation (NRF), and United Dance Merchants of America (February 24, 2009).

That said, several points make me comfortable with the staff's recommendation regarding the Ertl petition.

- *Totality of Factors:* Staff analyzed this case carefully and made its recommendation based on the totality of the factors present in this case, including costs, financial circumstances of the company, the size of the company, its distribution pattern, consumer preferences, congressional exemptions for similar products, and the specific relief sought by the company. Moreover, staff concluded that the component parts covered by the petition would not likely be placed in a child's mouth or ingested (or extensively touched) because of their function and location on the product and the agency's familiarity with pedals and similar component parts of products such as bicycles and youth off-highway vehicles.
- *The Company Will Continue to Meet a 300 ppm Lead Content Limit:* The company submitted extensive test results that showed that it could meet the 300 ppm lead limit for its product. Ertl did not seek a complete exemption from the lead content limits, only an increase in permissible lead limits up to 300 ppm. Accordingly, our decision still requires the company to meet a very low lead limit.¹⁰
- *Ride-On Pedal Tractors are Similar to Other Children's Products With Statutory Exemptions:* I agree with staff's assessment that an exemption for the company's ride-on pedal tractor is similar to the statutory exemption for metal component parts of bicycles and related products. Just as the statutory exemption is narrowly tailored to cover just those parts of a bicycle that cannot meet the 100 ppm lead content limit, our decision is similarly tailored to cover only those component parts of the ride-on tractor for which the 100 ppm standard is too much of a challenge, but 300 ppm is achievable.

Conclusion

I repeat my support for the Commission's decision. I believe that the functional purpose test in P.L. 112-28 represents a thoughtful and measured adjustment to the needs of the market, and I believe that our analysis of Ertl's petition in light of the statute was done appropriately. That said, I caution against too broad an interpretation of our decision. As the Commission found previously, the majority of manufacturers of children's products are able to meet the 100 ppm lead level. For those manufacturers who require higher levels of lead, the functional purpose exception should permit the Commission to grant relief as appropriate. In addition, I suggest that future petitions will be met with quicker Commission action if the petitioners provide actual data in support of the petitions. I also

¹⁰ Notwithstanding its statement that lead content up to 100,000 ppm would present a transfer of lead in a wipe test of less than 0.02 micrograms per test, staff in no way indicated that it would approve a request for an exemption for a product with such high lead levels or anything close to that amount.

hope that future Commission consideration of petitions for exemptions will provide us with actual test data rather than theoretical analyses.

Finally, I join my colleagues in noting with approval the unanimity of the vote on this petition, especially given that lead issues have often been vigorously debated over the years.