U.S. CONSUMER PRODUCT SAFETY COMMISSION
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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
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> - 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

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[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

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[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.