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

BALLOT VOTE SHEET

This document has been electronically approved and signed.

DATE: March 21, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: Hyun S. Kim, Acting Assistant General Counsel

SUBJECT: Petition Requesting Exception from Lead Content Limits; Notice Granting Exception

Ballot Vote Due: March 27, 2012

Attached is a draft *Federal Register* notice, granting an exception on a petition under section 101(b) of the Consumer Product Safety Improvement Act, as amended by H.R. 2715 (Public Law 112-28). The petition was submitted by Joseph L. Ertl, Inc., Scale Models and Dyersville Die Cast for its die-cast, ride-on pedal tractors.

Please indicate your vote on the following options:

I. Approve publication of the draft notice in the *Federal Register*.

_____ _____
(Signature) (Date)

II. Approve publication of the draft notice in the *Federal Register*, with changes. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve publication of the draft notice in the *Federal Register*.

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment:

Draft *Federal Register* Notice – Petition Requesting Exception from Lead Content Limits; Notice Granting Exception

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2011-0087]

Petition Requesting Exception from Lead Content Limits; Notice Granting Exception.

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission ("Commission" or "CPSC" or "we") has received a petition requesting an exception from the 100 ppm lead content limit under section 101(b) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), as amended by Public Law 112-28. We are granting an exception to the 100 ppm lead content limit for certain aluminum alloy components of children's die-cast, ride-on pedal tractors, and similar component parts made of aluminum alloy on similar ride-on children's products for children ages 3 years and older. Such products may include other children's ride-on tractors, children's ride-on cars, and other ride-on toys. These aluminum alloy components must meet a lead content limit of 300 ppm.

DATES: The effective date is [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; e-mail: khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION: Under section 101(a) of the CPSIA, consumer products designed or intended primarily for children 12 years old and younger that contain lead content in excess of 100 ppm are considered to be banned hazardous substances under the Federal Hazardous Substances Act ("FHSA").

Section 101(b)(1) of the CPSIA provides for a functional purpose exception from the lead content limits, under certain circumstances. The exception allows us, on our own initiative, or upon petition by an interested party, to exclude a specific product, class of product, material, or component part from the lead limits established for children's products under the CPSIA if, after notice and a hearing, we determine 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 section 101(a) of the CPSIA, 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. Under section 101(b)(1)(B) of the CPSIA, there is no measurable adverse effect on public health or safety if the exception will result in no measurable increase in blood lead levels of a child.

On September 29, 2011, Joseph L. Ertl, Inc., Scale Models and Dyersville Die Cast ("petitioner"), submitted a petition requesting an exception from the lead content limit of 100 ppm under section 101(b) of the CPSIA for its die-cast, ride-on pedal tractors, scaled for children ages 3–10 years. Given the highly technical nature of the information sought, including data on the lead content of the product and test methods used to obtain those data, we believe that notice and solicitation for written

comments is the most efficient process for obtaining the necessary information, and provides adequate opportunity for all interested parties to participate in the proceedings. Accordingly, we invited comments on the issues raised by the petition. In the *Federal Register* of November 16, 2011 (76 FR 70975), we invited comments on the issues raised by the petition with comments due on December 16, 2011. On January 5, 2012 (77 FR 478), we reopened the comment period for 30 days, with comments due on February 6, 2012. We received one comment in support of the petition. The commenter stated that pedal tractors with aluminum alloy components cannot practicably be manufactured in accordance with the 100 ppm lead content requirement. The commenter also stated that the aluminum alloy components are not likely to be placed in the mouth or ingested and will not have a measurable adverse effect on public health or safety.

The petitioner stated that the components of its pedal tractors are made of aluminum metal die castings, which are the best alloy of choice for pedal tractor production, based on weight, cost, structural properties, surface finish and coatings, corrosion resistance, bearing properties, and wear resistance. The pedal tractor components are manufactured via the aluminum die-casting process. Although the petitioner stated that it is able to meet the lead content requirements of 300 ppm for its pedal tractor components, it is unable to meet consistently the 100 ppm lead content limits, due to alloys used in the aluminum die-cast process. Accordingly, the petitioner requested an exception from the 100 ppm lead content limit.

For the reasons described in CPSC staff's briefing package, available at: http://www._____, we agree with the commenter that an exception to the

100 ppm lead content limit for certain children's ride-on pedal tractor component parts is appropriate. The petitioner indicated that two aluminum alloys with relatively low lead concentration can be purchased and used to manufacture the pedal tractor products. One of these aluminum alloys (A380.1) may contain more than 300 ppm lead, although the petitioner indicated that this alloy can be obtained, with careful purchasing, with a lead content of no more than 300 ppm. The petitioner indicated that the second aluminum alloy (A413.1) that can be used to manufacture the products is available with less than 200 ppm lead. While the petitioner indicated that it is possible to manufacture their products with the specific alloy with lead content less than 200 ppm, we believe that the A380.1 alloy, or a similar alloy, with lead content no more than 300 ppm, is an appropriate material for manufacturing the component parts of the pedal tractors because the A380.1 aluminum alloy is one of the most commonly used aluminum alloys in manufacturing and is more readily obtainable from sources than the A413.1 aluminum alloy. In addition, the A413.1 alloy costs $0.99 to $1.65 per unit more than the A380.1 alloy (about 1 percent of the cost of the product), resulting in additional material costs of the product. Obtaining aluminum alloys at 100 ppm or other substitute alloys was considered not practicable for the petitioner. The use of another metal alloy, such as steel, or using plastic molded component parts was not practicable because it would result in completely retooling the manufacturing process and result in products that appeared different from the current product, which uses die-cast component parts.

In addition, the products included in the petition are similar to two types of products that have specific statutory provisions regarding lead content requirements. The CPSIA, as amended by Public Law 112-28, established new provisions for specific exceptions from the 100 ppm lead content requirement. Section 101(b)(5) of the CPSIA provides that the lead content limit does not apply to off-highway vehicles. Section 101(b)(6) of the CPSIA also provides that for metal component parts of bicycles and related products, the lead limit is 300 ppm, not 100 ppm, as otherwise applicable to children's products.

We believe that the petitioner's children's ride-on pedal tractors made with aluminum alloys should be granted an exception from the 100 ppm lead content limit, and allowed to have a lead limit of 300 ppm instead, because it is not practicable to impose the lower lead limit on such aluminum alloys. These aluminum components include: body castings (right and left sides), rear wheel hubs, wide front axle yoke, wide front-end adaptor bracket, and similar component parts that would not likely be placed in the mouth or ingested or extensively contacted by children because of their function and location on the product. The exposure to lead in such parts at the 300 ppm limit is expected to be so low that it would have no measurable effect on blood lead levels and no adverse effect on public health or safety.

For the same reasons, children's products that are similar, such as other children's ride-on tractors, children's ride-on cars, and other ride-on toys intended for children ages 3 years and older that contain similar aluminum alloy component parts, including body castings (right and left sides), rear wheel hubs, wide front axle

yoke, wide front-end adaptor bracket, and similar component parts that are unlikely to be placed in the mouth or ingested, or extensively contacted by children because of their function and location on the product, must meet a lead content limit of 300 ppm for the aluminum alloy component parts. The exposure to lead in these similar component parts is expected to be so low that it would have no measurable effect on blood lead levels, and no adverse effect on public health or safety.

Dated: _____.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

Staff Briefing Package

Request for Exception
from CPSIA Section 101(a) Lead Content Limit
for Pedal Tractors
from Joseph L. Ertl, Inc., Scale Models and Dyersville Die Cast Divisions

March 21, 2012

Table of Contents

Briefing Memo

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

Memorandum

This document has been electronically approved and signed.

Date: March 21, 2012

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM : DeWane Ray, Assistant Executive Director, Office of Hazard Identification and Reduction
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Request for Exception from CPSIA Section 101(a) Lead Content Limit

1. Introduction

The Consumer Product Safety Improvement Act of 2008 (CPSIA), as amended by public law 112-28 (PL 112-28), provides specific limits for lead in children's products. Section 101(a) of the CPSIA provides that consumer products designed or intended primarily for children 12 years old and younger may not contain lead content in excess of 100 ppm.

Section 101(b)(1) of the CPSIA provides a functional purpose exception from the lead content limit under certain circumstances. The Commission shall grant an exception to the lead limit for a specific product, class of product, material, or component part if, after notice and a hearing, the Commission 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 section 101(a) of the CPSIA 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. The Act specifies that there is no measurable adverse effect on public health or safety if the exception will result in no measurable increase in blood lead levels of a child.

Section 101(b)(1) also provides that if the Commission grants an exception to the lead content limit (*i.e.*, 100 ppm, the current lead limit for component parts of children's products), the

Commission, as necessary to protect public health or safety, may establish a lead limit or place an expiration date on the exception.

2. Request

On September 29, 2011, Joseph L. Ertl, Inc., Scale Models and Dyersville Die Cast divisions ("Scale Models," or "petitioner"), submitted a request to the Commission for an exception from the 100 ppm lead content limit for die-cast ride-on pedal tractors, scaled for children ages 3–10 years. The request stated that components of the firm's pedal tractors (body castings on right and left sides, rear wheel hubs, wide front axle yoke, and wide front-end adaptor bracket) are made with die-cast aluminum alloy and that aluminum is the best alloy for pedal tractor production, based on weight, cost, structural properties, surface finish and coatings, corrosion resistance, bearing properties, and wear resistance.

The firm stated that it is able to meet a lead content limit of 300 ppm for the pedal tractor components, using either of two appropriate aluminum alloys (A380.1 and A413.1), but maintains that it is unable to meet a 100 ppm lead content limit because of the specific alloys used in the die-cast process. The firm indicated that the A380.1 alloy tends to have more than 300 ppm lead, but that its supplier has assisted in sourcing batches with less than 300 ppm by sorting its production melts. The firm also indicated that it could obtain the A413.1 alloy that contains less than 200 ppm lead. The firm requested an exception from the 100 ppm lead content limit to continue to manufacture its pedal tractors with the cast aluminum components.

A Federal Register notice soliciting comments was published on November 16, 2011 (76 FR 70975), and docket CPSC-2011-0087 was established at www.regulations.gov. The comment period was extended for an additional 30 days on January 5, 2012 (77 FR 478), with comments due no later than February 6, 2012.

3. Discussion

Staff's evaluation of the exception request for aluminum alloy pedal tractor component parts is based on information provided by the petitioner, staff technical expertise, written public comments, and other available information. This section presents staff's analysis of the key issues regarding lead content of aluminum alloy pedal tractor component parts.

a. Engineering Considerations (Tab A)

The CPSC's Directorate for Engineering Sciences staff prepared an evaluation of the petition with regard to the lead content of metals and metal alloys and the uses of such materials in manufacturing. This information is discussed below and detailed at Tab A.

The evaluation of whether it is practicable to manufacture Scale Models' children's products using die-cast aluminum alloys compliant with the 100 ppm lead content limit by removing the excessive lead or by making the lead inaccessible depends upon the examination of multiple factors[1]. When these factors are considered together, a determination of the practicability can be made. Scale Models considered the use of plastic, steel, zinc, magnesium, and zinc-aluminum

[1] Factors considered when reviewing practicability include: the utility of substitute material, the availability of materials with less than 100 ppm lead, relative costs, inaccessibility considerations, conformity assurance, technological feasibility, and other factors.

alloys instead of aluminum alloys. Zinc is much heavier than aluminum and the petitioner stated that its use would result in ride-on toys too heavy to pedal or turn for the smallest child users. Magnesium is known to burn if exposed to high heat, and it has effects on the environment from the emission of hazardous air pollutants during its production. The firm supplied no information on the suitability, cost, or availability of using a zinc-aluminum alloy for its children's products. For aesthetic reasons, the company rejected the option of using plastic molded component parts in place of aluminum. Scale Models expressed that its customers prefer metal children's products over plastic versions. Tooling designed for casting aluminum is not compatible for use with casting steels. Different casting tools or an investment in steel stamping tooling would be needed if Scale Models substituted steel for its cast aluminum component parts, resulting in a different product appearance than their current product.

Scale Models indicated that it could not obtain aluminum alloys with less than 100 ppm without purchasing a "heat batch" specifically formulated to meet the lead requirement. This entails a minimum order size of approximately seven years' worth of material and would require about 15 percent of the company's yearly sales just to purchase it. Scale Models considered that option prohibitively expensive. Scale Models, by working closely with their metals suppliers, indicated that it was possible to obtain A380.1[2] aluminum alloy with less than 300 ppm lead, and A413.1[3] aluminum alloy with less than 200 ppm lead.

Scale Models noted that it pays $1.12 per pound for aluminum. Zinc is priced comparably to aluminum. Magnesium is priced at about $1.81 per pound (in metric ton quantities); for Scale Models, use of magnesium would represent a 114 percent materials cost increase if the same volume of magnesium was used in a Scale Models children's product instead of aluminum. Cold-rolled steel is priced at about $0.35 per pound. Scale Models did not state how much steel would be required to manufacture a children's toy if a stamping process was used. Thus, we cannot determine if the lower price of steel would result in a lower unit materials cost for the product. Using steel would involve investing in metal stamping technology and training, which would result in an additional cost per product produced. The use of A413.1 aluminum alloy in a children's toy would increase the materials cost by about $0.99 to $1.65 per unit, or about 1 percent of the cost of the product.

All of the aluminum die-cast component parts of the ride-on toys made by Scale Models are accessible to children. A covering that is not considered paint or a surface coating with respect to the requirements of the CPSIA would be needed to make the body castings inaccessible to children. This would represent a change in Scale Models' current manufacturing process.

Scale Models stated that the materials used in its products are tested three times for conformance with the lead content requirements. First, every shipment received is accompanied by a metal analysis. Second, Scale Models uses a first party spectrometer to test incoming material. Third, a third party testing laboratory is used to test the component parts for lead content.

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[2] Aluminum alloy A380.1 allows up to 0.50 percent, or 5000 ppm, "other" materials to be present as trace materials (see http://www.matweb.com/search/DataSheet.aspx?MatGUID=2d09cb9bcfdb404ab71e6b8c18e5f84c for a composition listing of A380.1 aluminum alloy). Achieving 300 ppm or less lead content in this alloy requires extra monitoring or composition adjustments on the part of the supplier.

[3] Aluminum alloy A413.1 allows up to 0.20 percent, or 2000 ppm, "other" materials to be present as trace materials (see http://www.matweb.com/search/DataSheet.aspx?MatGUID=6185967f0a074363a27c0313637f1e84 for a composition listing of A413.1 aluminum alloy). Achieving 200 ppm or less lead content in this alloy requires extra monitoring or composition adjustments on the part of the supplier.

In a prior proceeding,[4] the Commission did not determine that 100 ppm aluminum was not technologically feasible. The materials submitted by Scale Models in support of their petition indicated that the company could obtain an aluminum alloy specifically formulated to meet the lead content requirement. Therefore, we conclude that the submission did not establish a basis to determine that aluminum die-casting alloys with less than 100 ppm lead are not technologically feasible.

Considering the factors together, CPSC staff considers it not practicable for Scale Models to manufacture their products with cast aluminum component parts compliant to a lead content limit of 100 ppm. It appears practicable to establish an alternate lead content limit of 300 ppm for the cast aluminum for component parts used in Scale Models' children's products.

b. Economics (Tab B)

The CPSC's Directorate for Economic Analysis staff prepared an evaluation of the possible economic issues related to lead content of aluminum alloy pedal tractor component parts. This information is discussed below and detailed at Tab B.

Pedal tractors were introduced in the late 1940s. Generally, they are intended for children between the ages of 3 and 10, but sales to collectors account for a significant portion of the sales of pedal tractors. In many cases, however, collectors also may allow children to ride the tractors. Staff's review found retail prices for pedal tractors ranged from about $75 to about $430. The bodies of the less expensive pedal tractors tend to be manufactured out of plastic, whereas the bodies of the more expensive pedal tractors are generally manufactured out of aluminum or steel. Many pedal tractors are scale replicas of working tractor models, both current models, as well as historical models.

The size of the petitioner's pedal tractor business appears to be relatively small. According to the petitioner, its toy business accounts for about 5 percent of its business; and based upon information provided by the petitioner, staff infers that Scale Models produces around 1,000 pedal tractors a year. Moreover, searches for pedal tractors on the websites of several mass market retailers did not turn up any models that were manufactured by the petitioner. Pedal tractors manufactured by the petitioner were found only on websites of specialty toy retailers. The retail prices for pedal tractors manufactured by the petitioner were $215 or higher.

According to the petitioner, two aluminum alloys are suitable for manufacturing its pedal tractors. However, neither of the alloys consistently will meet the 100 ppm lead limit. The petitioner discussed the possibility of using zinc or magnesium alloys instead of aluminum; but, as discussed above in the "Engineering Considerations" section, the petitioner concluded that neither of these alternative materials presented a practical alternative.

Pedal tractors made out of plastic or steel are available in the market place. Using these materials instead of aluminum might be an alternative for manufacturing pedal tractors that meet the 100 ppm lead limit. However, if there are differences between pedal tractors manufactured out of aluminum and pedal tractors manufactured out of plastic or steel, in terms of functionality, durability, detail, or general appeal to consumers, they could be considered to be different

[4] "Children's Products Containing Lead; Technological Feasibility of 100 ppm for Lead Content; Notice of Effective Date of 100 ppm Lead Content Limit in Children's Products." 76 FR 44463. Available at: http://www.cpsc.gov/businfo/frnotices/fr11/leadeffdate.pdf

products. For example, if plastic or steel pedal tractors are less durable or have less general appeal to consumers than aluminum pedal tractors, they may not be considered good substitutes by some consumers and could be considered to be different products.

The petitioner asserted that its customers "prefer the durability of metal farm toys over plastic farm toys," which suggests that there are some significant differences between aluminum and plastic pedal tractors, or it indicates that they serve different niche markets. On the other hand, the petitioner reported that one of its larger customers stated that they would obtain steel pedal tractors if the petitioner was unable to supply aluminum pedal tractors, which suggests that some consumers may consider steel pedal tractors to be suitable substitutes for aluminum pedal tractors.

However, even if plastic or steel pedal tractors could be very close substitutes for aluminum pedal tractors, manufacturing pedal tractors out of steel or plastic is not an economically practicable alternative for the petitioner. The petitioner's primary business is manufacturing various parts or components of products out of zinc or aluminum alloys using die-casting techniques. Manufacturing pedal tractors out of steel involves metal stamping processes and not die-casting processes. In order to manufacture steel pedal tractors, the company would have to invest in new equipment and tooling for metal stamping, and it would have to hire employees who are capable of designing and manufacturing products using metal stamping processes. Given the petitioner's toy business is only a small portion of its total business, and its annual production of pedal tractors is estimated to be less than 1,000 units, this is unlikely to be economically feasible.

The cost of granting the exception is the cost associated with adverse health impacts that could be attributable to the exception. However, as discussed below and at Tab D, staff expects that the exposure to lead from the pedal tractors would be so low that it would have no adverse effect on public health or safety. The benefit of granting the exception is that it would allow the petitioner, and possibly other manufacturers, to continue to sell die-cast aluminum pedal tractors. By allowing the petitioner and other firms to continue to manufacture die-cast aluminum pedal tractors, the variety of pedal tractors available to consumers will be maintained. This benefit is positive, but it cannot be quantified at this time.

c. Human Factors Considerations (Tab C)

The CPSC's Directorate for Engineering Sciences Human Factors Division staff analyzed the characteristics of the product and the behaviors and interactions with the product of the children expected to use the product. This information is discussed below and detailed at Tab C.

Human Factors staff assessed the information related to the die-cast ride-on pedal tractors, specifically the component parts in question, to determine the likelihood that any or all of the parts would 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.

Staff agrees that the youngest likely user of the die-cast pedal tractor is 3 years of age. The oldest likely user would depend on the size and interests of the child. This age assessment is true of similar ride-on products in this class of products. Staff also agrees that the likely use patterns would include inside and outside play, depending upon the weather. During typical use of the tractor, the rider is likely to touch the seat, steering wheel, and hitch pin, if there is an

attachment. In addition, it is likely that other children may straddle the front body to catch a ride, or even hold onto the front axle yoke to push the tractor backward. Regardless of which parts are touched, staff agrees with the petitioner's submission that the component parts in question are too large for a child to place in their mouth.

There is very limited information available to determine exactly how often a child plays with a specific toy and even less information is available on how often in a day a child plays with the toy. It is reasonable to assume that the toy will be played with more often when it is new and that play time with the toy will decline as the child gets older. The die-cast pedal tractor and similar products, which are for children between 3 and 10 years of age, are not likely to be used at the same rate of play across the age span specified.

d. Health Sciences Considerations (Tab D)

The CPSC's Directorate for Health Sciences staff evaluated the potential lead exposure for children using the product, considering information in the scientific literature and information provided by CPSC's Human Factors staff. Staff's analysis is summarized below and detailed at Tab D.

The petitioner indicated that children typically would not have contact with some parts of the product, such as the wheel and axle parts, which are made of aluminum alloy containing no more than 300 ppm lead, adding that children may contact the body of the product during play. The petitioner further stated that children would not have contact with the aluminum alloy because the firm uses a powder coat finish on the alloy's surface.

The Commission may not grant an exception for a product that does not conform to the condition that the product or part is not likely to be placed in the mouth or ingested. Given this restriction, for most products, transfer of lead to hands and fingers with subsequent hand-to-mouth contact is the most likely possible route of exposure.

The level of exposure to lead through handling and subsequent hand-to-mouth contact depends on a number of factors, such as the characteristics of the product and the characteristics and behaviors of the children expected to use the product. Key factors may include: the type of product and the specific lead-containing materials; the ages of children using the product; and where the product is used.

Staff does not have specific data concerning children's behaviors associated with the pedal tractor products or their behaviors that could result in exposure to lead. Data on human behaviors in general show that all people occasionally contact their mouths with hands, fingers, or objects. Children exhibit more mouthing behavior than people of other ages, and the youngest children have the most hand-to-mouth contacts during the day, with such behavior peaking at around age 2 years. The duration of hand-to-mouth contacts also peaks at around age 2 years. Furthermore, children engage in fewer hand-to-mouth contacts while outdoors compared to indoors.

The pedal tractors are relatively large, ride-on toys, likely used outdoors, although they may be used indoors, perhaps in a basement, during winter, for example. To the extent that the product is used outdoors, children's hand-to-mouth contacts and any potential for transfer of lead to the mouth from use of these products is expected to be less than when these products, or other toys, are used indoors.

Staff uses wipe-testing to assess exposures that might occur through hand-to-mouth contact after touching or handling a product. However, staff has not tested pedal tractors and does not know of any data from wipe-testing products, such as the aluminum alloy pedal tractors. Staff has tested other products for lead that might be present on the surface of a product. Data from testing metal jewelry and polyvinyl chloride products with lead content more than 100 ppm and up to 100,000 ppm (equivalent to 10 percent) lead show transfers of lead per wipe averaged less than 0.02 micrograms (µg) of lead.

If we assume that these data are informative of possible exposure from the pedal tractors, then staff would expect that the possible transfer of lead from a pedal tractor made with aluminum alloy containing no more than 200 or 300 ppm lead would be approximately the same level (*i.e.*, on average less than 0.02 µg per wipe).

While the powder coat finish of the product may not absolutely prevent contact with the metal itself, it will reduce the opportunity for a child's contact with the metal to instances in which the finish has been damaged or removed. While the amount of possible damage cannot be predicted without testing for the effects of weather and wear and tear, staff expects that it would most likely constitute a small fraction of the product's surface. Therefore, a child's contacts with a pedal tractor with a damaged finish will consist of contact with finished areas of the aluminum alloy parts, as well as areas of the alloy with missing or damaged finish. Staff believes that only the contacts with the damaged areas would potentially result in transfer of lead to the hands.

While the exposure from use of a pedal tractor has not been quantified, testing of other products resulted in an average of 0.02 µg per wipe. A child could have several contacts per day with a pedal tractor product, or no contact at all on days that do not include play with the product. Because staff does not have data on how many contacts per day a child might have with the aluminum alloy parts of a pedal tractor, staff cannot provide a quantitative estimate of how much lead might collect on a child's hands. Further, staff is unable to quantify how much lead may be transferred to the mouth and ingested.

The statute provides that an exception must result in no measurable increase in blood lead levels of a child. Extensive scientific literature and several physiologic models exist that describe the relationship between exposure and blood lead level. Thus, with a given exposure scenario, one can use a model to estimate the expected change in blood lead level. While staff cannot completely quantify the possible exposures form the pedal tractor products, based on data from other products, staff expects that lead ingestion from contact with a product like the pedal tractor would be a fraction of the daily exposure that would result in an increase in the blood lead level. Staff expects that possible daily exposure to lead from the pedal tractor would be very low, perhaps even nondetectable.

Therefore, if lead is transferred to a child's hands during use of the product, and the lead is then transferred to the mouth and ingested, staff expects the total amount of exposure to be so low that it would have no measurable effect on blood lead level and, therefore, given the applicable statutory definition, no measurable adverse effect on public health or safety, taking into account normal and reasonably foreseeable use and abuse.

Staff extends this conclusion to other products made with similar aluminum alloys that have similar expectations of contact by the mouth or hands.

4. Public Comments

The CPSC received public comments from one organization in response to the notices published in the Federal Register on November 16, 2011 (76 FR 70975) and on January 5, 2012 (77 FR 478). The Toy Industry Association comment (regulations.gov docket number CPSC-2011-0087-0005) discussed the statutory provision for exceptions to the lead limits, detailing how it believes the petitioner's pedal tractors qualify for an exception (*i.e.*, it is not practicable to manufacture the products with aluminum alloy conforming to the 100 ppm lead content limit; the product and components parts are not likely to be placed in the mouth or ingested; and there will be no measureable adverse effect on health and safety). Staff finds the commenter's statements to agree with staff's analysis of the petitioner's products.

5. Conclusions

The CPSIA, as amended by PL 112-28, provides that the Commission shall grant an exception to the lead content limit if three criteria are satisfied. Based on the information provided by the petitioner and other information available to staff, staff concludes that: (1) it is not practicable to manufacture the pedal tractor product using cast aluminum component parts that conform to the 100 ppm lead content limit; (2) the component parts of the product are not likely to be placed in the mouth or ingested; and (3) children are expected to have little exposure, if any, to the lead that is present in the aluminum alloy component parts, and thus, the product will have no measurable effect on blood lead level, and no adverse effect on public health or safety.

The petitioner indicated that two aluminum alloys with relatively low lead concentration may be purchased and used to manufacture the pedal tractor products. One of these alloys (aluminum alloy A380.1) may contain more than 300 ppm lead, although the petitioner indicated that this alloy can be obtained, with careful purchasing, with lead content no more than 300 ppm. The petitioner indicated that the second aluminum alloy (A413.1) that may be used to manufacture the products is available with less than 200 ppm lead. Staff believes that either alloy is suitable for use in manufacturing products such as the pedal tractors. While the petitioner indicated that it is possible to manufacture its products with the specific alloy with lead content less than 200 ppm, staff believes that the A380.1 alloy, or a similar alloy, with lead content no more than 300 ppm, is an appropriate material for manufacturing the component parts of the pedal tractors. The A380.1 alloy is also one of the most commonly used aluminum alloys in manufacturing, and is more readily obtainable from sources than the A413.1 aluminum alloy.

In addition, staff believes that the products included in the request are similar to two types of products that have specific statutory provisions regarding lead content requirements. The CPSIA, as amended, established these new provisions for specific exceptions from the 100 ppm lead content requirement. CPSIA section 101(b)(5) provides that the lead content limit does not apply to off-highway vehicles. CPSIA section 101(b)(6) provides that for metal component parts of bicycles and related products, the lead limit shall be 300 ppm, not 100 ppm, as otherwise applies to children's products. Further, the Consumer Product Safety Act (CPSA), as amended by PL 112-28 Section 2, provides an exclusion from third party testing for metal component parts of bicycles. Therefore, lead content of off-highway vehicles is not restricted, and metal parts of bicycles are restricted to 300 ppm lead, although no third party testing is required.

Based on staff's experience and knowledge concerning the potential for lead exposure from off-highway vehicles and metal parts of bicycles, staff believes that the new statutory provisions will

have no effect on the safety of the covered products with respect to potential lead exposure. Likewise, in the present case concerning pedal tractors made with aluminum alloys, staff believes that an exception to the 100 ppm lead content, providing a lead limit of 300 ppm instead, would have no negative effects with respect to children's health or safety.

It is likely that there are other children's products that are similar in design, manufacture, and use by children as Scale Models' products that contain similar cast aluminum component parts. Similar products could include other children's ride-on tractors, children's ride-on cars, and other ride-on toys intended for children ages 3 years and older.

These types of products may be considered a class of products for purposes of an exception to the lead limit for children's products. Staff believes that such products are likely to be part of a small market for which it is not practicable for manufacturers to produce similar cast aluminum component parts that conform to the 100 ppm lead content limit. Further, cast aluminum component parts that are similar to the component parts in Scale Models' products are component parts that are not likely to be handled during use, placed in the mouth, or ingested; and exposure to lead in the similar products is expected to be so low as to have no measurable effect on blood lead level, and no adverse effect on public health or safety.

6. Staff Recommendation

Staff recommends that the Commission grant the request for an exception from the 100 ppm lead limit for the aluminum alloy component parts of Scale Models' pedal tractors, including body castings (right and left sides), rear wheel hubs, wide front axle yoke, wide front-end adaptor bracket, and similar component parts that are unlikely to be placed in the mouth or ingested, or extensively contacted by children because of their function and location on the product. Staff recommends that the Commission grant an exception for similar component parts made of aluminum alloy on similar ride-on children's products for children ages 3 years and older. Such products may include other children's ride-on tractors, children's ride-on cars, and other ride-on toys.

Staff recommends that the Commission establish a lead content maximum limit of 300 ppm for these aluminum alloy component parts.

TAB A: Engineering Sciences Assessment for Request for Exception from CPSIA Section 101(a) Lead Content Limit

TAB A

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

This document has been electronically approved and signed.

Memorandum

Date: March 21, 2012

TO : Kristina Hatlelid, Ph.D., M.P.H.
Directorate for Health Sciences
Office of Hazard Identification and Reduction

FROM: Randy Butturini
Office of Hazard Identification and Reduction
Thomas E. Caton, General Engineer
Directorate for Engineering Sciences
Office of Hazard Identification and Reduction

SUBJECT: Technical Consideration of a Request for Exception from the 100 ppm Lead Content Limit by Scale Models

1. Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was signed into law. Section 101 imposed limits on the lead content of accessible component parts of children's products. Section 101 (a)(2)(C) of the CPSIA would reduce that limit to 100 parts-per-million (ppm) if the Commission did not determine that such a limit was not technologically feasible. The Commission voted that there was insufficient evidence to make a determination that manufacturers of children's products sold in the United States could not meet a total lead content limit of 100 parts per million (ppm) for a product or product category. Thus, the new total lead content limit of 100 ppm went into effect on August 14, 2011, for manufacturers, importers, retailers, and distributors of children's products.

On August 12, 2011, the President signed into law Public Law 112-28 (PL 112-28). Section 101(b)(1) of the CPSIA was amended by PL 112-28, to allow for a functional purpose exception to the 100 ppm lead content limit for a product, class of product, material, or component part if the Commission, on its own initiative, or in response to a petition, determines that, among other requirements,

> 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) [the 100 ppm limit] by removing the excessive lead or by making the lead inaccessible;

Scale Models, a division of Joseph L. Ertl, Inc., submitted a petition, dated September 29, 2011, in which the company requested an exception from the 100 ppm lead content limit for aluminum metal die-casting component parts of the children's products they manufacture. Scale Models has been using A380.1 and A413.1 aluminum alloys for its die-cast component parts. The

component parts mentioned by Scale Models are the aluminum alloy body castings (right and left sides), rear wheel hubs, wide front axle yoke, and wide front-end adaptor. This memorandum evaluates the materials submitted by Scale Models with regard to whether it is not practicable or not technologically feasible to manufacture the children's products with less than 100 ppm lead in listed accessible die-cast aluminum alloy component parts. Technological feasibility of metal alloys with less than 100 ppm lead has been previously considered by the Commission.[1] The Commission did not determine that it was not technologically feasible for a product or product category to meet the 100 ppm lead content limit for children's products under section 101(d) of the CPSIA.[2] Thus, further consideration of the petition in this memorandum is limited to whether it is practicable to manufacture the products with less than 100 ppm lead in accessible die-cast aluminum alloy component parts.

2. Practicability

The evaluation of whether it is practicable to manufacture Scale Models' children's products using die-cast aluminum alloys compliant with the 100 ppm lead content limit by removing the excessive lead or by making the lead inaccessible depends upon the examination of multiple factors. When considered together, a determination of the practicability can be made.

a. Substitute Materials

The consideration of substitute materials includes evaluating whether a material other than the one currently in use (in this case, die-cast aluminum alloy), and with a lead content less than 100 ppm, can be used its place. Application-specific features of a potential substitute must be considered.

Scale Models considered using zinc, magnesium, and zinc-aluminum alloys instead of aluminum alloys. Because zinc weighs substantially more than aluminum,[3] substituting zinc would result in ride-on toys that are too heavy to pedal or turn for the smallest child users, according to Scale Models. Magnesium has a density less than aluminum, and its use would result in a lighter children's product if equal volumes were used in the cast component parts. However, magnesium will burn if exposed to high heat. Scale Models claimed that magnesium had environmental impacts not seen with aluminum. However, magnesium's effect on the environment results from the emission of hazardous air pollutants from magnesium industrial plants, not from product use. The firm supplied no information on the suitability, cost, or availability of using a zinc-aluminum alloy[4] for its children's products.[5]

Each metal alloy is considered suitable in terms of strength and stiffness.

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[1] The staff technical memorandum can be found at: http://www.cpsc.gov/library/foia/foia11/brief/lead100tech.pdf .

[2] http://www.cpsc.gov/BUSINFO/frnotices/fr11/leadeffdate.pdf .

[3] The density of zinc is 0.258 pounds per cubic inch. The density of aluminum is 0.098 pounds per cubic inch. Thus, zinc weighs 2.6 times as much as aluminum, per unit volume.

[4] Zinc-aluminum alloy properties can be found at the website: http://www.matweb.com/search/CompositionSearch.aspx. Typical zinc-aluminum casting alloys are composed of mostly zinc, with between 8 and 28 percent aluminum as part of the composition. The alloys specify maximum lead content levels below 100 ppm.

[5] From *Metals Week* July 1, 2011 the price of zinc was $1.13 per pound, with the price of zinc alloy number 3 at $1.237 per pound. Aluminum A380 alloy was priced at $1.19 per pound, and aluminum A413 alloy was priced at $1.28 per pound.

Plastic molded component parts were considered by the company as a substitute for the die-cast aluminum alloys. For aesthetic reasons, the company rejected use of plastic molded component parts. Scale Models believes that its customers prefer metal children's products over plastic versions.

Scale Models considered using steel in a stamping process instead of die-casting. The use of steel would require investing in tooling for a completely different manufacturing process. Scale Models added that the resulting product would appear different from their current product, which uses cast component parts.

b. Availability of Material with Less Than 100 ppm Lead

In the documentation submitted by Scale Models, the firm provided the steps they had taken with their metals suppliers to obtain casting aluminum alloys with low lead content. Because most aluminum is recycled and many alloys allow lead in trace levels up to several hundred parts per million, the amount of lead in a given "melt" can vary considerably, often exceeding the 100 ppm limit, while remaining within the trace amount limits for a given alloy. Scale Models indicated that it could not obtain aluminum alloys with less than 100 ppm without purchasing a "heat batch" specifically formulated to meet the lead requirement. However, this entails a minimum order size of 120,000 pounds, which Scale Models indicated is approximately seven years' worth of material and would require about 15 percent of its yearly sales just to purchase it.[6] When the cost of storage and Scale Models' unfamiliarity with the material are included, the company determined that this type of investment would be prohibitively costly. Although CPSC staff's experience with metals sourcing is limited, it is a reasonable expectation that manufacturers requiring specialty metals in small quantities would experience some difficulty locating willing suppliers.

Scale Models, by working closely with their metals suppliers, indicated that it was possible to obtain A380.1[7] aluminum alloy with less than 300 ppm lead. They also indicated that they could obtain a regular supply of A413.1[8] aluminum alloy with less than 200 ppm lead. Scale Models has used A380.1 aluminum alloy in the past to manufacture children's toys. The company has been using A413.1 aluminum alloy for other die-cast products; and recently, it has been using this alloy for its children's toys.

c. Cost

Scale Models' submission stated that the materials cost of their ride-on children's toys amounts to about $20.33 per toy, or about 16 percent of its unit cost. The firm noted that it pays $1.12 per pound for aluminum, which is higher than the London Metals Exchange price of $0.85 per pound

[6] Production estimates based on information provided by Scale Models in submissions dated September 19, 2011 and September 29, 2011.

[7] Aluminum alloy A380.1 allows up to 0.50 percent, or 5000 ppm, "other" materials to be present as trace materials (see http://www.matweb.com/search/DataSheet.aspx?MatGUID=2d09cb9bcfdb404ab71e6b8c18e5f84c for a composition listing of A380.1 aluminum alloy). Achieving 300 ppm or less lead content in this alloy requires extra monitoring or composition adjustments on the part of the supplier.

[8] Aluminum alloy A413.1 allows up to 0.20 percent, or 2000 ppm, "other" materials to be present as trace materials (see http://www.matweb.com/search/DataSheet.aspx?MatGUID=6185967f0a074363a27c0313637f1e84 for a composition listing of A413.1 aluminum alloy). Achieving 200 ppm or less lead content in this alloy requires extra monitoring or composition adjustments on the part of the supplier.

for aluminum alloy.[9] Zinc is priced comparably to aluminum on the London Metals Exchange at $0.85 per pound, suggesting that Scale Models could acquire zinc for about the same price as they currently acquire aluminum. Magnesium is priced at about $1.81 per pound (in metric ton quantities), and would represent a 114 percent materials cost increase if the same volume of magnesium as aluminum were used in Scale Models' children's products. Cold-rolled steel is priced at about $0.35 per pound. Scale Models did not state how much steel would be required to manufacture a children's toy if a stamping process is used. Thus, we cannot determine if the lower price of steel would result in a lower unit materials cost for the product. However, using steel would involve investing in metal stamping technology and training, which would result in an additional cost per product produced.

Regarding the two aluminum alloys (A380.1 and A413.1), Scale Models stated that the A413.1 alloy costs about $0.06 to $0.10 more per pound than the A380.1 alloy. The added cost of using A413.1 aluminum alloy in a children's toy would increase the materials cost by about $0.99 to $1.65 per unit. This amount represents about 1 percent of the cost of the product.

d. Inaccessibility

All of the aluminum die-cast component parts on the ride-on toys made by Scale Models are accessible to children. Scale Models stated that all the cast aluminum component parts are powder coated.[10] Scale Models claims that this coating makes the substrate inaccessible. However, section 101(b)(3) of the CPSIA disqualifies this type of coating as a barrier that would render the substrate inaccessible to children. Thus, Scale Models did not address properly what factors could be considered to render the cast aluminum component parts inaccessible to children 12 years old and under. A different covering that is not considered paint or a surface coating with respect to the CPSIA would be needed to make the body castings inaccessible to children. This would represent a change in Scale Models' current manufacturing process.

e. Conformity Assurance

Scale Models indicated (as noted earlier) that they had been working with their metals suppliers to acquire aluminum alloys with low levels of lead. An arrangement had been made with one supplier to set aside A380.1 aluminum alloy with low lead levels when a "melt" was tested. However, the supplier indicted that they could guarantee only that the A380.1 aluminum would have no more than 300 ppm lead.

Scale Models stated that they can acquire A413.1 aluminum alloy with a maximum lead content of 200 ppm. They added that currently, they are using A413.1 aluminum alloy in their toys and have experience using it for other products.

Both alloys are considered readily available for use by Scale Models.

Scale Models stated that the materials used in their products are tested three times for conformance with the lead content requirements. First, every shipment received is accompanied by a metal analysis. Second, Scale Models uses a first party spectrometer to test incoming

[9] This estimate is from CPSC staff through its examination of the London Metals Exchange prices as of November 25, 2011.

[10] Powder coating is a type of coating that is applied as a free-flowing, dry powder, then heated to bond the powder particles to the surface to which it is applied.

material. Third, a third party testing laboratory is used to test the component parts for lead content.

f. Additional Factors Regarding Practicability

Scale Models did not provide other information relevant to the determination of the practicability or technological feasibility of manufacturing their products compliant to the 100 ppm lead content limit.

g. Technological Feasibility

Section 101(d) of the CPSIA defines technological feasibility as one or more of the following factors:

- a product that complies with the limit is commercially available in the product category;
- technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;
- industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
- alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

A more complete description of CPSC staff's interpretation of technological feasibility can be found in the staff briefing package, *Technological Feasibility of 100 Parts Per Million Total Lead Content Limit*.[11] In that briefing package, staff noted that all four factors associated with technological feasibility of aluminum alloys with less than 100 ppm lead are met.

As noted above, the Commission did not determine that the 100 ppm was not technologically feasible. The materials submitted by Scale Models in support of their petition indicated that they could obtain an aluminum alloy specifically formulated to meet the lead content requirement. Therefore, we conclude that the submission did not establish a basis to determine that aluminum die-casting alloys with less than 100 ppm lead are not technologically feasible.

3. Conclusions

CPSC staff considers the production of casting aluminum alloys with less than 100 ppm lead to be technologically feasible. However, that does not mean that the material is available to everyone at prices and in quantities that are practicable for their business needs. Scale Models addressed many of the factors involved in determining whether it is practicable to manufacture their products with less than 100 ppm lead in accessible parts. They considered substitute materials. They investigated the availability of casting aluminum with less than 100 ppm lead. They examined the costs associated with their materials options. They did not properly address what factors could be considered to render the cast aluminum component parts inaccessible to children 12 years old and under. They listed the testing undertaken to determine and control the lead content of the aluminum alloys they receive. Their conclusions were that it was practicable

[11] http://www.cpsc.gov/library/foia/foia11/brief/lead100tech.pdf.

to obtain A380.1 aluminum alloy with less than 300 ppm lead or A413.1 aluminum alloy with less than 200 ppm lead; but complying with the 100 ppm lead limit was not practicable.

Considering the factors together, CPSC staff considers it is not practicable for Scale Models to manufacture its products with die-cast aluminum component parts compliant to a lead content limit of 100 ppm.

TAB B: Economic Analysis

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

This document has been electronically approved and signed.

Memorandum

Date: March 21, 2012

TO : Kristina Hatlelid, Ph.D., M.P.H.,
Directorate for Health Sciences

THROUGH : Gregory Rodgers, Ph.D.
Associate Executive Director
Directorate for Economic Analysis

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT: : Economic Practicability of Manufacturing Pedal Tractors that Meet the Lead Content Requirements

Background

On September 29, 2011, Joseph L. Ertl, Inc., of Dyersville, Iowa ("the petitioner")[1] requested a functional purpose exception from the 100 parts per million ("ppm") lead content limit for children's products. Joseph L. Ertl, Inc. has two divisions, Dyersville Die Cast, which manufactures parts or components for other manufacturers, and Scale Models, which manufactures toy replicas of agricultural equipment (usually 1/8 or 1/16 scale) and pedal tractors (which are about 1/4 scale). The scale model toys and pedal tractors are die-cast using aluminum alloys. The company claims that it cannot locate a supplier that can provide it with suitable aluminum alloys that can meet on a consistent basis the 100 parts per million (ppm) lead limit. The company believes that it is the last firm in the United States that is manufacturing die-cast metal farm toys.

The Office of the General Counsel (OGC) has determined that the 1/16 and 1/8 scale model toys are "collectables not primarily intended for children 12 years of age and younger," and therefore, they are not subject to the 100 ppm lead content limit. However, the OGC also determined that pedal tractors are children's products and subject to the 100 ppm lead content limit.[2] Now, staff is evaluating whether an exception from the 100 ppm lead limit may be granted for the company's pedal tractors. This memorandum examines the economic

[1] Joseph L Ertl, Inc. and its Scale Models division are not the same company as the Ertl Company, also of Dyersville, IA. The Ertl Company was founded by Fred Ertl, Sr., but it is now owned by Tomy.

[2] CPSC Letter from Cheryl A. Falvey to Joseph L. Ertl (August 24, 2011).

practicability of manufacturing pedal tractors that meet the 100 ppm lead limit. The analysis is based upon materials submitted by the petitioner and other readily available information.

The Market for Pedal Tractors

According to one retailer, pedal tractors were introduced in the late 1940s.[3] Generally, pedal tractors are intended for children between the ages of 3 and 10,[4] but one source suggests that sales to collectors account for a significant portion of the sales of pedal tractors. In many cases, however, collectors may also allow children to ride the tractors.[5]

Various models of pedal tractors from several different manufacturers were found during a search of the websites of various retailers. The retail prices ranged from about $75 to about $430.[6] The bodies of the less expensive pedal tractors tend to be manufactured out of plastic, whereas the bodies of the more expensive pedal tractors are generally manufactured out of aluminum or steel, with some exceptions. Many pedal tractors are scale replicas of working tractor models, both current models, as well as historical models. The retail prices for pedal tractors manufactured by the petitioner were $215 or higher.

Little information on the overall size of the pedal tractor market was found. The size of the petitioner's pedal tractor business appears to be relatively small. According to the petitioner, 120,000 pounds of aluminum would supply its needs for about seven years. Because producing a single pedal tractor requires about 18 pounds of aluminum alloy for die-casting, this suggests that the petitioner would manufacture about 6,700 tractors over the seven years, or just under 1,000 pedal tractors a year.[7] Moreover, searches for pedal tractors on the websites of several mass market retailers did not turn up any models that were manufactured by the petitioner. Pedal tractors manufactured by the petitioner were found only on some websites of specialty toy retailers, such as Iowa Diecast Toys. This suggests that the pedal tractors produced by the petitioner are part of a specialty or niche market.

Practicability of Producing Pedal Tractors that Comply with the 100 ppm Limit

The petitioner states that it can use one of two aluminum alloys that are suitable for die-casting to manufacture its pedal tractors. However, neither of the alloys consistently will meet the 100 ppm lead limit. The petitioner states that it could meet a 300 ppm limit using its preferred aluminum alloy, or it could meet a 200 ppm lead limit using another aluminum alloy. The petitioner discussed several alternative materials that could be used instead of aluminum to meet the 100 ppm lead limit and why each of these alternatives was not a feasible option for the company.

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[3] Iowa Diecast Toys, LLC, discussion on company website at: http://www.agfarmtoys.com/scale/model/Pedal_Tractors.html (accessed 4 November 2011). Hereafter, it is cited as "Iowa Diecast Toys."

[4] Submission from Joseph L. Ertl, Inc (September 29, 2011).

[5] Iowa Diecast Toys.

[6] The websites were searched on or about November 15, 2011, and included the websites for the following retailers: Amazon.com, Toys r Us, Target, Wal-Mart, Sears, and Iowa Diecast Toys.

[7] Production estimates based on information provided by Scale Models in submissions dated September 19, 2011, and September 29, 2011.

One option discussed in the submission of September 29, 2011, was to use zinc alloys instead of aluminum alloys. However, the petitioner noted that zinc alloys weigh 2.5 times as much as aluminum. This would increase the assembled weight of a pedal tractor by 25 pounds, from about 35 pounds to 60 pounds. The intended users of pedal tractors are children from about the ages of 3 to 10 years, who usually weigh less than 80 pounds; thus, using zinc alloys instead of aluminum would increase substantially the weight of the pedal tractors, making them more difficult for children to maneuver. Because pedal tractors that are less maneuverable would not be as useful or desirable as the lighter, more maneuverable ones manufactured out of aluminum alloys, the demand for the petitioner's pedal tractors would be expected to decrease. Moreover, the petitioner noted that although the costs per pound of zinc and aluminum are about the same (about $1.10 per pound for zinc and about $1.12 per pound for aluminum),[8] because zinc is heavier, the cost of materials would increase significantly. The cost of the product would increase from about $125 (of which about $20.33 or 16 percent is the cost of the aluminum alloy) to about $147 (of which about $49.91 or 34 percent would be the cost of the zinc alloy).[9] The increased cost of manufacturing the product with zinc alloys could limit the company's ability to supply pedal tractors at prices that its customers would be willing to pay. Because using zinc alloys instead of aluminum would adversely affect the demand for the petitioner's products and the company's ability to supply the products at prices that its customers are willing to pay, it may be reasonable to conclude that it is not economically practicable for the petitioner to manufacture pedal tractors out of zinc alloys.

The petitioner stated that magnesium alloys can also be used for die-casting. However, the petitioner does not have experience with using magnesium alloys, nor does it have information about the lead content of magnesium alloys. The use of magnesium alloys for die-casting might require the company to acquire new equipment suitable for die-casting with magnesium alloys as opposed to aluminum alloys. The petitioner also stated that there were some environmental concerns and other hazards, such as flammability, that existed with magnesium that do not exist with aluminum. Magnesium alloys might corrode more readily, which would reduce the durability of the product and probably make it less desirable. This would have the impact of reducing the demand for the company's products.

Pedal tractors can be made out of plastic or steel, and pedal tractors made of both materials are available in the marketplace. Using these materials instead of aluminum might be an alternative for manufacturing pedal tractors that meet the 100 ppm lead limit. However, if there are significant differences in terms of functionality, durability, detail, or general appeal to consumers between pedal tractors manufactured out of aluminum and pedal tractors manufactured out of plastic or steel, then they could be considered to be different products. For example, if plastic or steel pedal tractors are less durable or have less general appeal to

[8] The cost of the aluminum alloy is from the materials provided in the petition. The cost of the zinc ally was provided in a telephone conversation between Kristine Hatlelid and Thomas Caton of the Consumer Product Safety Commission and Jane Ertl and Bob Willits of Joseph L. Ertl, Inc. (21 October 2011).

[9] The petitioner reports that the overall cost of the pedal tractors is $125, of which $20.33 is due to the cost of the aluminum. If a zinc alloy was substituted for the aluminum alloy, the cost would be about $147, of which $49.91 would be due to the cost of the zinc alloy (41.25 pounds x 1.1 (scrap factor used by the petitioner) x $1.10 (the cost of the zinc alloy per pound reported by the petitioner). Therefore, the cost of the zinc alloy would be about 34 percent of the cost of the product ($49.91 ÷ $147). The cost of the product using zinc alloy is the cost of the product using aluminum less the cost of aluminum alloy plus the cost of the zinc alloy ($125 - $20.33 + $49.91).

consumers than aluminum pedal tractors, they may not be considered good substitutes by some consumers and could be considered to be different products.

The petitioner asserts that its customers "prefer the durability of metal farm toys over plastic farm toys," which suggests that there are some significant differences between aluminum and plastic pedal tractors or that they serve different niches of the market. On the other hand, the petitioner reported that one of its larger customers stated that they would obtain steel pedal tractors if the petitioner was unable to supply it with aluminum pedal tractors. This suggests that some consumers may consider steel pedal tractors to be suitable substitutes for aluminum pedal tractors.

However, even if plastic or steel pedal tractors could be very close substitutes for aluminum pedal tractors, manufacturing pedal tractors out of steel or plastic is not an economically practicable alternative for the petitioner (Joseph L. Ertl, Inc.). The petitioner's primary business is the manufacture of various parts or components of products out of zinc or aluminum alloys using die-casting techniques. The petitioner states that its toy business is only about 5 percent of its business.[10] Manufacturing pedal tractors out of steel involves metal stamping processes and not die-casting. In order to manufacture steel pedal tractors, the company would have to invest in new equipment and tooling for metal stamping and would have to hire employees who are capable of designing and manufacturing products using metal stamping processes. Given the petitioner's toy business is only a small portion of its total business, and its annual production of pedal tractors is estimated to be less than 1,000 units, this is unlikely to be economically feasible.

The petitioner stated that it could invest in an aluminum alloy that was specifically formulated to comply with the 100 ppm lead content limits. However, this would require that the petitioner purchase the entire production lot or "heat." The minimum heat is 120,000 pounds, which is about a seven year supply for the company. Therefore, the company would incur the cost of financing a seven year supply of the alloy and then storing it on their premises until they use it. Moreover, the petitioner is not certain if they could use the resulting alloy without substantial retooling, which would add to the cost. Therefore, the petitioner does not consider this to be an economically practicable solution.[11] Other manufacturers of similar cast aluminum products are likely to face similar problems obtaining aluminum alloys that consistently meet the 100 ppm lead content limit.

Benefits and Costs of Granting the Exception

If an exception to the 100 ppm lead content limit is not granted, it is likely that it will not be practicable for the petitioner to continue manufacturing pedal tractors. As noted above, the pedal tractor market, and especially the niche represented by the petitioner, is small and consists largely of pedal tractors that are scale models of working modern and historical tractors. According to the petitioner, many of the customers who purchase their products are people (parents or grandparents) with "rural American roots." Given that the pedal tractor market is small, other manufacturers of pedal tractors and similar ride on toys may find it difficult to

[10] Telephone conversation between Kristine Hatlelid and Thomas Caton of the U.S. Consumer Product Safety Commission and Jane Ertl and Bob Willits of Joseph L. Ertl, Inc. (October 21, 2011).

[11] Submission from Scale Models, dated September 19, 2011.

obtain aluminum alloys that consistently meet the 100 ppm lead limit. The benefit of granting an exception to the 100 ppm lead requirement is that it would allow the petitioner to continue to sell die-cast aluminum pedal tractors. By allowing the petitioner, and possibly other companies, to continue to manufacture die-cast aluminum pedal tractors, the variety of pedal tractors available to consumers will be maintained. This benefit is positive, but it cannot be quantified at this time.

The cost of granting the exception is the cost associated with adverse health impacts that could be attributable to the exception. There are several reasons that this cost is expected to be negligible, at most. First, even if the exception is granted, the lead content of the excepted components is still expected to be low—less than 300 ppm. Second, none of the components affected are small enough to be swallowed. Any exposure to the lead would be through hand-to-mouth activity. Because the lead content would still be less than 300 ppm, little lead would be expected to be transferred to a child's hand and then to the child's mouth. Third, the components are not bare metal, but are powder-coated. This means that children might not be exposed to the lead content of the aluminum at all. Finally, an assessment by the Directorate for Health Sciences concluded that the total amount of exposure would not be expected to have a measurable effect on blood lead levels and no adverse effect on public health or safety.[12]

[12] CPSC Memorandum from Kristina M. Hatlelid to Mary Ann Danello, "Health Sciences Assessment for Request for Exemption from CPSIA Section 101(a) Lead Content Limit" (Tab D).

TAB C: Human Factors Assessment

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

This document has been electronically approved and signed.

Memorandum

Date: March 21, 2012

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

THROUGH : George A. Borlase, Ph.D., P.E., Associate Executive Director, Directorate for Engineering Sciences

FROM : Celestine T. Kiss, Engineering Psychologist, Division of Human Factors, Directorate for Engineering Sciences

SUBJECT : Human Factors Response to Request from Joseph L. Ertl, Inc. for Exception from 100 ppm Lead Content Limits

Introduction

This memorandum provides the U.S. Consumer Product Safety Commission's ("CPSC's" or the "Commission's") Human Factors staff's response to the request by Joseph L. Ertl, Inc., for an exception from the 100 ppm lead content limits for their die-cast ride-on pedal tractors, scaled for children ages 3–10.

Product

Joseph L. Ertl, Inc., Scale Models division, requests that their die-cast, ride-on pedal tractors, scaled for children ages 3–10, be excepted from the 100 ppm lead content requirement of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Specifically, the components in question are the aluminum alloy body castings (right and left sides), rear wheel hubs, wide front axle yoke, and wide front-end adaptor bracket.

Assessment

Section 101(b)(1) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) provides for a functional purpose exception from lead content limits under certain circumstances. The exception allows the CPSC, on its own initiative, or upon petition by an interested party, to exclude a specific product, class of product, material, or component part from the lead limits established for children's products under the CPSIA if, after notice and a hearing, we determine 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 section 101(a) of the CPSIA 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. Under section 101(b)(1)(B) of the CPSIA, there is no measurable adverse effect on public health or safety if the exception will result in no measurable increase in blood lead levels of a child.

Human Factors staff assessed the die-cast, ride-on pedal tractors information, specifically the component parts in question, to determine the likelihood that any or all of the parts would be placed in the mouth or ingested by a child 3–10 years old, taking into account normal and reasonably foreseeable use and abuse of such product, class of product, material, or component part by a child.

The Ertl's submission[1] stated that the pedal tractor end-user is typically a child between the ages of 3 and 10 years. The submission indicated that the typical use patterns are for "indoors in a basement (in mid-west winters), shed, or other out-building. Or used outdoors in a garage, on a driveway, a yard, etc." The submission also stated that "under normal use, the child is primarily touching the plastic steering wheel with his or her hands. The steering wheel is used to steer the pedal tractor, as well as provide leverage while pedaling. An additional area the child may touch is the hitch pin on the back of the pedal tractor. The purpose of the hitch pin is to connect or disconnect a pull behind object." The petitioner also specifically states: "outside of the body castings, the aluminum die cast components itemized are not touched by the children during normal use. The typical areas of the body casting which may be touched during play, but not during actual riding, include the front or top of the body casting, the center of the body casting between the seat and steering wheel and the hitch pin area at the back of the body casting. All metal casting surfaces are powder coated and too large for a child to place in their mouth."

According to the AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior (2002),[2] children at age 3 have developed the ability to pedal ride-on toys and have the coordination required to use a steering wheel or handlebar. These children enjoy tricycles and four-wheeled vehicles propelled by pedaling. Therefore, staff agrees that the youngest likely user of the die-cast pedal tractor is 3 years of age. The oldest likely user will depend on the size and interests of the child. This age assessment is true of similar ride-on products in this class of products.

Staff also agrees that the likely use patterns would include inside and outside activities, depending on the weather. During typical use of the tractor, the rider is likely to touch the seat, steering wheel, and hitch pin, if there is an attachment. However, it is also likely that other children may straddle the front body of the tractor to catch a ride, or even hold onto the front axle yoke to push the tractor backward. Regardless of which parts are touched, staff agrees with the Ertl submission that the components in question are too large for a child to place in their mouth.

According to the EPA's Exposure Factors Handbook: 2011 Edition,[3] Table 16-7. Mean Time (minutes/day) Children Under 12 Years of Age Spent in Ten Major Activity Categories, for All Respondents and Doers, the mean duration for "recreation" activities, which included active

[1] Letter from Jane Ertl, Executive Vice President, Joseph L. Ertl, Inc, to Office of the Secretary US Consumer Product Safety Commission, September 29, 2011, Re: Section 101 Request for Exemption from 100 ppm Lead Content.

[2] Smith, T.S. (Ed.). (2002). AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior, U.S. Consumer Product Safety Commission, Bethesda, MD, p. 169. http://www.cpsc.gov/BUSINFO/adg.pdf.

[3] U.S. Environmental Protection Agency. 2011. Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA. Available at: http://www.epa.gov/ncea/efh.

sports, leisure, hobbies, crafts, art, music/drama/dance, games, playing, and travel to leisure activities, was 260 minutes a day. "Games" was recorded in a detailed activity chart with the highest average minutes. Assuming a small percentage of that time is spent actually using the ride-on pedal tractor, we can estimate that a child will be using the pedal tractor roughly 13 minutes/day, but that does not mean they are touching the in-question components the whole time. As stated above, a single child riding the tractor is most likely to touch only the main tractor body parts during play. If other children are also playing with and on the tractor, the main body casting is the most likely leaded component that will be touched, and the wide front axle yoke is the next most likely component to be touched.

There is very limited information available to determine exactly how often a child plays with a specific toy, much less how often in a day a child plays with the toy. It is reasonable to assume that the toy will be played with more often when it is new, and then play time will decline as the child gets older. The die-cast pedal tractor and similar products, which are for children between 3 and 10 years of age, are not likely to be used at the same rate of play across the age span specified.

Staff Conclusion

It is Human Factors staff's opinion that during normal and reasonably foreseeable use and abuse, children between 3 and 10 years of age will touch the main body castings and the axle yoke of the pedal tractor. The rear wheel hubs and the wide front-end adaptor bracket do not appear to be within reach during normal and reasonably foreseeable use and abuse. It is not likely any of these component parts will be placed in the child's mouth. This assessment is based on pictures of ride-on tractors from Joseph L. Ertl, Inc., Scale Models division, but it can be applied to the class of products of similar design and function as the ride-on pedal tractors.

TAB D: Health Sciences Assessment

TAB D

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

Memorandum

This document has been electronically approved and signed.

Date: March 21, 2012

TO : Mary Ann Danello, Ph.D., Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences

FROM : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Health Sciences Assessment for Request for Exception from CPSIA Section 101(a) Lead Content Limit

Introduction

Section 101(b)(1) of the Consumer Product Safety Improvement Act of 2008, as amended by Public Law 112-28, (CPSIA, or Act), provides for a functional purpose exception from the lead content limit for children's products under certain circumstances. Among other requirements, an exception for a 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. The Act specifies that there is no measurable adverse effect on public health or safety if the exception will result in no measurable increase in blood lead levels of a child.

Request

On September 29, 2011, the Commission received a request for exception from Joseph L. Ertl, Inc., Scale Models and Dyersville Die Cast divisions, for die cast ride-on pedal tractors for children ages 3–10 years. The components of the pedal tractors include die-cast aluminum alloy that contains no more than 200 ppm or 300 ppm lead, depending upon the alloy used. The firm states that it is unable to meet a 100 ppm lead content limit because of the specific alloys used in the die-cast process. Accordingly, the firm requests an exception from the 100 ppm lead content limit to continue to manufacture its pedal tractors with components conforming to the 300 ppm lead content limit.

Discussion

Routes of exposure

The petitioner indicated that typically, children would not have contact with some parts of the product, such as the wheel and axle that are made with aluminum alloy containing no more than 300 ppm lead. The petitioner stated that children may contact the body of the product during play, but not during use (*i.e.*, riding) of the product. The petitioner also stated that children

would not have contact with the aluminum alloy because the firm uses a powder coat finish on the alloy's surface.

The possible routes of exposure to lead that might be present in a product or parts of a product typically include mouthing, ingestion of component parts, or touching and handling component parts during typical play or other activity, with transfer of lead to the hands and fingers. Material that collects on the hands and fingers subsequently may be transferred to the mouth and swallowed due to normal hand-to-mouth contact.

The Commission may not grant an exception for a product that does not conform to the condition that the product or part is not likely to be placed in the mouth or ingested. Given this restriction, for most products, transfer of lead to hands and fingers with subsequent hand-to-mouth contact is the most likely possible route of exposure.

Level of exposure

The potential for exposure and the level of exposure to lead from handling and subsequent hand-to-mouth contact depends on a number of factors, such as the characteristics of the product and the characteristics and behaviors of the children expected to use the product. Key factors may include the type of product and the specific lead-containing materials, the ages of children using the product, and where the product is used.

The U.S. Environmental Protection Agency, in its Exposure Factors Handbook,[1] has analyzed the available scientific literature related to children's behaviors associated with chemical exposure. Chapter 4 of the Exposure Factors Handbook discusses studies indicating that all people occasionally contact their mouth with hands, fingers, or objects. The number of hand-to-mouth contacts per hour for children peaks around age 2 years and decreases over several years (see summary of studies in Exposure Factors Handbook Table 4-1). This summary also indicates that children engage in fewer hand-to-mouth contacts while outdoors compared to indoors. Further, the duration of hand contacts with the mouth appears to peak around age 2 years, although less information is available for older children. The studies included in the Exposure Factors Handbook include an observational study conducted by CPSC staff of mouthing behaviors in young children.[2] This study, as well as other studies conducted by CPSC staff, focused on children younger than age 3 years.

The products under discussion here, pedal tractors, are relatively large, heavy, ride-on toys. A likely location for use of the product is outdoors. It is also possible for the product to be used indoors, perhaps in a basement during winter, for example. To the extent that the product is used outdoors, children's hand-to-mouth contacts and any potential for transfer of lead to the mouth from use of these products is expected to be less than when this product or other toys are used indoors because of the data that show that children have fewer hand-to-mouth contacts while playing outdoors.

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[1] U.S. Environmental Protection Agency. 2011. Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA. Available at: http://www.epa.gov/ncea/efh.

[2] Greene MA (2002) Mouthing times for children from the observational study. U.S. Consumer Product Safety Commission. In *Briefing Package: Response to Petition HP 99-1, Request to Ban PVC in Toys and Other Products Intended for Children Five Years of Age and Under.* Available at: http://www.cpsc.gov/library/foia/foia02/brief/briefing.html.

Children spend most of their time at home, and most of the time spent at home is indoors (studies summarized in Chapter 16 of the EPA Exposure Factors Handbook). Time spent outdoors can be divided between home and other locations, such as school or parks, and it includes the time spent with a particular activity, such as sports. Likewise, time spent indoors includes many different activities.

Staff cannot estimate precisely how often a child will use a pedal tractor during outdoor play, where mouthing behaviors are less frequent; nor can staff estimate precisely whether and how often the product is used indoors. Nonetheless, even if a child's typical day does not always include play with the pedal tractor, such play will occur with some frequency and regularity. If a family owns a pedal tractor, at least a portion of a child's play time will include contact with the product. Using the assumption that a small portion of the typical time spent in recreation will involve contact with a pedal tractor, CPSC Human Factors staff estimates that a child might spend 13 minutes a day using the product (Tab C).

Estimating exposure

Staff uses wipe-testing (also called wipe-sampling) to assess exposures that might occur through hand-to-mouth contact after touching or handling a product. The transfer of lead from a product to a child's hands is estimated using cloth or paper wipes rubbed across the product's surfaces. After wiping the product according to the standardized method, the paper or cloth wipes are analyzed for lead.

Staff knows of no data from wipe-testing such products as the aluminum alloy pedal tractors, although data from testing other products are available. Staff has tested hundreds of metal jewelry products[3] and many polyvinyl chloride (*i.e.*, PVC or vinyl) products[4] for lead that could be removed from the surface of the products, such as when a child touches or handles the product during use.

The metal jewelry items and vinyl bibs contained lead at levels less than 300 ppm (0.03 percent) to more than several percent lead. In comparison, the petitioner has indicated that pedal tractor products contain no more than 200 ppm or no more than 300 ppm lead in the aluminum alloy parts, depending on the alloy used. The available data from CPSC staff's wipe-testing of products with lead content more than 100 ppm and up to 100,000 ppm (equivalent to 10 percent) lead show transfers of lead, per wipe, averaged less than 0.02 micrograms (µg) of lead.

If we consider that the tested products have some similarities to the pedal tractors, these data could help in assessing the potential for lead exposure from the aluminum used in the pedal tractors. Accordingly, staff would expect that the possible transfer of lead from a pedal tractor made with aluminum alloy containing no more than 200 or 300 ppm lead would be approximately the same level (*i.e.*, on average less than 0.02 µg per wipe).

The pedal tractor includes a powder-coat finish on the metal component parts. While this finish may not absolutely prevent contact with the metal itself, it will reduce the opportunity for a child's contact with the metal to instances in which the finish has been damaged or removed. Should such damage occur, staff believes that it would affect a portion of the product, and not its

[3] Data included in Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry (Petition No. HP 06-1). Available at: http://www.cpsc.gov/library/foia/foia07/brief/LeadToyJewelry.pdf.

[4] Data from CPSC Staff Analysis of Lead Content and Accessible Lead in Vinyl Baby Bibs. Available at: http://www.cpsc.gov/CPSCPUB/PREREL/prhtml07/07175.pdf.

entire surface. While the size and location of the damage cannot be predicted without testing the product for the effects of weather and wear and tear, staff expects that it would most likely constitute a small fraction of the product's surface. Therefore, a child's contact with a pedal tractor with a damaged finish would consist of contact with finished areas of the aluminum alloy parts, as well as areas of the alloy with missing or damaged finish. Staff believes that only contact with the damaged areas potentially would result in the transfer of lead to the hands.

Exposure to lead could happen when some of the material that collects on children's hands is transferred to the mouth during normal hand-to-mouth contacts during the day. In the past, staff has analyzed data regarding the amount of dust and soil children ingest during the day from incidental transfers to the mouth, as well as the amount of dust and soil that sticks to the skin. Based on the idea that ingested dust and soil comes from the transfer of dust and soil from the hands, staff has concluded that for young children under age 6 years, approximately one-half of the lead that collects on the hands during the day will be transferred to the child's mouth during the day. This estimate would be influenced by a specific exposure scenario for children with particular characteristics. As discussed above, the factors that could affect hand-to-mouth transfer of lead include a child's age and whether the child is indoors or outdoors.

The statute provides that an exception must result in no measurable increase in blood lead levels of a child. Extensive scientific literature and several physiologic models exist that describe the relationship between exposure and blood lead level. Thus, with a given exposure scenario, one can use a model to estimate the expected change in blood lead level.

One such model is the U.S. Environmental Protection Agency's (EPA) Integrated Exposure Uptake BioKinetic Model for Lead in Children (IEUBK).[5] The user's guide[6] to the IEUBK indicates that the output for modeled blood lead concentrations is reported to one digit to the right of the decimal, and it explains that the true precision of any calculated output can be influenced strongly by the least precise input value. The model includes default inputs for lead exposure from sources such as diet and soil. One can also run the model adding other sources of lead, such as a consumer product, to assess the effect of a potential source of exposure on the blood lead level. The model calculates blood lead level based on exposure to lead every day during 1-year age intervals. While it may not be likely that a child would have contact with lead from a pedal tractor every day, staff used the model to illustrate the effect of a possible exposure scenario. Accordingly, staff found that running the model with the added input of daily exposure to as much as 0.6 micrograms per day (µg/day) in children ages 3–7 years results in a change in the blood lead level of 0.1 µg/dL (*i.e.*, one digit to the right of the decimal). The model does not include children older than age 7 years, but an exposure in older children would be expected to have a smaller effect on blood lead level because of their increased body size and larger blood volume. Staff notes that while the model can show an effect on blood lead level of 0.1 µg/dL *in theory*, such a small change is not measurable *in practice*, using standard laboratory techniques for blood lead measurements.

While the exposure from use of a pedal tractor has not been quantified, testing of other products resulted in an average of less than 0.02 µg per wipe. A child could have several contacts per day

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

[6] EPA (2007) User's Guide for the Integrated Exposure Uptake BioKinetic Model for Lead in Children (IEUBK) Windows®. EPA 9285.7-42 (Updated May 2007). Available at: http://www.epa.gov/superfund/lead/products/ugieubk32.pdf.

with a pedal tractor, or have no contact at all on days that do not include play with the product. Because staff does not have data on how many contacts per day a child might have with the aluminum alloy parts of a pedal tractor during the estimated duration of daily contact with the product, staff cannot provide a quantitative estimate of how much lead might collect on a child's hands. Staff includes the estimate of the effect on the blood lead level of daily exposure to 0.6 µg/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.

Conclusion

Overall, staff expects that lead ingestion from contact with a product such as the pedal tractor would be a fraction of the daily exposure that would result in an increase in blood lead level. Staff expects that possible daily exposure to lead from the pedal tractor would be very low, perhaps even nondetectable, using standard laboratory techniques.

Therefore, if lead is transferred to a child's hands during use of the product, and then transferred to the mouth and ingested, staff expects the total amount of exposure to be so low that it would have no measurable effect on blood lead level, and no measurable adverse effect on public health or safety, taking into account normal and reasonably foreseeable use and abuse..

In addition, staff believes that other products that contain cast aluminum component parts using aluminum alloys similar to those used in the pedal tractors under discussion here may also have a similar expectation of very low exposure. To the extent that such other products contain component parts that, due to their size, location, and expected use, are neither likely to be placed in the mouth, nor result in transfer of lead from the component to the hands, staff concludes that exposure to lead from such products would also be very low.