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

BALLOT VOTE SHEET

DATE: JUL - 9 2009

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Jacqueline Elder, Acting Executive Director JC

FROM: Philip Chao, Assistant General Counsel PC
Hyun S. Kim, Attorney, OGC HK

SUBJECT: Request from the Fashion Jewelry Trade Association, et al. for Exclusion from Lead Content Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act (CPSIA)

Ballot Vote Due: JUL 16 2009

Attached are the staff memoranda and initial recommendation on the request from the Fashion Jewelry Trade Association, Manufacturing Jewelers and Suppliers of America, Footwear Distributors and Retailers of America, National Retail Federation, and United Dance Merchants of America (FJTA) for exclusion of crystal and glass beads used in children's products, including rhinestones and cubic zirconium, under section 101(b)(1) of the CPSIA.

Please indicate your vote on the following options.

I. Accept staff's initial recommendation and deny FJTA's request for exclusion.

_____ _____
(Signature) (Date)

II. Accept staff's initial recommendation and grant FJTA's request for exclusion.

_____ _____
(Signature) (Date)

Note: This document has not been reviewed or accepted by the Commission.
Initials ph Date 7-9-09

CPSA 6(b)(1) CLEARED for PUBLIC 7/9/09
NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED
EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG
ENTIRE PORTIONS REMOVED:

III. Take other action.
(Please specify.)

_____

_____

_____

_____ _____

(Signature) (Date)

EXHR Staff Memorandum: Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from the Fashion Jewelry Trade Association and Others dated July, 2009.

Hazard Analysis Division Staff Memorandum: Analysis of Data on Child Ingestions, November 30, 2006

Human Factors Response to Request from the Fashion Jewelry Trade Association and Others for Exclusion from Lead Limits under Section 101(b)(1)) of the Consumer Product Safety Improvement Act dated July, 2009.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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Memorandum

Date: JUL - 9 2009

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Jacqueline Elder, Acting Executive Director JE

FROM : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction RR for JH
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences KH

SUBJECT : Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from the Fashion Jewelry Trade Association and Others

Introduction

The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

Section 101(b)(1) of the CPSIA provides that the Commission may exclude a specific product or material from the lead limits established for children's products under the CPSIA if the Commission, after notice and a hearing, determines on the basis of the best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither: (a) result in the absorption[1] of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking,

[1] In toxicology, absorption refers to the transfer of a chemical into the systemic circulation from the site of exposure, primarily through the skin, respiratory tract and gastrointestinal tract [Gregus Z (2008) Mechanisms of Toxicity In: C. Klaassen, (Ed.) Casarett & Doull's Toxicology, The Basic Science of Poisons. (p. 46) New York: McGraw Hill Medical]. In this memorandum, the term exposure is used to refer to the amount of lead a child comes into contact with, as well as the amount taken into the body through ingestion. A portion of ingested lead will be absorbed into the body, depending on factors such as the child's age, fasting and nutritional status, and chemical and physical form of the lead.

or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.

By rule[2], the Commission has established procedures by which interested people may request an exclusion from the lead limits of section 101 of the CPSIA. This rule states that upon receipt of a request for an exclusion, the Office of Hazard Identification and Reduction (EXHR) will assess the request to determine whether, on the basis of its review of the submitted materials, the normal and reasonably foreseeable use and abuse activity by a child (including swallowing, mouthing, breaking, or other children's activities) and the aging of the material or product for which exclusion is sought, will not result in the absorption of any lead into the human body nor have any other adverse impact on health or safety.

This memorandum provides the EXHR staff review of materials submitted by the Fashion Jewelry Trade Association, Manufacturing Jewelers and Suppliers of America, Footwear Distributors and Retailers of America, National Retail Federation, and United Dance Merchants of America in their request for exclusion of crystal and glass beads and related products.

Product

The associations request that crystal and glass beads, including rhinestones and cubic zirconium, used in children's products, including jewelry, apparel, accessories, footwear and other decorative applications be excluded from the lead content limits of the CPSIA. The associations also request exclusions for "any crystal decorative items," such as picture frames, lamps, figurines and the like.

Assessment

The associations included in their request an evaluation prepared by Exponent, Inc. The report presents a description of crystal beads and stones, estimates of the amount of lead released from crystal beads under certain conditions of exposure, and an interpretation of the amount potentially taken up into the body.

The report describes methods used to measure leaching of lead into saline or acid solutions. The results show leaching into saline of 0.008-0.701 micrograms (μg) lead per crystal bead (average: 0.12 μg). Reported by weight, the saline leaching method resulted in 0.041-0.779 μg lead per gram of crystal (average: 0.27 μg). These extraction results were used as estimates of possible exposure to lead from a child mouthing a crystal bead or stone.

The acid extraction resulted in 0.01-2.8 μg lead per crystal bead (average: 0.52 μg); or 0.139-35.9 μg lead per gram of crystal (average: 11.7 μg). These acid extraction results were used as estimates of possible exposure to lead from a child swallowing a crystal bead or stone.

The authors concluded that actual lead exposures for children who might mouth or swallow crystal or glass beads or stones would be much less than the experimental estimates, especially if one considers the amount of leaching per gram of bead because one gram of beads could actually be hundreds of beads depending on the size of the beads. Further, the authors indicated that the saline extraction was conducted for one hour, which would be conservative because children's daily mouthing of objects is much less than 1 hour, and that the estimated exposures to lead from

[2] "Children's Products Containing Lead; Final Rule; Procedures and Requirements for a Commission Determination or Exclusion," 74 Federal Register 10475 (11 March 2009), codified at 16 C.F.R. § 1500.90.

crystal beads would be lower than children's exposure to lead from normal dietary sources. The authors also considered the potential impact of lead exposure from beads using the U.S. Environmental Protection Agency's Integrated Exposure Uptake Biokinetic Model (IEUBK) software, and concluded that a hypothetical exposure would result in a very small increase in blood lead level or no predicted change. The authors also indicated that such small changes would be difficult or impossible to discern analytically.

The requestors also pointed out that the potential lead exposure from crystal beads is less than the possible exposure to lead from metal jewelry items that are in compliance with the CPSIA lead limits, since data show that lead leaches out of metal objects to a greater extent than out of crystal or glass.

Staff Conclusion and Recommendation

The staff believes that the assessment approach is generally sound. The staff agrees[3] with the report's conclusion that extensive mouthing of beads or repeated swallowing of beads is not expected, but the staff has reviewed data[4] indicating that such events may occasionally occur in children in a wide range of ages.

While the authors estimated possible exposure to lead from mouthing or swallowing crystal or glass beads, they concluded that the potential impact of the lead exposure on a child's blood lead level would be low or that the IEUBK software would not show an increase in the blood lead level.[5] The staff notes that, physiologically, if ingestion of lead occurs, some portion of the ingested lead will be absorbed into the body, whether or not the absorption results in a significant change in blood lead level as estimated by modeling software.

The staff is aware that regulatory paradigms for lead in other products exist within other federal regulatory agencies. For example, in 2006, the U.S. Food and Drug Administration (FDA) issued guidance[6] providing a recommended maximum lead level of 0.1 ppm in candy (equivalent to 0.1 μg/g). If, for example, a child consumed a piece of hard candy weighing 5 grams and containing lead at the recommended maximum level, the total intake of lead would be 0.5 μg.

The requestors cited this FDA guidance and the FDA staff conclusions that the potential lead exposures from candy would not constitute a health hazard. The requestors also cited legislation in the State of California that restricts lead content of certain children's jewelry products, but that allows for the use of up to 1 gram of crystals in such products. They also noted that the State has asked the Commission to exclude from the scope of preemption the State legislation that includes children's jewelry and the exemption for up to 1 gram of crystals.

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[3] Memorandum from Celestine T. Kiss to Kristina M. Hatlelid, "Human Factors Response to Request from the Fashion Jewelry Trade Association and Others for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act," April, 2009.

[4] Memorandum from Craig O'Brien to Kristina Hatlelid, "Analysis of Data on Child Ingestions," November 30, 2006.

[5] For a more detailed discussion of the outputs of IEUBK model software, see memorandum from Kristina M. Hatlelid and Robert J. Howell to The Commission, "Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from Motorized Recreational Vehicle Firms and Associations," March 2009.

[6] Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), November 2006 (available at http://www.cfsan.fda.gov/guidance.html).

Prior to enactment of the CPSIA, the staff's assessments of lead-containing children's products, under the Federal Hazardous Substances Act (FHSA), were based on estimates of lead intake and the subsequent effects of the exposure on blood lead level, considering the toxicology of lead and the demonstrated health effects associated with increasing blood lead levels. Regulation of a consumer product as a "hazardous substance" under the FHSA requires assessment of exposure and risk from reasonably foreseeable use and abuse of the product. In this case, given the assessment provided by the requestors, the staff likely would have concluded that the estimated exposure to lead from children's use of crystals would have little impact on the blood lead level. Accordingly, based on the staff's assessment, the staff would have recommended that the Commission not consider the product to be a hazardous substance to be regulated under the FHSA.

However, the CPSIA establishes the standard by which the staff evaluates the materials submitted with a request for exclusions. The law states that an exclusion may be granted if lead in such product or material will neither: (a) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.

Because the requestors' report indicated that children's use of crystal beads could result in absorption of lead, however small the absorbed amount, the staff's initial recommendation to the Commission is to not grant the request on the grounds that the statutory standard has not been met.

The associations' request for exclusions for any other crystal decorative items was accompanied by little information regarding the specific products mentioned in the request. The request did not include data relevant to any particular product or analysis of children's possible interactions with any particular item, nor a formal assessment of whether a particular product would result in absorption of any lead into the body. Consequently, the staff is unable to address this part of the associations' request.

One of the points raised by the requestors is that potential lead exposure from crystals is less than the possible exposure to lead from metal jewelry items that are in compliance with the CPSIA lead limits (*i.e.*, lead content less than 300 parts per million), using data generated by their consultant and by the CPSC staff. Inspection of the data shows that it is not necessarily true that a child that swallows a crystal bead would always experience a lead exposure that is lower than exposure from swallowing a piece of metal jewelry containing less than 300 ppm lead. Rather, the data indicate that variability in the leaching data spans orders of magnitude, with some crystal samples leaching more lead than some metal samples and *vice versa*.

Even if it were true that lead exposure from certain crystal products might be lower than from some metal jewelry items, it might also be true for other products that contain lead at levels that exceed the CPSIA lead limits. Thus, if the exclusion for crystals were granted based on the comparison of lead exposure from crystal items to lead exposure from complying metal jewelry items, other industries could be encouraged to make similar comparisons for their lead-containing products. If the staff were directed to make such comparisons, the staff would be assessing products based on exposure and risk, as was the practice under the FHSA, rather than based on the lead content requirements of the CPSIA.

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Memorandum

Date: November 30, 2006

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

THROUGH: Russell Roegner, Ph.D., Associate Executive Director RR
Directorate for Epidemiology

Kathleen Stralka, M.S., Division Director RR for KS
Hazard Analysis Division

Robin L. Ingle, M.A., Health Statistician RI
Hazard Analysis Division

FROM : Craig O'Brien, M.S., Mathematical Statistician
Hazard Analysis Division

SUBJECT : Analysis of Data on Child Ingestions

I. Introduction

This memorandum gives results of an analysis of consumer products swallowed by children. The data source for the analysis is the National Electronic Injury Surveillance System (NEISS), maintained by the Consumer Product Safety Commission (CPSC). Estimates are provided for the number of emergency-room treated injuries involving ingested foreign objects by product and age category.

II. Background

In April of 2006 the Sierra Club petitioned CPSC regarding lead in consumer products, especially toy jewelry (Sierra Club, 2006). One of the concerns mentioned in the petition is the ingestion by children of consumer products containing lead.

III. Injury Data

A. Methodology

The National Electronic Injury Surveillance System (NEISS) is a probability sample of approximately 100 U.S. hospitals having 24-hour emergency rooms (ERs) and more than six beds. NEISS collects injury data from these hospitals. Coders in each hospital code the data from the ER record and the data is then transmitted electronically to CPSC. Because NEISS is a probability sample, each case collected represents a number of cases (the case's *weight*) of the total estimate of injuries in the U.S. Different hospitals carry different weights, based on stratification by their annual number of emergency room visits (Schroeder and Ault, 2001).

Hazard Analysis staff searched NEISS for all cases with diagnosis code 41 (Ingested Foreign Object) and patients 18 years of age or younger. Staff then used SAS® version 9 to categorize the data by product code and age categories by quartile, and to compute estimates and the associated coefficients of variation for the number of injuries as well as the estimated number of injuries with particular characteristics such as age and associated product. A coefficient of variation (C.V.) is the ratio of the standard error of the estimate (i.e., variability) to the estimate itself. This is generally expressed as a percent. A C.V. of 10% means the standard error of the estimate equals 0.1 times the estimate. Large C.V.'s alert the reader that the estimate has considerable variability. This is often due to a small sample size.[1] Estimates and confidence intervals are not reported here unless the number of cases is 20 or more, the estimate is greater than 1,200, and the C.V. is less than 33%.

B. Results

1. Overall

From 2000 to 2005 staff found 11,994 NEISS cases involving ingestion of a foreign object and a child aged 18 years or younger. Based on these 11,994 cases there were an estimated 302,587 emergency-room treated injuries from 2000 to 2005 involving a child 18 years old or younger ingesting a foreign object. The 95% confidence interval about the number of emergency-room treated injuries from 2000 to 2005 for children 18 years of age or younger is 255,120 to 350,055. A breakdown of the incidents by age group is given in Table 1. The age groups in Table 1 were chosen based on quartiles of age using estimated injuries.

Table 1: Emergency-Room Treated Ingestions by Age Group, 2000-2005

Age Range	Estimate[2]	Percent of Total[2]	Sample Size	C.V.	95% Confidence Interval
0 – 21 months	77,380	25.6%	3,241	9.78%	62,554 – 92,205
22 months – 3 years	92,451	30.6%	3,677	8.51%	77,023 – 107,878
4 – 6 years	71,444	23.6%	2,850	7.82%	60,498 – 82,391
7 – 18 years	61,313	20.3%	2,226	7.63%	52,140 – 70,485
Total	302,587	100.0%	11,994	8.00%	255,120 – 350,055

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, September 2006

The cases were also categorized by the product associated with the ingestion injury. The ten product categories with the highest estimates are shown in Table 2 on the next page. Note that NEISS allows for the coding of one or two products for each incident. An incident with two associated products would be counted twice in the breakdown by product category, once for each product. Of the 11,994 incidents analyzed, 555 incidents had two associated products. There are several situations where two products may be coded for an ingestion. Both products may have

[1] For a more detailed discussion of measures of variation associated with NEISS estimates, see Schroeder and Ault, 2001.
[2] Columns may not sum to totals due to rounding.

been swallowed. If a part of a product is swallowed, such as a battery from a toy, both the part (the battery) and the whole (the toy) may be coded. One product may also be associated with the incident but not swallowed, such as a toddler swallowing a coin found on the floor, with both the coin and the floor being coded.

Table 2: Top Ten Swallowed Products by Individuals 18 Years Old and Younger, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Code Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	147,768	48.8%	6,145	8.82%
1616	Jewelry	19,859	6.6%	807	10.42%
5004	Toys, not elsewhere classified	18,275	6.0%	697	10.58%
1819	Nails, screws, tacks, or bolts	18,187	6.0%	636	8.02%
0884	Batteries	12,053	4.0%	527	12.37%
1354	Marbles	9,663	3.2%	357	13.12%
1650	Desk supplies	6,175	2.0%	219	11.27%
1682	Hair curlers, curling irons, clips, and hair pins	4,996	1.7%	226	13.71%
1729	Christmas decorations (nonelectric)	4,901	1.6%	182	13.80%
1685	Pens and pencils	4,236	1.4%	148	14.12%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, September 2006

2. Age Groups by Quartile

From 2000 to 2005 staff found 3,241 NEISS cases involving ingestion of foreign objects and children aged 21 months or younger. Based on these 3,241 cases there were an estimated 77,380 emergency-room treated injuries from 2000 to 2005 involving children under the age of 21 months and the ingestion of foreign objects. The cases were categorized by the product associated with the ingestion injury. The ten product categories with the highest estimates are shown in Table 3 on the next page. Of the 3,241 cases analyzed, 203 cases had two associated products.

Table 3: Top Ten Swallowed Products by Children 21 Months Old and Younger, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	31,745	41.0%	1,418	12.27%
1819	Nails, screws, tacks, or bolts	6,248	8.1%	210	10.51%
1616	Jewelry	4,628	6.0%	223	15.29%
5004	Toys, not elsewhere classified	3,998	5.2%	148	21.17%
1729	Christmas decorations (nonelectric)	3,733	4.8%	133	16.06%
0884	Batteries	2,818	3.6%	138	14.42%
1682	Hair curlers, curling irons, clips, and hair pins	2,582	3.3%	122	16.29%
1137	Paper products	2,099	2.7%	76	18.45%
1807	Floors or flooring materials[3]	2,043	2.6%	73	22.59%
1650	Desk supplies	1,823	2.4%	73	16.80%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

From 2000 to 2005 staff found 3,677 NEISS cases involving ingestion of foreign objects and children aged 22 months through three years old. Based on these 3,677 cases there were an estimated 92,451 emergency-room treated injuries from 2000 to 2005 involving a child between the ages of 22 months and three years and the ingestion of a foreign object. The cases were categorized by the product associated with the ingestion injury. The six product categories with the highest estimates are shown in Table 4. Only six product categories are shown in Table 4 due to low, and therefore unreportable, estimates for all other product categories. Note that of the 3,677 cases analyzed, 131 cases had two associated products.

Table 4: Top Six Swallowed Products by Children 22 Months through Three Years Old, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	56,587	61.2%	2,293	8.86%
5004	Toys, not elsewhere classified	6,160	6.7%	238	13.37%
1819	Nails, screws, tacks, or bolts	5,204	5.6%	167	12.62%
0884	Batteries	3,696	4.0%	163	13.64%
1616	Jewelry	3,530	3.8%	167	12.41%
1354	Marbles	2,689	2.9%	107	20.45%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

[3] Note that in the case of product code 1807 (floors and flooring materials), the children are not actually swallowing parts of floors, but rather objects that were found on the floor.

From 2000 to 2005 staff found 2,850 NEISS cases involving ingestion of foreign objects and children aged four through six years old. Based on these 2,850 cases there were an estimated 71,444 emergency-room treated injuries from 2000 to 2005 involving a child between the ages of four and six years and the ingestion of a foreign object. The cases were categorized by the product associated with the ingestion injury. The six product categories with the highest estimates are shown in Table 5. Only six product categories are shown in Table 5 due to low, and therefore unreportable, estimates for all other product categories. Note that of the 2,850 cases analyzed, 77 cases had two associated products.

Table 5: Top Six Swallowed Products by Children Four through Six Years Old, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	41,323	57.8%	1,685	8.13%
5004	Toys, not elsewhere classified	5,345	7.5%	211	11.99%
1354	Marbles	4,573	6.4%	153	16.59%
1616	Jewelry	4,120	5.8%	162	12.39%
1819	Nails, screws, tacks, or bolts	2,722	3.8%	119	13.03%
0884	Batteries	2,555	3.6%	120	20.05%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, September 2006

From 2000 to 2005 staff found 2,226 NEISS cases involving ingestion of foreign objects and individuals aged seven through 18 years old. Based on these 2,226 cases there were an estimated 61,313 emergency-room treated injuries from 2000 to 2005 involving a child between the ages of seven and 18 years and the ingestion of a foreign object. The cases were categorized by the product associated with the ingestion injury. The ten product categories with the highest estimates are shown in Table 6 on the next page. Note that of the 2,226 cases analyzed, 144 cases had two associated products.

Table 6: Top Ten Swallowed Products by Individuals Seven through 18 Years Old, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	18,113	29.5%	749	10.46%
1616	Jewelry	7,581	12.4%	255	12.08%
1819	Nails, screws, tacks, or bolts	4,014	6.5%	140	11.63%
884	Batteries	2,984	4.9%	106	19.42%
5004	Toys, not elsewhere classified	2,771	4.5%	100	14.39%
1685	Pens and pencils	2,750	4.5%	93	15.73%
1650	Desk supplies	2,571	4.2%	80	20.10%
1103	Self-contained openers[4]	2,349	3.8%	82	17.43%
1669	Pins and needles	2,037	3.3%	77	16.70%
1354	Marbles	1,941	3.2%	71	18.19%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

IV. Summary

Coins are by far the most common consumer product ingested, accounting for almost half of the estimated injuries (Table 2) when viewed across age. With respect to age quartiles, the highest percentage of injuries due to ingestion of coins is in the 22 month- through three year-old age group (61.2%) and lowest in the seven through 18 year-old age group (29.5%). The next three most commonly ingested product categories are jewelry; toys, not elsewhere classified; and nails, screws, tacks or bolts. These three are always in the top five regardless of age category. The only other product categories to make it into the top five in any age category are batteries, marbles, and nonelectric Christmas decorations.

As jewelry was specifically mentioned in the Sierra Club petition, Table 7 provides a summary of estimated emergency-room treated jewelry ingestion injuries, with confidence intervals.

Table 7: Emergency-Room Treated Jewelry Ingestions by Age Group, 2000-2005

Age Range	Estimate	Percent of Total	Sample Size	C.V.	95% Confidence Interval
0 – 21 months	4,628	23.3%	223	15.29%	3,241 – 6,015
22 months – 3 years	3,530	17.8%	167	12.41%	2,671 – 4,338
4 – 6 years	4,120	20.7%	162	12.39%	3,119 – 5,120
7 – 18 years	7,581	38.2%	255	12.08%	5,787 – 9,357
Total	19,859	100.0%	807	10.42%	15,802 – 23,915

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

[4] Note that product code 1103 (self-contained openers) refers to pop-top openers from soda cans.

References

Schroeder T, Ault K. *The NEISS Sample (Design and Implementation)*. U.S. Consumer Product Safety Commission. 2001.

Sierra Club. "Citizen Petition to CPSC and EPA Regarding Lead in Consumer Products, Especially Toy Jewelry." 17 April 2006.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
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Memorandum

Date: JUL - 9 2009

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

THROUGH: Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction
Hugh M. McLaurin, 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 the Fashion Jewelry Trade Association and Others for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act

Introduction

This memorandum provides the Human Factors staff response to the request by the Fashion Jewelry Trade Association, Manufacturing Jewelers and Suppliers of America, Footwear Distributors and Retailers of America, National Retail Federation, and United Dance Merchants of America for exclusion of crystal and glass beads and related products.

Product

The associations request that crystal and glass beads, including rhinestones and cubic zirconium, used in children's products, including jewelry, apparel, accessories, footwear and other decorative applications, be excluded from the lead content limits of the CPSIA. The associations also request exclusions for "any crystal decorative items," such as picture frames, lamps, figurines and the like.

Assessment

Section 101(b)(1) of the CPSIA provides that the Commission may exclude a specific product or material from the lead limits established for children's products under the CPSIA if the Commission, after notice and a hearing, determines on the basis of the best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither: (a) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.

Human Factors staff looked at the reasonably foreseeable use and abuse of children's products, including jewelry, apparel, accessories, footwear and other decorative applications, and any crystal decorative items, such as picture frames, lamps, figurines and the like, to assess the likely interaction of children and those items.

Jewelry and accessories

According to the AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior (2002)[1], around 12 months of age, children enjoy dress-ups and costumes like easy-to-put-on one-piece bracelets and hair accessories. Although they may need help, by 18 months children like easy-to-put-on, sleeveless, slip-on costumes without fasteners and with large openings for arms and legs. Toddlers between 19 and 23 months are attracted to a variety of basic dress-up materials such as shoes, hats, headscarves, other hair accessories, snap-on ties, bracelets, and necklaces. By 4 and 5 years of age, dress-up/pretend play takes on more elaborate, detailed costumes, accessories, and kits. By 9 years of age, children use unfinished materials, accessories, and kits to customize and design their own outfits, costumes, and disguises.

Children under 3 years of age are at a peak of mouthing behaviors and can be expected directly or indirectly (i.e., hand-to-mouth) to mouth jewelry and accessories. Children 3 and 4 years of age are starting to move away from direct mouthing, but could still have some mouthing and indirect mouthing behaviors. While children 5 years and older do not typically engage in direct mouthing behavior, it is not unreasonable to assume they may wipe their mouths or faces with their hands while using or right after using crystal jewelry or accessories. In addition, anecdotal evidence suggests children and adults will touch and mouth necklaces on chains/lanyards that are long enough to allow the charm/pendent to reach the wearer's mouth.

Apparel and footwear

As stated above, children under 3 years of age are most likely to be directly and indirectly mouthing items. Then as the children get older, they move away from the mouthing behaviors. When it comes to wearing apparel and footwear, the size of the garment will determine the actual user. As the garment is being worn, it is reasonable and foreseeable that the user will touch the crystal decorations. In addition, depending on how well the crystals are attached to the item, it is reasonable and foreseeable that crystals could come off (e.g., after several washes) or be picked off by the wearer.

Crystal decorative items

The associations also asked CPSC staff to exclude crystal decorative items, such as picture frames, lamps, figurines, and the like. They did not identify specific products in this request and therefore, it is difficult to assess the likely interaction of children and these types of products. Products that are clearly decorated in babyish or childish themes and that are marketed and advertised for children would reasonably be used and handled by children. Items with fragile, delicate, adult motifs are not likely to be used and handled by children.

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[1] 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.

Staff Conclusion

It is Human Factors staff's opinion that during normal day-to-day play and activities children starting as young as 12 months of age use dress-up costumes and props that could potentially have crystal decorations. Because children under 3 years of age are at a peak of mouthing behavior it is reasonable to assume they will mouth and/or have hand-to-mouth contact with crystals. As children get older they move away from mouthing behavior, however, it is still reasonable to assume there will be some hand-to-mouth behavior. It is also reasonable to assume that older children and adults will on occasion mouth crystal jewelry they are wearing.

With respect to apparel and footwear, children are most likely to have exposure to crystals through touching the crystals while wearing the item and then touching their mouth.

Crystal decorated picture frames, lamps, figurines and the like, are more difficult to assess because the assessment depends on the theme of the items and how they are marketed and advertised.