United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

CPSC/OFFICE OF THE SECRETARY

1998 DEC 10 P 2:52

BALLOT VOTE SHEET

DATE: December 9, 1998

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Jeffrey S. Bromme, General Counsel
Stephen Lemberg, Asst. General Counsel
Harleigh Ewell, Attorney, GCRA (Ext. 2217) HE

SUBJECT: Codification of policy for lead in consumer products

BALLOT VOTE DUE DEC 18 1998

On January 22, 1998, the Commission published in the Federal Register the text of a document that provides guidance for manufacturers, importers, distributors, and retailers of consumer products that may contain harmful amounts of the element lead. 63 FR 3310. To protect children and other persons from the toxic effects of exposure to lead, the Commission recommended that such persons obtain sufficient tests and analyses to ensure that their products do not contain harmful levels of lead.

The staff believes that this policy would be more accessible to interested parties if it were part of the Code of Federal regulations. Accordingly, a Federal Register notice that would issue this policy as 16 C.F.R. § 1500.501 is attached for the Commission's consideration. Since this is not a substantive rule, and is a statement of policy and interpretative rule, notice and comment rulemaking and a delayed effective date are not required. 5 U.S.C. § 553.

Please indicate your vote on the following options.

I. CODIFY THE POLICY ON LEAD IN CONSUMER PRODUCTS. Please check the relevant option(s) below.

____ 1. APPROVE THE ATTACHED DRAFT FEDERAL REGISTER NOTICE WITHOUT CHANGE.

____ 2. PUBLISH THE DRAFT FEDERAL REGISTER NOTICE WITH CHANGES (please specify).

NOTE: This document has not been reviewed or accepted by the Commission.
Initial rh **Date** 12/10/98

CPSA 6 (b)(1) Cleared
12/10/98
X No Mfrs/Prvt Lblrs of Products Identified
X Accepted by
X Firms Notified.

II. DO NOT CODIFY THE POLICY ON LEAD IN CONSUMER PRODUCTS.

_____ _____
(Signature) (Date)

Attachment
Comments/Instructions:

Billing Code 6355-01P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Codification of Guidance Policy on Lead in Consumer Products

AGENCY: Consumer Product Safety Commission.

ACTION: Final policy statement.

SUMMARY: The Commission codifies a policy statement, previously approved by the Commission and published in the **Federal Register**, that provides guidance for manufacturers, importers, distributors, and retailers of consumer products that may contain harmful amounts of the element lead. To protect children and other persons from the toxic effects of exposure to lead, the Commission recommends that such persons obtain sufficient tests and analyses to ensure that their products do not contain harmful levels of lead.

DATE: This policy has been in effect since December 24, 1997.

FOR FURTHER INFORMATION CONTACT: Mary Toro, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0608, ext. 1378.

SUPPLEMENTARY INFORMATION:

On January 22, 1998, the Commission published in the **Federal Register** the text of a document that provides guidance for manufacturers, importers, distributors, and retailers of consumer products that may contain harmful amounts of the element lead. 63 FR 3310. To protect children and other persons from the toxic effects of exposure to lead, the Commission recommends that such persons obtain sufficient tests and analyses to ensure that their products do not contain harmful levels of lead.

In order to make this policy more accessible to interested parties, the Commission is codifying the policy as 16 CFR 1500.501.

Since this is a statement of policy and interpretative rule, neither a general notice of proposed rulemaking or a delayed effective date is required. 5 U.S.C. 553(d)(2). A delayed effective date is not required for the additional reason that this policy is not a substantive rule. 5 U.S.C. 553(d)(3). Accordingly, this codification will become effective immediately upon its publication in the **Federal Register**.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, Reporting and Recordkeeping requirements, and Toys.

Effective date. This codification is effective _____ [insert date of publication].

For the reasons given above, the Commission amends 16 CFR Part 1500 as follows:

1. The authority citation for part 1500 is revised to read as follows:

Authority: 15 U.S.C. 1261-1278; Agency policy, 63 FR 3310.

2. A new § 1500.501 is added, to read as follows:

§ 1500.501 Guidance for lead (Pb) in consumer products.

(a) *Summary*. (1) The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from hazardous exposure to lead in consumer products.[1] The Commission identifies the major factors that it considers when evaluating products that contain lead, and informs the public of its experience with products that have exposed children to potentially hazardous amounts of lead.

(2) To reduce the risk of hazardous exposure to lead, the Commission requests manufacturers to eliminate the use of lead that may be accessible to children from products used in or around households, schools, or in recreation. The

[1]This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Companies should read that Act and the accompanying regulations at 16 CFR Part 1500 for more detailed information.

Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that those products do not contain lead that may be accessible to children.

(b) *Hazard*. Young children are most commonly exposed to lead in consumer products from the direct mouthing of objects, or from handling such objects and subsequent hand-to-mouth activity. The specific type and frequency of behavior that a child exposed to a product will exhibit depends on the age of the child and the characteristics and pattern of use of the product. The adverse health effects of lead poisoning in children are well-documented and may have long-lasting or permanent consequences. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and to the subsequent risk of adverse health effects. Therefore, any unnecessary exposure of children to lead should be avoided. The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood as a threshold level of concern with respect to lead poisoning. To avoid

exceeding that level, young children should not chronically ingest more than 15 micrograms of lead per day from consumer products.

(c) *Guidance*. (1) Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261(f)(1), household products that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are "hazardous substances." A household product that is not intended for children but which creates such a risk of injury because it contains lead requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children which contains a hazardous amount of lead that is accessible for children to ingest is a banned hazardous substance. 15 U.S.C. 1261(q)(1)(B). In evaluating the potential hazard associated with products that contain lead, the Commission staff considers these major factors on a case-by-case basis: the total amount of lead contained in a product, the bioavailability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product.

(2) Paint and similar surface coatings containing lead have historically been the most commonly-recognized sources of lead poisoning among the products within the Commission's jurisdiction. The Commission has, by regulation, banned paint and other similar surface coatings that contain more than 0.06% lead ("lead-containing paint"), toys and other articles intended for use by children that bear lead-containing paint, and furniture articles for consumer use that bear lead-containing paint. 16 CFR Part 1303. In recent years, however, the Commission staff has identified a number of disparate products—some intended for use by children and others simply used in or around the household or in recreation—that presented a risk of lead poisoning from sources other than paint. These products included vinyl miniblinds, crayons, figurines used as game pieces, and children's jewelry.

(3) In several of these cases, the staff's determination that the products presented a risk of lead poisoning resulted in recalls or in the replacement of those products with substitutes, in addition to an agreement to discontinue the use of lead in future production. The Commission believes that, had the manufacturers of these lead-containing products acted with prudence and foresight

before introducing the products into commerce, they would not have used lead at all. This in turn would have eliminated both the risk to young children and the costs and other consequences associated with the corrective actions.

(4) The Commission urges manufacturers to eliminate lead in consumer products to avoid similar occurrences in the future. However, to avoid the possibility of a Commission enforcement action, a manufacturer who believes it necessary to use lead in a consumer product should perform the requisite analysis before distribution to determine whether the exposure to lead causes the product to be a "hazardous substance." If the product is a hazardous substance and is also a children's product, it is banned. If it is a hazardous household substance but is not intended for use by children, it requires precautionary labeling. This same type of analysis also should be performed on materials substituted for lead.

(5) The Commission also notes that, under the FHSA, any firm that purchases a product for resale is responsible for determining whether that product contains lead and, if so, whether it is a "hazardous substance." The Commission, therefore, recommends that, prior to the acquisition or distribution of such products, importers, distributors, and

retailers obtain information and data, such as analyses of chemical composition or accessibility, relevant to this determination from manufacturers, or have such evaluations conducted themselves.

Dated: _____, 1998.

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Sayde E. Dunn, Secretary
Consumer Product Safety Commission