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.

(a) Summary. The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from exposure to hazardous chemicals found in liquid-filled children's products, such as rolling balls, bubble watches, necklaces, pens, paperweights, keychains, liquid timers, and mazes. The Commission identifies the major factors that it considers when evaluating liquid-filled children's products that contain hazardous chemicals, and informs the public of its experience with exposure to these hazardous chemicals to children. To reduce the risk of exposure to hazardous chemicals, such as mercury, ethylene glycol, diethylene glycol, methanol, methylene chloride, petroleum distillates, toluene, xylene, and related chemicals, the Commission requests manufacturers to eliminate the use of such chemicals in children's products. The Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that liquid-filled children's products do not contain hazardous liquid chemicals.

(b) Hazard. During reasonably foreseeable handling or use of liquid-filled children's products, hazardous chemicals may become accessible to young children in a manner that places children at risk. Young children are exposed to the chemicals from directly mouthing them or from handling such objects and subsequent hand-to-mouth or hand-to-eye 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 these chemicals to children include chemical poisoning from ingestion of the chemicals, pneumonia from aspiration of the chemicals into the lungs, and skin and eye irritation from exposure to the chemicals. The chemicals may also be combustible.

(c) Guidance. (1) Under the Federal Hazardous Substances Act (FHSA), products that are toxic or irritants and that may cause substantial injury or illness under reasonably foreseeable conditions of handling or use, including reasonably foreseeable ingestion by children, are "hazardous substances."
§ 1500.232  Statement on animal testing policy.

(a) Summary. (1) The U.S. Consumer Product Safety Commission issues this statement of policy on animal testing and alternatives to animal testing of hazardous substances regulated under the Federal Hazardous Substances Act (FHSA). The FHSA requires appropriate cautionary labeling on certain hazardous household products to alert consumers to the potential hazard(s) that the products may present. Among the hazards addressed by the FHSA are toxicity, corrosivity, sensitization, and irritation.

(2) In order to determine the appropriate cautionary labeling, it is necessary to have objective criteria by which the existence of each hazard can be determined. Hazards such as toxicity, tissue corrosiveness, eye irritancy, and skin irritancy result from the biological response of living tissue and organs to the presence of the hazardous substance. One means of characterizing these hazards is to use animal testing as a proxy for the human reaction. In fact, the FHSA defines the hazard category of “highly toxic” in terms of animal toxicity when groups of 10 or more rats are exposed to specified amounts of the substance. The Commission’s regulations under the FHSA concerning toxicity and irritancy allow the use of animal tests to determine the presence of the hazard when human data or existing animal data are not available.

(3) Neither the FHSA nor the Commission’s regulations requires animal testing. The FHSA and its implementing regulations only require that a product be labeled to reflect the hazards associated with that product. If animal testing is conducted, Commission policy supports limiting such tests to a minimum number of animals and advocates measures that eliminate or reduce the pain or discomfort to animals that can be associated with such tests. The Commission has prepared this statement of policy with respect to animal testing to encourage the

15 U.S.C. 1261(f)(1). A product that is not intended for children, but that creates a risk of substantial injury or illness because it contains hazardous chemicals, requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children that contains an accessible and harmful amount of a hazardous chemical is banned. 15 U.S.C. 1261(q)(1)(A). In evaluating the potential hazard associated with children’s products that contain hazardous chemicals, the Commission’s staff considers certain factors on a case-by-case basis, including: the total amount of the hazardous chemical in a product, the accessibility of the hazardous chemicals to children, the risk presented by that accessibility, the age and foreseeable behavior of the children exposed to the product, and the marketing, patterns of use, and life cycle of the product.

(2) The Commission’s staff has identified a number of liquid-filled children’s products, such as rolling balls, bubble watches, necklaces, pens, paperweights, maze toys, liquid timers, and keychains, that contain hazardous chemicals. In several of these cases, the staff determined that these products violated the FHSA because they presented a risk of chemical poisoning and/or chemical pneumonia from aspiration. This determination resulted in recalls or in the replacement of those products with substitutes, as well as in agreements with the manufacturers to discontinue the use of hazardous chemicals in liquid-filled children’s products in future production. The Commission believes that these hazardous substances pose a risk to young children and, consequently, manufacturers should not have included them in the product design or manufacturing process.

(3) Therefore, the Commission considers the use of hazardous chemicals in children’s products such as those described above to be ill-advised and encourages manufacturers to avoid using them in such products. Further, the Commission recommends that, before purchasing such products for resale, importers, distributors, and retailers obtain assurances from the manufacturers that liquid-filled children’s products do not contain hazardous liquid chemicals.

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