

Revision of Regulations for Toys Intended for Preschool Children under the Food Sanitation Law

1. Outline

In Japan, the scope is shown¹ of toys which the Minister of Health, Labour and Welfare designates based on the Food Sanitation Law as potentially toxic to infant health through contact therewith, hereafter referred to as “designated toys”. Also, necessary standards and specifications are established.² Any product that does not meet the established standards or specifications, is prohibited from being manufactured or sold in Japan or imported into Japan.³

Notes: 1. Enforcement Regulations Article 78 under Law Article 62

2. Law Article 18 Paragraph 1 applied pursuant to Article 62

3. Law Article 18 Paragraph 2 applied pursuant to Article 62

The current scope of designated toys is, however, no longer able to cover diversified toy products. The Ministry of Health, Labour and Welfare (MHLW) has reviewed the existing regulations and started the necessary procedure to revise them in order to ensure toy safety.

Proposed revision has two major points, i) expansion of the scope of the designated toys and ii) strengthening heavy metals specifications for coatings of toys, and establishment of specifications for “metal toy accessories” which have the possibility that infants may swallow. The migration specifications of the ISO (International Organization for Standardization) (ISO8124-3) for lead, cadmium, and arsenic are intended to be introduced to the specification of “coatings” for toys. Lead migration specification for “metal toy accessories” is intended to be established based also on ISO8124-3 specification.

2. Details

(1) Revision of the scope of designated toys

The current scope of designated toys is given in the table 1 below. The existing restriction of materials will be abolished, and as a result, the proposed scope will comprehensively cover almost all kinds of infant toys that have the possibility to come into contact with infant’s mouth. The toy categories intended to be added include toy accessories, educational/learning toys, and toys used in combination with designated toys (e.g., rails for a toy train set).

Table 1: Designated Toys

Proposed revision	Current
<p>1. Toys intended to come into direct contact with infant's mouth.</p> <p>2. <u>Toy accessories</u>, <i>Utsushi-e</i>*1, roly-polies, masks, <i>origami</i>*2, rattles, <u>educational/learning toys (excluding those unlikely to come into contact with infant's mouth)</u>, wooden blocks, toy telephones, toy animals, dolls, clay, toy vehicles, balloons, toy building bricks, balls, housekeeping toys, and <u>other toys to be used in combination with toy(s) above.</u></p>	<p>1. Toys made of paper, wood, bamboo, rubber, leather, celluloid, plastic, metal, or ceramic that are intended to come into direct contact with infant's mouth.</p> <p>2. <i>Hozuki</i>*3</p> <p>3. <i>Utsushi-e</i>*1, <i>origami</i>*2, wooden blocks</p> <p>4. Toys made of rubber, plastic, or metal that are listed below: roly-polies, masks, rattles, toy telephones, toy animals, dolls, clay, toy vehicles (excluding spring-driven or electric powered vehicles), balloons, toy building bricks, balls, and housekeeping toys.</p>

*1: Transfer pictures

*2: Folding papers

*3: A natural material which is used to make sound in the mouth by pressing the air out

(2) Revision of the standards and specifications

Currently, there are standards and specifications for toy categories as listed in the table 2 attached. This time, the MHLW is considering to add specification for new category “metal toy accessories” and to modify the specifications for “coating agents”.

A. Coatings

The current specifications for coating agent are targeted only to vinyl chloride resin coating agent. The proposed modification of specification will make it possible to cover all kinds of coatings in their dry state as part of finished products.

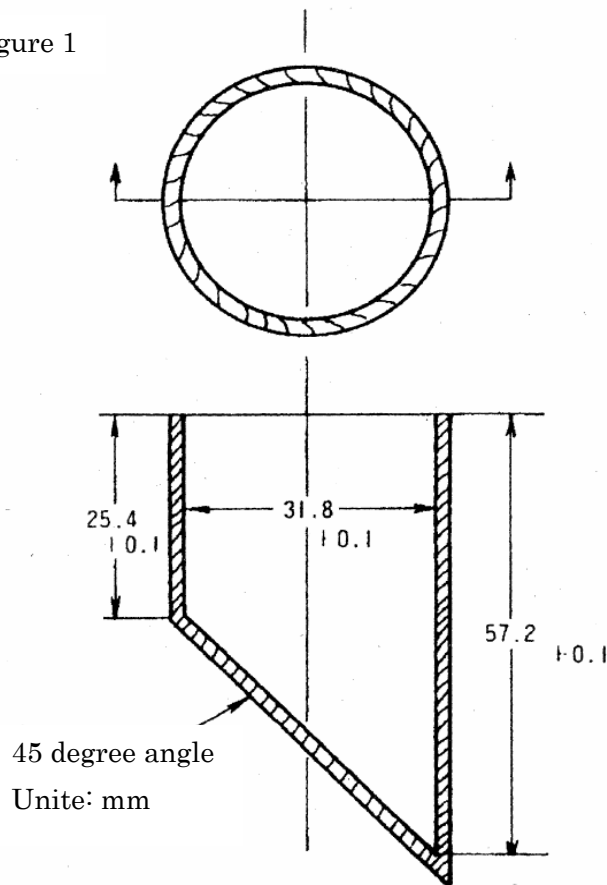
The current migration tests are targeted to heavy metals (regarded as Pb), cadmium (Cd), and arsenic (As). The total concentration of heavy metal (as Pb) is judged whether it exceeds the limit value by comparing the color of prepared test solution with the color of control lead solution. Whereas the proposed new analytical

method will directly determine the concentration of lead. Also, the unit of the specification is proposed to be changed from [$\mu\text{g}/\text{ml}$] (the amount of each element that migrated into the unit volume of a specified solvent) to [mg/kg] (the amount of each element that migrated from one kg of a sample coating into a specified solvent). As the solvent, water is used in the current tests, but 0.07 mol/L hydrochloric acid is used in the proposed new tests, based on ISO8124-3. The migration tests for arsenic and cadmium are intended to be modified, based also on ISO8124-3.

B. Specifications for metal toy accessories

Specifications for the category “metal toy accessories” is proposed to be applied only to those which are small enough to be swallowed by infants. For metal toy accessories products, a migration specification for lead is intended to be established based on ISO8124-3. The metal toy accessories that can be swallowed by infants are defined as those that can be placed within a slanted bottom cylinder, illustrated in the figure 1 below, without being compressed.

Figure 1



C. Specifications for base materials

Currently, there are specifications for materials made mainly of polyvinyl chloride (PVC) or polyethylene (PE). The proposed modified specifications are targeted to finished products, not including the coatings on them, made mainly of PVC or PE.

An outline of the proposed revision of the regulations is given in the attached table.

Table 2: Revision of categories for which individual specifications are established

	Proposed Modification (draft)	Current
Categories for which individual specifications are established	<ol style="list-style-type: none"> 1. <i>Utsushi-e</i> 2. <i>Origami</i> 3. Rubber pacifiers 4. <u>Coatings *</u> 5. Finished toy products made of materials which is made mainly of PVC, not including the coating on them 6. Finished toy products made of materials which is made mainly of PE, not including the coatings on them 7. <u>Metal toy accessories (that can be swallowed by infants)</u> 	<ol style="list-style-type: none"> 1. <i>Utsushi-e</i> 2. <i>Origami</i> 3. Rubber pacifiers 4. Vinyl chloride resin coating agents 5. Materials made mainly of PVC 6. Materials made mainly of PE

*: in the dry state applied on finished products

Table 3: Outlines of revision of migration specification for lead etc.

Migration Tests of Coatings	Leaching Specifications	<u>Coatings</u> Pb: 90 mg/kg Cd: 75mg/kg As: 25mg/kg Maximum limits, expressed as the amount that migrates into solvent per kg coating Evaporation Residue } Applied only to vinyl Consumption of KMnO ₄ } chloride coatings <u>Metal toy accessories (that can be swallowed by infants)</u> Pb: 90 mg/kg Amount that migrates into solvent per kg coating	<u>Vinyl chloride resin coating agents</u> Heavy metal: 1µg/ml as Pb Cd: 0.5µg/ml As: 0.1µg/ml as As ₂ O ₃ Maximum limits, expressed as the amount that migrates into solvent per ml sample solution (1 ml of sample solution corresponds to 4 mg coating)
	Leaching conditions	<u>Pb, Cd, As in coatings</u> Solvent: 0.07 mol/L HCl 1 hr of shaking at 37°C, followed by 1 hr of still standing <u>Pb in metal toy accessories</u> Solvent: 0.07 mol/L HCl 2 hrs of still standing at 37°C	<u>Heavy metals, Cd, As in Vinyl chloride resin coating agents</u> Solvent: Water 30 mins of still standing at 40°C with occasional stirring
	Analytical methods	<u>Pb, Cd, As in coatings and Pb in metal toy accessories</u> Atomic absorption spectrophotometry (AA), or Inductively coupled plasma atomic emission spectrometry (ICP)	<u>Heavy metals, As in Vinyl chloride resin coating agents</u> Colorimetric method <u>Cd in Vinyl chloride resin coating agents</u> Atomic absorption spectrophotometry (AA), or Inductively coupled plasma atomic emission spectrometry (ICP)
	Note	For categories listed in 5 and 6, objects will be changed from coating agents to finished dry coatings, but the existing specifications will remain unchanged. Leaching conditions : 30 mins of still standing at 40°C in 2 ml of water per square centimeter of sample surface with occasional stirring	The Ministry of Health and Welfare Announcement No370 (1959)