Outline of the 31st March 2008 revision of the preschool children toy regulation based on the Food Sanitation Law of JAPAN

1. Background

In Japan, the scope is prescribed[1] 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. the Article 78 of the Enforcement Regulations under the Article 62 of the Food Sanitation Law of Japan
2. the Article 18 Paragraph 1 of the Food Sanitation Law applied pursuant to the Article 62 of the Food Sanitation Law
3. the Article 18 Paragraph 2 of the Food Sanitation Law applied pursuant to the Article 62 of the Food Sanitation Law

The scope of designated toys before revision on 31st March 2008 was, however, unable to cover diversified toy products currently on the market. Hence, the Ministry of Health, Labour and Welfare (MHLW) had reviewed the existing regulations and revised them in order to ensure toy safety.

The revision on 31st March 2008 has two major points, i) expansion of the scope of the designated toys and ii) strengthening migration specifications for lead by revising specifications for coatings of toys, and by establishing specifications for "metal jewelry toy" which is small enough for infants to swallow. The migration specifications of the ISO (International Organization for Standardization) (ISO8124-3) for lead, cadmium, and arsenic were introduced to the specification of "coatings" for toys. Lead migration specification for "metal jewelry toy" was established based also on ISO8124-3 specification.

2. Details

(1) Revision of the scope of the designated toys

The scope of designated toys after revision on 31st March 2008 is given in the table 1 below. The existed restriction on materials was abolished, and as a result, the revised scope covers almost all kinds of infant toys that have the possibility to come

into contact with infant's mouth. The toy categories added include jewelry toy, intellectual development facilitating toys, and toys used in combination with designated toys (e.g., rails for a toy train set).

Table 1: Designated Toys

After revision	Before revision
1. Toys intended to come into direct contact with infant's mouth.	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.
2. Jewelry toy, *Utsushi-e**1, rolly-polies, masks, *origami**2, rattles, intellectual development facilitating toys (only those which has the possibility to come into contact with infant's mouth, and excluding those listed in this paragraph), wooden blocks, toy telephones, toy animals, dolls, clay, toy vehicles, balloons, toy building bricks, balls, housekeeping toys	2. *Hozuki* *3 3. *Utsushi-e**1, *origami**2, wooden blocks 4. Toys made of rubber, plastic, or metal that are listed below: rolly-pollies, 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.
3. Toys to be played with in combination with toy(s) above.	

*1: decal sticker toy

*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

There were standards and specifications for toy categories as listed in the table 2 attached. The MHLW added specification for new category "metal jewelry toy" and to modify the specifications for "coating agents".

A. Coatings (c.f. table 3 attached)

The specifications before revision on 31st March 2008 for coating agent were targeted only to vinyl chloride resin coating agent. The modification of specification

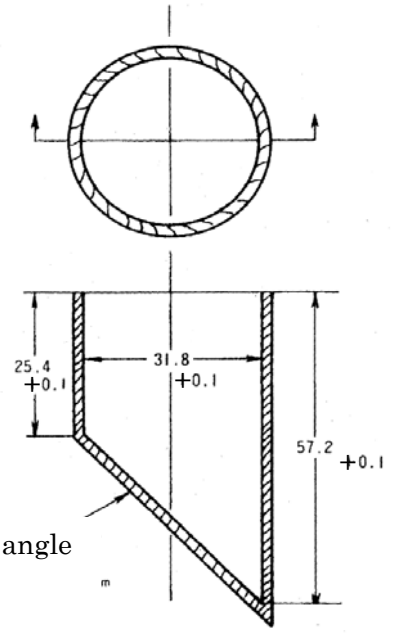
made it possible to cover all kinds of coatings in their dry state as part of finished products.

The migration tests before revision on 31st March 2008 were targeted to heavy metals (regarded as Pb), cadmium (Cd), and arsenic (As). The total concentration of heavy metal (as Pb) was judged whether it exceeds the limit value by comparing the color of prepared test solution with the color of control lead solution. Whereas, the new analytical method will directly determine the concentration of lead. Also, the unit of the specification was changed from [μg/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 was used in the tests before revision, but 0.07 mol/L hydrochloric acid is used in the new tests, based on ISO8124-3. The migration tests for arsenic and cadmium were modified, based also on ISO8124-3.

B. Specifications for metal jewelry toys

Specifications for the category "metal jewelry toy" are applied only to those which are small enough to be swallowed by infants. For "metal jewelry toy" products, a migration specification for lead was established based on ISO8124-3. The metal jewelry toys 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



45 degree angle

Unit: mm

C. Specifications for base materials

Before revision on 31st March 2008, there were specifications for materials made mainly of polyvinyl chloride (PVC) or polyethylene (PE). The modified specifications are targeted to the base material, made mainly of PVC or PE, of the finished products, not including the coatings on them.

An outline of the revision on 31st March 2008 of the regulations is given in the attached table.