

Explanation on the revision of migration specifications for cadmium and lead in glass, ceramic, and enameled equipments and containers that come into contact with food

1. Background

On 31st July 2008, the Ministry of Health, Labour and Welfare (MHLW) of Japan revised the migration specifications of lead and cadmium in glass, ceramic, or enameled equipment and containers that come into contact with food.

When the specifications were revised in 1986, taken into account were the following standards by International Organization for Standardization (ISO); ISO6486 for ceramic ware, glass-ceramic ware and glass dinnerware established in 1981 and ISO7086 for glass hollowware established in 1982.

Then in 1998, ISO4531 for vitreous and porcelain enameled ware was newly established, followed by the revision of ISO6486 in 1999 and ISO7086 in 2000.

The draft revised migration specifications for lead and cadmium from glass, ceramic or enameled equipments and containers were proposed in the report of the health, labour and welfare science research conducted in the fiscal years 2004 and 2005, based on the ISO specifications.

2. Details

Before the revision on 31st July 2008, the maximum migration levels of cadmium and lead were specified as common specifications to glass, ceramic, and enameled equipments and containers in the section “D Specifications by materials of the equipments and containers or their source materials” in the section 3 “Equipments and containers/packages” of the Ministry of Health, Labour and Welfare Announcement No.370 (1959).

By the 31st July 2008 revision, the migration specifications were revised and set on material by material basis, taking into account ISO specifications (ISO4531, ISO6486 and ISO7086). In addition, specifications were set capacity by capacity of the equipments and containers for each material category (e.g., three categories for glass equipments and containers: 1) less than 600 ml, 2) 600 ml and over and less than 3 L, and 3) 3 L and over), and the specifications for heat-cooking equipments were newly introduced for each material category, i.e. glass, ceramic and enameled one.

The revised specifications by material categories are given in the next page. Also, the revised specifications and testing methods which were promulgated are given in the Appendix in the form of translated text.

Tables of the revised specifications by material categories
(Revised on 31st July 2008)

The amount migrated into test solution shall be equal to or less than the limit shown in the table below.

Glass equipments and containers

Category			Cadmium (Cd)	Lead (Pb)
2.5 cm or deeper (*1)	Heat-cooking ware		0.05 µg/ml	0.5 µg/ml
	Other than heat-cooking ware	Less than 600 ml	0.5 µg/ml	1.5 µg/ml
		600 ml and more, and less than 3 L	0.25 µg/ml	0.75 µg/ml
		3 L and more	0.25 µg/ml	0.5 µg/ml
Cannot be filled, or less than 2.5 cm depth (*2)			0.7 µg/cm ² (*3)	8 µg/cm ² (*3)

Ceramic equipments and containers

Category			Cadmium (Cd)	Lead (Pb)
2.5 cm or deeper (*1)	Heat-cooking ware		0.05 µg/ml	0.5 µg/ml
	Other than heat-cooking ware	Less than 1.1 L	0.5 µg/ml	2 µg/ml
		1.1 L and more, and less than 3 L	0.25 µg/ml	1 µg/ml
		3L and more, and less than 3 L	0.25 µg/ml	0.5 µg/ml
Cannot be filled, or less than 2.5 cm depth (*2)			0.7 µg/cm ² (*3)	8 µg/cm ² (*3)

Enameled equipments and containers

Category			Cadmium (Cd)	Lead (Pb)
2.5 cm or deeper(*1)	less than 3L	Heat-cooking ware	0.07 µg/ml	0.4 µg/ml
		Other than heat cooking ware	0.07 µg/ml	0.8 µg/ml
	3 L or over		0.5 µg/cm ² (*3)	1 µg/cm ² (*3)
Cannot be filled, or less than 2.5 cm depth (*2)	Heat-cooking ware		0.5 µg/cm ² (*3)	1 µg/cm ² (*3)
	Other than heat cooking ware		0.7 µg/cm ² (*3)	8 µg/cm ² (*3)

Note: (*1): Equipments and containers whose depth is 2.5 cm or deeper when filled with liquid
 (*2): Equipments and containers that cannot be filled with liquid or those whose depth is less than 2.5 cm when filled with liquid
 (*3): The amount migrated per unit surface area of the sample equipments or containers

Appendix

This is a provisional translation of an excerpt from “Standards and specifications for food, food additives etc.”, the Announcement No.370 of the Ministry of Health and Welfare (1959)
The 31st July 2008 revision is reflected in the following text.

Section 3. Equipment and containers/packages

D. Specifications by material category for equipment, containers/packages, or their raw materials

I. Glass, ceramic, or enameled equipments and containers

Glass, ceramic, or enameled equipments and containers shall meet the requirements when tested by the following methods.

1. Test sample whose depth is 2.5 cm or deeper when filled with liquid - excluding enameled ones with the capacity*¹ of 3 L and over -

(1) Preparation of test solution

After washing the test sample well with water, fill it with 4% acetic acid solution*², and leave it at ordinary temperature*³ in a dark place for 24 hours. Transfer this solution into a beaker, and use it as the test solution.

(2) Migration test

a Cadmium and lead

① Generation of calibration curves

Dilute Cadmium Standard Solution and Lead Standard Solution with 4% acetic acid into appropriate concentrations, determine the concentrations by atomic absorption spectrophotometry or inductively coupled plasma atomic emission spectrometry, and generate respective calibration curves.

② Quantification method

When the concentrations of cadmium and lead leached in the test solution are determined by atomic absorption spectrophotometry or inductively coupled plasma atomic emission spectrometry, the amount leached per unit area shall be equal to or less than the limits given in Columns 2 for cadmium and Column 3 for lead, for corresponding category given in Column 1 of the following table.

Column 1			Column 2	Column 3
Glass equipment and containers	Heat-cooking ware		0.05 µg/ml	0.5 µg/ml
	Those other than heat-cooking ware	Capacity less than 600 ml	0.5 µg/ml	1.5 µg/ml
		Capacity 600 ml and over and less than 3 L	0.25 µg/ml	0.75 µg/ml
		Capacity 3 L and over	0.25 µg/ml	0.5 µg/ml
Ceramic equipment and containers	Heat-cooking ware		0.05 µg/ml	0.5 µg/ml
	Those other than heat-cooking ware	Capacity less than 1.1 L	0.5 µg/ml	2 µg/ml
		Capacity 1.1 L and over and less than 3 L	0.25 µg/ml	1 µg/ml
		Capacity 3 L and over	0.25 µg/ml	0.5 µg/ml
Enameled equipment and containers	Heat-cooking ware whose capacity is less than 3 L		0.07 µg/ml	0.4 µg/ml
	Those other than heat-cooking ware whose capacity is less than 3 L		0.07 µg/ml	0.8 µg/ml

II. Test sample that cannot be filled with liquid, or test sample whose depth is less than 2.5 cm when filled with liquid, or enameled test sample with the capacity of 3 L and over

1. Preparation of test solutions

After washing the test sample (for enameled products with the capacity of 3 L and over, prepare flat pieces of the test sample and use it as test sample) well with water, leave it at ordinary temperature in a dark place for 24 hours using 4% acetic acid solution as solution for simmering.

2. Migration test

a. Cadmium and lead

① Generation of calibration curves

Dilute Cadmium Standard Solution and Lead Standard Solution with 4% acetic acid into appropriate concentrations, determine the concentrations by atomic absorption spectrophotometry or inductively coupled plasma atomic emission spectrometry, and generate respective calibration curves.

② Quantification method

Determine the concentration (C µg/ml) of cadmium and lead respectively in the test solution by atomic absorption spectrophotometry or inductively coupled plasma atomic

emission spectrometry. Obtain the amount of migration per unit area for each element by the formula given below, in which the surface area of the sample product is expressed as S (cm²) and the total volume of the solution used to elute the element as V (ml). The amount leached per unit area shall be equal to or less than the limits given in Columns 2 for cadmium and Column 3 for lead, for corresponding category given in Column 1 of the following table.

$$\text{Amount of migration per unit area } (\mu\text{g}/\text{cm}^2) = (C \times V)/S$$

Column 1			Column 2	Column 3
Glass equipment and containers			0.7 $\mu\text{g}/\text{cm}^2$	8 $\mu\text{g}/\text{cm}^2$
Ceramic equipment and containers			0.7 $\mu\text{g}/\text{cm}^2$	8 $\mu\text{g}/\text{cm}^2$
Enameled equipment and containers	Those that cannot be filled with liquid, or those whose depth is less than 2.5 cm when filled with liquid	Heat-cooking ware	0.5 $\mu\text{g}/\text{cm}^2$	1 $\mu\text{g}/\text{cm}^2$
		Products other than heat-cooking ware	0.7 $\mu\text{g}/\text{cm}^2$	8 $\mu\text{g}/\text{cm}^2$
	Those whose depth is 2.5 cm or deeper when filled with liquid and have the capacity of 3 L or over		0.5 $\mu\text{g}/\text{cm}^2$	1 $\mu\text{g}/\text{cm}^2$

(A note by translator)

In the D 1 of the Section 3 of the Announcement No.370;

*1: By “capacity”, internal capacity is meant.

*2: By “solution”, aqueous solution is meant.

*3: By “ordinary temperature”, 15°C to 25°C is meant, as it is in the Japanese Pharmacopoeia.