Regulatory Developments in Food Contact; an Update from Japan

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Basis of Regulations

Japanese food safety regulations are based on

“Food Safety Basic Law” (2003)

and

“Food Sanitation Law” (1947)

to protect the health of the people through the food safety.
Food Sanitation Law

Article 4 (Definitions)

Utensils: Tableware, kitchen utensils, machines, implements and other articles, which intended to come into direct contact with food except below.

Packages: Bags, trays, boxes, bottles, cans, film and other articles in which foods are offered for trade.

Utensils + Packages (as Japanese low) = Food contact articles
Article 15
Principle for handling of utensils and packages used in business shall be clean and sanitary.

Article 16
Toxic or injurious utensils or packages prohibit the sale, manufacture, import or business use.
Food Sanitation Law

Article 18

Establishment of “specifications and standards” for utensils and packages

◆ Specifications and Standards of Food, Food Additives, etc.
◆ Compositional Standards for Milk and Milk Products.

Products which do not conform to the established specifications prohibit the sale, manufacture, import or business use.
Japanese Legislation for Food Contact Articles

Food Safety Basic Law

Food Sanitation Law

Compositional Standards for Milk and Milk Products

Annex 4. Specifications and Standards of Utensils and Packages of Milk etc. and Their Materials

Specifications and Standards of Food, Food Additives, etc

Section 1 Food
Section 2 Food Additives
Section 3 Utensils and Packages
Section 4 Toys
Section 5 Detergents

A. Specification of utensils, packages, and their materials
B. General test methods of utensils and packages
C. Reagents, test solutions, etc
D. Specifications of utensils and packages and their raw materials by material
   1. Glass, ceramic and enameled ware
   2. Plastics
   3. Rubber
   4. Metal can
E. Specifications of utensils or packages by applications
F. Standards of manufacture of utensils and packages

Normal liquid milk
Certified milk
Goat milk
Skimmed milk
Liquid milk
Recombined
Cream

Fermented milks
Lactic acid drinks
Milk drinks

Formulated milk powder

- PE, PP, PET or PS packages
- PE-processed paper package
- PE, PP, PS or PET packages with aluminum foil
- Plastic-laminated packages
- Metal can with sealing of PE or PET

- PE or PET packages
- PE-processed paper package
- Composite packages of above materials
Specifications and Standards for Utensils and packages

Websites
Specifications and Standards for Utensils and packages

Contents

A General specifications for materials
B General test methods
C Reagents, test Solutions, etc.
D Specifications by materials
E Specifications by applications
F Manufacturing standards
**General Specifications for Materials**

*Lead and antimony in metals*

<table>
<thead>
<tr>
<th>Material</th>
<th>Past limit</th>
<th>New limit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metals (general)</td>
<td>Pb &lt; 10%</td>
<td>Pb ≤ 0.1%</td>
</tr>
<tr>
<td></td>
<td>Sn &lt; 5%</td>
<td>Sn &lt; 5%</td>
</tr>
<tr>
<td>Tin for coating</td>
<td>Pb &lt; 5%</td>
<td>Pb ≤ 0.1%</td>
</tr>
<tr>
<td>Solder</td>
<td>Pb &lt; 20%</td>
<td>Pb ≤ 0.2%</td>
</tr>
</tbody>
</table>

*Limits were revised on July 31, 2008 for the reduction of lead intake.*
General Specifications for Materials

**Colours** shall not be contained except the designated food colours, or shall not dissolve or migrate into food.

**Bis(2-ethylhexyl) phthalate (DEHP)** shall not be used to the PVC articles which is intended to come into direct contact with fatty food (content \( \leq 0.1\% \)) or no migration into heptane (migration level \( \leq 1\text{ppm} \)).
Specifications by Materials

1 Glass, Ceramic & Enameled Ware

2 Plastics
   - General specifications
   - Individual specifications
     PF, MF, UF, PVC, PE, PP, PS, PVDC, PET, PMMA, PA, PMP, PC, PVA, PLA: 15 polymers

3 Rubbers
   - General article
   - Nipple

4 Metal cans
## Glass Ware & Bottle

### Migration limits

<table>
<thead>
<tr>
<th>Depth</th>
<th>Capacity</th>
<th>Cd (μg/cm²)</th>
<th>Pb (μg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2.5 cm or can not filled</td>
<td>&lt; 0.6 L</td>
<td>0.7</td>
<td>8</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>&lt; 0.6 L</td>
<td>0.5</td>
<td>1.5</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>0.6 – 3 L</td>
<td>0.25</td>
<td>0.75</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>≥ 3 L</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>Cooking ware</td>
<td>0.05</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

- Test conditions: 4% acetic acid, 24 hr, 20±5°C
- These specifications were revised on July 31, 2008 based on ISO 6486 and 7086 (2000).
## Ceramic Ware

### Migration limits

<table>
<thead>
<tr>
<th>Depth</th>
<th>Capacity</th>
<th>Cd</th>
<th>Pb</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2.5 cm or can not filled</td>
<td>0.7</td>
<td>8</td>
<td>μg/cm²</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>&lt; 1.1 L</td>
<td>0.5</td>
<td>2</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>1.1 – 3 L</td>
<td>0.25</td>
<td>1</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>≥ 3 L</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>Cooking ware</td>
<td></td>
<td>0.05</td>
<td>0.5</td>
</tr>
</tbody>
</table>

- **Test conditions:** 4% acetic acid, 24 hr, 20±5°C
- These specifications were revised on July 31, 2008 based on ISO 6486 (1999).
# Enameled Ware

## Migration limits

<table>
<thead>
<tr>
<th>Depth</th>
<th>Usage etc.</th>
<th>Cd</th>
<th>Pb</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2.5 cm or can not filled</td>
<td></td>
<td>0.7</td>
<td>8</td>
</tr>
<tr>
<td>&lt; 2.5 cm</td>
<td>Cooking ware</td>
<td>0.5</td>
<td>1</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>&lt; 3 L</td>
<td>0.07</td>
<td>0.8</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>Cooking ware</td>
<td>0.07</td>
<td>0.4</td>
</tr>
<tr>
<td>≥ 2.5 cm</td>
<td>≥ 3 L</td>
<td>0.5</td>
<td>1</td>
</tr>
</tbody>
</table>

- Test conditions: 4% acetic acid, 24 hr, 20±5°C
- These specifications were revised on July 31, 2008 based on ISO 4531 (1998).
Specifications for plastic articles are consist of

General Specifications for all polymers

+ 

Individual Specifications for particular polymer
General Specifications for Plastics

Material test

\[ \text{Cd} \leq 100 \ \mu\text{g/g}, \ \text{Pb} \leq 100 \ \mu\text{g/g} \]

Migration test (Simulant: 2 ml/cm²)

Heavy metals \( \leq 1 \ \mu\text{g/ml} \) as Pb

\( \text{KMnO}_4 \) consumed amount \( \leq 10 \ \mu\text{g/ml} \)

(Index of total organic migrant)

- All plastics shall be conform to these specifications.
Evaporation residue test  
(Overall migration test)

**Limit:** 30 μg/ml (when using heptane, PE and PP ≤ 150, PS ≤ 240, PMP ≤ 120 μg/ml)

**Determination:** Weigh residue of migrant after drying and heating at 105°C for 2 hr.

**Test condition**

<table>
<thead>
<tr>
<th>Food</th>
<th>Simulant</th>
<th>Temp(°C)</th>
<th>Time(min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal(pH&gt;5)</td>
<td>water</td>
<td>60 or 95*</td>
<td>30</td>
</tr>
<tr>
<td>Acidic(pH≤5)</td>
<td>4% acetic acid</td>
<td>60 or 95*</td>
<td>30</td>
</tr>
<tr>
<td>Alcoholic</td>
<td>20% ethanol</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>Fatty</td>
<td>heptane</td>
<td>25</td>
<td>60</td>
</tr>
</tbody>
</table>

Use 2 ml/cm² of simulant. *When use temp>100°C.

Test conditions are reviewing now.
Individual Specifications for Plastics

Resin from formaldehyde (PF, MF, UF)
- Phenol $\leq 5 \mu g/ml$, formaldehyde: ND (ca. 4 $\mu g/ml$)
  (simulant: water)

Polyvinyl chloride (PVC)
- Dibutyl tin $\leq 50 \mu g/g$,
- Cresyl phosphate $\leq 1 mg/g$, VCM $\leq 1 \mu g/g$

Polystyrene (PS)
- Total volatile substances (styrene, ethylbenzene, toluene, n- & isopropyl-benzene) $\leq 5 mg/g$

PS foam using with hot water
- Total volatile substances $\leq 2 mg/g$
- Styrene, ethylbenzene $\leq 1 mg/g$ each
**Individual Specifications for Plastics**

**Polyvinylidene chloride (PVDC)**  
Barium $\leq 100 \ \mu g/g$, VDC $\leq 6 \ \mu g/g$

**Polyethylene telephthalate (PET)**  
Sb $\leq 0.05 \ \mu g/ml$, Ge $\leq 0.1 \ \mu g/ml$ (4% AA)

**Polymethylmethacrylate (PMM)**  
Methylmethacrylate $\leq 30 \ \mu g/ml$ (20% EtOH)

**Polyamide (PA)**  
Caprolactam $\leq 15 \ \mu g/ml$ (20% EtOH)

**Polycarbonate (PC)**  
Bisphenol A $\leq 500 \ \mu g/g$ and $\leq 2.5 \ \mu g/ml$  
Diphenyl carbonate $\leq 500 \ \mu g/g$  
Triethyl and tributyl amines $\leq 1 \ \mu g/g$
Polylactic Acid (PLA)

Specifications for Polylactic acid (PLA) was established on October 2007.

HOOC-C(CH₃)-O-[CO-C(CH₃)-O]ₙ-CO-C(CH₃)-OH

**Total lactic acid:** $\leq 30 \ \mu g/ml \ (water)$

Concentration of lactic acid generated from migrant by alkaline decomposition

**Limitation of usage temperature** for PLA

consisting more than 6% D-LA: not used higher

than 40°C (except $\leq 100°C/30min$ or $\leq 66°C/2hr$)
# Specifications for Rubbers

<table>
<thead>
<tr>
<th>Test item</th>
<th>General</th>
<th>Nipple</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Material Test</strong></td>
<td>(μg/g)</td>
<td>(μg/g)</td>
</tr>
<tr>
<td>Cadmium (Cd)</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Lead (Pb)</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>2-Mercaptoimidazoline*</td>
<td>ND</td>
<td>-</td>
</tr>
<tr>
<td><strong>Migration test</strong></td>
<td>(μg/ml)</td>
<td>(μg/ml)</td>
</tr>
<tr>
<td>Phenol</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Zinc (Zn)</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Heavy metals</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Evaporation residue</td>
<td>60</td>
<td>40</td>
</tr>
</tbody>
</table>

*only for rubber containing chlorine
Specifications for Metal Cans

**Migration test**

- Arsenic $\leq 0.2$ $\mu$g/ml as $\text{As}_2\text{O}_3$
- Cadmium $\leq 0.1$ $\mu$g/ml,
- Lead $\leq 0.4$ $\mu$g/ml

**Additional tests for coating cans**

- Phenol $\leq 5$ $\mu$g/ml
- Formaldehyde: ND (ca. 4 $\mu$g/ml)
- Evaporation residue $\leq 30$ $\mu$g/ml
- Epichlorohydrin $\leq 0.5$ $\mu$g/ml
  (pentane, 25°C, 60 min)
- Vinyl chloride monomer $\leq 0.05$ $\mu$g/ml
  (EtOH, $< 5$°C, 24hr)
Specifications by Applications

- Retort packages (except can or bottle)
- Soft drink packages - glass, metal, plastics and laminate
- Manufacturing equipment for flavored ice
- Automatic vending machine in contact with foodstuff

These specifications are mainly consist of physical natures, strength tests and structural properties.
Manufacturing Standards

- **Copper or copper alloy utensils**
  The part in contact with food shall be tin or silver coated, or processed not to cause any sanitary hazards.

- **The spine of specified (BSE) cattle** shall not be used as raw material, except its fat and oil hydrolyzed, saponified or interesterified under high temperature and high pressure.

- **Colours**

- **Sterilization of packages for the flavored ice**

- **Limitation of usage temperature for the polylactic acid** consisting more than 6% D-LA
Control of Plastic Safety

Japanese food contact plastics are controlled by

Government (Ministry of Health, Labour and Welfare, MHLW)

Industrial Hygienic Associations

- Government controls mainly final products by the national laws.
- Industrial hygienic associations control mainly materials by their voluntary standards including positive lists and the certification system.
Industrial Hygienic Associations

Main associations

- Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)  
  http://www.jhospa.gr.jp/

- Japan Hygienic PVC Association (JHPA)  
  http://www.jhpa.jp/

- Japan Hygienic Association of Vinylidene Chloride (JHAVC)  
  http://vdkyo.jp/

Purpose: They have been established for the safety of food contact materials since 40 years before.
Industrial Hygienic Associations

Member (JHOSPA: ca. 800 companies)
Resin and additive manufactures, fabrication companies, converters, distributors and food companies

Activities
1. Establishment and amendment of “Voluntary Standards”
2. Certification and registration
3. Study and research on hygiene of food contact utensils and containers/packages
4. Communication with regulatory authorities and related organizations
<table>
<thead>
<tr>
<th>No.</th>
<th>Resin Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Polyethylene</td>
</tr>
<tr>
<td>2</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>3</td>
<td>Polymethylpentene</td>
</tr>
<tr>
<td>4</td>
<td>Polybutene-1</td>
</tr>
<tr>
<td>5</td>
<td>Butadiene resin</td>
</tr>
<tr>
<td>6</td>
<td>Ethylene/tetracyclododecen polymer</td>
</tr>
<tr>
<td>7</td>
<td>Polystyrene</td>
</tr>
<tr>
<td>8</td>
<td>SAN resin</td>
</tr>
<tr>
<td>9</td>
<td>ABS resin</td>
</tr>
<tr>
<td>10</td>
<td>Polyphenylene ether</td>
</tr>
<tr>
<td>11</td>
<td>Polyacrylonitrile</td>
</tr>
<tr>
<td>12</td>
<td>Fluorine resin</td>
</tr>
<tr>
<td>13</td>
<td>Polymethacryl styrene</td>
</tr>
<tr>
<td>14</td>
<td>Methacryl resin</td>
</tr>
<tr>
<td>15</td>
<td>Nylon resin</td>
</tr>
<tr>
<td>16</td>
<td>Polyethylene terephthalate</td>
</tr>
<tr>
<td>17</td>
<td>Polycarbonate</td>
</tr>
<tr>
<td>18</td>
<td>Polyvinyl alcohol</td>
</tr>
<tr>
<td>19</td>
<td>Polyacetal</td>
</tr>
<tr>
<td>20</td>
<td>Polybutyleneterephthalate</td>
</tr>
<tr>
<td>21</td>
<td>Polyaryl sulfone</td>
</tr>
<tr>
<td>22</td>
<td>Polyacrylate</td>
</tr>
<tr>
<td>23</td>
<td>Polyesters of hydroxybenzoic acid</td>
</tr>
<tr>
<td>24</td>
<td>Polyether imide</td>
</tr>
<tr>
<td>25</td>
<td>Polycyclohexylene di-methylene terephthalate</td>
</tr>
<tr>
<td>26</td>
<td>Polyethylene naphthalate</td>
</tr>
<tr>
<td>27</td>
<td>Polyester carbonate</td>
</tr>
<tr>
<td>28</td>
<td>Poly lactic acid</td>
</tr>
<tr>
<td>29</td>
<td>Polybutylene succinic acid</td>
</tr>
<tr>
<td>30</td>
<td>Ethyrene/2-norbornen resin</td>
</tr>
</tbody>
</table>
Voluntary Standards of Associations

Positive Lists (PL) for each polymer
Base polymers, Monomers, Additives
*Aids, Colorants, etc.
*Aids are depending on polymers.

Hygienic Tests for Products

Governmental specifications

Additional specifications
# Substances in Positive Lists of JHOSPA

<table>
<thead>
<tr>
<th>Classification</th>
<th>Sub Classification</th>
<th>No. of substance</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic polymer</td>
<td>Basic polymer</td>
<td>30</td>
<td>Polyolefin, polystyrene, polyesters</td>
</tr>
<tr>
<td></td>
<td>Monomer</td>
<td>150</td>
<td>Ethylene, propylene, styrene,</td>
</tr>
<tr>
<td></td>
<td>Polymerization aid</td>
<td>77</td>
<td>Catalyst, initiator, modifier,</td>
</tr>
<tr>
<td>Additives</td>
<td>Stabilizer</td>
<td>140</td>
<td>Anti-oxidant, UV stabilizer</td>
</tr>
<tr>
<td></td>
<td>Surfactant</td>
<td>77</td>
<td>Anti-foggy agent, anti-static electricity, emulsifier</td>
</tr>
<tr>
<td></td>
<td>Lubricant</td>
<td>88</td>
<td>Anti blocking agent, friction agent</td>
</tr>
<tr>
<td></td>
<td>Filler</td>
<td>68</td>
<td>Filler and inorganic colorants</td>
</tr>
<tr>
<td></td>
<td>Blowing agent</td>
<td>10</td>
<td>Foaming agent and its aids</td>
</tr>
<tr>
<td></td>
<td>Polymer additive</td>
<td>126</td>
<td>Polymer for modifier of synthetic resin</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>123</td>
<td>Radical agent</td>
</tr>
<tr>
<td>Colorants</td>
<td></td>
<td>269</td>
<td>Inorganic pigment, organic pigment, dye, food colorant</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1158</td>
<td></td>
</tr>
</tbody>
</table>
Recent Developments of Japanese Regulation
Test Method of Cd and Pb in Silicone Rubber

Existing test method for rubbers:
Carbonized and ashed with H$_2$SO$_4$, dissolved into HNO$_3$, and determined by AAS or ICP.

Problem: Silicone changes to SiO$_2$ by ashing. The SiO$_2$ can not resolve and absorbs Cd and Pb, therefore, their recoveries become very low.

Additional test method for silicone rubber:
Fusioned with NaOH and H$_3$BO$_4$ by burner heating (Alkali-fusion), dispersed residue into hot water. Add the liquid to HNO$_3$, purified by Chelate cartridge, determined by AAS or ICP.

This amendment was published on December 2012.
Test Method of Volatiles in Polystyrene

Volatiles: Styrene, Ethylbenzene, Toluene, Isopropylbenzene, Propylbenzene

Existing test method of volatiles in polystyrene:
   Dissolve in tetrahydrofuran (THF) and determine by GC-FID

Problem: Styrene thermoplastic elastomer (STPE) and syndiotactic polystyrene (SPS) can not dissolve into THF and their recoveries are low.

Proposed test method for STPE and SPS:
   Dissolve into dichlorobenzene during heating in headspace sampler (130°C, 1 hour), and determine by Headspace-GC-FID

This amendment was published on December 2012.
**Guideline for use of Recycled Plastics in Food Contact Articles**

**Post-Consumer Plastics**

- **Collecting**
  
- **Recycling Process**
  - **Recycled Materials**

**Routine Management (GMP, QC)**

- Source control
  - In principle Post-consumer plastic should be from the **food contact use**, and collected separately from waste.

- **Verification for safety**
  - Surrogate removed testing
  - Validation for material and barrier
  - Material and/or Migration testing

- Limitation for usage of food type and conditions

**Food Contact Articles Contain recycled plastic**

This guideline was published on May 2012.
Guideline for Use of Recycled Papers in Food Contact Articles

Post-Consumer Papers

Collecting

Source Control
Post-consumer paper which was collected separately and got mixed no harmful or dangerous chemicals or bacteria.

Routine Management (GMP, QC)

Recycling process

Recycling Processes
Verification of the decontamination capability of harmful substance derived additives, inks, etc.

Recycled Materials

Limitation of use for food type or conditions
- Not for baking purposes
cake plate, cooking sheet
- Not for boil-in-bag
  - Tea bag, coffee filter

Food Contact Materials Contain Recycled Paper

This guideline was published on May 2012.
Ongoing and Future Works
Phthalates and bisphenol A is ongoing the risk assessment by the Food Safety Commission. After that, their regulation maybe revised:

- Existing prohibition of 2-ethylhexyl phthalate (DEHP) in PVC for fatty foods will be expanded to more phthalates and other plasticized polymers.
- Migration limit of bisphenol A will be reduced 2.5 µg/ml to ?? µg/ml and metal can coating will be regulated.
Review of Specifications

General Rule
- Definition of materials
- General rule of test methods

Management of Multi-layer Films
- Consist of only plastic layers
- Contain paper or aluminum layer

Evaporation residue test
- testing condition, solvents, limits, etc

Validation method for testing

They are discussing on the meeting under the MHLW now.
MHWL is considering to introduce a positive list system for the food contact regulation.

The following works or discussions are being performed...

- Listing of the existing additives
- Research for these in other countries
- Framework for regulation and restriction
- Construction of the application system
Thank you for your kind attention!