

***Regulatory Developments  
in Food Contact;  
an Update from Japan***

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# ***Basis of Regulations***

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**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***

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## ***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 law)  
= Food contact articles**

# ***Food Sanitation Law***

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## ***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***

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## ***Article 18***

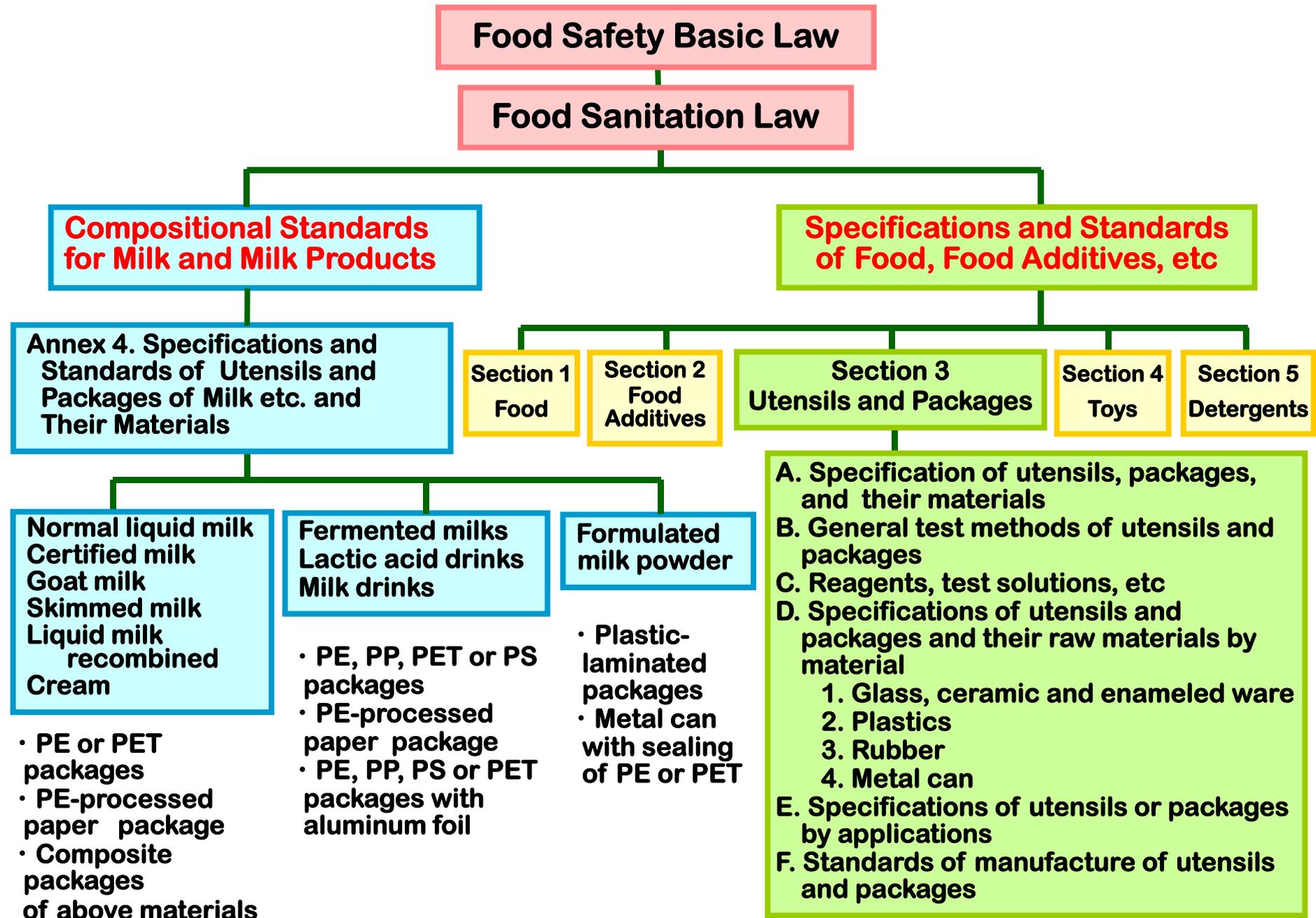
**Establishment of “specifications and standards” for utensils and packages**

- ◆ **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



# ***Specifications and Standards for Utensils and packages***

## ***Websites***

**Japanese** [http://www.hourei.mhlw.go.jp/  
cgi-bin/t\\_docframe.cgi?MODE=hourei&DMODE  
=CONTENTS&SMODE=NORMAL&KEYWORD=  
&EFSNO=729](http://www.hourei.mhlw.go.jp/cgi-bin/t_docframe.cgi?MODE=hourei&DMODE=CONTENTS&SMODE=NORMAL&KEYWORD=&EFSNO=729)

**English abstract** [http://www.jetro.go.jp/en/  
reports/regulations/pdf/foodadd2010apr-e.pdf](http://www.jetro.go.jp/en/reports/regulations/pdf/foodadd2010apr-e.pdf)

# *Specifications and Standards for Utensils and packages*

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## *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***

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## ***Lead and antimony in metals***

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

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

# ***General Specifications for Materials***

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***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*

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## **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

Depth	Capacity	Cd	Pb	
< 2.5 cm	or can not filled	0.7	8	$\mu\text{g}/\text{cm}^2$
$\geq 2.5$ cm	< 0.6 L	0.5	1.5	$\mu\text{g}/\text{ml}$
$\geq 2.5$ cm	0.6 – 3 L	0.25	0.75	$\mu\text{g}/\text{ml}$
$\geq 2.5$ cm	$\geq 3$ L	0.25	0.5	$\mu\text{g}/\text{ml}$
Cooking ware		0.05	0.5	$\mu\text{g}/\text{ml}$

- ◆ **Test conditions: 4% acetic acid, 24 hr,  $20 \pm 5^\circ\text{C}$**
- ◆ **These specifications were revised on July 31, 2008 based on ISO 6486 and 7086 (2000).**

# Ceramic Ware

## *Migration limits*

Depth	Capacity	Cd	Pb
< 2.5 cm or can not filled		0.7	8 $\mu\text{g}/\text{cm}^2$
$\geq 2.5$ cm	< 1.1 L	0.5	2 $\mu\text{g}/\text{ml}$
$\geq 2.5$ cm	1.1 – 3 L	0.25	1 $\mu\text{g}/\text{ml}$
$\geq 2.5$ cm	$\geq 3$ L	0.25	0.5 $\mu\text{g}/\text{ml}$
Cooking ware		0.05	0.5 $\mu\text{g}/\text{ml}$

- ◆ **Test conditions: 4% acetic acid, 24 hr,  $20\pm 5^\circ\text{C}$**
- ◆ **These specifications were revised on July 31, 2008 based on ISO 6486 (1999).**

# ***Enameled Ware***

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## ***Migration limits***

<b>Depth</b>	<b>Usage etc.</b>	<b>Cd</b>	<b>Pb</b>	
<b>&lt; 2.5 cm</b>	<b>or can not filled</b>	<b>0.7</b>	<b>8</b>	<b>μg/cm<sup>2</sup></b>
<b>&lt; 2.5 cm</b>	<b>Cooking ware</b>	<b>0.5</b>	<b>1</b>	<b>μg/cm<sup>2</sup></b>
<b>≥ 2.5 cm</b>	<b>&lt; 3 L</b>	<b>0.07</b>	<b>0.8</b>	<b>μg/ml</b>
<b>≥ 2.5 cm</b>	<b>Cooking ware</b>	<b>0.07</b>	<b>0.4</b>	<b>μg/ml</b>
<b>≥ 2.5 cm</b>	<b>≥ 3 L</b>	<b>0.5</b>	<b>1</b>	<b>μg/cm<sup>2</sup></b>

- ◆ **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 Plastics*

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**Specifications for plastic articles are consist of**

**General Specifications**  
for all polymers



**Individual Specifications**  
for particular polymer

# *General Specifications for Plastics*

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## ***Material test***

**Cd**  $\leq 100 \mu\text{g/g}$ , **Pb**  $\leq 100 \mu\text{g/g}$

## ***Migration test*** (Simulant: 2 ml/cm<sup>2</sup>)

**Heavy metals**  $\leq 1 \mu\text{g/ml}$  as Pb

**KMnO<sub>4</sub> consumed amount**  $\leq 10 \mu\text{g/ml}$   
(Index of total organic migrant)

- ◆ **All plastics shall conform to these specifications.**

# ***Evaporation residue test (Overall migration test)***

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***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***

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

Use 2 ml/cm<sup>2</sup> of simulant. \*When use temp>100°C.

***Test conditions are reviewing now.***

# *Individual Specifications for Plastics*

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## *Resin from formaldehyde (PF, MF, UF)*

**Phenol**  $\leq 5 \mu\text{g/ml}$ , **formaldehyde**: ND (ca.  $4 \mu\text{g/ml}$ )  
(simulant: water)

## *Polyvinyl chloride (PVC)*

**Dibutyl tin**  $\leq 50 \mu\text{g/g}$ ,  
**Cresyl phosphate**  $\leq 1 \text{ mg/g}$ , **VCM**  $\leq 1 \mu\text{g/g}$

## *Polystyrene (PS)*

**Total volatile substances** (styrene, ethylbenzene, toluene, *n*- & isopropyl-benzene)  $\leq 5 \text{ mg/g}$

## *PS foam using with hot water*

**Total volatile substances**  $\leq 2 \text{ mg/g}$   
**Styrene, ethylbenzene**  $\leq 1 \text{ mg/g}$  each

# *Individual Specifications for Plastics*

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## *Polyvinylidene chloride (PVDC)*

**Barium** ≤ 100 µg/g, **VDC** ≤ 6 µg/g

## *Polyethylene terephthalate (PET)*

**Sb** ≤ 0.05 µg/ml, **Ge** ≤ 0.1 µg/ml (4% AA)

## *Polymethylmethacrylate (PMM)*

**Methylmethacrylate** ≤ 30 µg/ml (20% EtOH)

## *Polyamide (PA)*

**Caprolactam** ≤ 15 µg/ml (20% EtOH)

## *Polycarbonate (PC)*

**Bisphenol A** ≤ 500 µg/g and ≤ 2.5 µg/ml

**Diphenyl carbonate** ≤ 500 µg/g

**Triethyl and tributyl amines** ≤ 1 µg/g

# ***Polylactic Acid (PLA)***

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



**Total lactic acid:**  $\leq 30 \mu\text{g/ml}$  (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  $40^\circ\text{C}$  (except  $\leq 100^\circ\text{C}/30\text{min}$  or  $\leq 66^\circ\text{C}/2\text{hr}$ )**

# Specifications for Rubbers

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Test item	General	Nipple
<b><i>Material Test</i></b>	( $\mu\text{g/g}$ )	( $\mu\text{g/g}$ )
Cadmium(Cd)	100	10
Lead (Pb)	100	10
2-Mercaptoimidazoline*	ND	-
<b><i>Migration test</i></b>	( $\mu\text{g/ml}$ )	( $\mu\text{g/ml}$ )
Phenol	5	5
Formaldehyde	ND	ND
Zinc (Zn)	15	1
Heavy metals	1	1
Evaporation residue	60	40

\*only for rubber containing chlorine

# *Specifications for Metal Cans*

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## *Migration test*

**Arsenic**  $\leq 0.2 \mu\text{g/ml}$  as  $\text{As}_2\text{O}_3$

**Cadmium**  $\leq 0.1 \mu\text{g/ml}$ ,

**Lead**  $\leq 0.4 \mu\text{g/ml}$

## *Additional tests for coating cans*

**Phenol**  $\leq 5 \mu\text{g/ml}$

**Formaldehyde**: ND (ca.  $4 \mu\text{g/ml}$ )

**Evaporation residue**  $\leq 30 \mu\text{g/ml}$

**Epichlorohydrin**  $\leq 0.5 \mu\text{g/ml}$   
(pentane,  $25^\circ\text{C}$ , 60 min)

**Vinyl chloride monomer**  $\leq 0.05 \mu\text{g/ml}$   
(EtOH,  $< 5^\circ\text{C}$ , 24hr)

# Specifications by Applications

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- ◆ **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*

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- ◆ **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*

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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*

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## **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***

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***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**

# *Resins Covered by JHOSPA*

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<b>1</b>	<b>Polyethylene</b>	<b>17</b>	<b>Polycarbonate</b>
<b>2</b>	<b>Polypropylene</b>	<b>18</b>	<b>Polyvinyl alcohol</b>
<b>3</b>	<b>Polymethylpentene</b>	<b>19</b>	<b>Polyacetal</b>
<b>4</b>	<b>Polybutene-1</b>	<b>20</b>	<b>Polybutyleneterephthalate</b>
<b>5</b>	<b>Butadiene resin</b>	<b>21</b>	<b>Polyaryl sulfone</b>
<b>6</b>	<b>Ethylene/tetracyclododecen polymer</b>	<b>22</b>	<b>Polyacrylate</b>
<b>7</b>	<b>Polystyrene</b>	<b>23</b>	<b>Polyesters of hydroxybenzoic acid</b>
<b>8</b>	<b>SAN resin</b>	<b>24</b>	<b>Polyether imide</b>
<b>9</b>	<b>ABS resin</b>	<b>25</b>	<b>Polycyclohexylene di-</b>
<b>10</b>	<b>Polyphenylene ether</b>		<b>methylene terephthalate</b>
<b>11</b>	<b>Polyacrylonitrile</b>	<b>26</b>	<b>Polyethylene naphthalate</b>
<b>12</b>	<b>Fluorine resin</b>	<b>27</b>	<b>Polyester carbonate</b>
<b>13</b>	<b>Polymethacryl styrene</b>	<b>28</b>	<b>Poly lactic acid</b>
<b>14</b>	<b>Methacryl resin</b>	<b>29</b>	<b>Polybutylene succinic acid</b>
<b>15</b>	<b>Nylon resin</b>	<b>30</b>	<b>Ethyrene/2-norbornen resin</b>
<b>16</b>	<b>Polyethylene terephthalate</b>		

# ***Voluntary Standards of Associations***

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***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***

<b>Classifi- cation</b>	<b>Sub Classification</b>	<b>No. of substance</b>	<b>Examples</b>
<b>Basic polymer</b>	<b>Basic polymer</b>	<b>30</b>	<b>Polyolefin, polystyrene, polyesters</b>
	<b>Monomer</b>	<b>150</b>	<b>Ethylene, propylene, styrene,</b>
	<b>Polymerization aid</b>	<b>77</b>	<b>Catalyst, initiator, modifier,</b>
<b>Additives</b>	<b>Stabilizer</b>	<b>140</b>	<b>Anti-oxidant, UV stabilizer</b>
	<b>Surfactant</b>	<b>77</b>	<b>Anti-foggy agent, anti-static electricity, emulsifier</b>
	<b>Lubricant</b>	<b>88</b>	<b>Anti blocking agent, friction agent</b>
	<b>Filler</b>	<b>68</b>	<b>Filler and inorganic colorants</b>
	<b>Blowing agent</b>	<b>10</b>	<b>Foaming agent and its aids</b>
	<b>Polymer additive</b>	<b>126</b>	<b>Polymer for modifier of synthetic resin</b>
	<b>Others</b>	<b>123</b>	<b>Radical agent</b>
<b>Colorants</b>		<b>269</b>	<b>Inorganic pigment, organic pigment, dye, food colorant</b>
<b>Total</b>		<b>1158</b>	

# **Recent Developments of Japanese Regulation**

## ***Test Method of Cd and Pb in Silicone Rubber***

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### **Existing test method for rubbers:**

Carbonized and ashed with  $\text{H}_2\text{SO}_4$ , dissolved into  $\text{HNO}_3$ , and determined by AAS or ICP.

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

### **Additional test method for silicone rubber**

**Fusioned with NaOH and  $\text{H}_3\text{BO}_4$**  by burner heating (**Alkali-fusion**), dispersed residue into hot water. Add the liquid to  $\text{HNO}_3$ , purified by Chelate cartridge, determined by AAS or ICP.

**This amendment was published on December 2012.**

## ***Test Method of Volatiles in Polystyrene***

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**Volatiles: Styrene, Ethylbenzene, Toluene, Isopropylbenzene, Propylbenzene**

**Existing test method of volatiles in polystyrene:**

**Dissolve in tetrahydrofuran (THF) and determine by GC-FID**

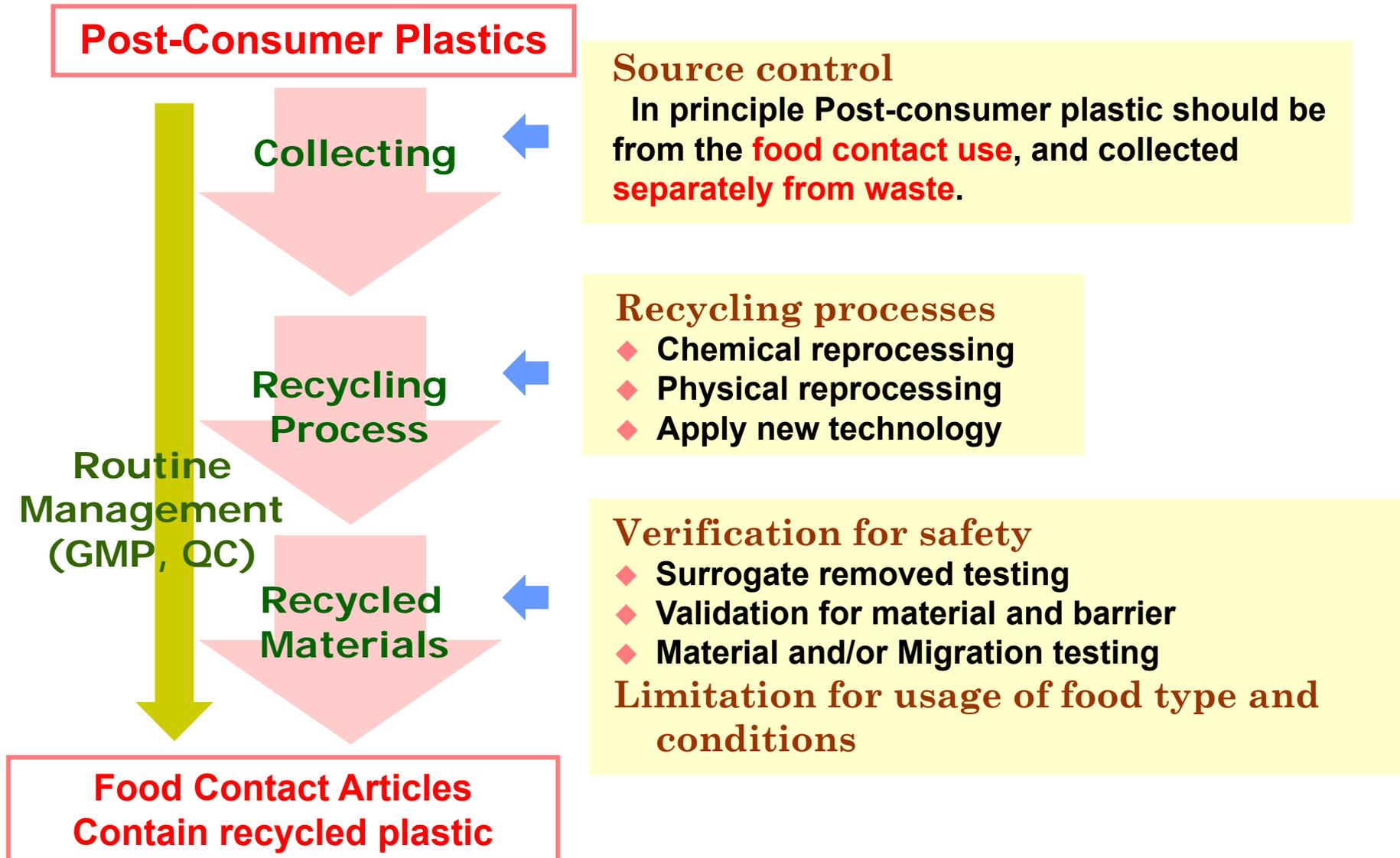
**Problem:** Styrene thermoplastic elastomer (STPE) and syndiotactic polystyrene (SPS) can not dissolve into THF and their recoveries are low.

**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**

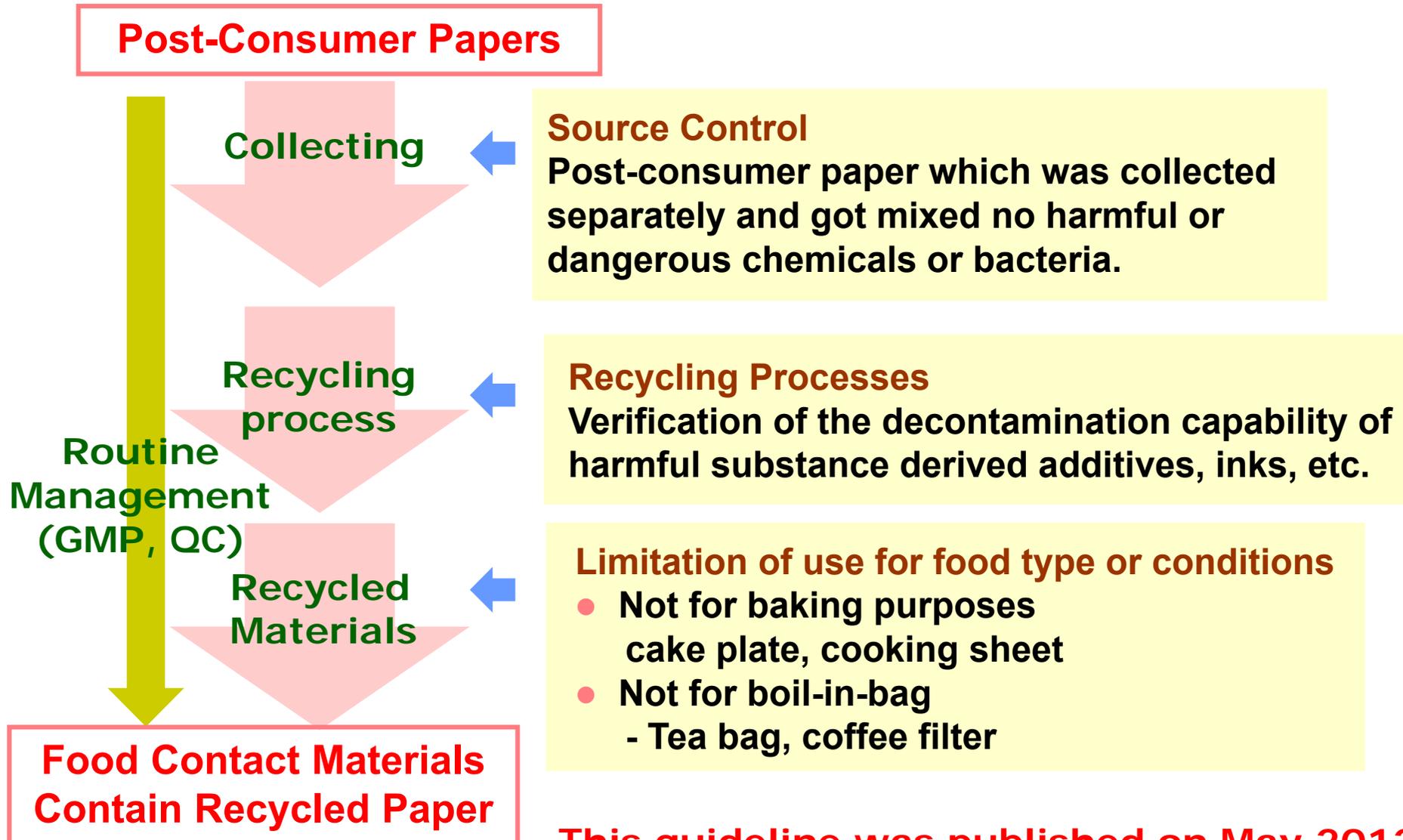
**This amendment was published on December 2012.**

# Guideline for use of Recycled Plastics in Food Contact Articles



This guideline was published on May 2012.

# Guideline for Use of Recycled Papers in Food Contact Articles



This guideline was published on May 2012.

**Ongoing  
and  
Future Works**

# *Phthalates and bisphenol A*

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**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*

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## **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.**

# ***Positive List of Monomers and Additives for Food Contact Plastics***

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**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!**