

# Agenda

1. Overview of amendments to the Food Sanitation Act
2. Amended provisions
3. Details

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# Food Sanitation Act: What are apparatus (utensils), containers and packaging?

## Article 4 [Definition]

- (4) The term “apparatus” shall mean tableware, kitchen utensils, and other machines, implements, and other articles which are used for collecting, producing, processing, cooking, storing, transporting, displaying, delivering, or consuming food or additives and which come into direct contact with food or additives.

Example:



Tableware



Kitchen utensils



Others

- (5) The term "containers and packaging" shall mean articles which contain or wrap food or additives and are offered "as is" when delivering food or additives.

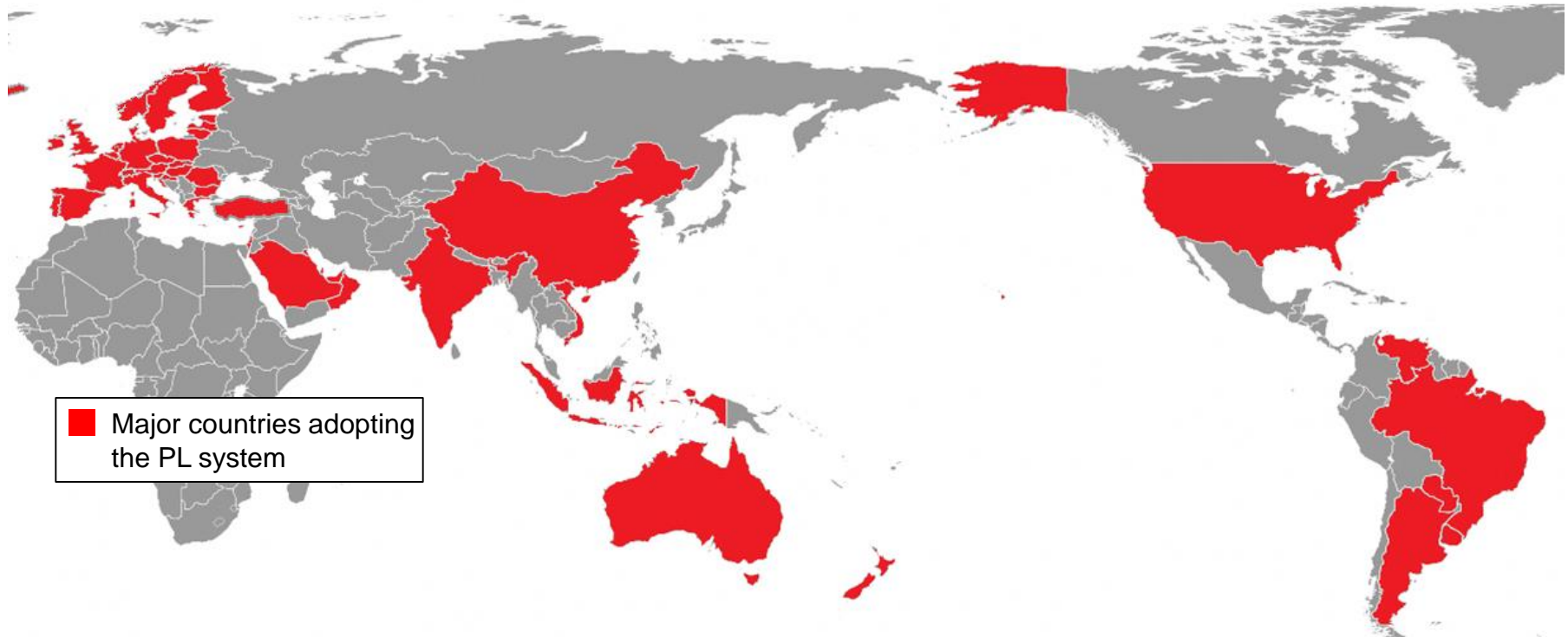
Example:



# Countries Adopting the Positive List System for Food Utensils, Containers and Packaging

<b>Positive List (PL) system</b> (Basically forbid usage and then list substances whose use is permitted)	<b>Negative List system</b> (Basically allow usage and then list substances whose use is limited)
The United States, EU, Israel, India, China, Indonesia, Vietnam, Australia, New Zealand, Saudi Arabia, Brazil, and more	Canada, Russia, Japan, Korea*, Thailand* and more  *Korea and Thailand are considering to adopt the PL system

Source: "The regulations of food utensils, containers and packaging in overseas—trends and applications, revised edition", JOHOKIKO CO., LTD.



# Outline of the Act Partially Amending the Food Sanitation Act etc.

(Promulgated on June 13, 2018)

## Purpose of the amendment

To respond to the change of environment on food in Japan and the globalization, and to ensure food safety, enhance measures for food poisoning on a wider scale, improve operators' hygiene control, gather food-related health hazard information and take the countermeasures appropriately. In addition, organize sanitary regulations for utensils, containers and packaging (UCP) considering international consistency, and take measures such as updating a business approval and application system that reflect the reality of operators' businesses, and establishing a reporting system for food recalls.

## Outline of the amendment

### **1. Enhance measures for food poisoning on a wider scale**

The government and regional governments will collaborate with each other to prevent food poisoning and the spread on a wider scale. The Minister of Health, Labour and Welfare will establish a council of a wide-scale partnership with associates and respond to emergencies through the council.

### **2. Requirement of food hygiene control based on HACCP system\***

In principle, all food operators will be required to conduct hygiene control that complies with HACCP as well as general hygiene control. However, hygiene control by operators with certain scale and specific business type should be conducted according to the character of the food they handle.

\* HACCP is a hygiene control approach with which operators understand risk factors including food poisoning contamination, manage key processes at all stage from procurement of raw ingredients to product shipment in order to remove or reduce risk factor, and ensure safety. It is becoming mandatory in developed countries.

### **3. Gathering health hazard information on the foods containing ingredients that require special caution**

To prevent health hazards in advance, urge operators to submit health hazard information to the government about foods containing ingredients that require special caution.

### **4. Improvement of sanitary regulations for UCP considering international consistency**

Introduce the Positive List system to food UCP, which only substances assured its safety and considered safe are permitted to be used for UCP.

### **5. Revision of licensing system and establishment of notification system for food business**

Update the current business categories reflecting their business more accurately and establish a notification system for operators who does not belong to the current business categories (34 categories specified by the cabinet order).

### **6. Establishing a reporting system for food recalls**

Establish a reporting framework for operators to report to their local government when they voluntarily recall their products.

### **7. Others** (for example, a requirement of a hygiene certificate to import dairy products or seafood and establishment of regulations on local governments' works for food export)

## Effective date of the amended Act

The day specified by the cabinet order, within two years (1 year for above 1. and 3 years for 5. and 6.) from the date of promulgation of the amended Act

# Improvement of Sanitary Regulations for Utensils, Containers and Packaging Considering International Consistency

- To ensure international consistency on safety and regulations of utensils, containers and packaging (UCP), only substances whose safety has been ensured are permitted to be used for UCP, and the UCP made of raw materials without specifications and standards are prohibited to be sold etc.

## Current system

- All substances are basically permitted to be used and substances whose use should be limited are specified. The government cannot regulate immediately the substances whose use is prohibited in other countries unless the specifications and standards are established.

## New system (Positive List system)

- All substances are basically prohibited to be used, and only substances assured its safety are permitted to be used for UCP.

\* Subject to the system: synthetic resin

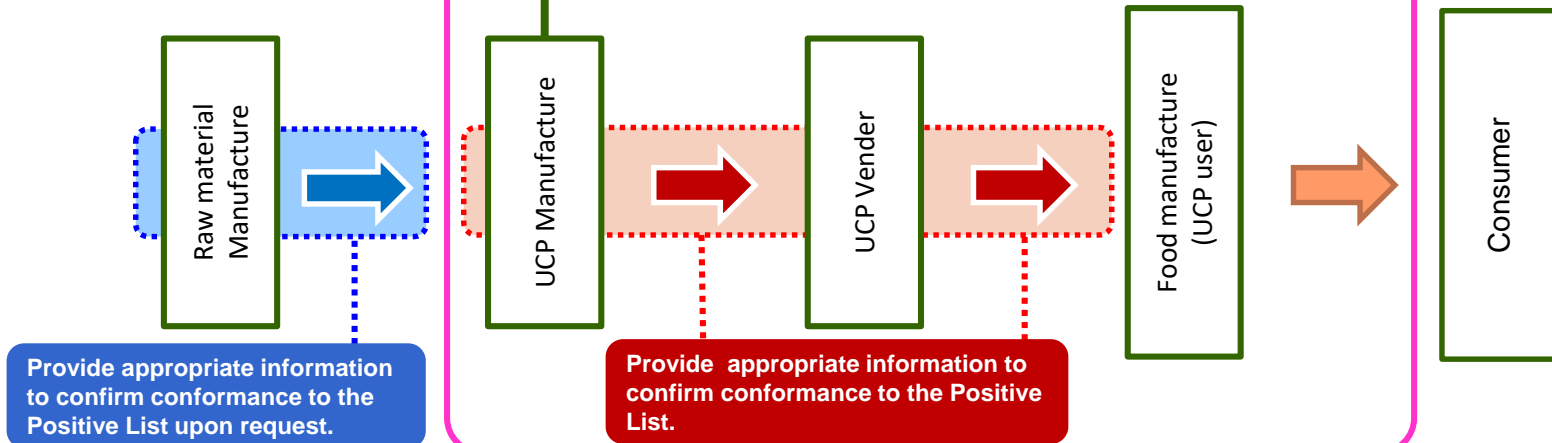
### Overview of the Positive List system

#### Risk management under the Positive List system by the Government

- Inspection (Have UCP business operators submit notification of business and instruct them.)
- Import monitoring

#### Management according to the Good Manufacturing Practice (GMP)

- Check raw materials
  - Save manufacturing records, etc.
  - Provide product information to confirm conformance to the standards and the specification
- \* To the manufacturers not covered by the Positive List system, general hygienic management is applied.



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# Food Sanitation Act: Key Relevant Articles Concerning Utensils and Containers and Packaging

## Chapter I General Provisions

- Article 1 [Purpose], Article 3 [Responsibility of food business operators], Article 4 [Definitions]

## Chapter III Apparatus (Utensils) and Containers and Packaging

- Article 15 [Principles of handling utensils and containers and packaging used in business]
- Article 16 [Prohibition on sale etc. of toxic or harmful utensils or containers and packaging]
- Article 17 [Prohibition on sale etc. of specific utensils etc.]
- Article 18 [Establishment of specifications and standards for utensils or containers and packaging]

## Chapter VII Inspections

- Article 26 [Inspection order], Article 27 [Notification concerning imports], Article 28 [On-site inspection and removal]

## Chapter IX Business

- Article 55 [Rescission etc. of approval]

## Chapter X Miscellaneous Provisions

- Article 58 [Notification concerning poisoning]

## Chapter XI Penal Provisions

- Articles 71, 72 and 73 [Penal provisions]



# Amended Food Sanitation Act (Excerpt of provisions related to utensils, containers and packaging)

## Article 18 (Paragraph (3) was newly added.)

(1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may establish standards for the utensils or containers and packaging, or the raw materials thereof to serve the purpose of marketing or to be used in business, or establish the criteria for the production methods thereof, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

(2) (Omitted)

(3) **Raw materials for materials specified by the Order for Enforcement of the Food Sanitation Act (the Cabinet Order) by taking into consideration the impact of eluting or seeping out ingredients into food on public health, **which contain substances** (excluding substances generated by chemical change of such substances) **for which the standards prescribed in paragraph 1 have not been established in terms of the quantity allowed to be contained in utensils or containers and packaging manufactured using such raw materials or the quantity allowed to be eluted or seeped out into food from utensils or containers and packaging manufactured using such raw materials, shall not be used in any utensils or containers and packaging. However, this shall not apply when utensils or containers and packaging have been processed so that such substances are not be eluted or seeped out into food in a quantity exceeding the quantity that the Minister of Health, Labour and Welfare specifies as being unlikely harm to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council (excluding cases where such substances are used in part of utensils or containers and packaging that will directly contact food).****



**Targeted materials:  
synthetic resin**

Prescribed in the Order for Enforcement of the Food Sanitation Act



**The Positive List**

Prescribed in the Public Notice of the MHLW



**The quantity that is unlikely harm to human health**

Prescribed in the Public Notice of the MHLW

\* This is provisional translation. Please refer to the original amended Act written in Japanese.

# Amended Food Sanitation Act (Excerpt of provisions related to utensils, containers and packaging)

## Article 52 (Newly added)

(1) **The Minister of Health, Labour and Welfare shall establish the criteria for the matters listed below by an Ordinance of the Ministry of Health, Labour and Welfare concerning sanitary management of business facilities where utensils or containers and packaging are manufactured and other measures necessary for public health** (hereinafter referred to as the “Necessary Public Health Measures” in this Article):

- (i) maintaining the cleanliness of the interior and exterior of business facilities and other general matters concerning sanitary management; and**
- (ii) matters concerning efforts to properly manage the manufacture which are necessary to prevent the food sanitation hazards.**

(2) **A business person who manufactures utensils or containers and packaging shall take necessary measures for public health in accordance with the criteria established pursuant to the provisions of the preceding paragraph (limited to the matters listed in the preceding paragraph, item 1 if a business person produces utensils or containers and packaging using only raw materials for the materials other than those specified by the Cabinet Order as prescribed in Article 18, paragraph 3.)**

(3) The prefectural governor etc. may establish the necessary provisions concerning the necessary measures for public health unless they are consistent with the criteria established pursuant to the provisions of paragraph 1.



- General sanitary management
- Management of manufacture according to the Good Manufacturing Practice

Prescribed in the Ordinance for Enforcement of the Food Sanitation Act

\* This is provisional translation. Please refer to the original amended Act written in Japanese.

# Amended Food Sanitation Act (Excerpt of provisions related to utensils, containers and packaging)

## Article 53 (Newly added)

(1) A person who sells or manufactures or imports for the purpose of marketing any utensils or containers and packaging in which the materials specified by the Cabinet Order as prescribed in Article 18, paragraph 3 are used shall explain to a party to whom he/she sells the utensils or containers and packaging he/she handles that the utensils or containers and packing so handled by him/her fall under either of the following items, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare:

- (i) the utensils or containers and packaging only use raw materials for the materials specified by the Cabinet Order as prescribed in Article 18, paragraph 3 that conform to the standards established pursuant to the provisions of the same Article, paragraph 1; or
- (ii) the utensils or containers and packaging have been processed in the manner prescribed in the proviso of Article 18, paragraph 3.



Obligation to provide necessary information between manufacturer, vender and importer

Prescribed in the Ordinance for Enforcement of the Food Sanitation Act

(2) A person who sells or manufactures or imports for the purpose of marketing the raw materials for utensils or containers and packaging which fall under the materials specified by the Cabinet Order as prescribed in Article 18, paragraph 3, if requested by a person who manufactures any utensils or containers and packaging using such raw materials to confirm that such raw materials conform to the standards established pursuant to the provisions of the same Article, paragraph 1, shall endeavor to provide necessary explanation pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.



Endeavor to provide necessary information by business operators handling raw materials

Prescribed in the Ordinance for Enforcement of the Food Sanitation Act

\* This is provisional translation. Please refer to the original amended Act written in Japanese.

# Amended Food Sanitation Act (Excerpt of provisions related to utensils, containers and packaging)

## Article 57 (Newly added)

(1) A person who intends to conduct a business (excluding businesses prescribed in Article 54, businesses which have a minor impact on public health and are specified by the Cabinet Order and poultry slaughtering businesses) **shall notify the prefectural governor**, in advance, of the name and location of the business and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(2) (Omitted)

## Effective Date

### Article 1 of the Supplementary Provisions

This Act comes into effect **on the day specified by the Cabinet Order within a period not exceeding two years from the date of promulgation.** (Omitted)

## Transitional Measures

### Article 4 of the Supplementary Provisions

The provisions of Article 18, paragraph 3 and Article 50-4 (omitted) of the new Food Sanitation Act shall not apply to **utensils (omitted) and containers and packaging (omitted) sold, produced or imported for the purpose of marketing, or used in business (omitted) at the time of the enforcement of this Act.**

Notification system of manufacturing for domestic manufacturers



Prescribed in the Ordinance of Enforcement of the Food Sanitation Act

# Supplementary Resolutions to the Bill Partially Amending the Food Sanitation Act etc.

<The House of Councillors' Committee on Health, Welfare and Labor on April 12, 2018 >

**1. to 3.** (Omitted)

**4.** When introducing the Positive List system for food utensils and containers and packaging, take all possible measures to ensure the smooth enforcement of the Act such as establishing specifications and standards in a systematic manner based on the assessment of the effect of food on health. Also, consider to develop the positive lists for materials other than synthetic resin considering the risk level and international trends.

**5. to 8.** (Omitted)

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## Materials Specified by Cabinet Order as Applicable to the Positive List (PL)

- Materials including synthetic resins, paper and rubber products are used in food utensils, containers and packaging (UCP), and specifications by material are specified in the Specifications and Standards for Food, Food Additives, etc. (Ministry of Health and Welfare Notification no.370, 1959).

Article 18, paragraph 3 of the amended Food Sanitation Act prescribes that the raw materials for materials applicable for the PL system shall be those which standards have been prescribed in paragraph 1, and that the applicable materials shall be specified by the Order for Enforcement of the Food Sanitation Act (the Cabinet Order).

- Based on the following reasons, synthetic resins shall first be applicable for the PL system:
  - (1) The material is used extensively in various utensils, containers and packaging and its impact toward public sanitation must be taken into consideration;
  - (2) The material is included in the PL systems of other countries such as in Europe and the United States;
  - (3) The material has been independently managed by a trade association

# Scope of the Positive List for “Synthetic Resins”

## Classification of Synthetic Resins (Overview)

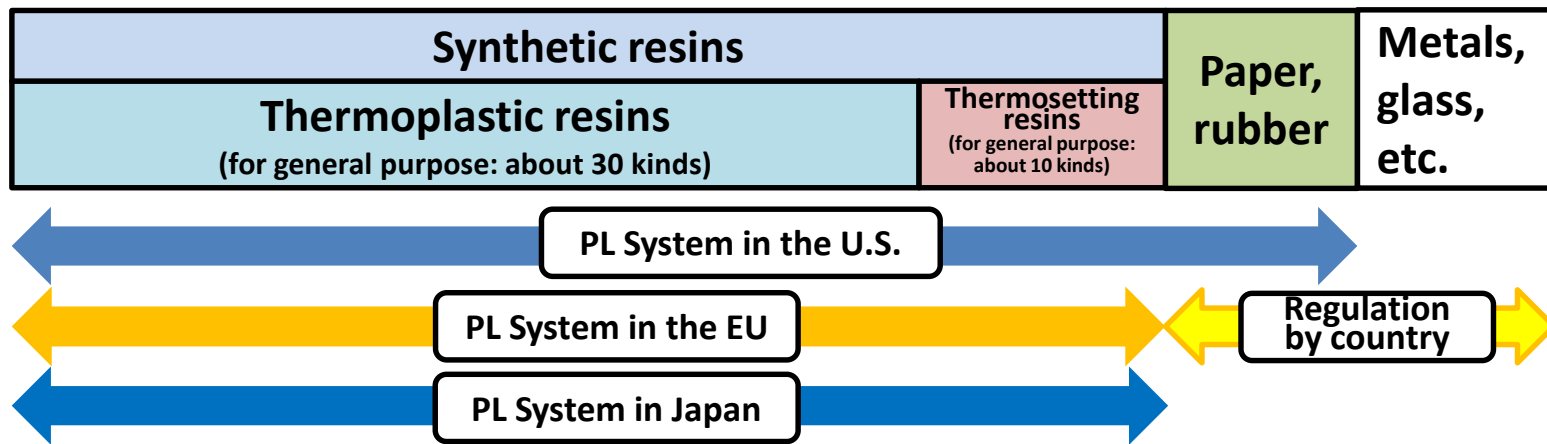
	Thermoplastic resins	Thermosetting resins
Plastic	Thermoplastics e.g., polyethene, polystyrene	Thermosetting plastics e.g., melamine resin, phenol resin
Elastomer	Thermoplastic elastomer e.g., polystyrene elastomer, styrene-block copolymer	Rubber (thermosetting elastomer) e.g., butadiene rubber, nitrile rubber
Supplement	Without a cross-linked structure	With a cross-linked structure

## Applicable criteria to the Positive List (draft)

- “Rubber” will be differentiated from synthetic resins as “a non-thermoplastic, high-polymer elastic body with a cross-linked structure.”
- The part excluding “rubber” will be handled as synthetic resin and subject to the positive list system.



# Comparison of the Regulations in Japan, Europe, and the United States (After the amendment)



- The United States:

A Positive List system for synthetic resins, paper, and rubber products was established in 1958, which confines the chemical substances that can be used with those listed in the Code of Federal Regulations (CFR). For synthetic resins, the CFR prescribes the monomers and additives that can be used and their content for each type of polymer. Also, the Food Contact Notification (FCN) system, a premarket notification for food contact substances, was established in 2000, which limits their use to the notifier for each product, in order to accelerate the process of inclusion in the Positive List.

Manufacturing products under the Good Manufacturing Practice (GMP) is mandated for manufacturers including raw material manufacturers. However, there is no particular regulation on information sharing among business operators, which is left to self-management and self-declaration.

- Europe (EU):

A PL system for synthetic resins was established in 2010, which limits the migration levels, use conditions, and other necessary matters for each monomer and additive. Additionally, the system also regulates the total migration level of ingredients contained in the products and their materials.

Manufacturing products under the Good Manufacturing Practice (GMP) are mandated for manufacturers including raw material manufacturers. The issuance of a “declaration of compliance,” which certifies the compliance of raw materials and products with the Positive List, is mandated to share information among business operators.

- Japan:

A PL system for synthetic resins will be introduced first. Manufacturing control under the GMP and information sharing with purchasers are mandated for manufacturers of utensils, containers, and packaging (UCP). Additionally, UCP raw material manufacturers should provide information upon request.

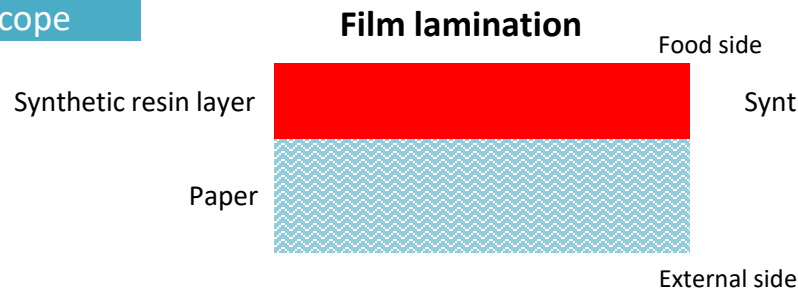
# Synthetic resins etc. used in paper

## Summary

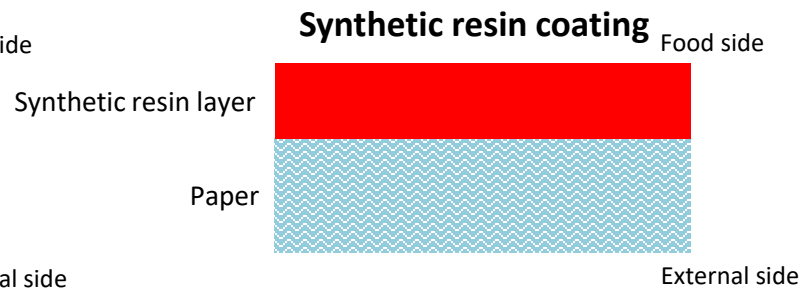
Synthetic resins etc. used in paper which have a synthetic resin layer on the food-contact surface are subject to the positive list system for synthetic resins.

## Scope of the positive list for synthetic resins

### In scope



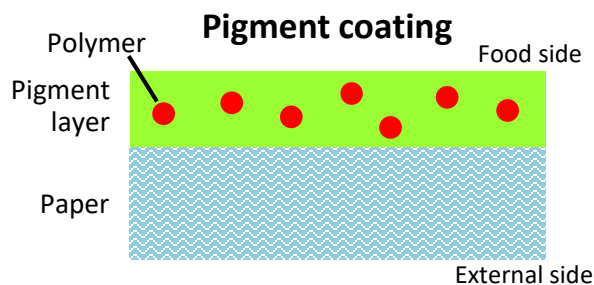
A synthetic resin film is laminated to the surface of paper



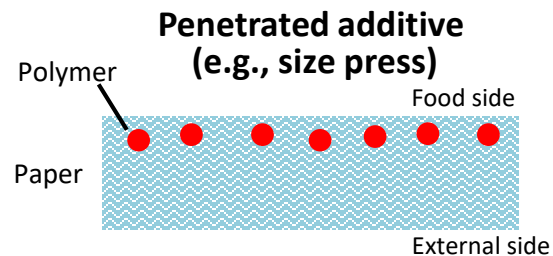
Synthetic resin coating is formed on the surface of paper

### Out of scope

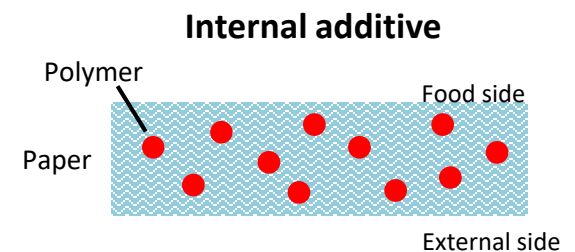
⇒ To be controlled by the positive list for paper in the future



Polymers function as a binder of pigments such as kaolin and calcium carbonate



Polymers are penetrated into pre-dried or dried paper as a roll



Polymers are added to pulp slurry

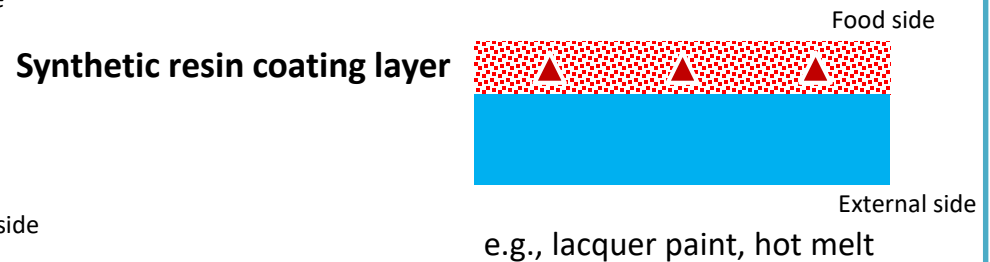
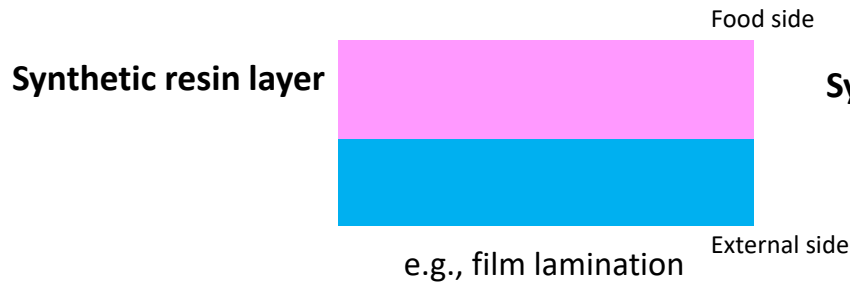
# Handling of Synthetic Resin Layer (e.g., ink, adhesives)

## Summary

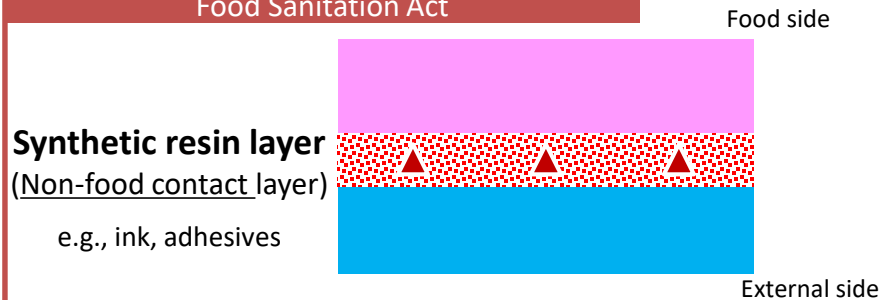
If substances used in synthetic resin (including ink and adhesives) of the middle layer (non-food contact layer) are controlled not to migrate into foods exceeding a certain level, they shall be subject to the proviso in Article 18(3) : if a substance does not listed in the Positive List but the migration into food does not exceed a certain level, the substance can be used for utensils, containers and packaging.

## Scope of the positive list for synthetic resins

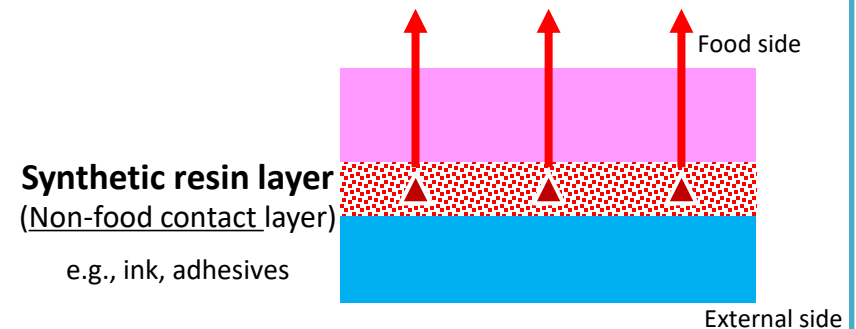
### In Scope



### Application of Proviso in Article 18(3) of the Food Sanitation Act



Control manufacturing to prevent the substance in the layer from migrating into food exceeding a certain level before the expiration/use-by date. In the future, conditions to ensure there is no migration exceeding a certain level will be considered.



If migration into food exceeds a certain level, individual substances are required to be included in the Positive List.

# About “Quantity Being Unlikely to Harm” in the Proviso in Article 18 (3)

According to Article 18 (3) of the amended Food Sanitation Act, although the raw materials for materials (synthetic resins) specified by the Cabinet Order must be substances in the Positive List, substances not listed in the list may also be used if not used in areas that come in contact with food and do not transfer to food in quantities that exceed amounts deemed as unlikely to harm human health.

In that case, the quantity deemed as unlikely to harm human health shall be specified according to the concentration within food-simulating solvents rather than the dietary concentration of the substance eluted or seeped out from utensils, containers and packaging (\*) when considering the effectiveness of risk management.

\* Calculations of dietary concentrations require conversions that apply factors etc. to values obtained from dissolution tests that use food-simulating solvents.

[Excerpt from Reference Material 2 of utensils, containers and packaging (UCP) section (July 8, 2019)]

- The quantity that the Minister of Health, Labour and Welfare specifies as being unlikely to harm human health pursuant to the proviso in Article 18 (3) of the amended Food Sanitation Act shall be 0.01mg/kg for food.
- The quantity migrated into food is calculated by multiplying the concentration in the food-simulating solvent by the factor (weight of food that contacts with UCP/quantity of food-simulating solvent) . This factor may be approximated to 1. Therefore, the migration (0.01mg/kg) into food may be considered as 0.01mg/L for the concentration in the food-simulating solvent.

# Specifications and Standards in the PL System

- The substances to be managed in the PL system shall be prescribed in the Public Notice.
- The substances to be managed under the PL system shall be the following:
  - Main components of synthetic resin (base polymers)
  - Substances that are expected to remain in final products to physically or chemically change the properties of synthetic resin
- Catalysts and polymerization aids are used for polymerization of monomers. They do not become part of base polymers and are not expected to remain in final products. Therefore, they shall be managed according to the conventional risk management methods not according to the PL.
- Coloring materials shall be comprehensively specified as “(1) Colorants listed in Appended Table 1 of the Order for Enforcement of the Food Sanitation Act (Ordinance No. 23 of the Ministry of Health and Welfare, 1948) and (2) Colorants processed so they will not be eluted or seeped out into food” based on the current management method according to the Notification No. 370 of 1959 and consistency with international standards while maintaining the same approach as the current management method pertaining to colorants specified in the Notification.
- The migration and other necessary restrictions for additives etc. shall be stipulated as needed, assuming additives etc. will be managed according to the amount added (content) to each substance.
- Synthetic resins shall be classified into some groups according to their characteristics and current use status; and the use level of additives etc. shall be specified and managed by the group.

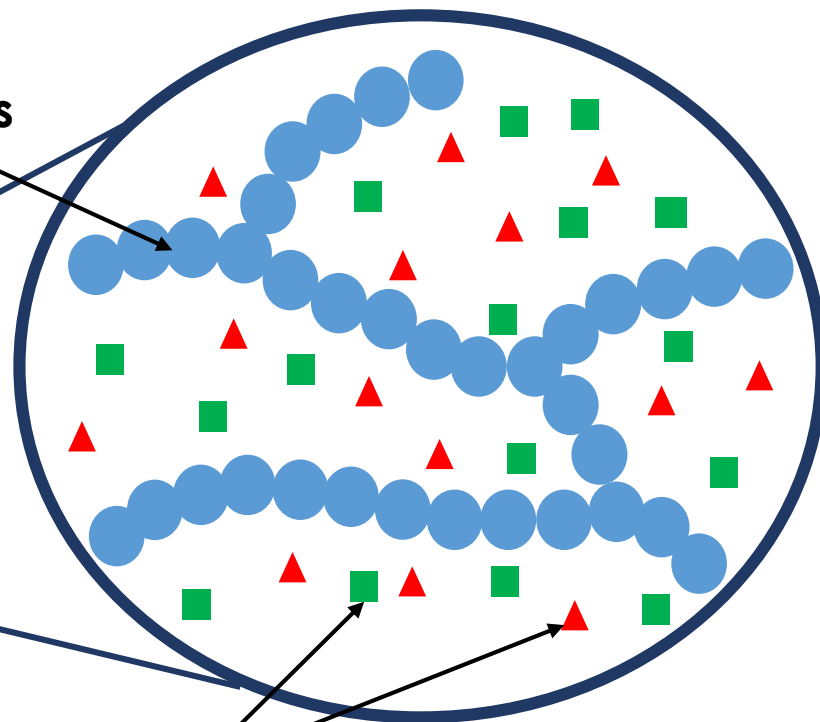
# Materials Consist of Utensils, Containers and Packaging

Utensils, Containers or Packaging  
(Final Product)

Materials consist of UCP (Raw materials)

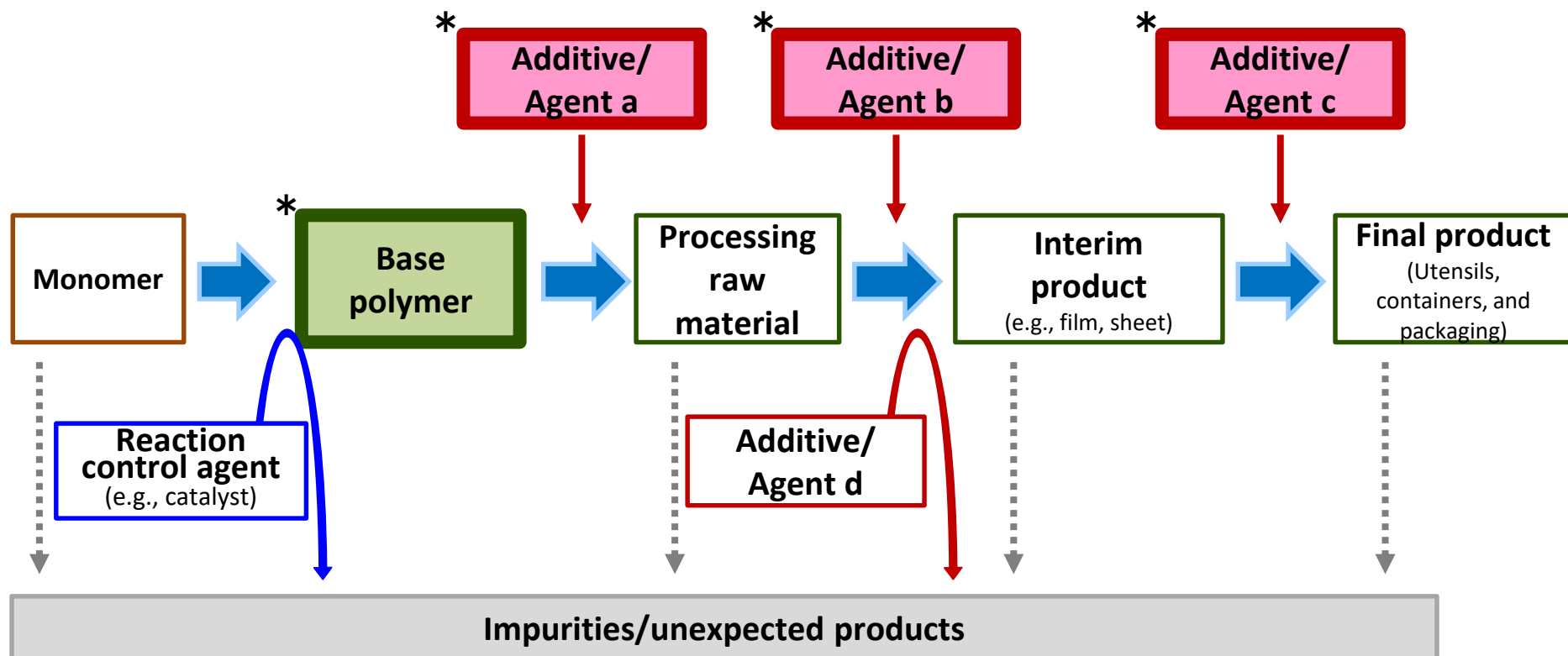


Base Polymers



Additives

# Substances Controlled by the Positive List



\*To be controlled under the Positive List system

## Scope of substances to be included in the Positive List

- Substances which are expected to remain in final products are managed in the Positive List (\*).
- Substances which are not expected to remain in final products are managed by the existing risk management method.

\* Coloring is a substance which is expected to remain in final products and thus is subject to the Positive List system for synthetic resins. Based on the concept same as the current risk management method (chemical artificial coloring other than designated food additives shall be processed not to be mixed into food by migrating or leaching), it will be comprehensively included in the Positive List and managed.

# Classifying Method for the Positive List (Grouping Method of Synthetic Resin)

## Summary

Classify resins into several groups based on base polymers, their property (physiochemical property), and current use status; and determine use level of additives etc. according to the group.

## Objectives

- Assure wide range of combination of resins and additives etc. while managing migration levels of additives into food.
- Protect intellectual property by not specifying the combinations of resins and additives.
- Simplify the Positive List.

## Idea of base polymer grouping

Consumption factor	Resin property	
	Oil resistance	Water resistance
Small	Very strong	Very strong
	Weak	Strong
	Strong	Weak
Large	-	-

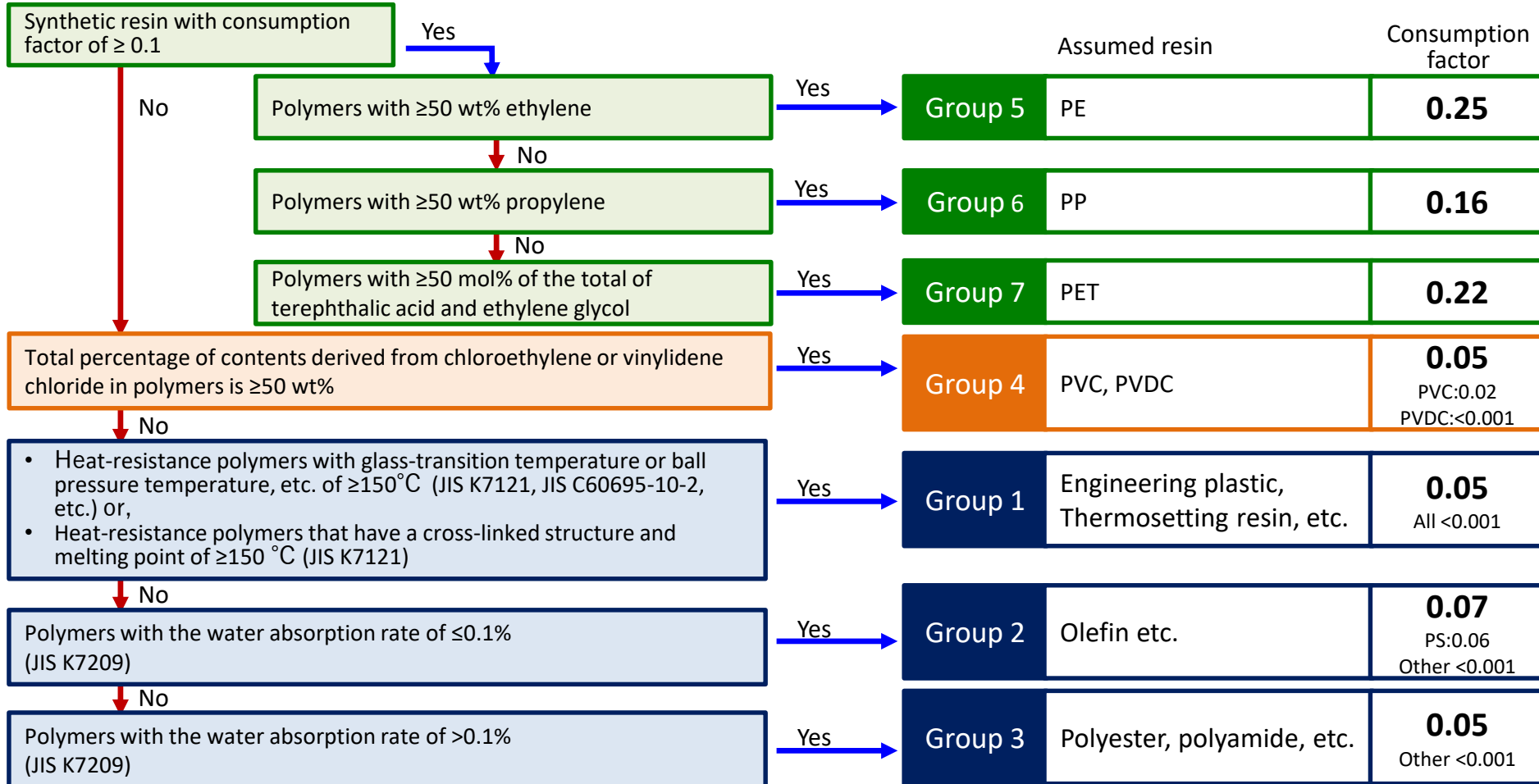
Note: The number of groups may be changed based on property and use status.



# Synthetic Resin Grouping Method

## Summary

Classify resins into several categories based on base polymers, their property (physiochemical property) and current use status; and determine use level of additives etc. according to the category.



\*Consumption factor is obtained by estimating percentage of the diet that contacts with specific materials used for UCP in total.

\*Groups 1 to 3 can be applied to resins in Groups 5-7 if the consumption factor is very small due to their specific use etc.

\*Although the principle of grouping criteria is above chart, substances may be comprehensively classified based on heat-resistance temperature, chemical resistance, etc.

# Reference: Calculation of consumption factors etc.

- Consumption factors and food-type factors are used when calculating the dietary concentration of a substance under the PL system when confirming its safety. (Described in the Guideline for Assessment of the Effect of Food on Human Health Regarding Food Utensils, Containers and Packaging by the Food Safety Committee of Japan.)
- A survey project by the MHLW (2010) investigated material types and their weight of containers and packaging used for food in the market by food item. Consumption factors were derived from the percentage of materials by the food item and that of food overall. Food-type factors were derived from the quantity used for container and packaging by material for each food-type (aqueous, acid, oil, alcoholic, dairy, dry foods, etc.). Consumption factors etc. for synthetic resin below were set by classifying these factors by material into groups of synthetic resin according to characteristics of polymers.

Consumption factor: Factor obtained by estimating percentage of the diet that contacts with specific materials used for UCP in total.

Food-type factor: Factor obtained by estimating percentage of UCP used for foods of a specific food type by material.

\*UCP: utensils, containers and packaging

Synthetic resin group (type) *	Consumption factor (CF)	Food-type factor (DF)					
		Normal foods		Acidic food	Alcoholic beverage	Dairy etc.	Oils and fats
		D <sub>1</sub>	D <sub>1sub</sub>				
<b>Resin Group 1</b>	0.05	The food group factor for the food group with the highest migration quantity shall be 0.96, and the factor of other food groups being 0.01.					
<b>Resin Group 2 (PS etc.)</b>	0.07	0.38	0.02	0.27	0.01	0.11	0.23
		When PS is not used for a migrating test: Use 0.96 for DF of the food group with the highest migration quantity (Q), and use 0.01 for DF of other food groups.					
<b>Resin Group 3 (PA etc.)</b>	0.05	0.92	0.01	0.01	0.01	0.01	0.05
		When PA is not used for a migrating test: Use 0.96 for DF of the food group with the highest migration quantity (Q), and use 0.01 for DF of other food groups.					
<b>Resin Group 4 (PVC, PVDC)</b>	0.05	0.93	0.01	0.01	0.01	0.01	0.04
<b>Resin Group 5 (PE)</b>	0.25	0.88	0.03	0.04	0.01	0.02	0.05
<b>Resin Group 6 (PP)</b>	0.16	0.80	0.05	0.05	0.01	0.02	0.12
<b>Resin Group 7 (PET)</b>	0.22	0.86	0.01	0.09	0.01	0.01	0.03

\*Synthetic resin groups are classified based on the properties of base polymers (physicochemical properties) and current use status.

PS: polystyrene, PA: polyamide, PVC: polyvinyl chloride, PVDC: polyvinylidene chloride, PE: polyethylene, PP: polypropylene, PET: polyethylene terephthalate

# Specifications of Base Polymers

## Summary

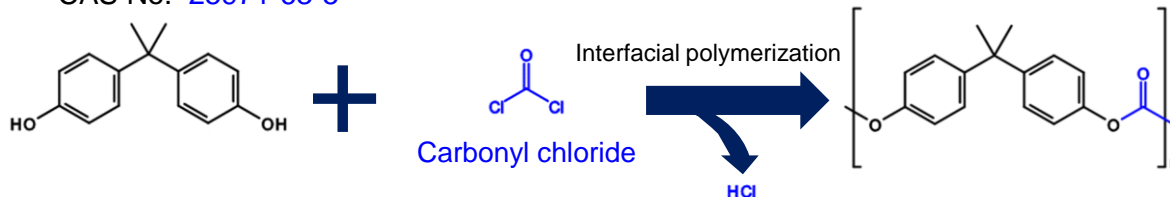
- When initial monomers and manufacturing method differ, the polymers shall generally be treated as different base polymers even if the synthesized base polymer structures are the same.
- Base polymers with different source-based names shall be listed separately in the Positive List even if they have the same structure-based name.

Example: Polycarbonates

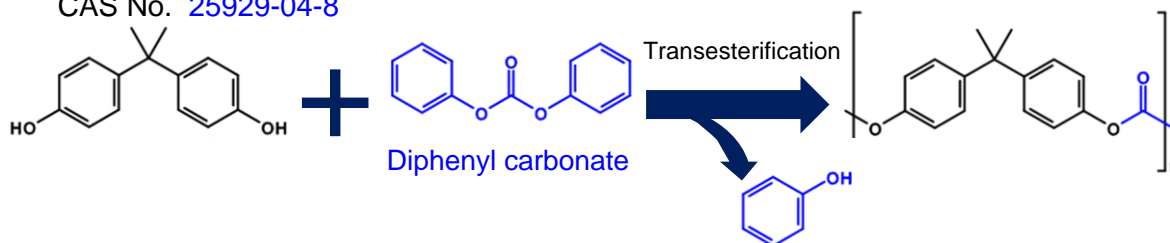
No	Polymers	English name	CAS No.
1	2, 2-bis (4-hydroxyphenyl) propane, <b>carbonyl chloride</b> copolymer	<b>Carbonic dichloride</b> , polymer with 4,4'-(1-methylethylidene)bis[phenol]	<b>25971-63-5</b> <b>24936-68-3</b>
2	2, 2-bis (4-hydroxyphenyl) propane, <b>diphenyl carbonate</b> copolymer	<b>Carbonic acid, diphenyl ester</b> , polymer with 4,4'-(1-methylethylidene)bis[phenol]	<b>25929-04-8</b> <b>24936-68-3</b>

## ➤ Source-based name

- (1) 2, 2-bis (4-hydroxyphenyl) propane, **carbonyl chloride** copolymer  
CAS No. **25971-63-5**

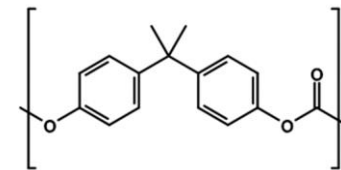


- (2) 2, 2-bis (4-hydroxyphenyl) propane, **diphenyl carbonate** copolymer  
CAS No. **25929-04-8**



## ➤ Structure-based name

- Poly [oxycarbonyloxy-1,4-phenylene (dimethylmethylene) -1,4-phenylene]  
CAS No. **24936-68-3**



## Source-based name

Name based on the ingredient monomer.

## Structure-based name

Name based on the chemical structure of the polymer's repeating unit.

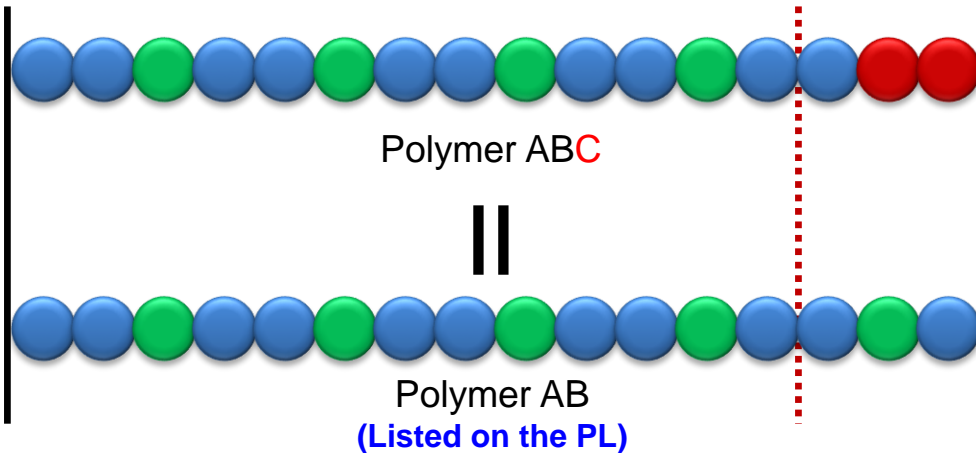
# Rules for the Positive List (PL) on Base Polymers and Minor Monomers (98% Rule)

## Summary

- Information of minor monomers constitute polymers directly correlates with trade secrets of companies. Therefore, consideration is required for the way of listing while ensuring the safety of public health.
- More than 98 wt% of the components of a base polymer shall be constituted with polymers listed in the PL.
- Substances of which the remaining components of the polymer consists (minor monomers) shall be listed in and managed by the list of minor monomers compiled separately from the list of polymers by resin.

## 98% rule (draft)

0 wt% 98 wt% 100 wt%



- Monomer A
- Monomer B
- Monomer C (Listed on the PL (Minor Monomer List))

## Conditions

- (1) Polymer AB is included in the PL as a base polymer
- (2) A and B in Polymer ABC exceed 98% weight as the polymer's structural components
- (3) Monomer C is included in the PL as a [minor monomer](#)

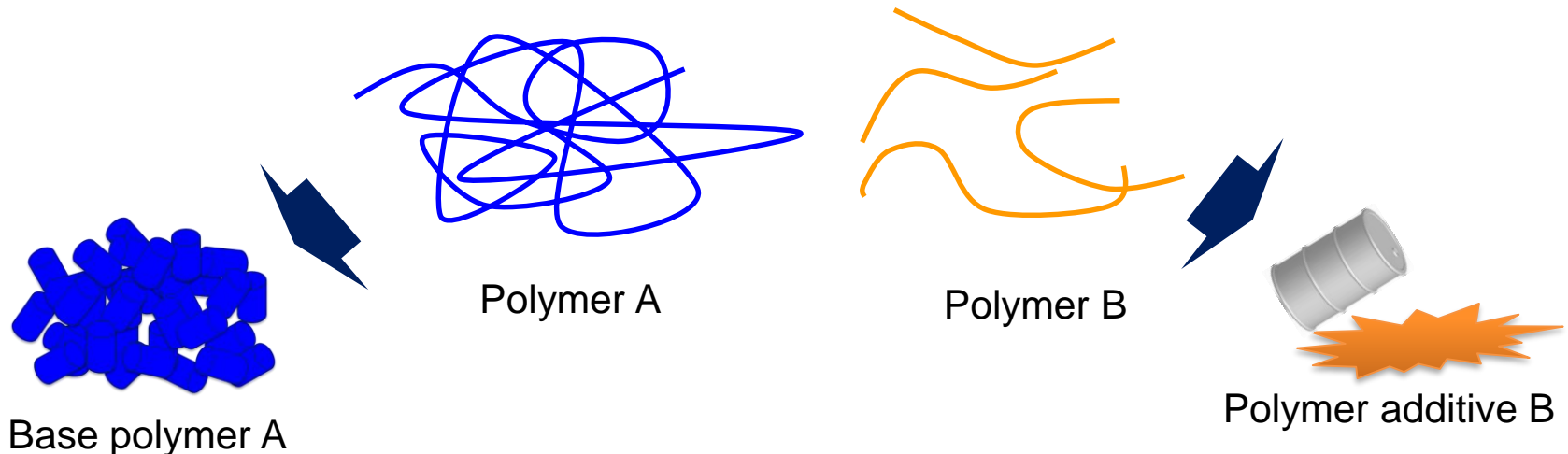


The polymer ABC may be treated as Polymer AB only if it satisfies all three conditions above.

\* As needed, minor monomers are restricted to be used in some polymers and managed by the current risk management method (negative list system).

# Rules for Substances with Polymer Structures

- Substances with polymer structures are sometimes used as additives to manufacture synthetic resins. These substances shall be included in the list as additives.
- Specifically, the following substances with polymer structures shall be listed as additives:
  - (1) Substances of materials classified apart from synthetic resin (rubber, cellulose, etc.)
  - (2) Substances with polymer structures such as the following that normally will not become UCP when used alone
    - Substances with low viscosity and that become liquid at room temperature (polyethylene glycol, ester, etc.)
    - Substances with under 1,000 in molecular weight (excluding when they can become UCP)
    - Other substances that are appropriate to manage as additives based on the purpose of use and quantities
- In addition, if synthetic resins are mixed together, the synthetic resin with polymer structure shall be listed and managed as a base polymer rather than an additive for the other synthetic resin.



# Positive List Format

## (1) Base polymers

More than 98 wt% of the components of a base polymer shall be polymers listed below.

### ● AA resin

No	Polymers		CAS No	Food types					Maximum temperature I. ≤70°C II. ≤100°C III. ≥101°C	Group	Remarks
				Acidic	Oily and fatty	Milk and milk product	Alcoholic beverage	Others			
	Japanese name	English name									
1	Homopolymer of AA	AA polymer	0000-00-0	○	○	○	○	○	III	1	
2	Copolymer of AA and BB	AA polymer with BB	1111-11-1	○	—	—	○	○	III	2	

### ● BB resin

No	Polymers		CAS No	Food type					Group	Remarks	
				Acidic	Oily and fatty	Milk and milk product	Alcoholic beverage	Others			
	Japanese name	English name									
1	Homopolymer of BB	BB polymer	2222-22-2	○	○	○	○	○	III	3	
2	Copolymer of BB and ZZ	BB polymer with ZZ	3333-33-3	—	○	○	○	○	II	3	

Set "group" for each polymer

### ● Minor monomers can be used for polymerization of base polymers

No	Minor monomers		CAS No	Remarks
	Japanese name	English name		
1	XX	XX	5555-55-5	
2	YY	YY	6666-66-6	

※ Minor monomers are restricted to be used in some polymers and managed by the current risk management method (negative list system) as needed.

Restrictions on use level of additives and other agents will be set by polymer group.

## (2) Additives, coating agents, etc.

No	Substance name		CAS No	Maximum use level by group (wt%)						
	Japanese name	English name		1	2	3	4	5	6	7
1	aaa	aaa	9999-99-9	1.0	1.0	-	-	1.5	1.0	-
2	bbb	bbb	8888-88-8	-	5.0	2.0	2.0	2.0	2.0	2.0

The use level of the additives etc. is described in percentage for the whole synthetic resin including the additives etc.

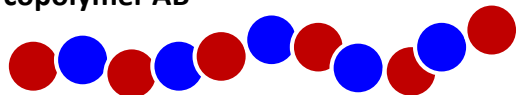
# Single Resin and Mixed Resin

## Single Resin

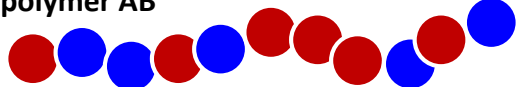
Single copolymer A



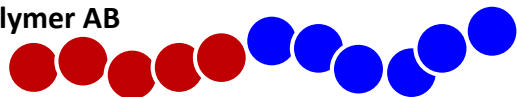
Alternating copolymer AB



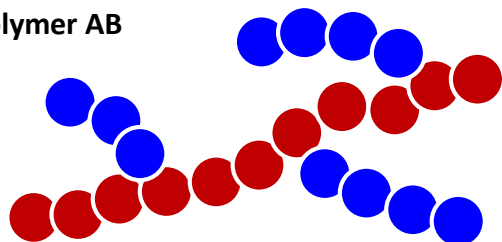
Random copolymer AB



Block copolymer AB



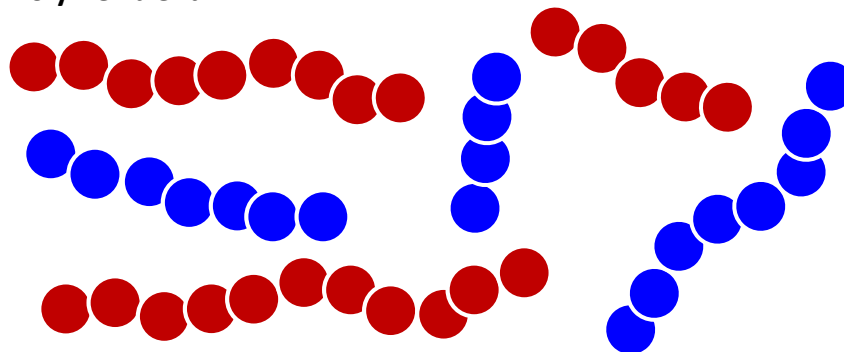
Graft copolymer AB



Need to be listed as base polymer in the Positive List

## Mixed Resin

Polymer blend



Two or more polymers are blended

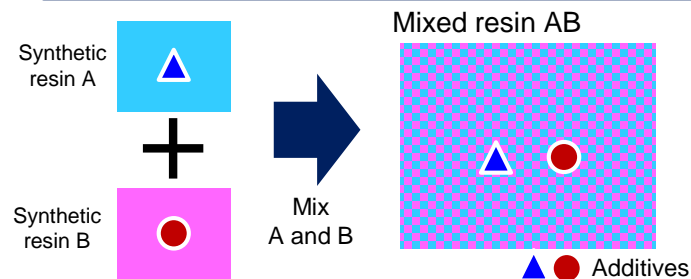
No need to be listed as mixed resin in the Positive List

- ✘ Each Polymer shall be listed in the Positive List.
- ✘ If a resin has a chemical reaction, the resin is not regarded as mixed resin.

# Mixture of Synthetic Resins (Mixture Rule 1)

## Summary

- When multiple resins in the PL are mixed, the mixed resin shall be treated as applicable to the PL.
- In this case, restrictions for each resin (applicable food type, applicable temperatures, additive quantities, etc.) shall also apply for the mixed resin.



## Conditions of synthetic resins for mixed resin and the additives

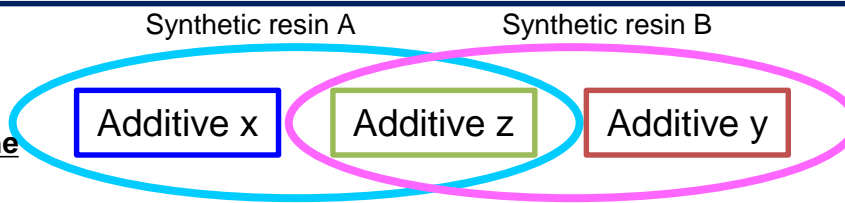
	Base polymer	Additive ▲	Additive ●
Synthetic resin A	Needs to be listed in the PL (Treated as food contact layer)	Needs to be listed in the PL with use limit of the group for synthetic resin A or B	Needs to be listed in the PL with use limit of the group for synthetic resin A or B
Synthetic resin B	Needs to be listed in the PL (Treated as food contact layer)		

## Maximum use levels of additives

Ex. Additives x and z may be used for synthetic resin A.  
Additives y and z may be used for synthetic resin B.

→ **Additives x, y and z may all be used** for mixed resin AB.

However, **the maximum use level shall be according to the standards of the resin before being mixed.**



	Synthetic resin A	Synthetic resin B
Resin weight	2 kg	1 kg
Maximum use level	Additive x (Maximum: 10 wt%)	0g (Not listed in PL)
	Additive y (Not listed in PL)	50g (Maximum: 5 wt%)
	Additive z (Maximum: 20 wt%)	100g (Maximum: 10 wt%)

Mixed resin AB	Remarks
3 kg	
200g (Maximum: 6.7 wt%)	Not 300g (10 wt% of the total weight, 3kg)
50g (Maximum: 1.7 wt%)	Not 150g (5 wt% of the total weight, 3kg)
500g (Maximum: 17 wt%)	

Mix A and B

- The maximum temperature shall be severer between the resins A and B. Food types of the mixed resin shall be the types of both resins.



# Mixture of Synthetic Resins (Mixture rule 2)

## Summary

- When multiple resins listed in the PL are mixed, the restrictions for the each resin before mixture (applicable food types, applicable maximum temperature, etc.) shall apply to the mixed resin. In general, the severest conditions of the resins shall apply to the mixed resin.
- In some case, more lenient restrictions may apply when a polymer with lenient restrictions is mixed with small amounts of a polymer with severe restrictions.  
Example: If a mixed resin consists of a polymer with maximum temperature I and small amounts of a polymer with maximum temperature III, the temperature III is applied to the maximum temperature of the mixed resin.
- Such mixed resins shall be managed with descriptions in the Remarks columns, which clarify exceptions for the mixture rule.

## Example

No	Polymers		CAS No	Food types					Max. temperature I: 70°C or lower II: 100°C or lower III: a temperature exceeding 100°C	Group	Remarks
	Japanese name	English name		Acidic	Oily and fatty	Milk, dairy product	Alcoholic beverage	Others			
1	Copolymer of AA and BB	AA polymer with BB	1111-11-1	○	-	-	○	○	II	2	If mixed with resin ●●, restrictions for the resin may be applied.

\*The migration and the safety need to be confirmed accordingly to describe the applicable restrictions of the resin being mixed into.

# Special Case 1: Rules for Substances Used Only in Non-contact Food Layers

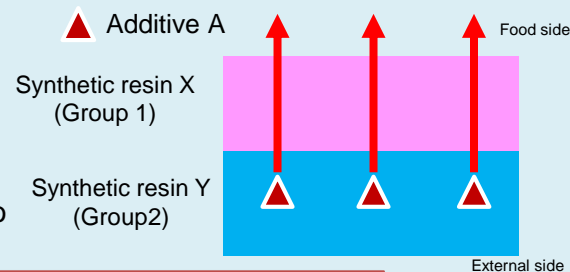
## Summary

- When substances used only in non-contact food layers migrate to food in amounts that exceed certain levels, the said substance needs to be listed in the PL (the proviso in Article 18 (3) does not apply).
- In such case, the use limit of the additives is described in the group that the base polymer used in the non-contact food layer belongs.

## Example

### (1) When Additive A is used only in non-contact food layers

- Additive A shall be listed under the group in which Synthetic resin Y falls under (Group 2).  
\*Not Group 1 in which Synthetic resin X used in contact food layers falls under.
- Synthetic resin Y's resin group needs to be confirmed to set the use limit of Additive A.
- Description of limitation in the Remarks column is mandatory.
- If the monomer etc. derived from the base polymer of Synthetic resin Y does not migrate into food exceeding a certain level, Synthetic resin Y does not need to be listed in the PL.



Needs to be classified into the group of the non-contact food layer, Synthetic resin Y (Group 2).

### Description in the public notice (draft)

No	Substance name	Use limit by group							Remarks
		1	2	3	4	5	6	7	
1	Additive A	-	2.0	-	-	-	-	-	Used only in non-contact food layers

### (2) When base polymers of a synthetic resin are used only in non-contact food layers (When the monomer etc. migrates into the food exceeding a certain level)

- The Base polymers shall be listed in the PL with limitation in the Remarks column (Example: “Used only in non-contact food layers”).

### Description in the public notice (draft)

No	Polymers	Food types					Max. temperature	Group	Remarks
		Acidic	Oily and fatty	Milk, dairy product	Alcoholic beverage	Others			
1	Polymer Z	-	-	-	-	-	III	3	Used only in non-contact food layers

# Special Case 2: Rules for Restrictions of Base Polymers Used in Non-contact Food Layers

## Summary

- When a base polymer is used in non-contact food layer of utensils, containers and packaging with multiple layers, the restrictions on food types of the base polymer shall not apply. However, the maximum temperature of the base polymer shall apply in principle.

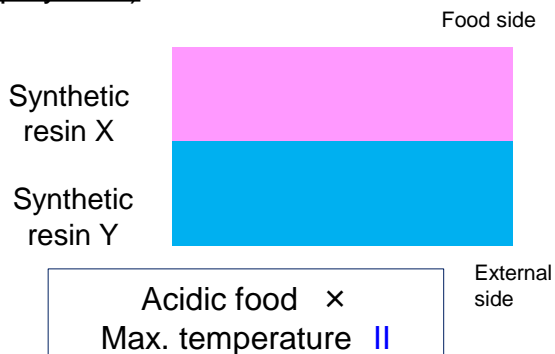
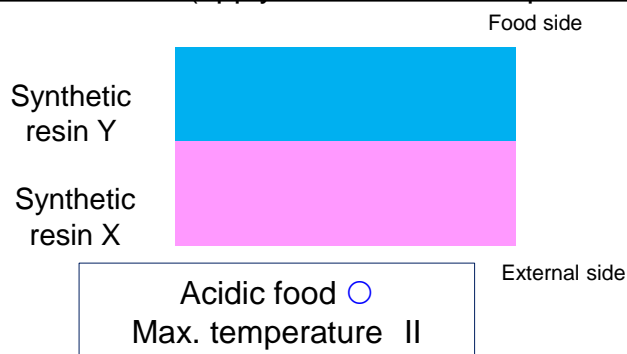
## Example

No	Polymers	Food types					Max. temperature I: 70°C or lower II: 100°C or lower III: a temperature exceeding 100°C	Group	Remarks
		Acidic	Oily and fatty	Milk, dairy product	Alcoholic beverage	Others			
1	<b>Polymer X</b>	-	○	○	○	○	III		
2	<b>Polymer Y</b>	○	○	○	○	○	II	2	
3	<b>Polymer Z</b>						II	2	If used in non-contact food later, the max. temperature falls under III.

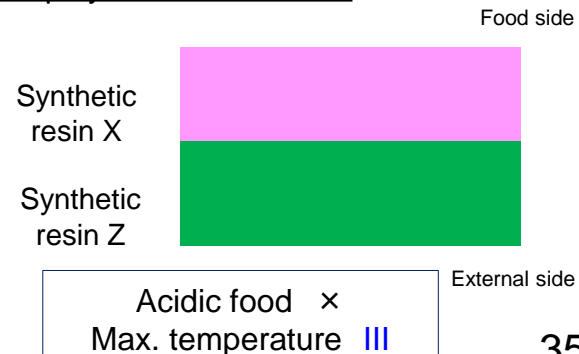
Max. temperature 100°C or lower (II) even for non-contact layer

May be used for acidic food if used in non-contact layer

### General rules (apply restrictions of respective polymers)



### If a polymer has remarks.

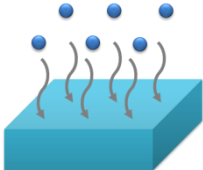
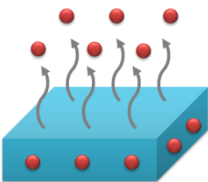








# Special Case 3: Functional Ingredients (Active/Intelligent Ingredients)

## Summary

- In the EU, ingredients that extend food shelf-life or conditions through releasing or absorbing specific chemical substances are defined as “active ingredients” and those that monitor packaged foods and surrounding environments are defined as “intelligent ingredients” and systemize regulations on these food contact ingredients.
- Chemical substances contained in UCP are managed as substances applicable for PL as raw ingredients of UCP, regardless of their effects on food.
- Chemical substances released from UCP expected to have effects on food are applicable for regulations as food additives, regardless of their migration amounts (they are raw ingredients of UCP as the status of part of a base material).

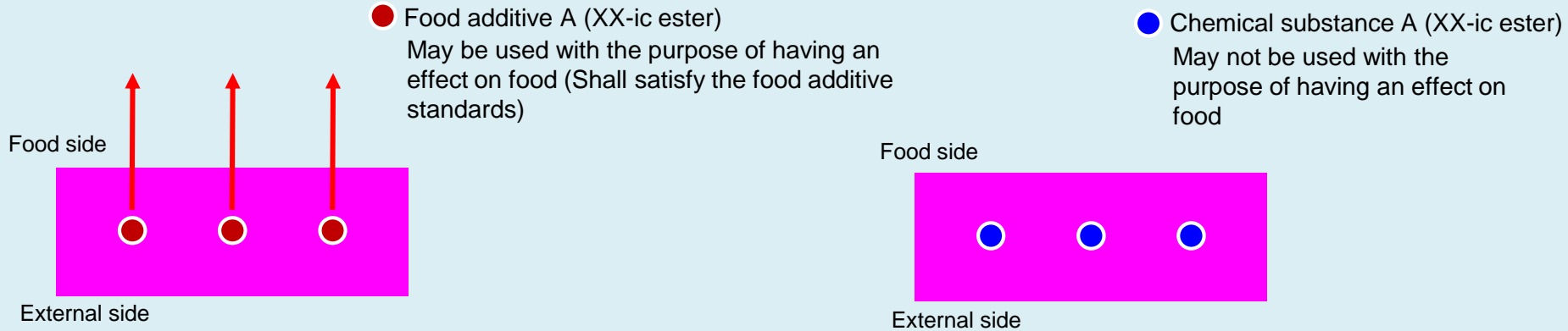
\*UCP: utensils, containers and packaging

Classification		Regulatory framework	Example	
Active ingredients	Absorbing 	Managed as substances applicable for PL for UCP	- Oxygen scavenger - Drip absorber	
	Releasing 	Released substance 	<b>Managed as substance applicable for PL in UCP and as food additive</b> (Because the substance is a raw ingredient for the UCP material before being released from UCPs, and have effects on the condition of food after being released from UCPs)	Freshness-keeping agent that releases mustard extract (food additive)
		Base material 	Managed as substances applicable for PL for UCP	
	Immobilized 	Immobilized substance 	Managed as substances applicable for PL for UCP	Anti-microbial product that contains silver zeolite
	Base material 			
Intelligent ingredients 		Managed as substances applicable for PL for UCP* *Based on the same concept as the current risk management method (chemical artificial coloring other than designated food additives shall be processed not to be mixed into food by migrating or leaching), colorants will be comprehensively included in the Positive List.	Temperature indicator	

# Special Case 4: Rules for Active Ingredients

- When use a substance released from utensils, containers and packaging (UCP) for the purpose of working on the foods, the substance shall be listed in the PL as the substance satisfies the standards of food additive. The amount of the substance is not specified in the PL; however, it shall satisfy the use limit as a food additive when having an effect on food.
- Even if a substance listed on the PL for UCP has the same name as a food additive, unless it has the remarks to satisfy the food additive standards, it may not be used as the substance released from UCP with the purpose of having an effect on food.

## Example



## Description in the public notice (draft)

### ● Additives, coating agents, etc.

	Substance name	Use restriction by group							Remarks
		1	2	3	4	5	6	7	
1	XX-ic ester (Food additive)	*	*	*	*	*	*	*	Shall satisfy the standards of food additive
2	XX-ic ester	1.0	1.0	-	-	1.5	1.0	-	

# Specifications and Standards in the PL System (Existing Substances)

- The MHLW is collecting information of the substances that to be specified in the Public Notice while ensuring the consistency of this system with the international standards. At present, more than 2,500 substances are planned to be listed.

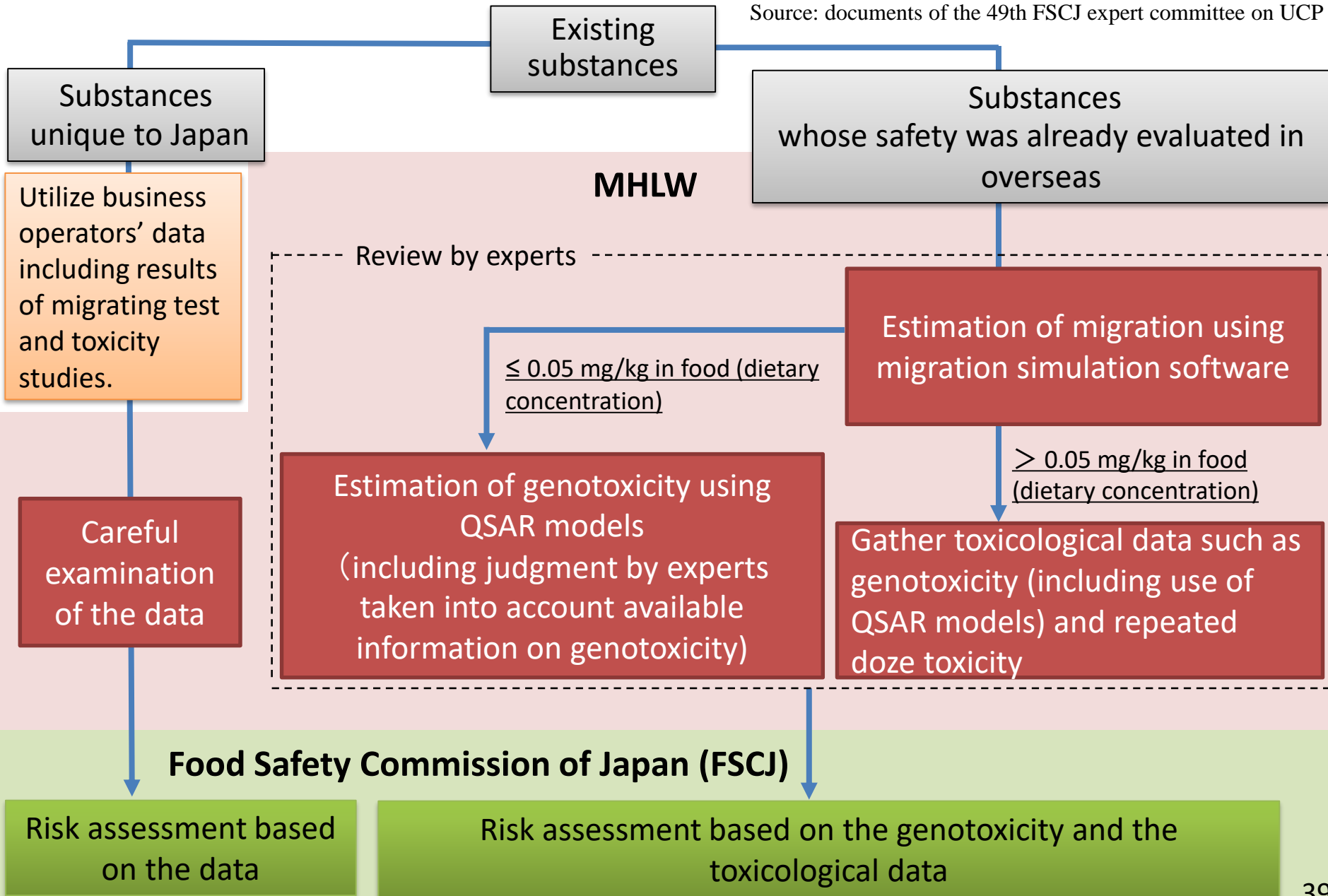
Specifications for these substances is need to be established through deliberation of the Committee for UCP of the Food Sanitation Council based on the evaluation results of effects of food on human health by the Food Safety Commission of Japan (FSCJ) pursuant to the Food Safety Basic Act. The FSCJ has been considering evaluation of the substances currently used in UCP that are sold, manufactured, imported and used for business in Japan (Existing substances) based on information available, including use of migration simulation software. However, even with this evaluation method, it seems to take considerable time to complete evaluation for the specifications.

- Existing substances are substances that are already used in UCP, and certain levels of safety information are confirmed prior to their usage to ensure compliance with Article 16 (Prohibition of sale, etc. of toxic or harmful apparatus (utensils) or containers and packaging) of the Food Sanitation Act. Additionally, if the use of substances that have been used in UCP for a long time is prohibited, confusion of manufacturing and sales of food etc. and consequently the stable supply of food are expected.

Therefore, it is necessary to identify all substances that are already being used in UCP and gradually proceed to evaluation of health effects of food after specifying them as the substances specified pursuant to Article 18 (1). To introduce this system smoothly considering the time required for the procedure including the evaluation, it shall be conducted as follows for some substances: improve procedure to establish the Public Notice assuming that the evaluation will be conducted afterwards because these substances are applicable to “Where there is no time to conduct an Assessment of the Effect of Food on Health in advance in cases where the measure is urgently necessary to prevent or restrain an adverse effect on human health” as prescribed in Article 11(1)-3 of the Food Safety Basic Act.

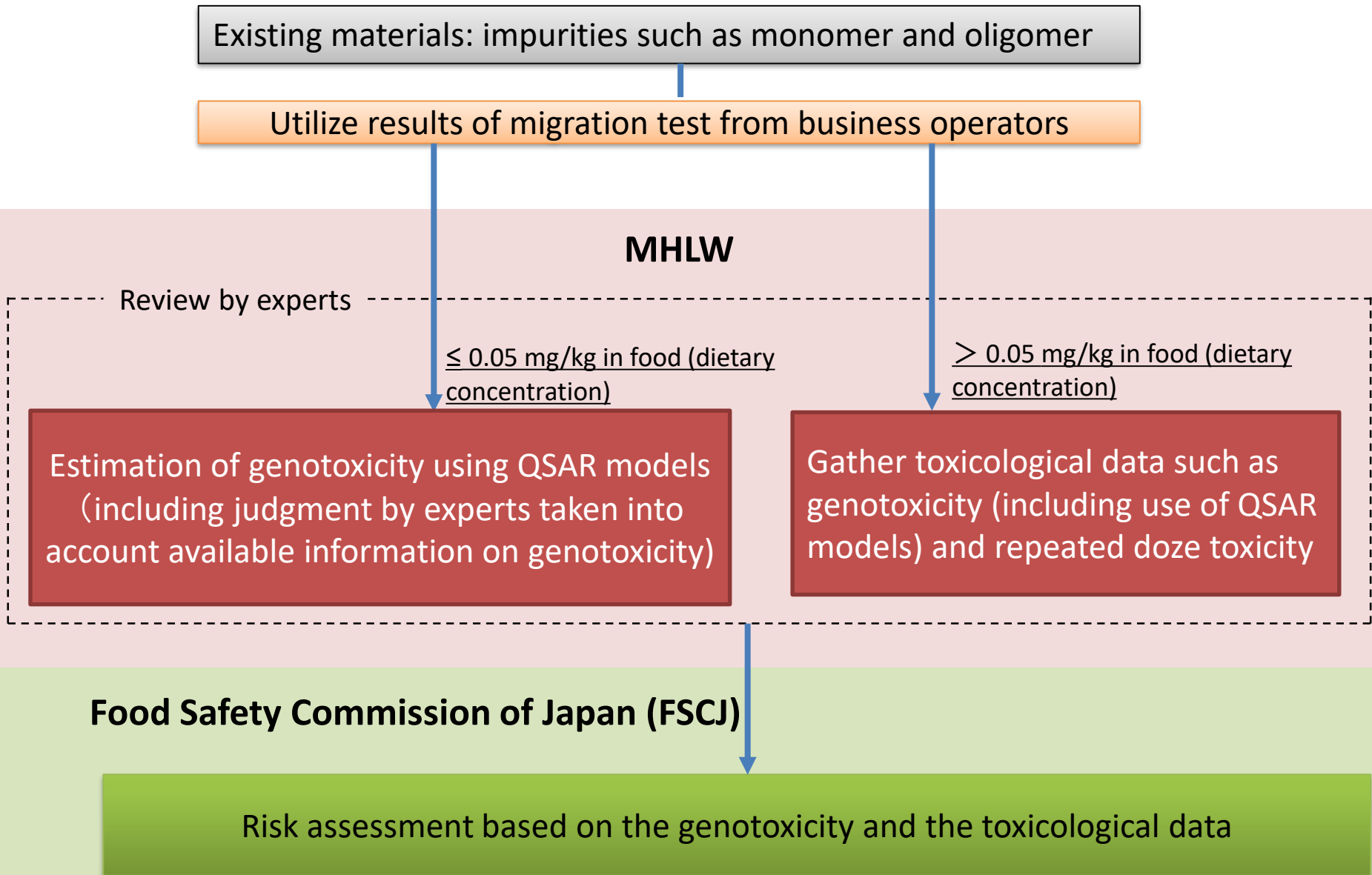
# Risk Assessment of Existing Substances (Additives)

Source: documents of the 49th FSCJ expert committee on UCP



# Risk Assessment of Existing Materials (Base Polymers)

Source: documents of the 49th FSCJ expert committee on UCP





# Schedule for Establishment of the PL for the Existing Materials

- List substances using the information from business operators and associations
- Preparation of the draft PL

May-June 2019 The draft PL / Committee for UCP established under the Pharmaceutical Affairs and Food Sanitation Council

Summer 2019 Update of the draft PL / Public comment / WTO notification

August 2019 Ask the Food Safety Commission for risk assessment

- List substances to be added in the PL List
- Final work of the draft PL

As necessary The draft PL / Committee for UCP established under the Pharmaceutical Affairs and Food Sanitation Council

December 2019 Public notice of the PL

June 2020\* Start of the PL system : enforcement of the amended Food Sanitation Act

\*within two years from the date of promulgation of the amended Act

# Outline of Proposed Amendment to the Standards and Regulations of Foods, Food Additives, etc. (Ministry of Health and Welfare Notification No.370)

- Under the provisions of Article 18 (3), the raw materials for synthetic resins shall be those listed in Appended Table 1.
- 
- Substances used for coloring shall be colorants specified or colorants processed so that they will not be eluted or seeped out into food.
- Base polymers listed in the list of polymers in Table 1 (2) of Appended Table 1 shall be produced by polymerizing or cross-linking prepolymers on appropriate base materials.
- More than 98 wt% of the components of a base polymer shall be constituted with the polymers in Table 1 (1) or (2) of Appended Table 1, and the remaining components shall be copolymers of monomers listed in Table 1 (3) of in Appended Table 1.

## Appended Table 1

### Table 1 Base polymers

(1) Base polymers (Plastics)

(2) Base polymers (Coatings etc.)

(3) Minor monomers can be used for polymerization of base polymers

### Table 2 Additives etc.

(1) Additives, coating agents, etc.



# Reference

- MHLW website (utensils, containers and packaging: UCP)  
[http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryuu/shokuhin/kigu/index.html](http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/kigu/index.html)
  - ✓ Committee of Utensils, Containers and Packaging of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council
  - ✓ Committee for Reviewing the Regulations on Food Utensils, Containers and Packaging
  - ✓ Report and Interim Report by the Committee for Reviewing the Regulation of Food Utensils, Containers and Packaging (Japanese and English)
  - ✓ Guideline for safety assurance in the manufacture, etc. of food utensils, containers and packaging (Japanese and English)  
  
<http://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzendu/0000188507.pdf>
- About the amendment of the Food Sanitation Act  
<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000197196.html>