USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary - Public

Date: 8/9/2019
GAIN Report Number: JA9104

Japan

Post: Tokyo

Japan 225th Food Safety Group

Report Categories:
Snack Foods
Policy and Program Announcements

Approved By:
Barrett Bumpas
Prepared By:
Tomohiro Kurai

Report Highlights:
On August 2, 2019, Japan's Ministry of Health, Labor and Welfare (MHLW) shared more details on proposed shifts to the positive list system for utensils, containers and packaging (UCP). This positive list system for UCP will only be applied to those made of or containing synthetic resins. As Japan will announce this revision to the World Trade Organization (WTO) soon, there is no embassy comment period.

Keyword: JA9104, Utensils, Containers, Packaging

General Information:

On August 2, 2019, Japan's Ministry of Health, Labor and Welfare (MHLW) shared more details on proposed shifts to the positive list system for utensils, containers and packaging (UCP). This positive list system for UCP will only be applied to those made of or containing synthetic resins. The current lists of approved substances for base polymers can be found here, and additives and coating agents can be found here. In addition, interested parties are requested to pay close attention to the list of currently non-approved/non-reviewed substances found here. These lists are primarily prepared in Japanese, but English names are also listed for reference. Since Japan is going to announce this revision as well as the list of approved substances for UCP with their regulatory maximum allowance to the World Trade Organization (WTO) soon, there is no embassy comment period for these revisions. Interested parties are requested to be familiar with Japan's proposals and ready for making comments through WTO notification if desired.

(The following is taken from Japan's documents at the Food Safety Group)

The manner of submitting comments

The Ministry of Health, Labour and Welfare introduces Positive List system for UCP and sets the quantity of substances that is unlikely harm to human health as shown in this document. The MHLW will provide the information through SPS notification and TBT notification. Therefore, any comment (especially comments for the proposed amendment to the Standards and Regulations of the Item 1) should be submitted to the enquiry point in accordance with the WTO/SPS Agreement and the WTO/TBT Agreement.

Contact person

Mr. Junichi KIDOU (kidou-junichi@mhlw.go.jp)
Tel: 03-5253-1111 (ex 2487) Fax: 03-3501-4868

Utensils, Containers and Packaging Section,
Food Safety Standards and Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916

Item 1. The Positive List system for utensils, containers and packaging (UCP)

Summary

- By the amendment of the Food Sanitation Act (the Act) including the purpose to improve sanitary regulations for UCP considering international consistency, the Ministry of Health, Labour and Welfare (MHLW) introduces a system only substances assured its safety are permitted to be used for UCP: the Positive List system.

- The paragraph (3) of Article 18 of the Act prescribes that the raw material for materials specified by the Cabinet Order (synthetic resin) shall be the substances listed in the Positive List (PL). The substances shall have standards prescribed in the paragraph (1) of Article 18 of the Act.

- Based on the ideas deliberated in the Pharmaceutical Affairs and Food Sanitation Council, the MHLW has prepared a proposed amendment to the Standards and Regulations as attached. The draft lists the substances currently used for UCP that are sold, produced, imported, and used for business in Japan (Existing substances); and need to be listed in the PL. The information of the substances was collected from business operators and associations, organized, and examined the necessity of listing.

- The MHLW will collect information on the substances that are need to be added to the draft PL through public comment and WTO notification, examine carefully about them, proceed the essential procedure to promulgate the PL around December 2019, and come it into effect in June 2020.

Item 2. The quantity that is unlikely harm to human health prescribed in the public notice based on the amendment of the Food Sanitation Act

Summary

- Paragraph (3) of Article 18 of the Act prescribes that the raw material for materials specified by the Cabinet Order (synthetic resin) shall be the substances listed in the PL. However, this shall not apply when substances are used in the part that does not contact with food and the substance dose not migrate into food with a quantity exceeding the quantity specified as being unlikely harm to human health. In this case, substances not listed in the PL may be used for UCP.

- The Minister of Health, Labour and Welfare intends to decide the quantity that is unlikely harm to human health, which is prescribed in the proviso of paragraph (3) of Article 18 of the Act, shall be 0.01 mg/kg in food based on the deliberation of the Pharmaceutical Affairs and Food Sanitation Council.

- 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.

  Confirmation using food-simulating solvent shall basically be migration test provided in the Guideline for Assessment of the Effect of Food on Human Health Regarding Food Utensils, Containers and Packaging (issued by the Food Safety Commission of Japan on May 28, 2019).

- The MHLW will provide public comment and WTO notification, examine the results carefully, proceed the essential procedure to promulgate the quantity around December 2019, and come it into effect in June 2020.

Agenda

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

1

Agenda

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

2

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.

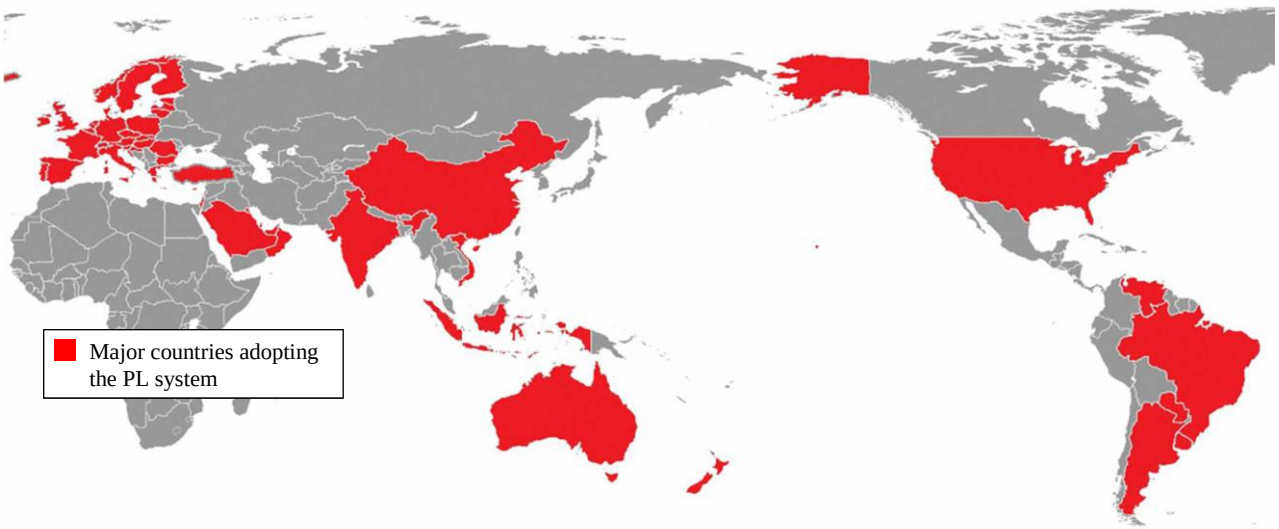
Example:

3

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

Positive List (PL) system **(Basically forbid usage and then list substances whose use is permitted)**	**Negative List system** **(Basically allow usage and then list substances whose use is limited)**
The USA, 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.



4

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

5

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.

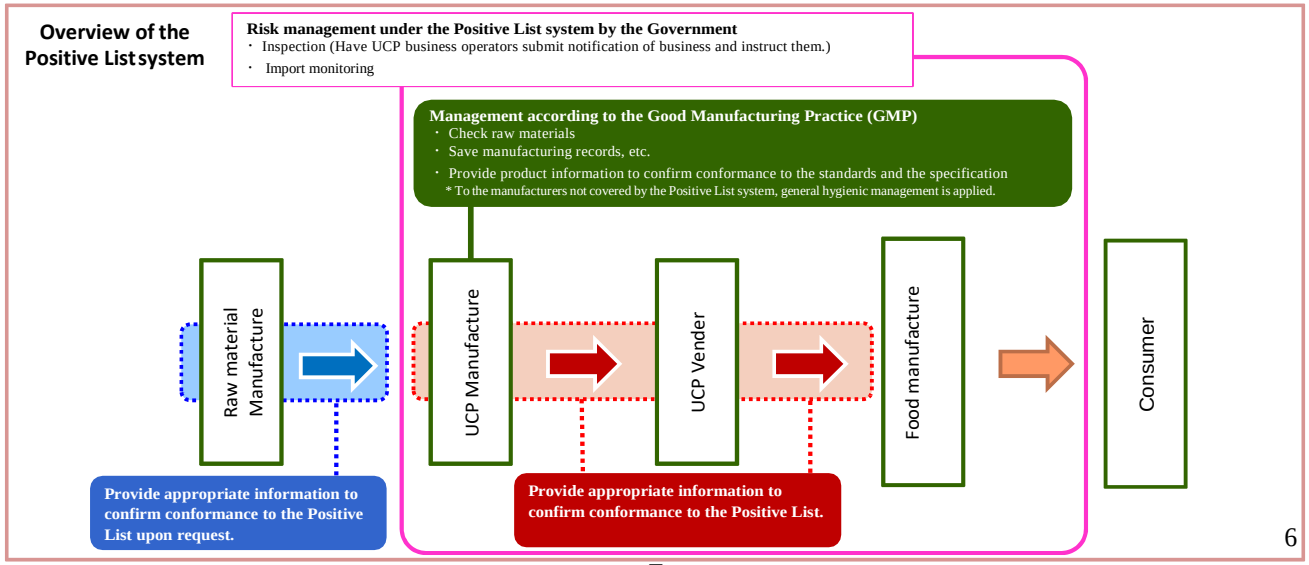
* Subject to the system: synthetic resin

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.



6

Agenda

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

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

Attached Document

Chapter I General Provisions

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

Chapter III 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 standards or specifications 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]

* 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 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.

9

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.

10

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.

11

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)

Notification system of manufacturing for domestic manufacturers

→ Prescribed in the Ordinance of Enforcement of the Food Sanitation Act

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.

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

12

Resolutions Incidental to the Bill to Partially Amend the Food Sanitation Act etc.

<April 12, 2018 House of Representatives' Health, Welfare and Labour Committee>

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 standards and specifications in a systemic manner based on the assessment of the effect of food on health. Also, consider to develop the positive lists for materials other than synthetic resins considering the risk level and international trends.

5. to 8. (Omitted)

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

13

Agenda

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

14

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

15

Scope of the Positive List for "Synthetic Resins"

Classification of Synthetic Resins (Overview)

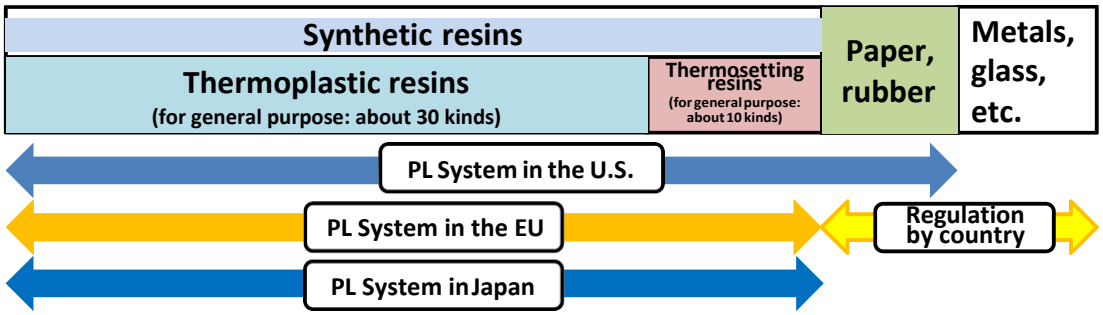
	Thermoplastic resins	Thermosetting resins
Plastic	Thermoplastics e.g., polyethene, polystyrene	Thermosetting plastics e.g., melamine resin, phenol resin
Elastomer	Thermoplastic elastomer e.g., polystyrene elastomer, styrene-block copolymer	Rubber (thermosetting elastomer) e.g., butadiene rubber, nitrile 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.

16

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.

17

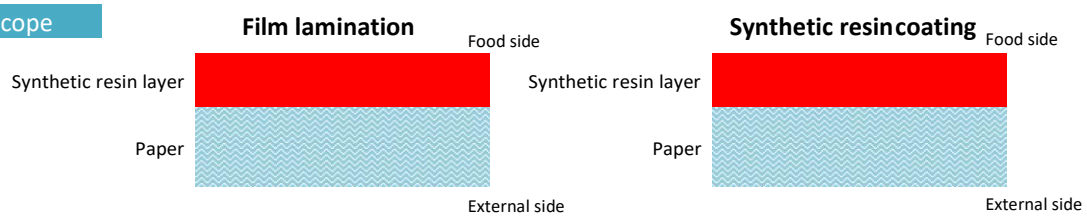
Synthetic resins etc. used in paper

Summary

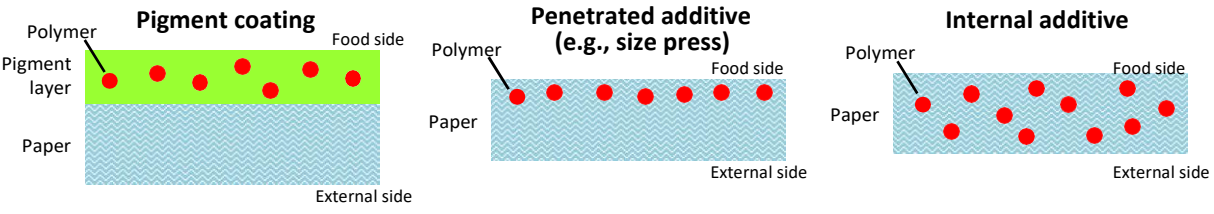
Synthetic resins etc. used in paper which have a synthetic resin layer on the food-contact surface are subject to the positive list system for synthetic resins.

Scope of the positive list for synthetic resins

In scope



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



18

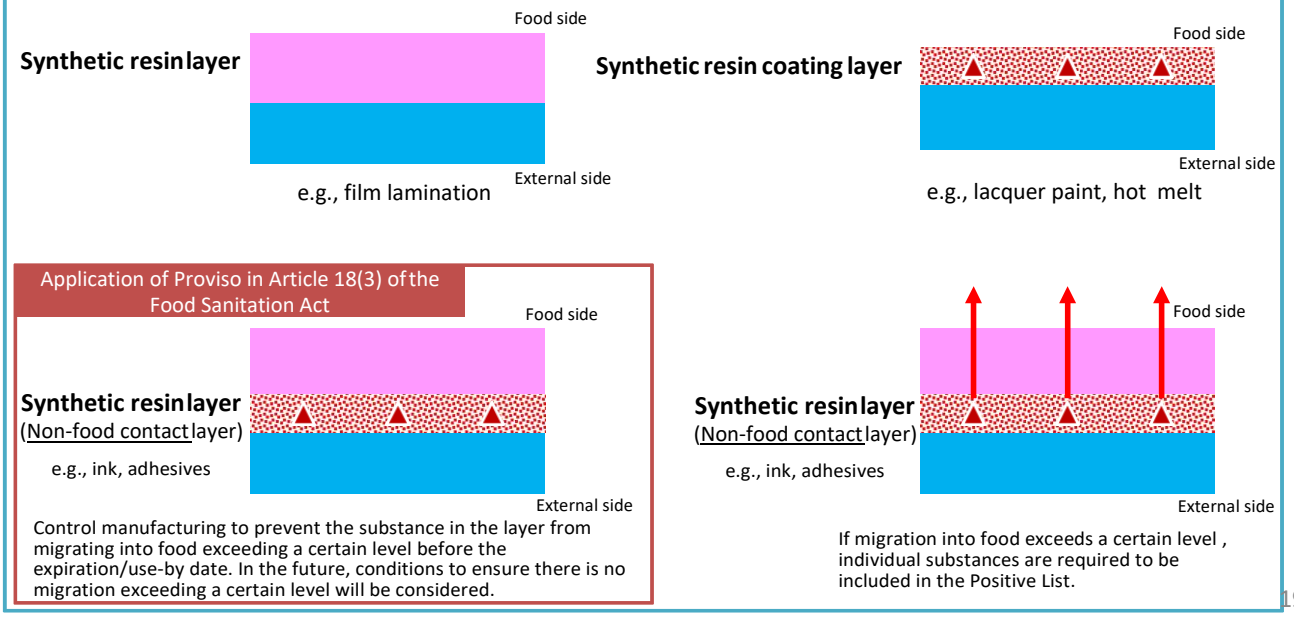
Handling of Synthetic Resin Layer (e.g., ink, adhesives)

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



19

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.

20

Specifications and Standards in the PL system (Overall)

○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 not expected to remain in final products and are not main constituents for base polymers, although they are used for polymerization reactions of monomers. Therefore, they shall be managed according to the conventional risk management methods rather than management under the PL.

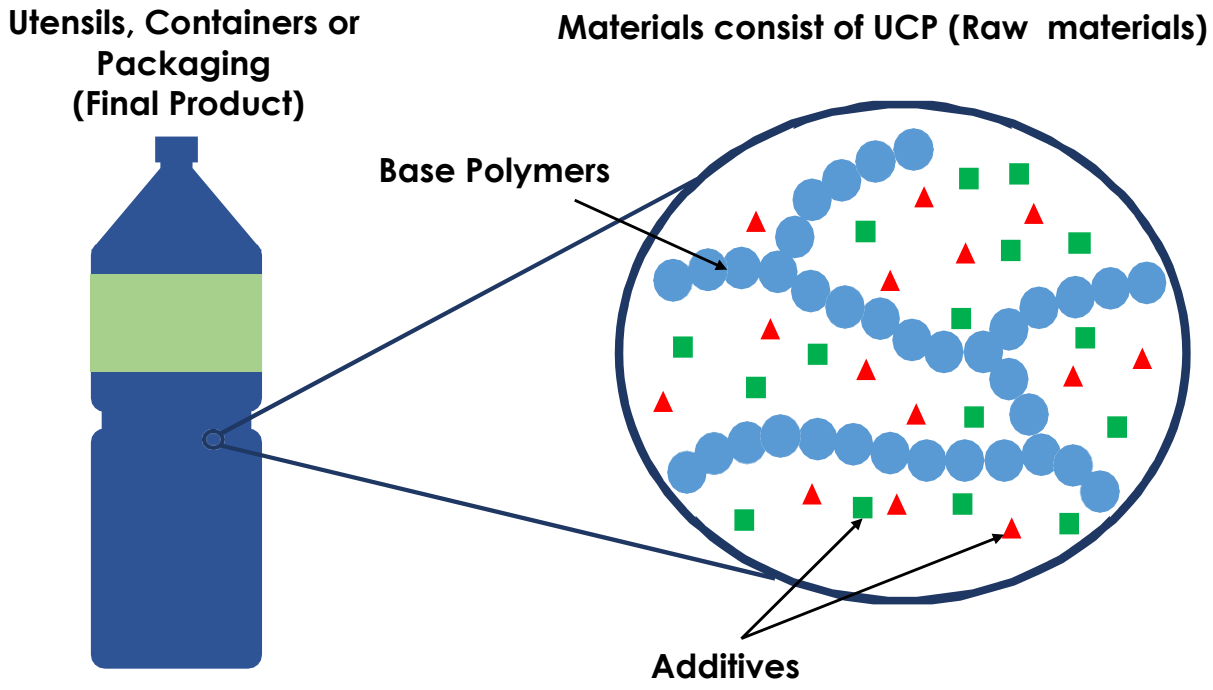
○ Coloring materials shall be comprehensively specified as "(1) Colorants listed in Annex 1 of the Order for Enforcement of the Food Sanitation Act (Ordinance No. 23 of the Ministry of Health and Welfare, 1948) and (2) Colorants processed so they will not be eluted or seeped out into food" based on the current management method according to the Notification 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 quantity etc. of additives shall be specified and managed by the group.

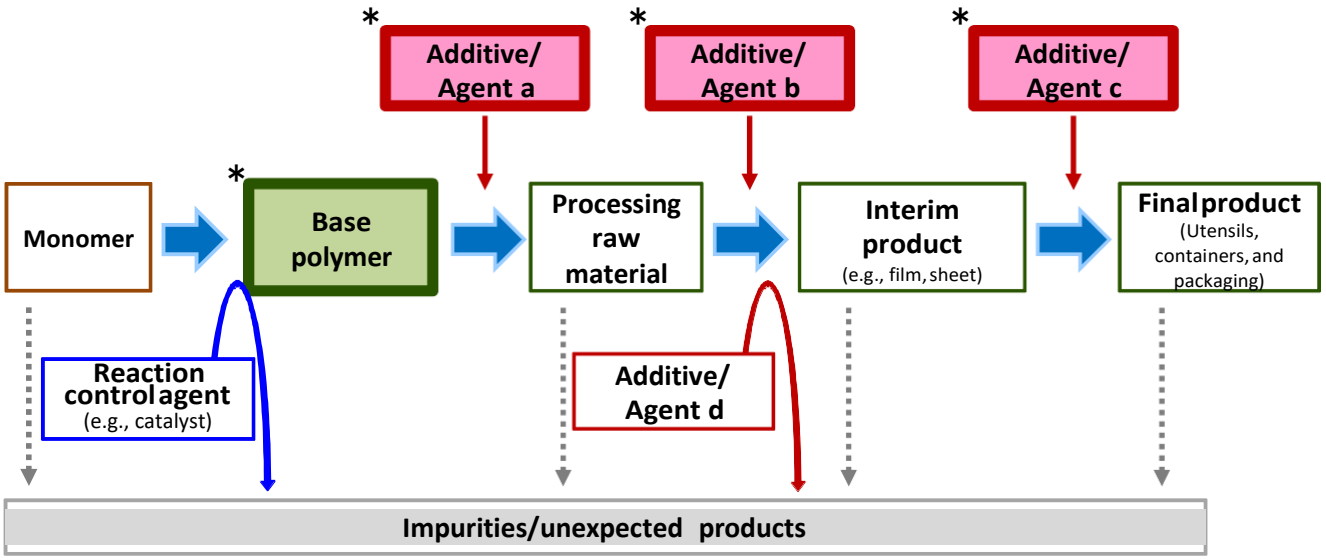
21

Materials Consist of Utensils, Containers and Packaging



22

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.

23

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 according to the group.

Objectives

- Assure wide range of combination of resins and additives 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	-	-

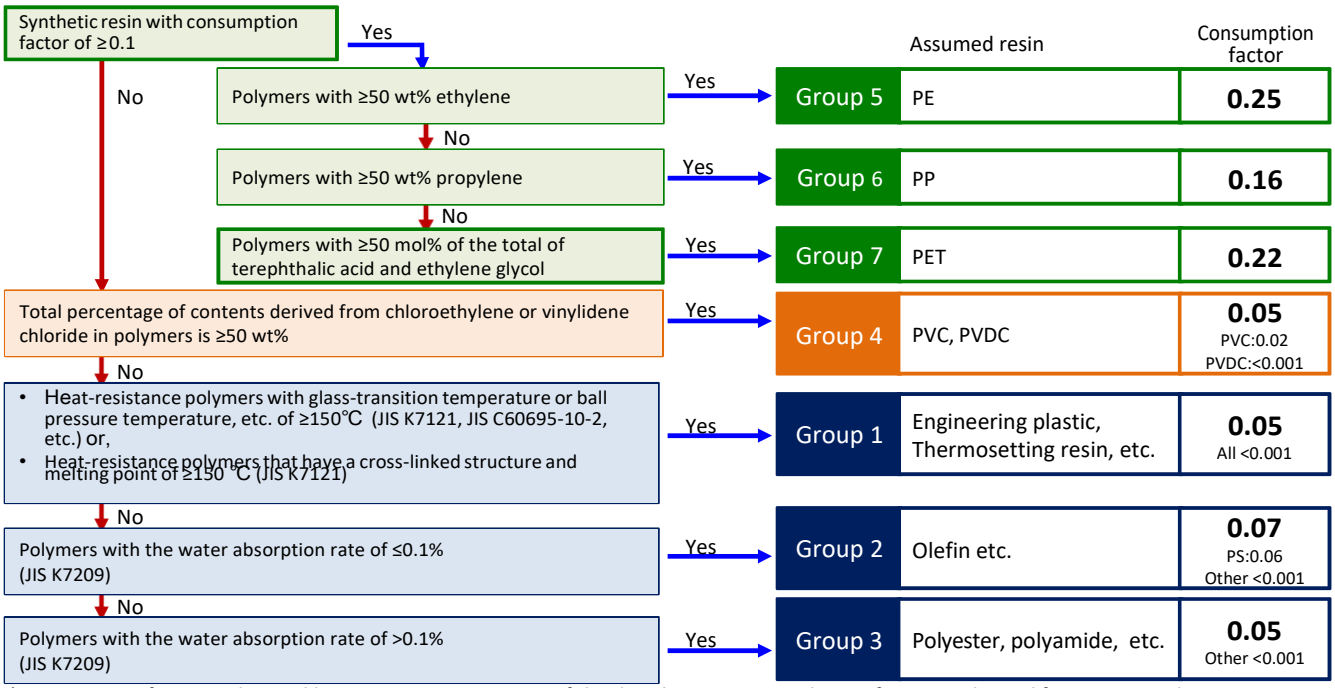
Note: The number of groups may be changed based on property and use status.

24

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 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.

25

(Reference) Calculation of consumption factors, etc.

○ Consumption factors and food group 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)

○ A survey project by the MHLW (2010) investigated food in the market on the types of materials and their weight of containers and packaging by food item. Consumption factors were derived from the ratio of materials by item and that of food overall. Food group factors were derived from the quantity used by container and packaging material according to food group (water-based, acidic, oil-based, alcoholic, dairy, dry foods, etc.). These were then classified between synthetic resin groups according to polymer characteristics, with the following consumption factors, etc. for synthetic resins assigned.

Consumption factor: Factor derived by estimating the dietary content ratio that will come in contact with specified UCP materials Food group factor: Factor derived by estimating the ratio of UCP used in specified food groups by material

Synthetic resin group (type) *1	Consumption factor (CF)	Food group factor (DF)					
		Normal foods		Acidic food	Alcoholic beverage	Dairy, etc.	Oils and fats
			Dry foods				
		D_1	D_{1sub}	D_2	D_3	D_4	D_5
Resin Group 1	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.					
Resin Group 2 (PS, etc.)	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.					
Resin Group 3 (PA, etc.)	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.					
Resin Group 4 (PVC, PVDC)	0.05	0.93	0.01	0.01	0.01	0.01	0.04
Resin Group 5 (PE)	0.25	0.88	0.03	0.04	0.01	0.02	0.05
Resin Group 6 (PP)	0.16	0.80	0.05	0.05	0.01	0.02	0.12
Resin Group 7 (PET)	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 (physiochemical properties) and current use status.
PS (polystyrene), PA (polyamide), PVC (polyvinyl chloride), PVDC (polyvinylidene chloride), PE (polyethylene), PP (polypropylene), PET (polyethylene terephthalate)

26

Specification of base polymers

Summary

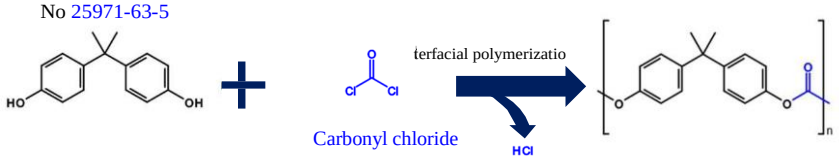
- In the event the initial monomer and manufacturing method differ, the polymers shall generally be treated as different base polymers even if the synthesized base polymer structures are the same.
- The base polymers will be classified under different source-based names in the PL even if under the same structure-based name.

(Example) Polycarbonates

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

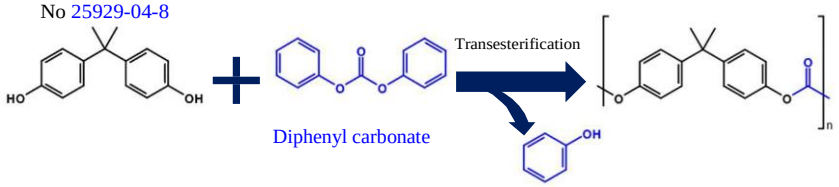
Source-based name

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



Carbonyl chloride

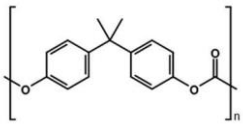
(2) 2, 2-bis (4-hydroxyphenyl) propane, diphenyl carbonate copolymer CAS No 25929-04-8



Diphenyl carbonate

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 units.

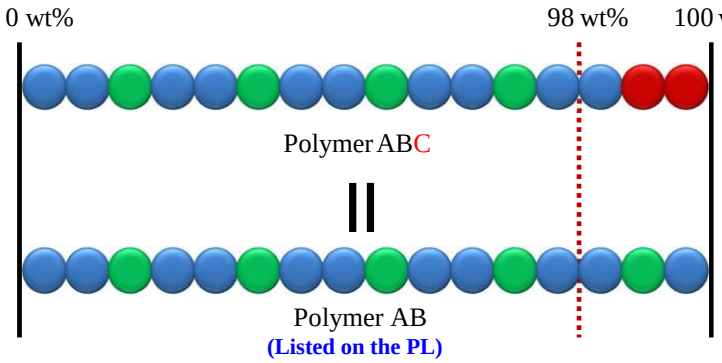
27

Rules for the Positive List (PL) on base polymers and minor monomers (98% Rule)

Summary

- Information on minor monomers constituting polymers directly correlates with trade secrets of companies. It also requires consideration upon ensuring the safety of public health under the PL system of the Food Sanitation Act.
- More than 98wt% of the components of a base polymer shall be comprised of polymers in the PL.
- Substances that may be used as remaining components of the polymer (minor monomers) shall be clarified in the Minor Monomers List compiled separately from the list of polymers by resin.

98% rule (draft)



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).

28

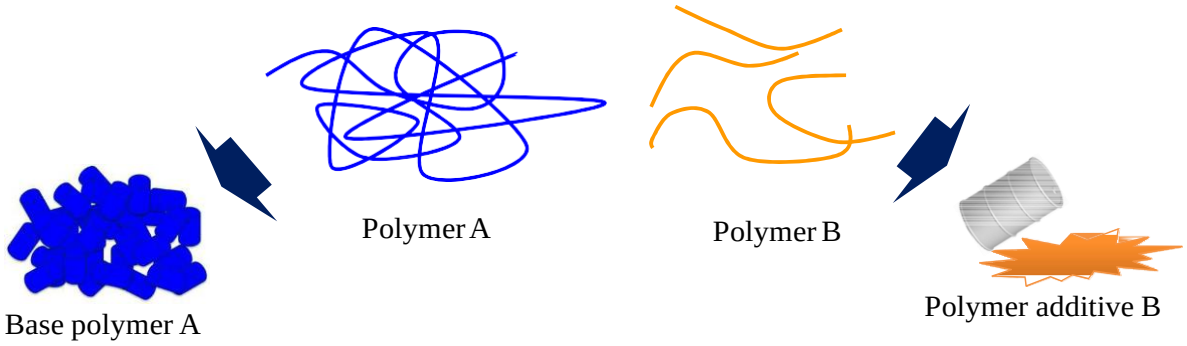
Treatment of substances with polymer structures

- When manufacturing synthetic resins, substances with polymer structures are sometimes used as additives. These will 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 resins (rubber, cellulose, etc.)
  (2) Substances with polymer structures such as the following that normally will not be UCPs when used alone
    - Substances with low viscosity and which become liquid under room temperature (polyethylene glycol, ester, etc.)
    - Substances with under 1,000 in molecular weight (excluding when they can become UCPs)
    - 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.

-



29

Positive List Format

(1) Base polymers

More than 98wt% 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
	Japanese name	English name		Acidic	Oily and fatty	Milk and milk product	Alcoholic beverage	Others			
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 types					Maximum temperature I. ≤70°C II. ≤100°C III. ≥101°C	Group	Remarks
	Japanese name	English name		Acidic	Oily and fatty	Milk and milk product	Alcoholic beverage	Others			
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 poly ner

- Minor monomers to 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.

(2) Additives 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

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

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

30

Single Resin and Mixed Resin

Single Resin

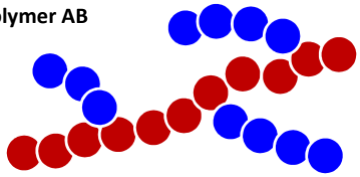
Single copolymer A

Alternating copolymer AB

Random copolymer AB

Block copolymer AB

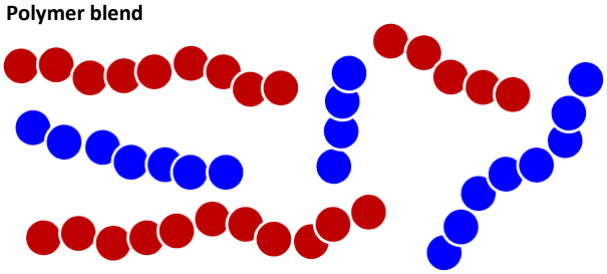
Graft copolymer AB



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

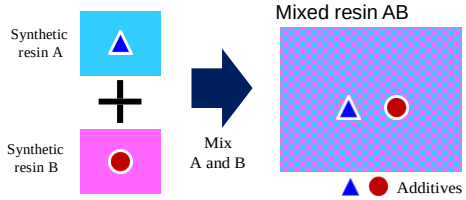
※ **Each Polymer shall be listed in the Positive List.**
※ **If a resin has a chemical reaction, the resin is not regarded as mixed resin.**

31

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.

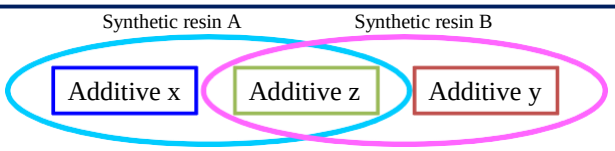


Conditions of synthetic resins for mixed resin and the additives

	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	Mixed resin AB	Remarks
Resin weight		2 kg	1 kg	3 kg	
Maximum use level	Additive x	200g (Maximum: 10 wt%)	0g (Not listed in PL)	200g (Maximum: 6.7 wt%)	Not 300g (10 wt% of the total weight, 3kg)
	Additive y	0g (Not listed in PL)	50g (Maximum: 5 wt%)	50g (Maximum: 1.7 wt%)	Not 150g (5 wt% of the total weight, 3kg)
	Additive z	400g (Maximum: 20 wt%)	100g (Maximum: 10 wt%)	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.

32

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: 70ºC or lower II: 100ºC or lower III: a temperature exceeding 100ºC or lower	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 only used in non-contact food layers**

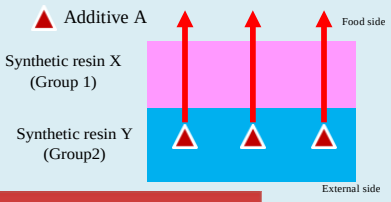
Summary

- When substances only used 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 only used 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 restriction by group							Remarks
		1	2	3	4	5	6	7	
1	Additive A	-	2.0	-	-	-	-	-	Only used in non-contact food layers

(2) When base polymers of a synthetic resin are only used 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: "Only used 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	-	-	-	-	-	II	3	Only used in non-contact food layers

Special case 2: **Rules for restrictions of base polymers used in non-contact food layers**

Summary

- When base polymers are used in non-contact food layer of UCP with multiple layers, restrictions on food types shall not apply. However, the maximum temperature allowed shall apply, in principle, even for non-contact layers.

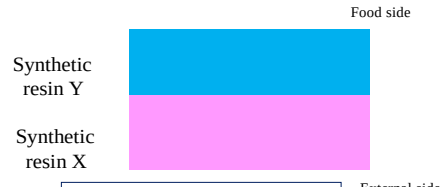
Example

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

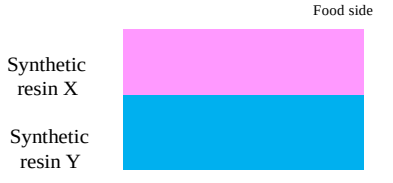
Max. temperature 100ºC or lower r (II) even fo non-contact layer

May be u sed for n- acidic f ood if used in no contact layer

General rules (apply restrictions of respective polymers)

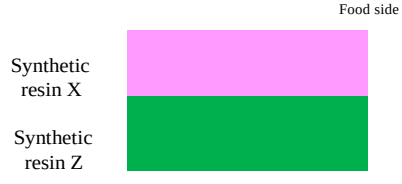


Acidic food ○
Max. temperature II



Acidic food ×
Max. temperature II

If the polymer has remarks.



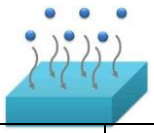
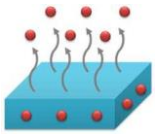
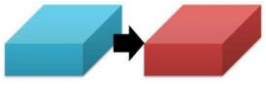
Acidic food ×
Max. temperature III

35

<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” to systemize regulations on food contact ingredients.
- Chemical substances contained in UCPs are managed as substances applicable for PL and as raw ingredients of UCPs, regardless of their effects on food. Chemical substances released from UCPs expected to have effects on food are applicable for regulations as food additives, regardless of their migration amounts (as raw ingredients of UCPs if incorporated in base material).

Classification			Regulatory framework	Example
Active ingredients	Absorbing 		Managed as substances applicable for PL for UCP	Oxygen scavenger Drip absorber
	Releasing 	Released substance 	**Managed as substance applicable for PL in UCPs and as food additive** (Because the substance is a raw ingredient for the UCP material before being released from UCPs, and influence 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

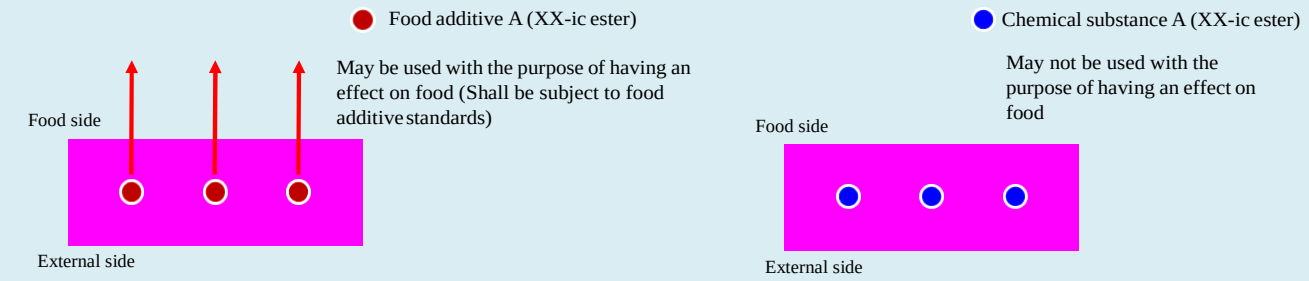
36

<Special case (4)>

Treatment of active ingredients

- In the event a substance released from UCPs with the purpose of having an effect on food will be used, the substance must be in the PL as a substance that fulfills food additive standards. Although the additive amount is not specified in that case, it shall be subject to restrictions as a food additive when having an effect on food.
- Even if a substance listed on the PL for UCPs has the same name as a food additive, it may not be used as a substance released from UCPs with the purpose of having an effect on food if it is not on the PL as a substance that fulfills food additive standards.

Example



Description in Notification (plan)

●**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 be subject to food additive standards
2	XX-ic ester	1.0	1.0	-	-	1.5	1.0	-	

37

Specifications and Standards in the PL system (listed substances)

○ The MHLW is currently identifying the substances subject to the Notifications while ensuring the consistency of this system with the international standards.At present, more than 2,500 substances are planned to become applicable.

Specifications need to be prescribed for these substances upon deliberation in the UCP Section based on the assessment results of effects of food on human health by the Food Safety Commission according to the Food Safety Basic Act. Although the Food Safety Commission has been considering on conducting an assessment of substances (existing substances) used in UCPs that are currently sold, manufactured, imported and used in business in Japan based on information available, including those from simulations, it is expected to require considerable time to complete these series of tasks even if this assessment method is chosen.

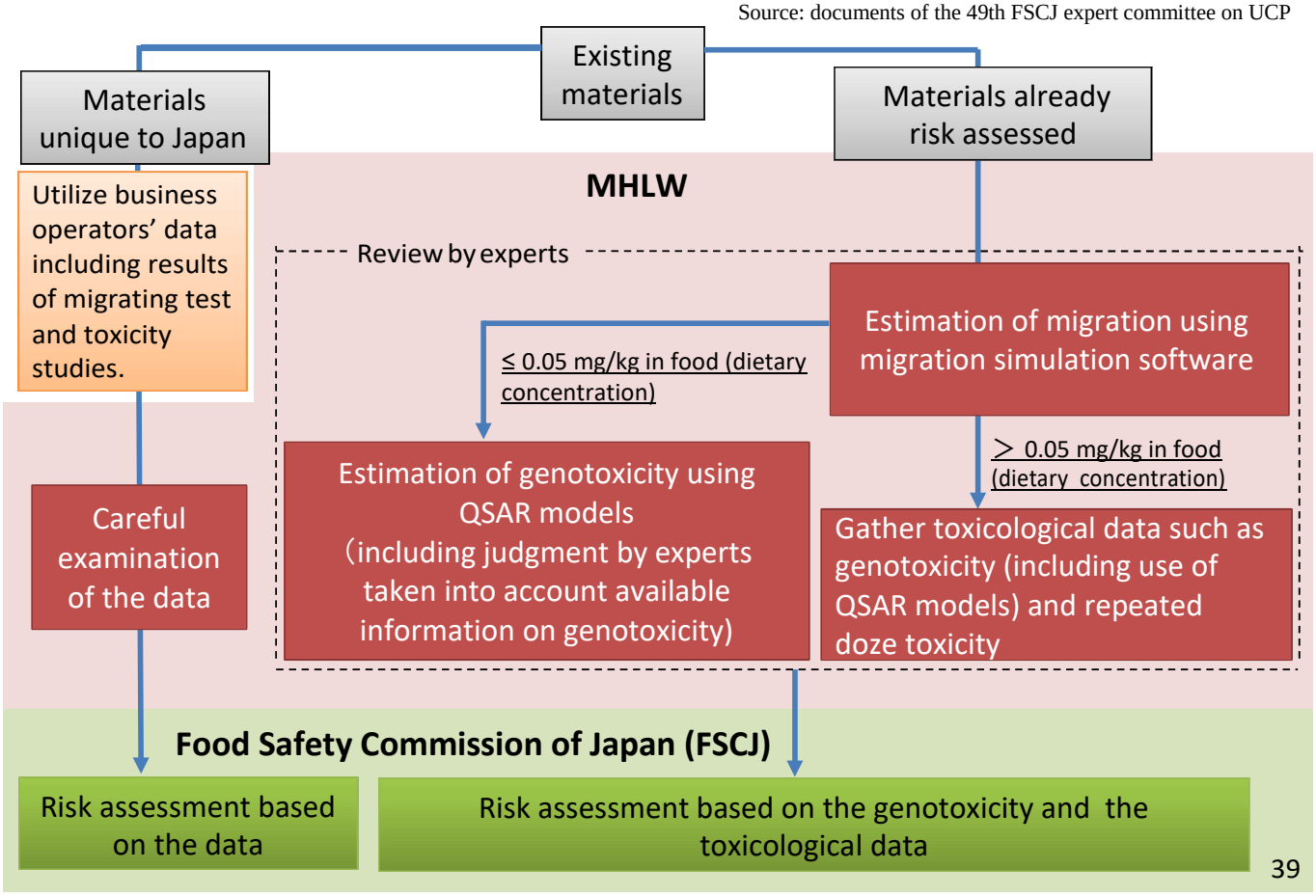
○ "Existing substances" are substances that are already used in UCPs, and certain levels of safety information are confirmed prior to their usage to ensure compliance with Article 16 (Prohibition of sales, etc. of toxic or harmful apparatus or containers and packaging). Additionally, if substances that have been used in UCPs for a long time are no longer allowed, obstruction towards the manufacturing and sales of food, etc., and consequently the stable supply of food are expected.

Therefore, it is necessary to first identify all substances that are already being used for UCPs and proceed to the assessment of health effects of food gradually upon specifying them as substances specified pursuant to Article 18 (1). In order to introduce this system smoothly in regards to the time required for the series of tasks involved, including assessment, for some substances, assuming the assessment will be conducted afterwards, working towards establishing the Notifications shall be conducted because they 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 stipulated in Article 11-1-3 of the Food Safety Basic Act.

38

Risk Assessment of Existing Materials (Additives)

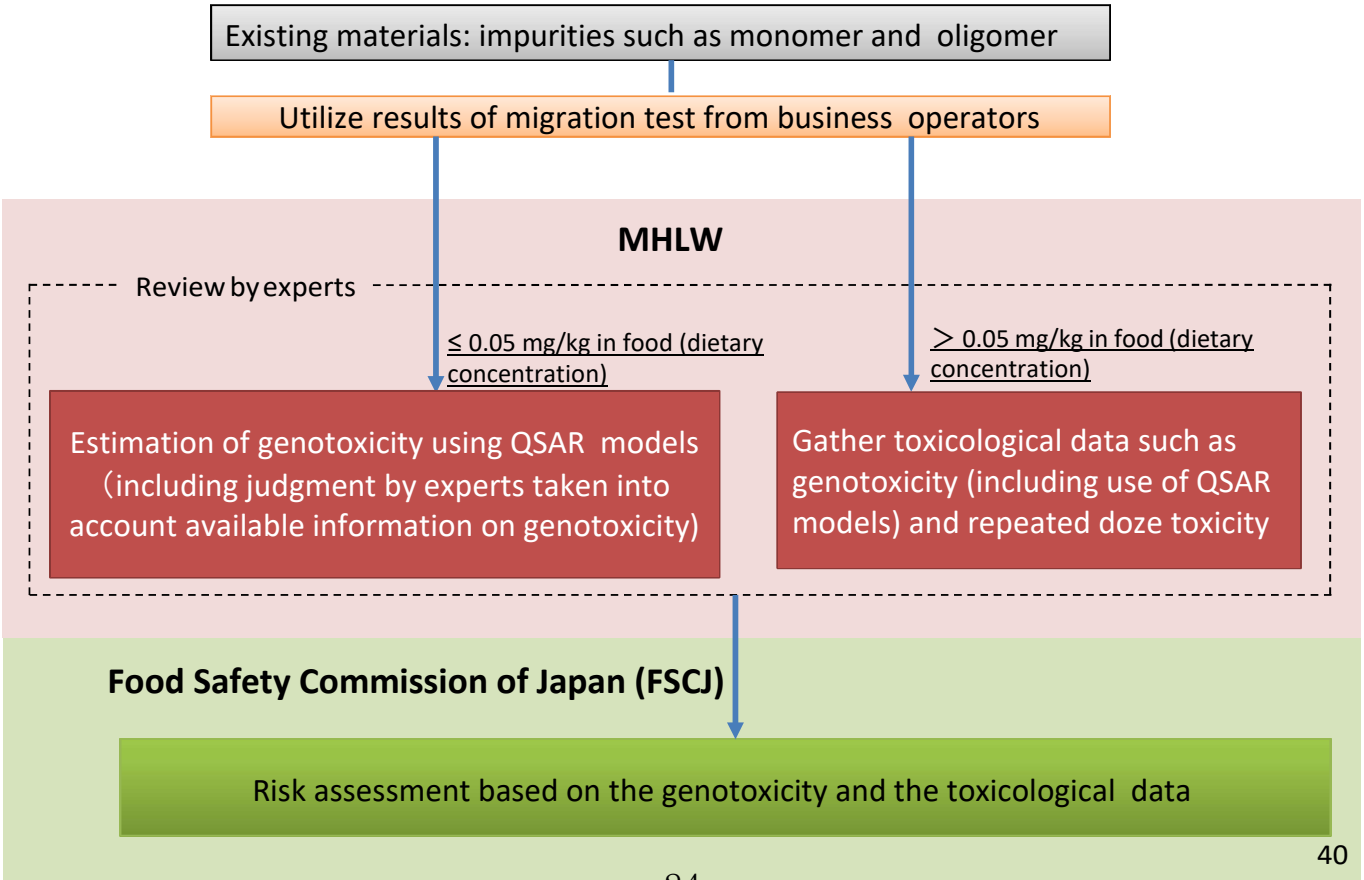
Source: documents of the 49th FSCJ expert committee on UCP



39

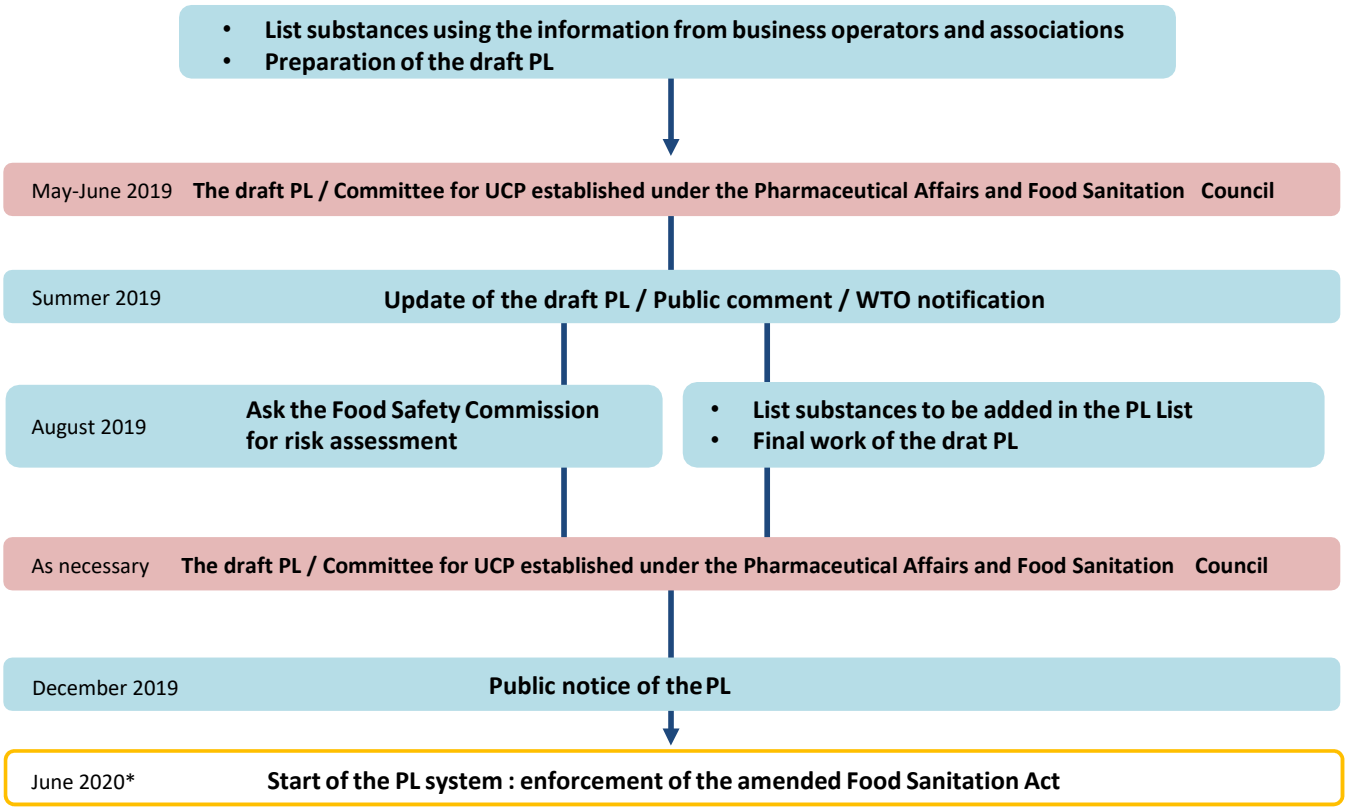
Risk Assessment of Existing Materials (Base Polymers)

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



40

Schedule for Establishment of the PL for the Existing Materials



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

41

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 Annex 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 Annex 1 shall have their pre-polymers be polymerized or cross-linked on appropriate base materials.
- At least 98% in weight of the structural components of base polymers shall be constituted with the substances in the list of polymers in Table 1 (1) or (2) of Annex 1, and the remaining structural components shall be composed of copolymers of monomers listed in Table 1 (3) of Annex 1.

Appended Table 1

Table 1 Base polymers

(1) Base polymers (Plastics)

(2) Base polymers (Coatings, etc.)

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

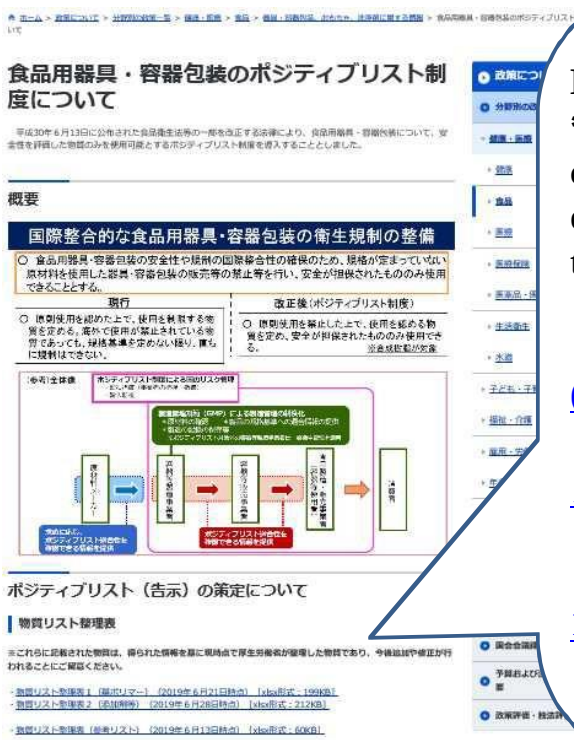
Table 2 Additives etc.

(1) Additives etc.

42

Website on the UCP Positive List system

MHLW website: “About the Positive List System for Food Utensils, Containers and Packaging”
https://www.mhlw.go.jp/stf/newpage_05148.html



Lists of substances
***The substances in these lists are those compiled by the MHLW as of [date] based on information available, and are subject to additions and modifications.**

・物質リスト整理表 1(Base polymer) (2019年６月21日時点) [xlsx形式：199KB]
・物質リスト整理表2(Additive等) (2019年６月28日時点) [xlsx形式：212KB]

・物質リスト整理表(参考リスト) (2019年６月13日時点) [xlsx形式：60KB]

43

Reference

- MHLW website (UCP)
http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/kigu/index.html
  - ✓ UCP Section, Food Sanitation Subcommittee, Pharmaceutical Affairs and Food Sanitation Council
  - ✓ Technical Committee for Reviewing the Regulations on Food Utensils, Containers and Packaging
  - ✓ Report and Interim Report by the Committee on 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-Shokuhinanzenbu/0000188507.pdf

- About the amendment of the Food Sanitation Act
http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000197196.html

44

Appended Table 1　Draft of the Table 1　(Base polymers)

Draft of the standards and regulations
（Partial excerpts）

✓ *The mark in "Food types" means as follows.*
〇: May be used in UCP for the type of food.
－: Not allowed to be used in UCP for the type of food.
✓ *The Roman numeral in "Maximum temperature" means as follows.*
I: May be used at 70℃ or lower. II: May be used at 100℃ or lower.
III: May be used at a temperature exceeding 100℃.
✓ *The mark in "Remarks" means as follows.*
#: Falls under Article 11, paragraph (1), item (iii) of the Food Safety Basic Act.

(1) Base polymers (Plastics)

1．Polyethylene（PE）

No	Polymers		CAS No	Food types				Maximum temperature I. ≤70℃ II. ≤100℃ III. ≥101℃	Group	Remarks
	Japanese name	English name		Acidic	Oily and fatty	Alcoholic beverage	Others			
1	エチレン単独重合体	Ethylene, homopolymer	9002-88-4	〇	〇	〇	〇	III	5	#
2	エチレン・１－アルケン共重合体	Copolymers of ethylene and 1-alken	9010-79-1 25087-34-7 25213-02-9 25213-96-1 25895-47-0 26221-73-8 25895-46-9 60785-11-7 28829-58-5 and others	〇	〇	〇	〇	III	5	#
3	エチレン単独重合体・無水マレイン酸グラフト化物	Ethylene, homopolymer and 2,5-furandione, graft	9006-26-2 106343-08-2	〇	〇	〇	〇	III	2	#
4	エチレン・１－アルケン共重合体・無水マレイン酸グラフト化物	1-Alkene, polymer with ethylene and 2,5-furandione, graft	31069-12-2 63625-36-5 86286-09-1 85244-45-7 108388-93-8 and others	〇	〇	〇	〇	III	2	#

(2) Base polymers (Coatings, etc.)

✓ *The mark in "Food types" means as follows.*
○: May be used in UCP for the type of food.
－: Not allowed to be used in UCP for the type of food.

✓ *The Roman numeral in "Maximum temperature" means as follows.*
I: May be used at 70°C or lower. II:
May be used at 100°C or lower.
III: May be used at a temperature exceeding 100°C.

✓ *The mark in "Remarks" means as follows.*
#: Falls under Article 1, paragraph (1), item (iii) of the Food Safety Basic Act.

Draft of the standards and regulations
（Partial excerpts）

1．Polyester coating resins

No	Polymers		CAS No	Food types				Maximum temperature I. ≤70°C II. ≤100°C III. ≥101°C	Group	Remarks
	Japanese name	English name		Acidic	Oily and fatty	Alcoholic beverage	Others			
1	Polyester copolymers produced by copolymerizing two or more components listed in the following (a) and (b).		－	Apply classifications of the corresponding components as marked below.						
	(a) Acid components									
	1）テレフタル酸	Terephthalic acid	100-21-0	○	○	○	○	III	3	#
	2）テレフタル酸ジメチル	Dimethyl terephthalate	120-61-6	○	○	○	○	III	3	#
	3）イソフタル酸	Isophthalic acid	121-91-5	○	○	○	○	III	3	#
	4）イソフタル酸ジメチル	Dimethyl isophthalate	1459-93-4	○	○	○	○	III	3	#
	5）無水フタル酸	Phthalic anhydride	85-44-9	○	○	○	○	III	3	#
	6）セバシン酸	Sebacic acid	111-20-6	○	○	○	○	III	3	#
	7）アジピン酸	Adipic acid	124-04-9	○	○	○	○	III	3	#
	8）アゼライン酸	Azelaic acid	123-99-9	○	○	○	○	III	3	#
	9）5-スルホイソフタル酸ジメチルナトリウム塩	5-sulfoisophthalic acid dimethyl ester sodium salt	3965-55-7	○	○	○	○	III	3	#
	10）2，6-ナフタレンジカルボン酸	2,6-Naphthalenedicarboxylic Acid	1141-38-4	○	○	○	○	III	3	#
	11）2，6-ナフタレンジカルボン酸ジメチルエステル	dimethyl naphthalene-2,6-dicarboxylate	840-65-3	○	○	○	○	III	3	#
	12）4，4'-ビス（4-ヒドロキシフェニル）ペンタン酸	4,4-Bis(4-hydroxyphenyl)pentanoic acid	126-00-1	○	○	○	○	III	3	#
	13）1，2-シクロヘキサンジカルボン酸無水物	1,2-Cyclohexanedicarboxylic anhydride	85-42-7	○	○	○	○	III	3	#
	14）1，4-シクロヘキサンジカルボン酸	1,4-Cyclohexanedicarboxylic acid	1076-97-7	○	○	○	○	III	3	#
	15）ダイマー酸	Dimer Fatty acid	61788-89-4	○	○	○	○	III	3	#
	16）無水コハク酸	Succinic anhydride	108-30-5	○	○	○	○	III	3	#
	17）フマル酸	Fumaric acid	110-17-8	○	○	○	○	III	3	#
	18）無水トリメリット酸	Trimellitic anhydride	552-30-7	○	○	○	○	III	3	#
	19）トリメリット酸	Trimellitic acid	528-44-9	○	○	○	○	III	3	#
	20）無水マレイン酸	Maleic anhydride	108-31-6	○	○	○	○	III	3	#
	21）マレイン酸	Maleic acid	110-16-7	○	○	○	○	III	3	#
	22）オルソフタル酸	Phthalic acid	88-99-3	○	○	○	○	III	3	#
	23）ε-カプロラクトン	ε-Caprolactone	502-44-3	○	○	○	○	III	3	#
	24）エチレングリコールビスアンヒドロトリメリテート	Ethylene glycol bis- (anhydrotrimellitate)	71342-70-6	○	○	○	○	III	3	# Limited to the monomer of trimellitic acid and ethylene glycol.
	25）イソフタル酸-5-スルホン酸ナトリウム塩	1,3-Benzenedicarboxylic acid,5-sulfo-,monosodium salt	6362-79-4	○	○	○	○	III	3	# Limited to the monomer of terephthalic acid and ethylene glycol.
	(b) Alcohol components									
	1）エチレングリコール	Ethylene glycol	107-21-1	○	○	○	○	III	3	#

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

Draft of the standards and regulations
（Partial excerpts）

✓The mark in “Remarks” means as follows.
#: Falls under Article 11, paragraph (1), item (iii) of the Food Safety Basic Act.

No	Minor monomers		CAS No	Remarks
	Japanese name	English name		
1	1，1－ジフルオロエタン	1,1-difluoroethane	75-37-6	#
2	1，2－プロパンジオール	1,2-propanediol	57-55-6	#
3	1，3，5－トリオキサン	trioxane	110-88-3	#
4	1，3－ジオキソラン	1,3-dioxolane	646-06-0	#
5	1，3－ブタジエン	butadiene	106-99-0	#
6	1，3－ブタンジオール	1,3-butanediol	107-88-0	#
7	1，3－プロパンジオール	1,3-propanediol	504-63-2	#
8	1，4－シクロヘキサンジメタノール	1,4-bis(hydroxymethyl)cyclohexane	105-08-8	#
9	1，4－ジクロロベンゼン	1,4-dichlorobenzene	106-46-7	#
10	1，4－ブタンジオール	1,4-butanediol	110-63-4	#
11	11－アミノウンデカン酸	11-aminoundecanoic acid	2432-99-7	#
12	1－オクタノール	1-octanol	111-87-5	#
13	1－オクテン	1-octene	111-66-0	#
14	1－デカノール	1-decanol	112-30-1	#
15	1－ノナノール	1-nonanol	143-08-8	#
16	1－ブタノール	1-butanol	71-36-3	#
17	1－ブテン	1-butene	106-98-9	#
18	1－ヘキサデカノール	1-hexadecanol	36653-82-4	#
19	1－ヘキセン	1-hexene	592-41-6	#
20	1－ペンタノール	1-pentanol	71-41-0	#
21	2，3，6－トリメチルフェノール	2,3,6-trimethylphenol	2416-94-6	#
22	2，6－キシレノール	2,6-dimethylphenol	576-26-1	#
23	2，6－トルエンジイソシアネート	2,6-toluene diisocyanate	91-08-7	#
24	2，6－ナフタレンジカルボン酸	2,6-naphthalenedicarboxylic acid	1141-38-4	#
25	2，6－ナフタレンジカルボン酸ジメチル	2,6-naphthalenedicarboxylic acid, dimethyl ester	840-65-3	#
26	2－スルホエチルメタクリレート	methacrylic acid, 2-sulphoethyl ester	10595-80-9	#

Draft of the Table 2　Additives, coating agents, etc.

(1) Additives, coating agents, etc.

Draft of the standards and regulations
（Partial excerpts）

✓ *The mark in "Maximum use level by group" means as follows.*
－: Not allowed to be used in UCP for the type of food.
＊: Does not have regulatory limit for use.
✓ *The mark in "Remarks" means as follows.*
#: Falls under Article 11, paragraph (1), item (iii) of the Food Safety Basic Act.

No	Substance name		CAS No	Maximum use level by group (wt%)							Remarks
	Japanese name	English name		1	2	3	4	5	6	7	
1	ホルムアルデヒド	formaldehyde	0000050-00-0	0.005	-	0.001	-	0.001	0.001	0.001	#
2	乳酸 (ナトリウム、カルシウム塩を含む)	lactic acid (including sodium, calcium salt)	0000050-21-5 0000072-17-3 0000079-33-4 0000598-82-3 0000814-80-2 0010326-41-7	1	0.5	0.001	5	0.001	0.001	0.001	#
3	ソルビトール	sorbitol	0000050-70-4	0.5	0.5	0.5	1	0.001	0.5	-	#
4	アスコルビン酸 (ナトリウム、カルシウム塩を含む)	ascorbic acid (including sodium, calcium salt)	0000050-81-7 0000134-03-2 0005743-28-2	0.3	0.3	0.3	5	0.3	0.3	0.3	#
5	2-ブロモ-2-ニトロ-1,3-プロパンジオール	2-bromo-2-nitro-1,3-propanediol	0000052-51-7	-	-	0.001	-	0.001	0.001	0.001	#
6	グリセロール	glycerol	0000056-81-5	2	0.5	0.5	2	0.5	0.5	0.5	#
7	脂肪酸 (C8-22) (ナトリウム、カリウム、マグネシウム、カルシウム、アルミニウム、アンモニウム塩を含む)	fatty acid (C8-22) (including sodium, potassium, magnesium, calcium, aluminium, ammonium salt)	0000057-10-3 0000057-11-4 0000112-85-6 0000124-07-2 0000143-07-7 0000300-92-5 0000408-35-5 0000506-30-9 0000544-63-8 0000555-35-1 0000557-04-0 0000593-29-3 0000637-12-7 0000822-16-2 0001592-23-0 0005136-76-5 0006535-20-2 0007047-84-9 0016453-54-6 etc.	10	5	2	5	5	5	2	# 油脂および脂肪性食品に接触する製品または層には使用不可 (区分 1 に限る) Not to be used for articles or layers in contact with fats and fatty foods
8	尿素	urea	0000057-13-6	1	1	1	1	1	-	-	#
9	プロピレングリコール	propyleneglycol	0000057-55-6	3	0.5	0.5	2	0.5	0.5	0.5	#