Questions & Answers of the Positive List System

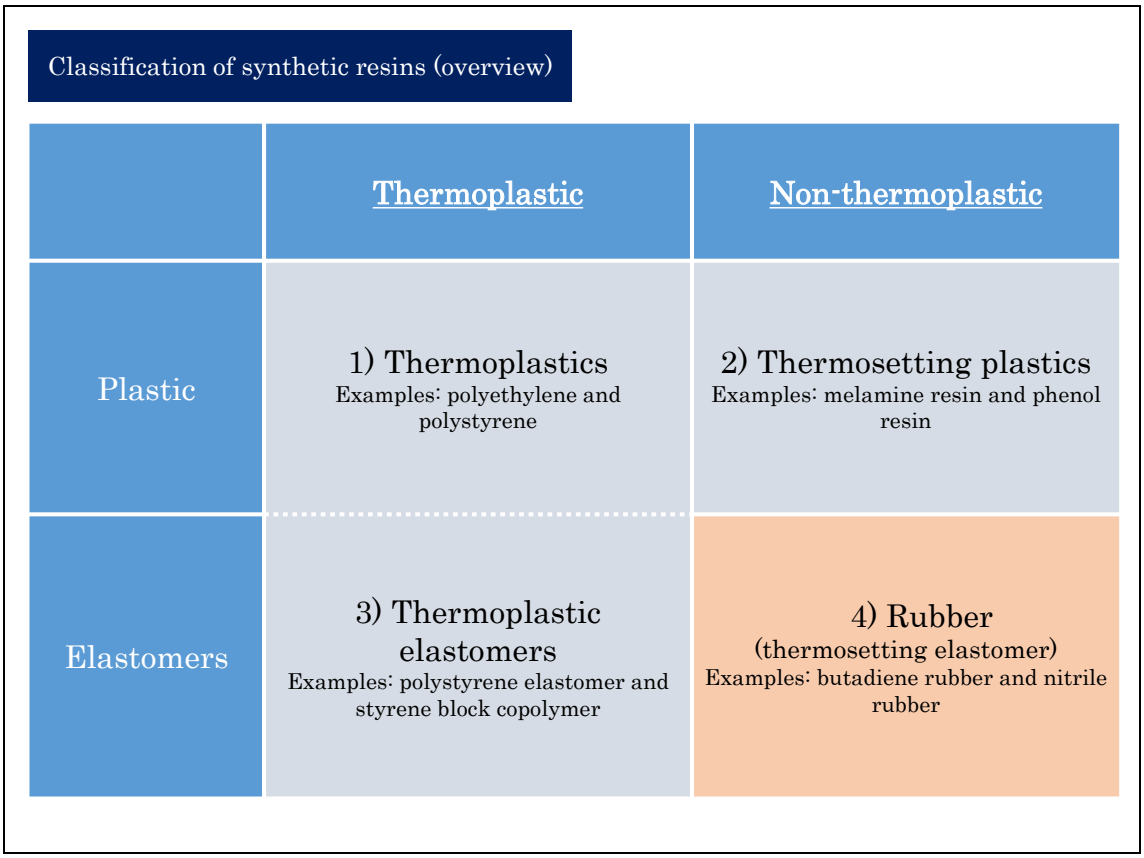
TABLE OF CONTENTS

1. Scope of the Positive List for synthetic resin used for food apparatus, containers, and packaging

Q1 The Order for Enforcement of the Food Sanitation Act defines the scope of the positive list as comprising synthetic resins. What does this include?

(Answer)

Among polymeric compounds, synthetic resins include 1) thermoplastic resins and 2) thermosetting resins, which are plastics, and 3) thermoplastic elastomers, which are elastic materials. 4) Thermosetting elastomers (rubber) are excluded. (In the figure below, 1), 2), and 3) are synthetic resins, excluding 4).)



Q2 What are excluded from the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

The items below are excluded from the positive list of synthetic resin used for food apparatus, containers, and packaging. The use of substances that are excluded from the positive list may be continued without inclusion in the positive list. However, business operators are required to comply with the existing management requirements based on the Food Sanitation Act and ensure safety at their own responsibility.

(1) Substances that do not fall under raw materials of synthetic resins (See the table below)

(Examples) ・Elastic bodies without thermoplasticity (substances that are raw materials of rubber)

・Inorganic substances

・Natural products (including extracts or distillates such as rosins, naphtha, etc., excluding substances and related substance groups that are obtained by refining only specific components) (See Q4)

・Chemical reactants of natural products (excluding chemically modified cellulose) (See Q5)

Category		Subcategory	Examples	PL scope
Inorganic substances		Metals	Iron, copper, and aluminum	Excluded
		Non-metals	Silicate, carbonate	Excluded
		Unrefined inorganics	Rocks, earth, and sand	Excluded
Organic substances	Natural organics	Unrefined natural products	Plants and extracts	Excluded
		Natural polymers	Plant fibers	Excluded
		Refined low-molecular substances	Oils and fatty acids	Table 2 (Additives)
	Synthetic organics	Synthetic organic polymeric substances (solids)	Polymers (synthetic resins)	Table 1 (Base materials)
			Polymers (rubber)	Excluded
		Synthetic organic polymeric substances (liquids)	PEG and polyglycerol	Table 2 (Additives)
		Synthetic organic low-molecular substances	-	Table 2 (Additives)

(2) Substances used for the purpose of being released from apparatus, containers, and packaging; migrating into food; and acting on that food (See Q6)

(3) Liquid or powdered substances to be adhered to the surface of raw materials of apparatus, containers, and packaging for the purpose of antistatic, antifog, etc. (See Q7)

(4) Substances generated by chemical changes of the substances contained in raw materials (See Q8)

(5) Substances that are not intended to remain in the final product (See Q9)

Q3 Are substances included in the positive list if they are contained in apparatus, containers, or packaging and have a certain function on the final product?

(Answer)

Inclusion into the positive list is not determined by whether or not the substance has a function on the final product. Refer also to Q4 through Q9 for making a determination.

Q4 What are the definitions of "natural products," which are excluded from the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

The term refers to, among naturally derived substances such as extracts or distillates of rosins, naphtha, etc., excluding substances and related substance groups that are obtained by refining only specific components. As a guideline, if the structure of the substance cannot be imagined from the name, it is regarded as a natural product.

Q5 How is cellulose handled on the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

Chemically modified cellulose (including cellulose obtained through chemical synthesis) is included in the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging because it has conventionally been handled as a synthetic resin.

On the other hand, cellulose refined from natural products (limited to cellulose that is not chemically modified), chemically modified natural products other than cellulose (including unrefined natural inorganics), and regenerated cellulose (such as rayon and cellophane) are excluded from the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging.

Q6 Please provide the details of "Substances used for the purpose of being released from apparatus, containers, and packaging; migrating into food; and acting on that food" to be excluded from the scope of the positive list.

(Answer)

"Substances used for the purpose of being released from apparatus, containers, and packaging; migrating into food; and acting on that food" refers to substances used for migration into food, not for functioning on the base materials of apparatus, containers, and packaging. Such substances are excluded from the scope of the positive list as not corresponding to the raw materials of synthetic resins.

Q7 Please provide the details of "Liquid or powdered substances to be adhered to the surface of raw materials of apparatus, containers, and packaging for the purpose of antistatic, antifog, etc." to be excluded from the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging.

(Answer)

"Coating agents: Liquid or powdered substances to be adhered to the surface of raw materials of apparatus, containers, and packaging for the purpose of antistatic, antifog, etc." are excluded from the scope of the positive list because they do not form a layered film.

Q8 Please provide the details of "Substances generated by chemical changes in the substances contained in raw materials" to be excluded from the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging.

(Answer)

In apparatus, containers, and packaging, a trace of an unintended substance may be generated after manufacture. If such an unintended substance that may be generated is included in the scope of the positive list, the detection of a trace of the substance would signify a violation of the Food Sanitation Act, unless there is an established specification for the substance. Because it is difficult to predict all unintended substances that may be generated in apparatus, containers, and packaging and impossible to include them in the positive list with the respective specifications, substances generated by chemical changes in the substances contained in raw materials are excluded from the scope of the positive list.

For an unintended substance that may be generated, if there is a new finding that indicates its toxicity, a specification may be established for the parent substance considering its possible effect, coupled with necessary regulation on its content and migration level.

Q9 Please provide the details of "Substances that are not intended to remain in the final product" to be excluded from the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging.

(Answer)

"Substances that are not intended to remain in the final product" refers to, for example, substances used on the assumption that they are removed during the manufacturing process (such as solvents for additives) and impurities contained in raw materials (such as residual monomers, catalysts, polymerization aids, and by-products).

Q10 How are substances contained in the raw materials of synthetic resins used in apparatus, containers, and packaging composed of multiple layers handled as to the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

Those substances are handled as follows.

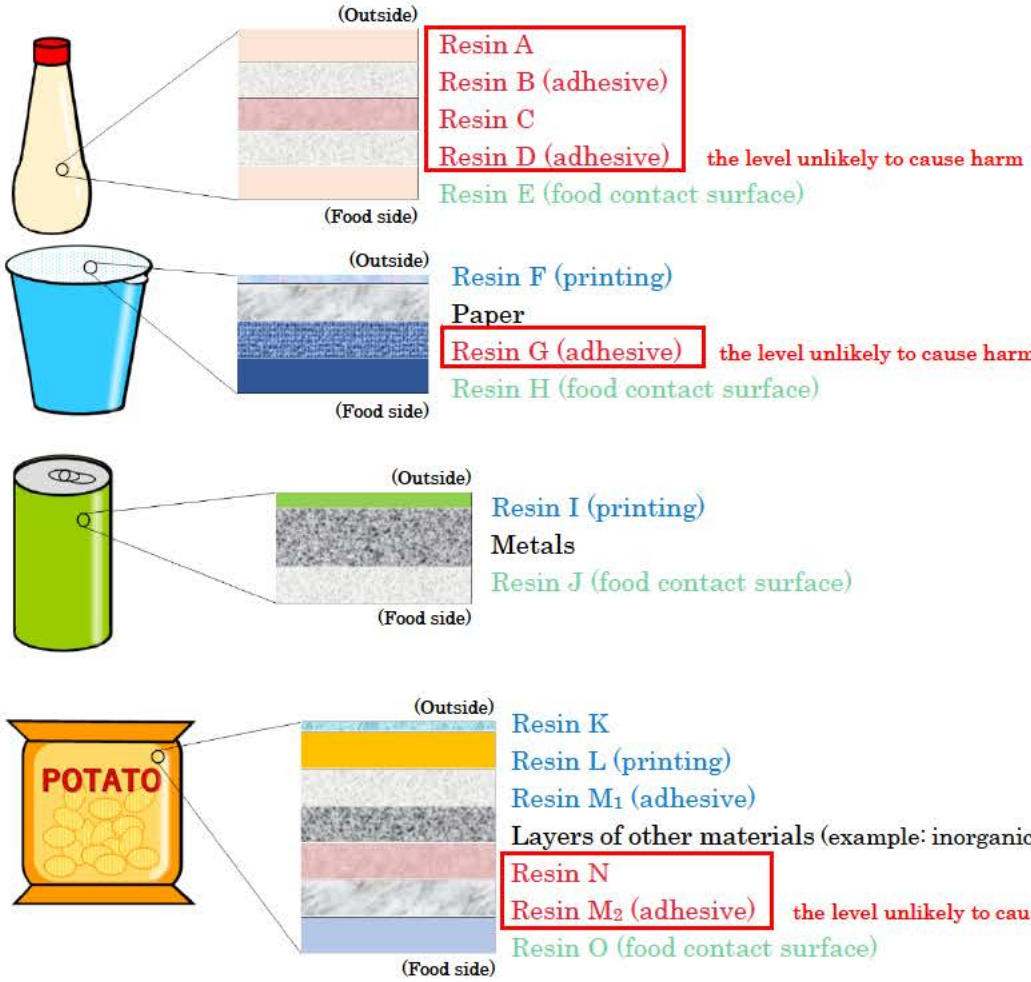
(1) If all layers are composed of synthetic resins (referred to below as "synthetic resin layer(s)"), and if the layers that do not come into contact with food are processed so that those substances are unlikely to be eluted or seep out into food at levels exceeding the quantity specified by the Prime Minister as Unlikely to Cause Harm to Human Health (referred to below as "the level unlikely to cause harm") as prescribed in the proviso of Article 18, paragraph (3) of the Food Sanitation Act, those substances are excluded from the scope of the positive list. Refer also Q42.

(2) If the layer that comes into contact with food is made from a non-synthetic resin, such as wood or paper (referred to below as "non-synthetic resin layer(s)"), and if there is a synthetic resin layer in addition to such layer, the synthetic resin layer is excluded from the scope of the positive list.

(3) If the layer that comes into contact with food is a synthetic resin layer, and if there is a non-synthetic resin layer that does not come into contact with food, only the synthetic resin layers

among other layers nearer to the layer that comes into contact with food than such a non-synthetic resin layer are included in the scope of the positive list. However, such layers may be excluded from the scope of the positive list as prescribed in the proviso of Article 18, paragraph (3) of the Food Sanitation Act.

(Examples)



PL scope	A、B、C、D、E、G、H、J、N、M2、O
Excluded from PL	F、I、K、L、M1

* Note that even substances excluded from PL are subject to the regulation of the specifications and standards for food apparatus, containers, and packaging.

Resins A, B, C, D, G, N, and M_2 are excluded from PL if they are processed so that those substances are unlikely to be eluted or seep out into food at levels exceeding the quantity specified as unlikely to cause harm to human health.

Q11 Are films formed by chemical deposition (CVD films) after molding of a product included in the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

Because chemical deposition is performed after molding of apparatus, containers, and packaging,

the deposited film is considered a layer independent of the pre-deposition apparatus, containers, and packaging. Its inclusion in the scope depends on whether the independent layer is a synthetic resin layer.

Q12 There are cases where synthetic resins are used in apparatus, containers, and packaging that do not come into contact with food within the range of normal use. Are all parts made from synthetic resins included in the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

The parts that are assumed not to come into contact with food and that actually do not come into contact with food, within the range of normal use, are excluded from the scope of the positive list.

Examples) ・Grip of chopsticks
・Exterior of food-making machine
・Trays that do not come into direct contact with food

Q13 If the end surface of a film composed of multiple layers may come into contact with food, for example, do all substances contained in the multiple layers need to be included in the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

If the end surface of the multiple layers is only exposed as a small portion of the container or packaging, it is assumed as not intended for contact with food and is not regarded as a food contact surface.

Q14 How are base materials (Table 1) distinguished from additives (Table 2) in the positive list?

(Answer)

The positive list specifies base materials in Table 1 and additives in Table 2, pursuant to item (viii) under 'A. General Specifications for Apparatus, or Containers and Packaging; or Their Raw Materials' in "Chapter III. Apparatus, and Containers and Packaging" of the Specifications and Standards for Food, Food Additives, Etc. (Ministry of Health and Welfare Public Notice No. 370, 1959). The approach is as follows.

(1) Base materials (Table 1)

In principle, Table 1 lists polymers in synthetic resins that have a molecular weight of 1000 or more and are solid at ordinary temperature and pressure.

(2) Additives (Table 2)

In principle, Table 2 lists low molecular organic substances that have a molecular weight of less than 1000 and are used with intent to remain in the final product without chemical reaction, changing the physical/chemical characteristics of base materials. However, polymers that have a molecular weight of 1000 or more but are liquid at ordinary temperature and pressure, or have specific functional groups and whose functional groups exhibit characteristic effects on the base material, are listed in Table 2 as additives.

See Q2 for substances that are excluded from the scope of the positive list following the reorganization of the scope.

Q15 How are ethylene glycol and propylene glycol polymers classified on the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

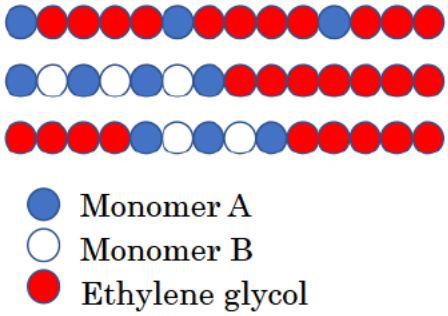
Polyethylene glycol (PEG), polypropylene glycol (PPG), and polyglycerol (PGL) are handled as additives regardless of their molecular weight. These substances with alcohol-treated terminals are also handled as additives.

On the other hand, there are polymers that include one or more of PEG, PPG, and PGL with a molecular weight of 1000 or more as component(s), which are classified as follows.

(1) Those classified as additives

Polymers in which the sum of PEG, PPG, and PGL (degree of polymerization 4 or more) accounts for 50% or more of the total (such as ethylene glycol homopolymer, propylene glycol homopolymer, polymers that contain ethylene glycol and propylene glycol as components, glycerol homopolymer, ethoxylated XX, and propoxylated XX, etc.)

[Examples of substances that are handled as additives]
Listing: ethoxylated XX
Satisfying both of the following conditions:
- PEG with degree of polymerization 4 or more
- Sum of PEG accounting for 50% or more of the total



(2) Those classified as base materials

Those other than (1).

If PEG or PPG with a molecular weight of 1000 or more is contained as component(s), those are handled as "ethylene glycol" (Note: including oxirane and including polymers with a molecular weight of 1000 or more) or "propylene glycol" (Note: including polymers with a molecular weight of 1000 or more and including 2-methyloxirane). Because of the necessity for a distinction from (1), the remark "Polymers such as ethylene glycol (limited to those with a polymerization degree of 4 or more) should account for less than 50% of the components of the polymer" is added in the restriction field.

Q16 Under "polymer mainly composed of urethane bonds," how are the polymers of ethylene glycol and propylene glycol handled on the positive list of synthetic resin used for food apparatus, containers, and packaging?

(Answer)

Under "polymer mainly composed of urethane bonds" as a base material, for which components are specified in Annex 11 to "Monomers, etc. constituting the base materials specified in Table 1 of Appended Table 1 of Specifications and Standards for Foods, Food Additives, Etc. (Notice of the Director of Food Safety Standards and Evaluation Division, Public Health Bureau, Ministry of Health, Labour and Welfare, November 30, 2023; referred to below as "Monomer Notification"), those with the sum of ethylene glycol, etc. (including polymers) accounting for 50% or more of the components of base materials (limited to those that are solid at an ordinary temperature and pressure) are also handled as base materials. Therefore, the remark "Polymers such as ethylene glycol (limited to those with a polymerization degree of 4 or more) should account for less than 50% of the components of the polymer" is not added in the restriction field.

Q17 How are substances only used for coloring (colorants) handled on the positive list?

(Answer)

Substances used only for the coloring of apparatus, containers, and packaging (referred to below as "colorants") are assumed to meet the provisions of item (v) under 'A. General Specifications for Apparatus, or Containers and Packaging; Their Raw Materials' in "Chapter III. Apparatus, and Containers and Packaging" of the Specifications and Standards for Food, Food Additives, Etc. (Ministry of Health and Welfare Public Notice No. 370, 1959), and are therefore excluded from the scope of the positive list. (For colorants, it is necessary to comply with the provisions above.)

Colorants that are used for purposes other than coloring (such as for filling or lubrication) and are raw materials of synthetic resins are listed as base materials or additives.

Q18 Do substances used only for coloring (colorants) include surface treatment agents?

(Answer)

A pigment source material with surface treatment integrally functions as a colorant (without separating from the colorant). Therefore, the entire substance, including the surface treatment agent, is handled as a colorant. However, substances other than colorants in a master batch (such as a base material and dispersants) must be individually listed in the positive list.

Q19 If a material substance other than a synthetic resin is used, is it correct to assume that the substance may be used without restrictions on the amount of use?

(Answer)

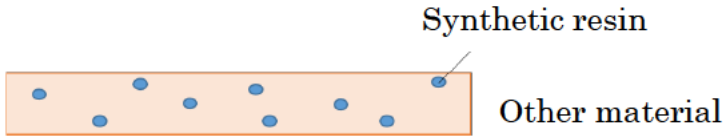
Such a substance is excluded from the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging and therefore is not subject to restriction under this system. However, business operators must comply with the conventional management and strive to ensure safety at their own responsibility.

See Q32 for the calculation of the amount of use of additives.

Q20 Is the use of raw materials mixed with synthetic resins with non-synthetic resin materials included in the scope of the positive list of synthetic resin used for food apparatus, containers, and packaging (except in cases where a synthetic resin layer is formed on the food contact surface)?

(Answer)

As shown in the figure below, if there are more non-synthetic resin materials than synthetic resins, and there is no synthetic resin layer formed on the food contact surface, management under the positive list system does not apply for operational reasons for the time being. However, attention should be paid to the effects on food sanitation due to the elution of the components of the synthetic resins used. In addition, business operators must comply with the conventional management in accordance with the Food Sanitation Act for a whole product and ensure safety at their responsibility.



Q20-2 Article 18, paragraph (3) of the Food Sanitation Act stipulates that the raw materials of apparatus, or containers and packaging subject to the positive list system must be specified in consideration of the impact on public health due to elution or leaching of the components of the raw materials into food. Is it correct to consider that apparatus, or containers and packaging are not subject to the positive list system when they are used for manufacturing/transporting or containing/wrapping, etc. of food additives?

(Answer)

Yes, it is correct.

Please note that they are subject to specifications and standards that are not based on the positive list system, such as specifications by material type.

Q20-3 Is it correct to consider that, at overseas manufacturing facilities that produce food products intended to be exported to Japan, food production machinery, including its parts, that come into direct contact with the corresponding food products is not subject to the positive list system? Also, is it correct to consider that containers and packaging for food ingredients that are used only at overseas manufacturing facilities and that are not intended to be exported to Japan are not subject to the positive list system?

(Answer)

Your understanding is correct.

Please note that when apparatus, or containers and packaging that have been manufactured overseas are exported to Japan, they are required to conform to Japan's specifications.

2. Base Materials Specified in the Positive List (Table 1)

Q21 What kind of substances are specified as base materials?

(Answer)

As for base materials, 21 types of polymers are listed, grouped according to their characteristics. The approach to base materials is as described in Q2.

As a reference, the following shows which polymers represent typical synthetic resins as base materials (Table 1).

Typical synthetic resins	Polymers as base materials (Table 1)
Phenolic resin, melamine resin, and urea resin	Polymer composed of formaldehyde as the main monomer (Attachment 9)
Polyvinyl chloride and polyvinylidene chloride	Polymer composed of chlorine-substituted ethylene as the main monomer (Attachment 20)
Polyethylene, polypropylene, and polymethylpentene	Polymer composed of alkenes as the main monomer (Attachment 13)
Polystyrene	Polymer composed of aromatic hydrocarbons as the main monomer (Attachment 15)
Polyethylene terephthalate, polylactic acid, and polyethylene naphthalate	Polymer mainly composed of ester bonds (Attachment 12)
Polymethyl methacrylate	Polymer composed of acrylic acids as the main monomer (Attachment 16)
Polyamide	Polymer mainly composed of amide bonds (Attachment 17)
Polycarbonate	Polymer mainly composed of carbonate bonds (Attachment 5)
Polyvinyl alcohol	Hydrolysates of polymer composed of vinyl acetate as the main monomer (Attachment 19)

Q22 If there are raw materials composed of the same chemical substance with the same CAS registry number, but with a molecular weight of less than 1000 or with a molecular weight of 1000 or more, how are they handled on the positive list?

(Answer)

If the substance is designed to have a molecular weight of 1000 or more, it is handled as a base material. The substance is handled as an additive if it has any of the following.

- a molecular weight of less than 1000
- a molecular weight of 1000 or more, those being liquid at ordinary temperature and pressure
- a molecular weight of 1000 or more, those having specific functional groups and whose functional groups exhibit characteristic effects on the base materials

Based on this approach, substances that are categorized as base material or as an additive are listed in Tables 1 or 2 after hearing opinions from business operators.

Q23 How are the components of base materials specified?

(Answer)

The components of base materials are shown in Attachments 1 to 21 of the Monomer Notification. However, if the remark "Limited to use as components of polymers that fall under serial numbers 108(1) and 108(2) in Table 2" is provided in the restriction field, it may not be used as a component of a base material.

For other precautions, see the Monomer Notification.

Q24 How should a substance be handled if more than one material category is indicated in Table 1 (for example, if there is an indication "1 or 3")?

(Answer)

See details provided in the remarks field for Table 1.

(Reference: details in the remarks field)

The material categories are specified as follows.

① Category "1" signifies polymers having a glass transition temperature or ball pressure temperature of 150°C or higher, or polymers having a cross-linked structure with a melting point of 150°C or higher, and other similar substances (excluding those correspond to polymer groups 2 and 4).

② Category "1 or 3" signifies that polymers having a glass transition temperature or ball pressure temperature of 150°C or higher and other similar substances (excluding those correspond to polymer groups 2 and 4) fall under polymer group 1, and that polymers having a glass transition temperature or ball pressure temperature of lower than 150°C and other similar substances (excluding those correspond to polymer groups 2 and 4) fall under polymer group 3.

③ Category "2" signifies polymers composed of hydrocarbons as the main monomer (excluding those correspond to polymer group 4).

④ Category "2 or 3" signifies that polymers composed of hydrocarbons as the main monomer (excluding those correspond to polymer group 4). Substances for which the sum of acrylic acid, acrylonitrile, N-phenyl-maleimide, maleic anhydride, and methacrylic acid in the polymer is 10% or more o fall under polymer group 3 ; and substances that are other than those categorized in group 3 fall under polymer group 2.

⑤ Category "3" signifies polymers with both glass transition temperature and ball pressure temperature less than 150°C and other similar substances (excluding those correspond to polymer groups 2 and 4).

⑥ Category "4" signifies polymers composed of chlorinated ethylene as the main monomer.

⑦ Category "4 or 5" signifies polymers that are used for coating involving chemical reaction during film formation. Substances for which the sum of vinylidene chloride and vinyl chloride in the polymer is 50% or more of fall under polymer group 4; and substances other than those categorized in group 4 fall under polymer group 5.

Q25 As for monomers specified in the Monomer Notification, is it acceptable to combine essential monomers categorized under the different numbers of Annexes in the Monomer Notification, combine any different substances, or combine different essential monomers with optional substances?

(Answer)

In the Monomer Notification, the components of each base material substance specified in Table 1 are indicated in Annexes 1 to 21. Within the range of the same attachment table, essential monomers and optional substances may be combined. However, it is not permitted to combine essential monomers with optional substances from different attachment tables.

Q26 Among the components of base materials, how are the substances that are only used in trace amounts handled?

(Answer)

As for the components of base materials for which the components are specified in Annexes 1 to 20 of the Monomer Notification, it is acceptable that the portions accounting for less than 2%, except for "essential monomers," "optional substances," "essential chemical treatment," and "optional chemical treatment" are not specified in Annexes 1 to 20.

In addition, as for the components of "polymers used for coating with chemical reaction at the time of film formation" as base materials for which the components are specified in Annex 21, it is acceptable that the portions accounting for less than 2%, except for "organic compounds," "natural components, inorganics, or derivatives thereof," and "optional chemical treatment" are not specified in Annex 21.

Even cross-linkers and terminal sealants must also be specified in Annexes 1 to 21, respectively, if they account for 2% or more as the components of base materials.

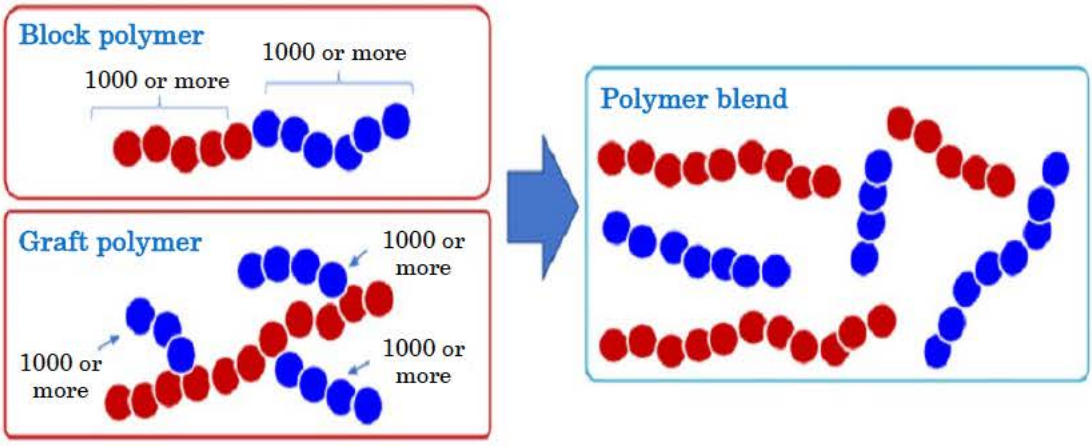
Q27 How is the mixture or bonding (such as block polymers and graft polymers) of multiple base materials handled?

(Answer)

A unit polymer with a molecular weight of 1000 or more can be regarded as a base material for each unit polymer. In the case of block polymers, a unit polymer with a molecular weight of 1000 or more is regarded as a base material for each unit polymer. In the case of graft polymers, the component trunk polymers and branch polymers with a molecular weight of 1000 or more are regarded as a base material for each of the component polymers.

Therefore, the states shown in the figures below are regarded in the same way as the mixture of multiple base materials ("polymer blend"). In this case, see Q32 for the method of calculating the amounts of additives listed in Table 2.

If the molecular weight of the component unit polymer is less than 1000, it must be regarded as a part of a single base material and indicated in Annexes 1 to 21.



Q28 How are the base materials of synthetic resins used for coating handled? What is the difference from the coating agents excluded from the scope of the positive list?

(Answer)

"For coating" refers to use for the purpose of forming of a layered film of surface coating and adhesive.

Base materials for which the components are specified in Annexes 1 to 20 of the Monomer Notification may also be used for coating. "Polymers used for coating with chemical reaction at the time of film formation" as base materials for which the components are specified in Annex 21 may only be used for coating. Note that "chemical reaction" here refers to the reaction that chemically changes the structure and excludes solvent vaporization.

On the other hand, see Q7 for coating agents.

3. Additives Specified in the Positive List (Table 2)

Q29 What kind of substances are specified as additives?

(Answer)

In principle, Table 2 lists low molecular organic substances that have a molecular weight of less than 1000 and are used with intent to remain in the final product without chemical reaction, changing the physical or chemical characteristics of base materials. However, substances that have a molecular weight of 1000 or more, but:

- liquid at ordinary temperature and pressure; or
- have specific functional groups and whose functional groups exhibit characteristic effects on the base material

are listed in Table 2 as additives.

Q30 How should Table 2 be referred to for the acceptability of and restriction on the use of additives?

(Answer)

For additives, the substances listed in Table 2 of the positive list should be used. For each additive, the material category for use and the limited ratio of use (%) are specified in the limited ratio (%) of use by material category field. This enables business operators to refer to the material categories in Table 1 of the base material to be used and use an additive within the limited ratio (%) of use for the relevant categories.

Statements in the remarks field must also be checked because specifications may be provided in that field for certain additives (See Q31).

See Q32 for the calculation of the amount of additives.

Q31 Among the substances specified in Table 2, how should those with statements in the remarks field be handled?

(Answer)

Statements in the remarks field indicate matters to be referred to for the substances listed in the substance name field, corresponding to the remarks field.

If "Requirements" column in the remarks field, regulation is enforced as otherwise specified in the remarks field, regardless of the amounts specified under the limited ratio of use by material category field in Table 2. "Requirements" column here signifies any statements in the remarks field concerning the use of the substance, such as the temperature of use, target foods, thickness of the material, presence/absence of direct contact with food, and the total amount of use. See the reference examples of each category provided in Attachment to 'Requirements column' in Table 2 of Appended Table1 of Specifications and Standards for Foods, Food Additives, Etc. (Notice of the Director of Food Safety Standards and Evaluation Division, Public Health Bureau, MHLW, November 30, 2023).".

In addition to matters otherwise specified in the remarks field, matters concerning the molecular weight, carbon number, and other restrictions may also be provided, which must also be complied with.

Q32 Please provide the method for calculating the amounts of additives.

(Answer)

The limited ratio (%) of use by material category for additives in Table 2 is applied as a permissible package of the weight of an additive to the total weight of raw materials used in apparatus, containers, and packaging. (Raw materials here include synthetic resins, non-synthetic resins, and other substances in which impurities are not intended to remain.) In the case of a multi-layered structure, calculate the amount for each layer as shown in Q10.

For the mixture or bonding of multiple base materials (including block polymers and graft polymers; see Q27), the values calculated from the weight ratios of the base materials in each category are applied. If the weight ratio of base materials in a certain category (if more than one base materials are included in a certain category, the sum of their weights) exceeds 50% of the total weight of the base materials, the limited ratio (%) of use by material category for the category of the base material exceeding 50% may be used as the upper limit.

If more than one synthetic resin that meets the limited ratio of use based on the values calculated from the weight ratios of base materials in each category (if otherwise specified in the remarks field, synthetic resins that meet such specifications) is mixed, the mixture is considered to meet the limited ratio of use.

See also the examples provided below.

[Examples]

Mixture of Category 2 base materials: 20% and Category 3 base materials: 80%

(1) If the limited ratio of use by material category for Additive A is 2.0% for Category 2 and 4.0%

for Category 3,

① Calculated from weight ratios: 2.0 x 20% + 4.0 x 80% = 3.6%

or

② Because Category 3 exceeds 50% of the total weight of the base materials, **it is acceptable to use 4.0%** based on the limited ratio of use by material category for Category 3 of Additive A.

(2) If the limited ratio of use by material category for Additive B is 10% for Category 2 and none (not permitted) for Category 3,

① Calculated from weight ratios: 10 x 20% + 0 x 80% = **2.0%**

Q33 As for "Polymers that fall under Table 1" under the substance names for serial numbers 108(1) and 108(2) in Table 2, what components may be used for these polymers that fall under Table 1?

(Answer)

These refer to the components specified in Attachments 1 to 20 of the Monomer Notification. (Those with the remark "Limited to use as components of polymers that fall under serial numbers 108(1) and 108(2) in Table 2" provided in the restriction field may also be used.) See also the Monomer Notification for precautions for the components of these polymers, which are the same as those for base materials.

As explained in Q25, it is not permitted to combine essential monomers and optional substances from different attachment tables.

Q34 How should the restriction of use of substances with "*" indicated in the limited ratio (%) by material category field in Table 2 be understood?

(Answer)

The "*" indication signifies that, when apparatus, containers, and packaging are designed using a base material in the relevant material category, the amount set as the minimum amount for exercising the intended characteristic at the business operator's responsibility is used as the limited ratio.

Q35 If the substance name is listed in Table 2 of the positive list, is it correct to understand that the substance is included in the positive list as an additive, even if the CAS registry number differs from that in the reference list provided on the website of the Consumer Affairs Agency?

(Answer)

The Public Notice is provided based on substance names. Substances within the range of the substance names are included in the positive list, even if the CAS registry numbers differ from those in the reference list. The CAS registry numbers are for reference only. Compliance assessment based on the CAS registry numbers only should be made at the business operator's responsibility.

Q36 If substances are removed from serial number 412, "Additives specified in the positive list (APPENDED TABLE 1) to the Regulations for Enforcement of the Food Sanitation Act (Order of the Ministry of Health and Welfare No. 23, 1948) or in the existing additives list (Public Notice of the Ministry of Health and Welfare No. 120, 1996)" in Table 2, may the use of such substances be continued as additives for apparatus, containers, or packaging?

(Answer)

If these additives are removed, they will no longer correspond to serial number 412 in Table 2 to the Specifications and Standards for Food, Food Additives, Etc. (Ministry of Health and Welfare Public Notice No. 370, 1959). The necessity of adding them to the positive list considering the reasons for removal will be examined.

4. Others

Q37 How are silicon-based compounds classified on the positive list?

(Answer)

Silicon-based compounds are possibly classified as follows based on their properties and purposes of use. (* Note that decisions must be made by business operators depending on their actual use.)

(1) Substances that do not fall under raw materials of synthetic resins

[Elastic bodies without thermoplasticity (substances that are raw materials of rubber)]

Among the polymers (silicones) that are mainly composed of siloxane bonds, the materials that use substances with rubber elasticity as main base materials are classified as silicone rubber. The substances that are the raw materials thereof are excluded from the scope of the positive list.

(Reference) Definitions of curable silicone resins (Silicone Industry Association of Japan)
https://www.siaj.jp/ja/pdf/CurableSiliconeResinDefinition.pdf

[Inorganic substances]

"Silicon oxide (SiO_2)" and "silicon oxide aggregates (silica and glass)" are inorganic substances and are therefore excluded from the scope of the positive list.

In addition, the chemical reactants (by surface treatment, etc.) of "silicon oxide aggregates (silica and glass)" and organic substances are chemical modifiers of inorganic substances and are therefore excluded from the scope of the positive list.

The chemical reactants of inorganic silicon compounds and organic compounds other than the above at the molecular level are classified as organic compounds and are substances contained in the raw materials of synthetic resins, and are therefore included in the scope of the positive list.

[Coating agents]

There are cases where silicone oil or other oils are applied to the surface of raw materials. If the substance remains adhered to the surface of synthetic resins in the final product, it falls under "Coating agents: Liquid or powdered substances to be adhered to the surface of raw

materials of apparatus, containers, and packaging" and is therefore excluded from the scope of the positive list.

(2) Substances contained in the raw materials of synthetic resins: included in the scope of the positive list

[Base materials]

Table 1 lists polymers in synthetic resins that have a molecular weight of 1000 or more and are solid at ordinary temperature and pressure.

[Additives]

In principle, Table 2 of the positive list lists low molecular organic substances that have a molecular weight of less than 1000 and are used with intent to remain in the final product without chemical reaction, not changing the physical/chemical characteristics of base materials. However, if the substance has a molecular weight of 1000 or more, but:

- liquid at ordinary temperature and pressure; or
- have specific functional groups and whose functional groups exhibit characteristic effects on the base material

are listed in Table 2 as additives.

Q38 How are polymeric additives classified on the positive list?

(Answer)

See Q14 and Q15 for making decisions.

Q39 How are recycled materials handled on the positive list?

(Answer)

They are classified as follows.

○ "Mechanical recycled" in the Monomer Notification (as specified as optional chemical treatment for "Polymer mainly composed of ester bonds" in Annex 12 and "Polymer composed of aromatic hydrocarbons as the main monomer" in Annex 15) refers to the manufacturing process using mechanical recycled post-consumer materials (limited to end-of-use products intended for food).

Additives derived from post-consumer materials contained in mechanical recycled polymers are handled as substances that are not intended to remain in the final product. Therefore, additives derived from post-consumer materials are not subject to restriction under Table 2.

○ The following manufacturing processes are not categorized as "mechanical recycled." Recycled materials obtained through these manufacturing processes are handled as primary raw materials and therefore may be used if they comply with Tables 1 and 2.

- A manufacturing process that uses chemically recycled post-consumer materials

- A manufacturing process that uses mechanical recycled pre-consumer materials (excluding materials obtained from the manufacturing process of recycled materials or products that use recycled materials as raw materials)

For reference, see also the "About the Guidelines on the Use of Recycled Materials as Raw Materials of Synthetic Resins in the Manufacturing of Food Apparatus, Containers, and Packaging" (Notice of the Director of Food Safety Standards and Evaluation Division and the Director of the Food Inspection and Safety Division, Public Health Bureau, Ministry of Health, Labour and Welfare, March 28, 2024).

Q.40 In "The Guidelines on the Use of Recycled Materials as Raw Materials of Synthetic Resins Used for Manufacturing of Food Apparatus, and Containers and Packaging" (Director Notice of the Ministry of Health, Labour and Welfare No. 0328-7 of March 28, 2024), why are the following materials excluded from those defined as "pre-consumer materials"?

- recycled materials
- materials, such as scraps, that are removed during the manufacturing process of products manufactured using recycled materials as raw materials

(Answer)

The reason why these materials are excluded from those defined as "pre-consumer materials" in the guideline is because such materials are removed before the completion of the manufacturing process and therefore it is not confirmed that such materials meet the quality standards for recycled materials. The same applies to the recycled materials that do not follow the guideline. On the other hand, recycled materials manufactured according to the guideline may be handled as "pre-consumer materials" because it is confirmed that such materials meet the quality standards for recycled materials. The same applies to unused products made from recycled materials manufactured according to the guideline.

Q41 For substances with isomers, if the type of the isomer is not indicated in the corresponding substance name column, is it possible to use any isomeric substance? For substances with hydrates, is it also possible to use any hydrate even if there is no such mention in the corresponding substance name column?

(Answer)

Any substance with structural isomers or stereoisomers may be used unless otherwise specified. Please note that there are cases where a substance is designated just under a conventional name, such as fumaric acid (trans type) or maleic acid (cis type). Hydrates also may be used even if there is no such mention in the corresponding substance name column. Hydration water does not need to be considered as part of the weight of the synthetic resin.

Q42 In applying the proviso of Article 18, paragraph 3, please tell us how to explain theoretically that the migration level does not exceed "the level unlikely to cause harm" (concentration in food: 0.01 mg/kg or concentration in food simulants: 0.01 mg/L), regardless of the results of migration tests.

(Answer)

As an example of a theoretical explanation, if a simulation is conducted under the expected conditions of use that would result in the highest level of elution into food, and it is predicted that the elution level will be less than 1/10 of "the level unlikely to cause harm" (0.001 mg/kg or less), it can be determined that the amount does not exceed "the level unlikely to cause harm."

[If the expected conditions of use cannot be specified]

Based on the glass transition temperature or ball pressure temperature of the food contact layer, the thickness of the food contact layer, and the usage temperature of the product, it can be predicted that the migration level of substances contained in the non-food contact layer will be 0.001 mg/kg or less for products where the contact time with food is shorter than the time specified in the table. Therefore, it can be determined that the provisions of Article 18, Paragraph 3, proviso are being applied.

Food contact layer	Temperature of use	Thickness of food contact layer									
		5μm	10μm	20μm	30μm	40μm	50μm	100μm	200μm	500μm	1000μm
Tg= ca. 130℃ or Polymer group 1	100℃	1.5 hr	5.7 hr	21 hr	1.9 d	3.4 d	5.3 d	19 d	73 d	1 yr	1 yr
	80℃	7.5 hr	1.2 d	4.4 d	9.4 d	16 d	25 d	94 d	360 d	1 yr	1 yr
	60℃	1.9 d	6.9 d	26 d	56 d	97 d	150 d	1 yr	1 yr	1 yr	1 yr
	40℃	14 d	51 d	190 d	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr
	20℃	130 d	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr
	0℃	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr
Tg= ca. 100℃	100℃	–	–	3.5 hr	7.6 hr	13 hr	20 hr	3.2 d	11 d	70 d	270 d
	80℃	1.2 hr	4.6 hr	17 hr	1.6 d	2.7 d	4.1 d	15 d	59 d	340 d	1 yr
	60℃	7.3 hr	1.1 d	4.2 d	9.2 d	16 d	24 d	92 d	350 d	1 yr	1 yr
	40℃	2.3 d	8.4 d	31 d	68 d	120 d	180 d	1 yr	1 yr	1 yr	1 yr
	20℃	22 d	82 d	310 d	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr
	0℃	300 d	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr
Tg= ca. 70℃	100℃	–	–	–	1.3 hr	2.2 hr	3.3 hr	12 hr	2.0 d	11 d	43 d
	80℃	–	–	2.8 hr	6.1 hr	11 hr	16 hr	2.7 d	9.2 d	56 d	210 d
	60℃	1.2 hr	4.4 hr	17 hr	1.5 d	2.6 d	4.0 d	15 d	57 d	330 d	1 yr
	40℃	8.9 hr	1.4 d	5.1 d	11 d	19 d	30 d	110 d	1 yr	1 yr	1 yr
	20℃	3.6 d	13 d	50 d	110 d	190 d	290 d	1 yr	1 yr	1 yr	1 yr
	0℃	49 d	180 d	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr
Tg= ca. 40℃	100℃	–	–	–	–	–	–	2.0 hr	7.7 hr	1.9 d	7.1 d
	80℃	–	–	–	–	1.7 hr	2.7 hr	10 hr	1.6 d	9.2 d	35 d
	60℃	–	–	2.7 hr	5.9 hr	10 hr	16 hr	2.5 d	9.3 d	54 d	210 d
	40℃	1.5 hr	5.4 hr	20 hr	1.8 d	3.2 d	4.8 d	18 d	69 d	1 yr	1 yr
	20℃	14 hr	2.2 d	8.2 d	18 d	31 d	47 d	180 d	1 yr	1 yr	1 yr
	0℃	8.0 d	30 d	110 d	240 d	1 yr	1 yr	1 yr	1 yr	1 yr	1 yr
Tg= ca. 0℃	100℃	–	–	–	–	–	–	–	–	4.0 hr	15 hr
	80℃	–	–	–	–	–	–	–	3.4 hr	20 hr	3.1 d
	60℃	–	–	–	–	–	1.4 hr	5.3 hr	20 hr	4.9 d	18 d
	40℃	–	–	1.8 hr	3.9 hr	6.8 hr	10 hr	1.6 d	6.2 d	36 d	140 d
	20℃	1.3 hr	4.7 hr	18 hr	1.6 d	2.8 d	4.2 d	16 d	60 d	350 d	1 yr
	0℃	17 hr	2.7 d	10 d	22 d	38 d	58 d	220 d	1 yr	1 yr	1 yr
Tg= ca. −50℃	100℃	–	–	–	–	–	–	–	–	–	–
	80℃	–	–	–	–	–	–	–	–	–	3.7 hr
	60℃	–	–	–	–	–	–	–	–	5.7 hr	22 hr
	40℃	–	–	–	–	–	–	1.9 hr	7.3 hr	1.8 d	6.8 d
	20℃	–	–	–	1.9 hr	3.3 hr	5.0 hr	19 hr	3.0 d	17 d	66 d
	0℃	–	3.2 hr	12 hr	1.1 d	2.3 d	2.9 d	11 d	40 d	240 d	1 yr

Tg: Glass transition temperature or Ball pressure temperature
−: Specific time cannot be provided as it will be less than one hour
For repeatedly used apparatus, only if the food contact layer is undamaged.
For use at or below room temperature for dried foods or foods with shells or skins, "1 year" is defined as long as the thickness of the food contact layer is at least 20 μm.

Q43 How will apparatus, or containers and packaging that were manufactured, imported, sold, or used in business by the end of the transitional measure period (the end of May 2025) be handled after the period?

(Answer)

Article 4 of the Supplementary Provisions of the Act Partially Amending the Food Sanitation Act, Etc. (Act No. 46 of 2018; the "Amendment Act") states that the amended Food Sanitation Act does not apply to apparatus, or containers and packaging that were marketed, manufactured, imported, or used in business at the time of enforcement of the Amendment Act (June 1, 2020). Therefore, the apparatus, or containers and packaging manufactured, imported, sold, or used in business before June 1, 2020 are subject to the regulation established before the introduction of the Positive List System and may be sold or used in business even after the transitional measure period.

When apparatus, or containers and packaging that are similar to those that were sold, manufactured, imported, or used in business before the enforcement date (June 1, 2020) were sold,

manufactured, imported, or used in business during the transitional measure period (from June 1, 2020 to May 31, 2025); considering the purpose of the Amendment Act, only such apparatus, or containers and packaging are regarded as being manufactured using substances considered to be listed in the Positive List, and therefore, even after the transitional measure period (after June 1, 2025), such apparatus, or containers and packaging may be sold or used in business as being conforming to the Positive List System.

[The transitional measures also apply to intermediate products in the manufacturing process of apparatus, or containers and packaging, at least to the following products and materials.

- The intermediate products manufactured by a person who is required to notify the business of manufacturing apparatus, or containers and packaging (including intermediate products that were manufactured by a foreign manufacturer equivalent to a person who is required to notify the business of manufacturing apparatus, or containers and packaging and that were imported and are stored for manufacturing the final products)
- The materials that are stored for manufacturing intermediate products]

When apparatus, or containers and packaging are manufactured or imported after the transitional measure period (on and after June 1, 2025), the substances listed in the Positive List must be used as raw materials of them. The transitional measure applies to apparatus, and containers and packaging manufactured for businesses that are subject to notification specified in "Notification of Businesses for Manufacturing Apparatus, or Containers and Packaging" (Notice of the Director of Food Safety Standards and Evaluation Division and the Director of the Food Inspection and Safety Division, Public Health Bureau, Ministry of Health, Labour and Welfare, March 28, 2024).

Note: "apparatus, containers, or packaging that are similar to those" mentioned in this answer refers to apparatus, or containers and packaging manufactured using substances (limited to raw materials of synthetic resin) that were used in apparatus, or containers and packaging that were sold, manufactured or imported for the purpose of marketing, or used in business before June 1, 2020 within the range in which they were used in the apparatus, or containers and packaging; or refers to the imports of such apparatus, or containers and packaging.

To apparatus, and containers and packaging manufactured, etc., before the enforcement of the Positive List System, the Supplementary Provisions of the Food Sanitation Act applies.

Supplementary Provisions of the Food Sanitation Act (Act No. 46 of 2018) (Excerpt)

Article 4 (1) The provisions of Article 18, paragraph (3) of the New Food Sanitation Act and Article 50-4 of the Food Sanitation Act (after the date of enforcement specified in Article 2, Article 53 of the New Food Sanitation Act specified in Article 2 of the Supplementary Provisions) do not apply the apparatus (apparatus specified in Article 4, paragraph (4) of the Food Sanitation Act), and containers and packaging (containers and packaging specified in paragraph (5) of the

preceding Article) that are sold, manufactured or imported for the purpose of marketing, or used in business (businesses specified in paragraph (7) of the preceding Article) at the time of enforcement of the Supplementary Provisions of the Food Sanitation Act.

Q43-2 In food manufacturing facilities, etc., when repairs, replacement of consumables, etc. are carried out on and after June 1, 2025 on machines, etc. that are similar to those that were used in business before June 1, 2020 and that were used in business before June 1, 2025, are such machines, etc. able to consider to subject to the transitional measures if they are similar to those that were used in business before June 1, 2020?

(Answer)

Even if repairs, replacement of consumables, etc. are carried out on or after June 1, 2025, if the machine, etc. is deemed similar to those used in business before June 1, 2020, it is acceptable to consider the machine, etc., including the repaired or replaced parts as those subject to the transitional measures.

Note: "apparatus, containers, or packaging that are similar to those" mentioned in this answer refers to apparatus, or containers and packaging manufactured using substances (limited to raw materials of synthetic resin) that were used in apparatus, or containers and packaging that were sold, manufactured or imported for the purpose of marketing, or used in business before June 1, 2020 within the range in which they were used in the apparatus, or containers and packaging; or refers to the imports of such apparatus, or containers and packaging.

Q44 What kind of procedures should be taken to use new substances in apparatus, or containers and packaging that are newly manufactured?

(Answer)

To enable new substance to be used in apparatus, or containers and packaging, one of the following two procedures should be taken: (1) Appended Table 1 or Monomer Notification is amended to list the information of the substance concerned and (2) the information to the effect that the substance concerned has undergone safety assessment is published. For the details of the procedures, please refer to the website of the Consumer Affairs Agency.

Reference: Consultation on New Substances, Etc.
https://www.caa.go.jp/policies/policy/standards_evaluation/appliance/positive_list/consultation