Policies being considered based on opinions and questions solicited.

（March 6, 2023）

※Based on the requests on the new draft lists of Positive List, revised part after September 30, 2022 is underlined.

【March 6, 2023】

1. Polymer group 3g ” polymer with adsorptive or ion exchange ability (excluding those correspond to Polymer Group 1, 2 and 4)”in Table 1(base materials)

As a general rule, polymers listed as polymer group 3 without adsorptive or ion exchange ability are classified into class 3a to 3f. There are some substances consist of monomers with adsorptive or ion exchange ability are classified into class 3g.

2. Polymer used for coating that involves chemical reaction during film formation

Substances without details of final chemical structure are not classified into polymer group 1 to 4, and these substances only used for coating that involves chemical reaction during film formation are classified into polymer group 5 “polymer used for coating that involves chemical reaction during film formation” as a special case.(Note that “Polymer group 5” in new draft of Table 1 is different from “Previous polymer group 5” in previous draft of Table 1.)

Use limit of each additives for substances classified as polymer group 5 are listed in Table 2. Use limit of polymers with heatproof resistance are more than 150℃ is applied to maximum use limit of polymers in polymer group 1 to 3. Use limit of polymers with heatproof resistance are less than 150℃ is applied to maximum use limit of polymers in polymer group 2 and 3.

3. Substances use limit are lowered

Some substances, requirements and use limit listed in Table 2 are modified after applications as below. If these substances have been used more than lowered use limit prior to June 1, 2020, please contact to Food Safety Standards and Evaluation Division Pharmaceutical Safety and Environmental Health Bureau until March 17, 2023.

Serial No.	Substance Name	Modifications
507	methyl ester of fatty acid from animal or vegetable oil and fat	Group 3(10→5)
648	acid refined tall oil	Group 3(10→－)
830	fatty acid from vegetable oil, cerium salt	Group 3(10→－)
917	ester of stearic acid with stearyldiethanolamine	Group 3(10→－)
1041	ester of fatty acid from animal or vegetable oil and fat with sorbitol	Group 3(10→0.21)

1044	fatty acid from animal or vegetable oil and fat, dicyclohexylamine salt	Group 3(10→－)
1139	dimerized and/or trimerized fatty acid (C=16-18) (including sodium and/or potassium salt)	Group 3(10→－)
1283	monoamide of pyrophosphoric acid with dibutylamine	Group 3(10→－)
1316	dibutyl phthalate	Requirements old: Not allowed to be used in the parts coming into contact with raw meat. ↓ new: Not allowed to be used in the parts coming into contact with food. (excluding when processed so as not to migrate to food) Group 1(16→－) Group 2(10→－) Group 3(30→－) Group 4(30→－) Group 5(30→－)
1447	dibutyl maleate	Group 3(10→－)
1579	sulfated animal or vegetable oil and fat (including sodium, potassium salt)	Group 3(10→0.1)

【September 30, 2022】

1. Reorganizing chemical compounds with hydrocarbon as a main component

Based on submitted opinions, base materials and additives are reorganized as follows so that each business can check compatibility easily.

(1) Base materials

① Polymer composed of hydrocarbon as the main monomer are listed as polymer class 2a~2c as below.(Excerpted from Table 1)

2a	polymer composed of conjugated diene hydrocarbon as the main monomer

	essential monomer	1,3-butadiene
		conjugated diene hydrocarbon (C=5)
		conjugated diene hydrocarbon (C=5), dimerized
	optional substance	essential monomer (Polymer Class = 2b)
		essential monomer (Polymer Class = 2c)
		other substance
2b	polymer composed of alkenes as the main monomer	
	essential monomer	ethylene
		propylene
		alkene (C=4)
		alkene (C=5)
		alkene (C=6)
		alkene (C=7)
		alkene (C=8)
		alkene (C≥9)
		cyclopentene
		cyclooctene
		2-norbornene
	optional substance	essential monomer (Polymer Class = 2a)
		essential monomer (Polymer Class = 2c)
		other substance
2c	polymer composed of aromatic hydrocarbons as the main monomer	
	essential monomer	xylene
		styrene
		aromatic hydrocarbon (C≥9)
	optional substance	essential monomer (Polymer Class = 2a)
		essential monomer (Polymer Class = 2b)
		other substance

② Petroleum hydrocarbon (C1305) and paraffin (C1311) are integrated as below.

・conjugated diene hydrocarbon (C=5)

・conjugated diene hydrocarbon (C=5), dimerized

・ethylene

・propylene

・alkene (C=4)

・alkene (C=5)

・alkene (C=6)

・alkene (C=7)

・alkene (C=8)

・nonaromatic hydrocarbon (unsaturated C=9)

・xylene

・styrene

・aromatic hydrocarbon (C≥9)

・1,3-butadiene

(2) Additives

Polymer composed of hydrocarbon as the main monomer are integrated and listed as below.

	carbon number	substance name	Requirements	Use limit
saturated hydrocarbon	C=2~7	972 : hydrocarbon (saturated C=2-7) (including alicyclic hydrocarbon) (excluding those correspond to serial No. 1666)		proper dose
	C≥8	1668 : hydrocarbon (saturated C≥8, including alicyclic hydrocarbon) (Mw<1000) (excluding those correspond to serial No. 1666)		proper dose
		1669 : hydrocarbon (saturated C≥8, (including alicyclic hydrocarbon) (Mw≥1000) (excluding those correspond to serial No. 1666, 1667)	Not solid at ordinary temperature and pressure	proper dose
unsaturated aromatic hydrocarbon	C=2~8	Each is listed in Table 2.		Each is listed in Table 2.
	C≥9	1670 : hydrocarbon (unsaturated C≥9, including aromatic hydrocarbon) (Mw<1000) (excluding genotoxicity		proper dose

		substance and those correspond to serial No. 1666)		
		1671 : hydrocarbon (unsaturated C≥9, including aromatic hydrocarbon) (Mw≥1000) (excluding genotoxicity substance and those correspond to serial No. 1666, 1667)	Not solid at ordinary temperature and pressure	proper dose

*Those which apply to serial No. 1666 (Additives listed in Appended Table 1 of Regulations for Enforcement of the Food Sanitation Act (Order of the Ministry of Health and Welfare No. 23, 1948) or the List of Existing Food Additives (Public Notice of the Ministry of Health and Welfare No.120)) and those which apply to polycyclic aromatic hydrocarbon listed individually are excluded from the above reorganizing.

2. Reorganizing polymer-state additives

Polymer-state additives are reorganized into the following 4 types and listed in Table 2.

On the other hand, solid polymers with more than 1000 molecular weight other than below are listed as usual in Table 1 as base materials.

(1) Polymers with more than 50% polymers in the total of ethylene glycol, propylene glycol, and/or glycerol (more than 4 polymerization degree) (excluding substances listed in Table 1 as “3b polymer mainly composed of carbamate bonds”, which is solid at normal temperature and pressure).

→ Each is listed in Table 2.

Exception：Polymers listed in Table 1 as “3b polymer mainly composed of carbamate bonds” , with more than 50% polymers in the total of ethylene glycol, propylene glycol, and/or glycerol, which is solid at normal temperature and pressure, fall under base materials.

substance name (example)：

「ethoxylated ○○」

「ethoxylated and/or propoxylated ○○」

「reaction product of ethoxylated ○○ and ▲▲」

「reaction product of polymer mainly composed of glycerol and ▲▲」

(2) polymer with a molecular weight of less than 1000

→ Each is listed in Table 2.

substance name (example)：

「reaction product of ○○ and △△（Mw<1000）」

「○○ homopolymer, ▲▲-processed（Mw<1000）」

「polymer mainly composed of ○○, △△（Mw<1000）」

「polymer mainly composed of ○○, △△, ▲▲-processed（Mw<1000）」

(3) Polymer with a specific functional group and the group has a particular effect on base material. (Mw≥1,000) (excluding substances in Table 1)

→ Each is listed in Table 2.

substance name (example)：

「reaction product of ○○ and △△」

「○○ homopolymer, ▲▲-processed」

「polymer mainly composed of ○○, △△」

「polymer mainly composed of ○○, △△, ▲▲-processed」

(4) polymer with over 1,000 molecular weight excluding (1), (3) and which is solid at normal temperature and pressure

→These are all listed in Table 2. (serial No. 1667)

→ Use limit is proper dose in all polymer group.

Substance name (draft):

Serial No. 1667：“polymer (Mw≥1000) listed in Table 1 (excluding Polymer Group 5), or block polymer (or graft polymer) which consist of polymer (Mw≥1000) listed in Table 1 (excluding Polymer Group 5) and ethyleneglycol and/or propyleneglycol .”

Requirements（draft）:

Not solid at ordinary temperature and pressure

The sum of ethyleneglycol and/or propyleneglycol condensate (EO, PO≥4): Not less than 50% in the polymer components.

【July 7, 2022】

1. Base materials for which polymer class (former name: synthetic resin category) is changed through reorganizing

- Cases which change to polymer group 3 are added in special notes in polymer class 2c.

"Polymers with 2c polymer composed of styrenes as the main monomer" in the "20220426 New draft of Table 1" was reorganized as a summary of polymers which fall under "54. Polystyrene" in the former reorganizing draft. Therefore, some of the polymers are in a different polymer class from the former reorganizing draft. Polymer group 3 is applied to polymers with more than 0.1% water absorption of those which fall under 2c. Specifically, polymer in which the total amount of acrylic acid, acrylonitrile, N-phenyl-maleimide, maleic acid, methacrylic acid is 10% or more as the components of the polymer, is classified as Polymer Group 3.

(*Acrylic acid (including ammonium salt) will be added as an optional substance of 2c.)

2. Reorganizing chemical compounds with silicon as a main component

Classification of chemical compounds with silicon as a main component can be considered as below depending on the property and usage of the substance. It is therefore necessary to judge according to the actual status of use, etc. of each business.

(1) Materials other than synthetic resin: no need of submitting application

- Rubber

Polymers mainly with siloxane bond (silicone) with rubber elasticity apply to silicone rubber and they are not included in Positive List.

(Reference) Definition of sclerotic silicone resin (Silicone Industry Association of Japan)
https://www.siaj.jp/ja/pdf/CurableSiliconeResinDefinition.pdf

- Inorganic substances

"Silicon oxide (SiO2)" and "silicon oxide aggregates (silica, glass)" are inorganic substances and they are not included in Positive List. Reaction products (surface processing, etc.) of "silicon oxide aggregates (silica, glass)" and organic substances are the chemical modification of inorganic substances and they are not included in Positive List. Reaction products of inorganic silicon compounds other than the above and organic chemical compounds in molecular level are organic chemical compounds and they are needed to be listed in Positive List.

- Coating agents

There are cases where oil solution such as silicone oil, etc. is coated on the surface of materials. If the substance is bound to the surface of synthetic resin in the stage of final products, it falls under "coating

agents” written in Slide 5 of the guide to submitting application about the new draft of the Positive List and is not included in Positive List.

(2) Substances of synthetic resin materials: it is necessary to submit opinions with detailed information based on the state of use (*added on September 30, 2022: opinion soliciting finished).

・Base materials

Polymer with more than 1000 molecular weight and solid in general（excluding materials which are considered that each risk management is appropriate as additive.）

・Additives

(1) When molecular weight is less than 1000, explain that it is a low molecular organic substance satisfying all of ①,② as follows.

①It changes the base material chemically or physically

②It remains in the base material without chemical reaction.

(2) When molecular weight is more than 1000, in addition to (1)①,②, explain that it is a material corresponding to any of the following.

③The thing which is liquid at normal temperature and pressure

④The functional group shows a special effect for base material having a specific functional group (molecular weight around 2000 are used as an indication)

3. Polymers of ethylene glycol and propylene glycol

- [Additives] in Slide 7 of the guide to submitting application about the new draft of the Positive List are newly reorganized.

Polyethylene glycol (PEG), polypropylene glycol (PPG) and polyglycerol (PGL) are managed as additives regardless of molecular weight. These substances which are end-treated with alcohol, etc. are handled in the same way.

On the other hand, as polymers which contain PEG, PPG and/or PGL with more than 1000 molecular weight as components exist, they are reorganized as below.

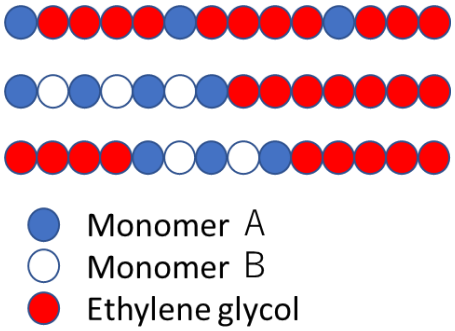
(1)[Substances which fall under additives]

Polymers with more than 50% polymers in the total of ethylene glycol, propylene glycol, and/or glycerol (more than 4 polymerization degree)

example：ethylene glycol homopolymer, propylene glycol homopolymer, polymer mainly composed of ethylene glycol and/or propylene glycol, glycerol homopolymer, ethoxylated ○○, propoxylated ○○、glycerol homopolymer, ○○-ether, etc.

【Substances which fall under additives】
Substance name：ethoxylated ○○

Satisfying all as follows.
- Polymers with more than 4 polymerization degree
- Polymers with more than 50% polymers in the total of ethylene glycol



(2) [Substances which fall under base materials]

Substances other than (1). If substances contain PEG and PPG with more than 1000 molecular weight as components, "ethyleneglycol or oxirane (including condensate Mw≥1000)" and "propyleneglycol or 2-methyloxirane (including condensate Mw≥1000)" are written in requirements. As they must be separated from (1) [Substances which fall under additives], a limit is added to the requirements - "Condensate (EO≥4): Less than 50% in the polymer components.".

4. Contamination of coating agent in final products when timber offcuts coated with an agent are used as a low material.

Coating agent which is expected to be contaminated is handled as an impurity contained in base material. As it falls under "substances that are not intended to remain in the final product," it is not included in Positive List. As the contamination of the coating agent can be expected from the timber offcuts generated in a factory, it is necessary to manage appropriately taking into account the type and contamination amount of the coating agent from the viewpoint of preventing the occurrence of food sanitation hazards.

5. Serial No. 756 "fatty acid (C=8-28) (including sodium, magnesium, aluminum, potassium, calcium, iron, ammonium salt)

As it was found that substances which do not fall under serial No. 1666 exist in "fatty acid (C=8-28) (including sodium, magnesium, aluminum, potassium, calcium, iron, ammonium salt)," serial No. 756 is modified and managed by writing in Table 2 as "fatty acid (C=8-28) (including sodium, magnesium, aluminum, potassium, calcium, iron, ammonium salt) (excluding those correspond to serial No. 1666).