

November 30, 2023  
Amendment: September 27, 2024

To: Heads of all prefectures, cities with health centers, and special wards

From : Director-General of Public Health Bureau,  
Ministry of Health, Labour and Welfare (MHLW)  
(Official seal omitted)

Partial amendment of the Specifications and Standards for Foods, Food  
Additives, Etc.

The public notice “Matters on Partially Amending the Specifications and Standards for Foods, Food Additives, Etc.” (Public Notice of the MHLW No.324 of 2023) was published today and thereby the public notice “Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No.370 of 1959; ‘the Public Notice No.370’)” was amended partially.

The purport of the amendment is as follows. You are asked to thoroughly inform your relevant parties of these matters, and make sure that this notice is properly implemented.

Details

I. Purport

For substances (excluding substances chemically modified from the substances; the same applies hereinafter) as raw materials of the material (meaning synthetic resin; the same applies hereinafter) specified by Cabinet Order under paragraph (3) of Article 18 of the Food Sanitation Act (“the Act”), the quantity allowed to be contained in apparatus, or containers and packaging produced using the substances; or the quantity allowed to be eluted or seep out into food from apparatus, or containers and packaging must be that specified in the standards provided in paragraph (1) of Article 18 of the Act. The standards are specified in Appended Table 1 of the Public

Notice No.370 (“the Positive List”) pursuant to the public notice “Matters on Partially Amending the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the MHLW No.196 of 2020; ‘the Public Notice No.196’)” and the standards have been applied since June 1, 2020, the enforcement date of the Act Partially Amending the Food Sanitation Act, Etc. (Act No. 46 of 2018) (“the enforcement date for Act No. 46 of 2018”). However, transitional measures were set under the Public Notice No.196: when products similar to apparatus, or containers and packaging that have been sold, manufactured or imported for the purpose of marketing, or used in business since the enforcement date for Act No. 46 of 2018 are manufactured or imported for the purpose of marketing until the date after five years from the enforcement date (May 31, 2025), synthetic resin used in apparatus, or containers and packaging as their raw materials can be considered to be those listed in the Positive List.

It was decided that before the end of the period of the transitional measures, for substances having been distributed in the marketplace before the enforcement date for Act No. 46 of 2018 as raw materials of apparatus, or containers and packaging, the Positive List in the Public Notice No.370 should be finalized. This time, the Positive List was finalized and consequently the Public Notice No.370 was amended.

## II. Main Points

Scope of Item 8 of A. *General Specifications for Apparatus, or Containers and Packaging; or Their Raw Materials* of Chapter III. *Apparatus, and Containers and Packaging* of the Public Notice No.370 (including Positive List) was organized as follows.

- (1) Table 1 of Appended Table 1 lists polymers in synthetic resins whose molecular weight is 1,000 or more and that are solid at ordinary temperature and pressure (“base materials”). The columns of “Food Category,” “Maximum Temperature,” and “Requirements” were deleted.
- (2) Table 2 of Appended Table 1 lists low molecular organic substances with a molecular weight of less than 1,000 that change the physical or chemical properties of base materials and that are used with intent to remain in the final product without chemical reaction. (These substances are referred to as “additive.”)

Even for substances with a molecular weight of 1,000 or more, those

being liquid at ordinary temperature and pressure; or those having specific functional groups and whose functional groups exhibit characteristic effects on base materials are listed in Table 2 as additives.

- (3) According to the organization of the scope to manage the Positive List for synthetic resin, necessary revisions including the deletion of substances, the integration of substance name, and the change of restrictions were done.

The amended Positive List is available at the MHLW's website by March 31, 2024. On or after April 1, 2024, it will be available at the Consumer Affairs Agency's website.\*

\* The website at which the Positive List is uploaded will change according to the transfer of the regulatory activities on food hygiene by the enforcement of the Act on Coordinating the Relevant Acts to Enhance the Functionality of Government Administration Relevant to Environmental Health and Other Such Matters (Act No. 36 of 2023).

### III. Notes on Operation

1. Matters on the Public Notice No.370 (A. *General Specifications for Apparatus, or Containers and Packaging; or Their Raw Materials of Chapter III. Apparatus, and Containers and Packaging*)

#### A. Scope of the Positive List

- (1) For substances contained in raw materials of synthetic resin used in apparatus, or containers and packaging that are composed of multiple layers, the scope of the Positive List is the following.
- i. When all layers are made of synthetic resin, substances contained in the layers not directly contact to food are out of the scope of the Positive List when the layers are processed so that those substances are unlikely to be eluted or seep out into food at levels exceeding the quantity specified by the Minister of Health, Labour and Welfare as unlikely to cause harm to human health.
  - ii. When the food contact layer is made of other than synthetic resin and there are layers made of synthetic resin in the parts not directly contact to food, the synthetic resin layers are out of the

scope of the Positive List.

- iii. When the food contact layer is made of synthetic resin and there are layer(s) made of other than synthetic resin in the parts not directly contact to food, only substances in the synthetic resin layers between the non-synthetic resin layer and the food contact layer are the scope of the Positive List. However, there is a case that such substance is out of the scope of the Positive List according to provisions in the proviso in paragraph (3) of Article 18 of the Act.

(2) The following substances given in i. through v. are out of the scope of the Positive List according to the organization of scope of the Positive List. The substances that are out of the scope of the Positive List can be used in apparatus, or containers and packaging as before even if they are not listed in the Positive List. In this case, business operators must observe their conventional management and must ensure the safety on its own responsibility. For such substances, if some effects on human health revealed as new findings, appropriate standards must be established in the Public Notice No. 370 as required.

i. Substances fall under raw materials of other than synthetic resins e.g.:

- ✓ Elastic bodies without thermoplasticity (substances that are raw materials of rubber)
- ✓ Inorganic substances
- ✓ Natural products (extracts or distillates such as rosins and naphtha, excluding substances that are obtained by refining only specific components and the related substance groups thereof)
- ✓ Chemical reactants of natural products (excluding chemically modified cellulose)

ii. Substances used for the purpose of being released from apparatus, or containers and packaging, and of migrating into food and acting in or on that food

iii. Liquid or powdered substances to be adhered on the surface of raw materials of apparatus, or containers and packaging for the purpose of antistatic, antifog, etc.

iv. Substances chemically modified from the substances contained in raw materials

v. Substances that are not intended to remain in the final product

B. Item 8 of A. *General Specifications for Apparatus, or Containers and Packaging; or Their Raw Materials* of Chapter III: *Apparatus, and Containers and Packaging* of the Public Notice No.370

(1) The substance “This does not apply when the substances are used as colorants” means that, among additives, substances used only for the purpose of coloring are not subject to being listed in the Table 2 of Appended Table 1, provided that the apparatus, or containers and packaging in which the substances are used satisfies provisions of item 5 of A. *General Specifications for Apparatus, and Containers and Packaging; or Their Raw Materials* of Chapter III: *Apparatus, and Containers and Packaging* of the Public Notice No.370. When the substances are used other than the purpose of coloring, they are subject to being listed in the Table 2.

C. Item 8 (1) of A. of Chapter III

(1) For monomers, etc. constituting base materials specified in Table 1 of Appended Table 1, please refer to the notice “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, MHLW, November 30, 2023).”

(2) For block polymers, when the molecular weight of a polymer unit being a part of the block polymer is 1,000 or more, such polymer unit is considered as base material by the unit. For graft polymers, when the molecular weight of a trunk polymer or branch polymer being a part of the graft polymer is 1,000 or more, such trunk polymer or branch polymer is considered as base material by the polymer.

D. Item 8 (2) of A. of Chapter III

(1) Base materials are categorized into five polymer groups in the “Polymer Group” column of Table 1 of Appended Table 1 based on their

distribution status and characteristics of synthetic resin.

- i. Substances categorized in as “1” in the “Polymer Group” column are polymers with 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 (excluding those correspond to polymer groups 2 and 4).
- ii. Of polymers categorized as “1 or 3,” substances with a glass transition temperature or ball pressure temperature of 150°C or higher (excluding those correspond to polymer groups 2 and 4) fall under polymer group 1; and substances with both glass transition temperature and ball pressure temperature of lower than 150°C (excluding those correspond to polymer groups 2 and 4) fall under polymer group 3.
- iii. Substances categorized as “2” are polymers composed of hydrocarbons as the main monomer (excluding those correspond to polymer group 4).
- iv. Substances categorized as “2 or 3” are polymers that are 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 fall under polymer group 3; and substances that are other than those categorized in group 3 fall under polymer group 2.
- v. Substances categorized as “3” are polymers with both glass transition temperature and ball pressure temperature less than 150°C (excluding those correspond to polymer groups 2 and 4).
- vi. Substances categorized as “4” are polymers composed of chlorinated ethylene as the main monomer.
- vii. Substances categorized as “4 or 5” are 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 fall under polymer group 4;

and substances other than those categorized in group 4 fall under polymer group 5.

- (2) Use limit by polymer group given in Table 2 of Appended Table 1 should be applied as the allowable ratio of weight of additives to total weight of raw materials (including synthetic resin and other materials than synthetic resin) used for apparatus, or containers and packaging.
- (3) When multiple base materials are mixed or bonded, the use limit by polymer group of substances under “Substance Name” column should be the limit calculated proportionally from the weight ratio of the base materials by each group. However, when the weight ratio of a base material in one group exceeds 50%, the use limit for the polymer group of the base material can be applied to the resulting polymer as the maximum limit (when multiple base materials are included in one group, sum all the weight of the base materials). The polymer produced by mixing or bonding multiple base materials includes block polymer or graft polymer.
- (4) When one or more of the following synthetic resins are mixed, the mixture can be considered to satisfy the use limit as the substance contained in raw materials listed in Appended Table 1.
  - a. synthetic resins satisfying use limit by applying the value calculated from the weight ratio of base materials by each polymer group
  - b. synthetic resins satisfying particular requirements in the “Requirements” column
- (5) For “Polymer used for coating that involves chemical reaction during film formation,” note that the use limit by polymer group of substances in “Substance Name” column differs according to whether a glass transition temperature or ball pressure temperature of the polymer is 150°C or higher, or the polymer has a cross-linked structure and its melting point is 150°C or higher.
- (6) When a substance listed in the substance name column of Table 2 of Appended Table 1 is described as “polymer mainly composed of XXX”, the substance must contain more than 98% of XXX (the sum of XXX if the number of XXX is more than one; e.g., “polymer mainly composed of XXX/XXX”) as a mass percentage of the constituent components of the polymer. The portion of less than 2% does not need

to be indicated in the substance name column.

- (7) The case where requirements are particularly specified in the “Requirements” column refers to the case where there are descriptions regarding the following items: the use temperature, target food, thickness of material, presence or absence of direct contact with food, and the sum of the amounts used. For the details and other requirements specified in the “Requirements” column, see the notice “The case where requirements are particularly specified in the ‘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).”
- (8) For monomers constituting “polymer listed in Table 1” specified in serial No. 108 (1) and 108 (2) in Table 2 of Appended Table 1, see the notice “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, MHLW, November 30, 2023).”

#### IV. Effective Date

This notice will become effective on June 1, 2025. However, when apparatus, or containers and packaging that are similar to those that were sold, manufactured or imported for the purpose of marketing, or used in business before the enforcement date for Act No. 46 of 2018 are manufactured or imported for the purpose of marketing, or used in business at the time of the applicability date of the public notice, substances as raw materials of synthetic resin(s) that are used in the products can be considered to be those listed in Appended Table 1. “The apparatus, or containers and packaging that are similar to those,” used to explain the transition measures, refers to products (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 the enforcement date for Act No. 46 of 2018 within the range in which they were used in the apparatus, or containers and packaging; or refer to the imports of such apparatus, or containers and packaging. Therefore, it needs to be explained that, by showing records of manufacturing or import, use amount



of additive is within the range in which they were used in apparatus, or containers and packaging because the cases such as the following are not subject to transitional measures.

- ✓ the case where an additive is used in a base material in which the additive has not been used
- ✓ the case where the use amount of an additive is increased to an amount exceeding the level at which the additive has been used

Until May 31, 2025, Positive List System is implemented according to the notice “Preparations of related public notices following the enforcement of paragraph (3) of Article 18 of the Food Sanitation Act amended based on the Act Partially Amending the Food Sanitation Act, Etc. (Notice of Councillor for Environmental Health and Food Safety, Minister’s Secretariat, MHLW, May 1, 2020; final amendment: Notice of Councillor for Environmental Health and Food Safety, Minister’s Secretariat, MHLW, August 5, 2021; "the Notice No.0501-6")

#### V. Amendments of Related Notices

1. The Notice of No.0501-6 will be amended as stated in the accompanying sheet as of the effective date. In particular, according to the application of the amended Public Notice No.370, items on the Public Notice No.196 will be deleted and other items will be amended.
2. The notice “Preparations of related public notices following the enforcement of paragraph (3) of Article 18 of the Food Sanitation Act amended based on the Act Partially Amending the Food Sanitation Act, Etc. (Notice of Councillor for Environmental Health and Food Safety, Minister’s Secretariat, MHLW, April 28, 2020)” is repealed by this notice (Notice No.1130-4, November 30, 2023).”

#### VI. Others

1. Regardless of listing or non-listing in the Positive List, note that Article 16 of the Act specifies that apparatus, or containers and packaging that contain or bear toxic or harmful substances and are likely to cause harm to human health, or apparatus, or containers and packaging that come into contact with food or food additives and have a harmful effect on them

and that are likely to cause harm to human health must not be sold, manufactured or imported for the purpose of sale, or used in business.

2. For the details of current Positive List specified by the Public Notice No.196, the related documents are made available for public inspection at Food Safety Standards and Evaluation Division, Public Health Bureau, MHLW, and available on the MHLW's website. From April 1, 2024, according to the transfer of regulatory activities on food hygiene by enforcement of the Act on Coordinating the Relevant Acts to Enhance the Functionality of Government Administration Relevant to Environmental Health and Other Such Matters, the documents will be made available for public inspection at Consumer Affairs Agency (CAA) and available on the CAA's website.