Namashoku No. 0501-6
May 1, 2020

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

From： Councillor for Environmental Health and Food Safety, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW)
(Official seal omitted)

Preparations of related public notices following the enforcement of paragraph (3) of Article 18 of the Amended Food Sanitation Act amended by the Act Partially Amending the Food Sanitation Act, Etc.

Article 18, Paragraph (3) of the Amended Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as "the New Act") amended by the Act Partially Amending the Food Sanitation Act, Etc. (Act No. 46 of 2018; hereinafter referred to as "the Amendment Act") is enforced on June 1, 2020 pursuant to the Cabinet Order Establishing Effective Date of the Act Partially Amending the Food Sanitation Act, Etc. (Cabinet Order No. 121 of 2019). Following the enforcement of the Amendment Act, the Matters on Partially Amending the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the MHLW No. 196 of 2020) and the Matters on Establishing the Quantity That the Minister of Health, Labour and Welfare Specifies as the Level That Is Unlikely to Cause Harm to Human Health, Which Is Prescribed in Article 18, the Proviso of Paragraph (3) of the Food Sanitation Act (Public Notice of the MHLW No. 195 of 2020; hereinafter referred to as "the Notice on the Level Unlikely to Cause Harm") were made public on April 28, 2020. The purport, main points, and notes on operation are as follows. You are asked to thoroughly inform your relevant parties of these matters, and make sure that these public notices are properly implemented.

Details

I. Purport

The Amendment Act required the quantity allowed to be contained in utensils* or containers and packaging (UCP) or the quantity allowed to elute or seep out from UCP into food—specified by each substance (excluding substances generated by chemical change of such substances) constituting the material categories specified

by the Order for Enforcement of the Food Sanitation Act (the Cabinet Order) based on Article 18, paragraph (3) of the New Act (meaning synthetic resin; the same shall apply hereinafter)—to be those provided by the provisions of Article 18, paragraph (1) of the Food Sanitation Act (hereinafter referred to as "the Act"). For synthetic resin contained in UCP made from synthetic resin, and synthetic resin contained in UCP that are made from other materials and that have a synthetic resin layer as a food- or food additive-contact surface (these two types of UCP are hereinafter referred to as "UCP made from synthetic resin"), the Amendment Act also required the Positive List System to be introduced. Based on the background, the specifications for UCP made from synthetic resin were specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959; hereinafter referred to as "the Notice on the Specifications and Standards").

* The term “Utensils” corresponds to “Apparatus” in the Food Sanitation Act, a translation of 食品衛生法, available at the following URL.
http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=01&dn=1&co=01&ia=03&ja=04&x=0&y=0&ky=%E9%A3%9F%E5%93%81%E8%A1%9B%E7%94%9F%E6%B3%95&page=1

Also, Article 18, the proviso in paragraph (3) of the New Act specifies that even substances not listed in the Positive List that was specified in the Notice on the Specifications and Standards can be used in UCP as raw materials for synthetic resins when the synthetic resins are not used in a food contact part of UCP and the UCP have been processed so that the substances do not elute or seep out into food at a quantity exceeding the level that the Minister of Health, Labour and Welfare specifies as unlikely to cause harm to human health (hereinafter referred to as “the level unlikely to cause harm”). Therefore, the level unlikely to cause harm was established this time.

Note that the scope of substances applied to Chapter III. “Utensils, Containers, and Packaging,” Section D. “Specifications by Material Type for Utensils, Containers, and Packaging or Their Raw Materials,” 2 (2) of the Notice on the Specifications and Standards remains unchanged in spite of names of substances given in the column under the heading “Substance” in Table 1 (1) and (2) of Appended Table 1.

II. Main points

(1) The Notice on the Specifications and Standards

As specifications for UCP made from synthetic resin, specifications for "substances constituting the material categories specified by the Cabinet Order," which is provided in Article 18, paragraph (3) of the New Act, were established in Chapter III. "Utensils, Containers, and Packaging," Section A. "General Specifications for Utensils, Containers, and Packaging or Their Raw Materials" of the Notice on the Specifications and Standards.

A. Specifications for each substance were specified in Appended Table 1.
B. For substances that are listed in Appended Table 1 and constitute synthetic resin, regulations were established.

The amended sections of the Notice on the Specifications and Standards, for which descriptions in an official gazette were omitted, are available at the following MHLW website (as of April 28, 2020).
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/kigu/index_00003.html

(2) The Notice on the Level Unlikely to Cause Harm

The level was established at 0.01mg/kg as the concentration in food.

III. Date of Application

The public notices mentioned above shall come into force on June 1, 2020.

Concerning the Notice on the Specifications and Standards, when products similar to UCP that have been sold, manufactured or imported for the purpose of marketing, and used in business before June 1, 2020 (hereinafter referred to as "the products under transitional measures") are manufactured or imported for the purpose of marketing until the date (May 31, 2025) after five years from the date of application, the substances used as raw materials of synthetic resin in the products can be considered to be those listed in Appended Table 1. The term "products similar to" used under the transitional measures means the UCP that are manufactured using substances (raw materials of synthetic resin) that have been used in the UCP sold, manufactured or imported for the purpose of marketing, or used in business before June 1, 2020 within the range in which the substances have been used; or means the imported UCP that are manufactured using substances within such range. Therefore, the following cases are not subjected to the transitional measures:

– in case an additive is used in the base polymers categorized in the synthetic resin groups in which the additive has never been used.
– in case the use amount of an additive is increased to the amount exceeding the

level to which the additive has been used.

– in case records of manufacturing, import, etc. cannot prove that the use range of a substance is within the range in which the substance has been used.

IV. Notes on operation

1. The Notice on the Specifications and Standards (Chapter III. "Utensils and Containers and Packaging," Section A. "General Specification for Utensils or Containers and Packaging or Their Raw Materials")

A. Item 8 of Chapter III, Section A

(1) The substances listed in Appended Table 1 are specified as those used with the intention to remain in final products. Base polymers are specified in Table 1 (1) through (3) of Appended Table 1 and additives are specified in Table 2 of the same Appended Table.

(2) When base polymers specified in Table 1 (1) or (2) of Appended Table 1 are mixed with one another, if a new polymer is generated by chemical reaction, the generated polymer is required to be specified in Table 1 (1) or (2), separately from each polymer used. When base polymers in Table 1 (1) are mixed with base polymers in Table 1 (2), the resulting mixture is not allowed to be used for purposes other than coating.

(3) Substances with a polymer structure that are not categorized as base polymers (in general, those that cannot be formed by alone as the structural body of UCP) and that are intended to be used as additives are required to be controlled as additives in Table 2 of Appended Table 1.

(4) Additives intended to be used only for the purpose of coloring are not specified in Table 2 of Appended Table 1 on the premise that the UCP in which these additives are used meet Chapter III. "Utensils and Containers and Packaging," Section A. "General Specification for Utensils or Containers and Packaging or Their Raw Materials," the provisions of item 5 of the Notice on the Specifications and Standards. When used for purposes other than coloring, additives are required to be specified in Table 2 of Appended Table 1 according to the purposes.

B. Item 8 (1) of Chapter III, Section A

(1) Catalysts and polymerization aids (including polymerization initiators, chain transfer agents, and end capping agents) that are used in manufacturing base polymers are not controlled as the targets of the Positive List System because they are intended to aid the polymerization reaction but not intended to be incorporated into the structure of base polymers. Also, substances that unintentionally occur in the manufacturing process—including impurities in monomers as raw materials of base polymers and impurities in additives—are not controlled as the targets of the Positive List System. These substances that are not intended to remain in final products are required to be controlled, as necessary, by establishing specifications and other necessary matters in the Notice on the Specifications and Standards.

(2) Food categories given in Table 1 (1) and (2) of Appended Table1 are the same as those defined in Guidelines for Risk Assessment of Food Apparatus, Containers and Packaging (the decision by the Food Safety Commission of Japan on May 28, 2019; hereinafter referred to as "Assessment Guidelines").

i. "Acidic foods" refers to foods in or on which the pH is 4.6 or less.
ii. "Fats/oils and fatty/oily foods" refers to foods in or on which the fat or oil content is 20% or more.
iii. "Milk and milk products" refers to foods that are specified in Article 2 of the Ministerial Ordinance of Milk and Milk Products Concerning Compositional Standards, Etc. (Ordinance of the Ministry of Health and Welfare No. 52 of 1951) and in or on which the fat or oil content is below 20%.
iv. "Alcoholic beverages" refers to drinks that contains 1% or more alcohol by volume.
v. "Other foods" refers to foods that are not categorized in i. through iv. above.

(3) When base polymers in Table 1 (1) or (2) of Appended Table 1 are mixed, the resulting mixture is allowed to be used only for food categories common to corresponding permissible categories specified—in the column under the heading "Food Category"—for each base polymers before mixing. In this case, the lowest one of the temperatures specified in the column under the heading "Maximum Temperature" for each base polymers before mixing is applied as the maximum temperature thereof.

C. Item 8 (2) of Chapter III, Section A

(1) Base polymers must be composed of substances listed in the column under the heading "Substance" in Table 1 (1) or (2) of Appended Table 1. However, when a base polymer contains more than 98% of substances listed in Table 1 (1) or (2) and the remaining component part of the base polymer is composed of substances listed in Table 1 (3) of the same Appended Table, the base polymer is not required to be newly specified individually in Table 1 (1) or (2).

D. Item 8 (3) of Chapter III, Section A

(1) "Coating" refers to a film that is made from painting agents or similar coating materials and that is in a layer form formed or deposited on a substrate. It is composed of base polymers and additives that are as necessary added to them.

E. Item 8 (4) of Chapter III, Section A

(1) Base polymers are categorized into seven groups according to the actual use and property of each synthetic resin. Each synthetic resin group (hereinafter referred to as "Group") of Table 1 (1) and (2) of Appended Table 1 is basically characterized as follows: Groups 1 includes base polymers that are high heat-resistant. These base polymers either have a cross-linked structure and a melting point of not less than 150°C; or meet a temperature requirement (any of temperatures including a glass-transition temperature, a ball pressure temperature, and a deflection temperature under load) of not less than 150°C. Groups 2 and 3 were set to categorize base polymers according to migration tendency of additives. Group 2 incudes base polymers with a water absorption rate of not more than 0.1%. Group 3 includes those with a water absorption rate of more than 0.1%. Determination of the water absorption rate should be based on the Japanese Industrial Standards. Basically, base polymers are categorized according to the above. In some cases, however, base polymers are categorized based on a comprehensive judgement concerning the actual use and property of each synthetic resin. For example, even in a case that a substance falls into any of Groups 5 through 7, if the use of it is limited and the consumption factor—a factor derived by assuming the ratio of amount of a meal that come into contact with specific types of materials of UCP—is extremely low, the substance may be actually categorized into Group 1, 2, or 3. (For the details of categorization, see Appendix 2, Table 4 of the Assessment Guidelines.)

(2) When synthetic resins are mixed, the limit by synthetic resin group given

in Table 2 of Appended Table 1 for the additive used is applied according to the amount of each resin used before mixing. However, when specific instructions are given in the column under the heading "Requirements," these instructions must also be applied, notwithstanding the corresponding use limit.

(3) The figures given in the column under the heading "Use Limit by Synthetic Resin Group" in Table 2 of Appended Table 1 show the percentage by weight in the total amount of a base polymer and an additive.

(4) The "thickness" given in the column under the heading "Requirements" in Table 2 of Appended Table 1 refers to the length of synthetic resin or resin layer to which the targeted additive is added, in vertical direction to the food or food additive contact surface.

F. Other

(1) "Coating agents" refers to liquid- or powder-form substances that are adhered on the surface of synthetic resin, mainly for the purposes of antistatic and antifog. The agents are specified in Table 2 of Appended Table 1. The use levels as coating agents are specified as a quantity per unit of area.

2. The Notice on the Level Unlikely to Cause Harm
(Related to Article 18 Paragraph (3) of the New Act)

A. The concentration in food, 0.01mg/kg, can be considered to be 0.01mg/L as the concentration in a food-simulating solvent.

B. To confirm by using a food-simulating solvent that a substance does not elute or seep out into food exceeding the level unlikely to cause harm, basically follow the migration testing provided in Appendix 2 of the Assessment Guideline.

C. To confirm by using the migration tests that a substance does not elute or seep out into food exceeding the level unlikely to cause harm, use an analytical method whose detection limit is not more than the concentration that are equivalent to the level unlikely to cause harm.

D. To apply the provisions in Article 18, the proviso of paragraph (3) of the New Act to a substance used in a non-food contact part of UCP (hereinafter referred to as "substance used in a non-food contact surface"), the migration testing is not necessarily mandatory, if it is possible to obtain a method to explain theoretically based on structures of UCP, substances to which the provisions are applied, the quantity of the substances to be added, etc.

E. Even if the quantity derived from migration testing results, etc. for a substance used in a non-food contact surface is not more than the level unlikely to cause harm, in case it is determined that the substance has genotoxic potential based on considerations from available information and results of genotoxicity tests, etc., the substance is not allowed to be used because it is likely to cause harm to human health.

IV. Other

(1) Adding to Appended Table 1 stipulated in the Notice on the Specifications and Standards, Japanese/English bilingual version of Appended Table 1 including English substance name are available at the following MHLW website (as of April 28, 2020).

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/kigu/index_00003.html

(2) During the period of the transitional measures concerning the Notice on the Specifications and Standards, the relevant business operators need to confirm that UCP that are treated as the products under transitional measures will conform to the Notice on the Specifications and Standards after the end of the transitional measures. If additions to Appended Table 1 or corrections of information in the same Table is necessary, the relevant business operators need to notify the MHLW of the necessary information. If the replacement of raw materials of UCP is necessary, the relevant business operators need to replace them appropriately. How to notify the information, etc. are provided on the MHLW website.

(3) After the enforcement of the Positive List System, when substances are first used in UCP or substances are used out of range of the specifications given in Appended Table 1, the business operators handling them must be thoroughly informed that they must follow the way, which is separately provided, to file the application documents required for the amendment to the public notice.