

May 1, 2020
Final amendment: November 30, 2023
Effective Date: June 1, 2025

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 Food Sanitation Act amended based on the Act Partially Amending the Food Sanitation Act, Etc.

Article 18, Paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947; the amended Food Sanitation Act is hereinafter referred to as "the New Act") amended based on 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 Amendment Act (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 Public 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 this notice is properly implemented.

Note

I. Purport

The Amendment Act required the quantity allowed to be contained in apparatus, or containers and packaging or the quantity allowed to elute or seep out from apparatus, or containers and packaging into food—specified by each substance (excluding substances generated by chemical change of such substances) as raw materials of materials specified by the Cabinet Order based on Article 18, paragraph (3) of the New Act (meaning synthetic resin; the same applies hereinafter)—to be those specified in the specifications provided by the provisions of Article 18, paragraph (1) of the Food Sanitation Act (hereinafter referred to as "the Act"). The specifications 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 Public Notice No.370").

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 Public Notice No.370 can be used in apparatus, or containers and packaging when the synthetic resins are not used in a food contact part of apparatus, or containers and packaging and the apparatus, or containers and packaging 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 recently established.

Note that the scope of substances applied to Item 2 (2) of D. *Specifications by Material Type for Apparatus, or Containers, and Packaging or Their Raw Materials* of Chapter III. *Apparatus, and Containers and Packaging* of the Public Notice No.370 remains unchanged in spite of names of substances listed in the "Substance Name" column in Table 1 of Appended Table 1.

II. Main Points

(1) Deleted

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

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

III. Effective Date

The notice comes into force on June 1, 2020.

IV. Notes on Operation

1. Deleted

2. The Public Notice on the Level Unlikely to Cause Harm

A. The concentration in food, 0.01mg/kg, may be considered to be 0.01mg/L as the concentration in a food simulants.

B. To confirm, by using a food simulants, that apparatus, or containers and packaging have been processed so that a substance does not elute or seep out into food exceeding the level unlikely to cause harm, basically follow the migration testing method, provided in Appendix 2 of the Guidelines for the Risk Assessment of Food Apparatus, and Containers and Packaging (Decision by the Food Safety Commission on May 28, 2019).

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 part not directly contact to food of apparatus, or containers and packaging (hereinafter referred to as “substance used in a surface not directly contact to food”), the migration testing is not necessarily mandatory, if it is possible to obtain a method to explain theoretically based on structures of apparatus, or containers and packaging, 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 surface not directly contact to food 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.

F. Even if the quantity derived from migration testing results, etc. for a substance used in a surface not directly contact to food is not more than the level unlikely to cause harm, pursuant to Article 16 of the New Act,

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 and have a harmful effect on them and that are likely to cause harm to human health must not be sold, produced or imported for the purpose of sale, or used in business.

V. Deleted