

The quantity specified by the Minister of Health, Labour and Welfare as the quantity that is unlikely harm to human health

The government of Japan will establish “the quantity specified by the Minister of Health, Labour and Welfare as the quantity that is unlikely harm to human health” for raw materials used for food utensils, containers, and packaging (UCP).

Summary

- The Act Partially Amending the Food Sanitation Act, etc. (Act No. 46 of 2018; hereinafter referred to as “the Amendment Act”), promulgated in June 2018, requires the Positive List (PL) system be established. Under this system, substances that are included in the raw materials of the material categories specified by the Cabinet Order (the targeted category: synthetic resin) shall have been evaluated as safe when used in UCP. By this amendment, “the quantity specified by the Minister of Health, Labour and Welfare as the quantity that is unlikely harm to human health” prescribed in the proviso of Paragraph (3) of Article 18 of the Food Sanitation Act amended by the Amendment Act (Act no.233 of 1947; hereinafter referred to as “the amended Food Sanitation Act”) will be established.
- Stipulations on the quantity will be promulgated in the winter of 2019 and enforced in the summer of 2020.

Outline of the stipulations

- Paragraph (3) of Article 18 of the amended Food Sanitation Act prescribes that the raw material of the material categories specified by the Cabinet Order (synthetic resin) shall be the substances listed in the PL; however, this shall not apply when substances are used in the part that does not contact with food and the substance not migrate into food with a quantity exceeding the quantity specified as being unlikely harm to human health. In this case, the substances not listed in the PL may be used for UCP.
- The Minister of Health, Labour and Welfare intends to decide the quantity that is unlikely harm to human health, which is prescribed in the proviso of paragraph (3) of Article 18 of the amended Food Sanitation Act, shall be 0.01 mg/kg in food based on the deliberations of the Committee on Utensils, Containers and Packaging of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council.
- The quantity migrated into food is calculated by multiplying the concentration of the food-simulating solvent by the factor (weight of food that contacts with UCP/amount of food-simulating solvent). This factor may be approximated to 1. Therefore, the quantity of migration into food (0.01mg/kg) may be considered to be 0.01mg/L as the concentration of

the food-simulating solvent.

Confirmation with food-simulating solvent shall be based on the migration test method provided in the Guideline for Assessment of the Effect of Food on Human Health Regarding Food Utensils, Containers and Packaging (issued by the Food Safety Commission of Japan on May 28, 2019).