

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

The government of Japan will revise the specifications and standards for apparatus, and containers and packaging (ACP).

Outline

Under Article 18, Paragraph (1) of the Food Sanitation Act (Act No.233 of 1947), the Prime Minister may establish specifications for ACP or the raw materials thereof to be served for the purpose of sale or to be used for business, or may establish the standards for the manufacturing methods thereof, by hearing the opinions of the Food Safety Standards Council. The specifications and standards are stipulated in the 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").

This time, the Consumer Affairs Agency (CAA) will partially revise "B. General Tests for Apparatus or Containers and Packaging," "C. Reagents and Test Solutions," "D. Specifications by Material Type for Apparatus or Containers and Packaging, or Their Raw Materials," and "E. Specifications by Application for Apparatus or Containers and Packaging" in "Chapter III: Apparatus, and Containers and Packaging" in the Public Notice No.370.

Details of Revision

B. General Tests for Apparatus or Containers and Packaging

- Delete the following test methods.
 - ✓ Xylene Solubility Substance Test
 - ✓ Strength Test
 - ✓ Heavy Metals Limit Test (Material Test)
 - ✓ Arsenic Limit Test (Material Test)
 - ✓ *n*-Hexane Extract Test

- Establish the Overall Migration Test as below.

Overall Migration Test

The Overall Migration Test is a method to measure the total amount of substances migrating from a sample into a food simulant.

Put 200–300 mL of the test solution into a platinum, quartz, or heat-resistant glass evaporating dish, previously dried at 105°C and weighed. (When heptane is used as a food simulant, put 200–300 mL of the test solution into an eggplant-shaped flask, and concentrate it to a volume of several milliliters under reduced pressure. Wash the flask twice with about 5 mL of heptane each time. Transfer the concentrated solution and washings into the evaporating dish.) Evaporate it to dryness on a water bath. Cover the dish with an aluminum foil with five 1-mm diameter holes and dry the residue at 105°C for 2 hours, and let it cool in a desiccator. After the residue cools down, remove the foil and measure the weight of the dish with the residue. Obtain the weight (a (mg)) of the residue by deducing the weight of the evaporation dish. Calculate the amount of the overall migration by the following formula:

$$[\text{Overall migration (mg/cm}^2)] = [(a - b) \times 2 \text{ (mL/cm}^2)] / [\text{Volume of collected test solution (mL)}]$$

b (mg): the blank value obtained using the food simulant of the same volume as the test solution

- Modify “Preparation Methods for the Test Solutions for Migration Tests” that are specified in B-15.
 - ✓ Compile the preparation methods for the test solutions used for the evaporation residue and for bisphenol A (including phenol and *p tert*-butylphenol) in the migration test in D, and incorporate them into B-15, which will be renumbered as B-12.
 - ✓ Incorporate the preparation methods for the test solution used for the overall migration test, which will be newly introduced, into B-15 to be renumbered.

C. Reagents and Test Solutions

Delete some reagents, solutions, and other reference materials that are not required to be specified any more.

D. Specifications by Material Type for Apparatus or Containers and

Packaging, or Their Raw Materials

- Transfer test methods that are specified in D to B.
- Set specifications for the overall migration in item 2 “Migration Specifications,” that will be newly set, in (1) “General Specifications” of 2 “Apparatus, or Containers and Packaging Made of Synthetic Resins” of D. (the newly set specifications will not be applied to synthetic-resin ACP for which individual specifications are specified).

E. Specifications by Application for Apparatus or Containers and Packaging

- Delete the specifications for the strength tests that are specified in (3)-(5) of 1 “Containers and Packaging Used for Food That Are Packed in Containers/Packaging and Sterilized by Autoclaving and Heating (Excluding canned foods or bottled foods).”
- Delete the specifications that are specified in 2 “Containers and Packaging Used for Soft Drinks (Excluding Fruit Juice as Raw Materials).”
- Delete the specifications for the materials that are specified in item 8 “Cups Used When Selling the Relevant Products” of (2) “Cup Vending Machines to Sell Pasteurized Fermented Milk Drinks” of 3 “Specifications for Apparatus used for Milk, Etc. (Referring to Milk and Milk Products as Well as Foods Using These as Principal Ingredients).”
- Delete specifications that are specified in 4 “Specifications for Containers and Packaging used for Milk, Etc. or the Raw Materials Thereof, and Standards for the Manufacturing Methods Thereof.”
- Delete the specifications for the materials that are specified in (3) “Containers” of 6 “Food Vending Machines (Limited to Those Having Structures for Which the Parts of the Machine Come into Direct Contact With Foods) and Containers Used to Sell the Food Through These Vending Machines.”
- Delete the specifications that are specified in (2) “Synthetic-resin ACP” of 7 “Specifications for Apparatus or Containers and Packaging to Carry

Undiluted Liquids of Soft Drinks in Cup Vending Machines or Fully Automatic Preparation Machines.”

This revision will be enforced within 2025.