

## **Amendment of the Specifications and Standards for Foods, Food Additives, Etc.**

The government of Japan will establish specifications and standards for Utensils, Containers and Packaging made of synthetic resins whose main component is polyethylene naphthalate (PEN).

### **1. Summary**

The Food Sanitation Act (in Article 18) authorizes the Minister of Health, Labour and Welfare to establish 1) specifications for food contact utensils, containers, and packaging, and their materials and 2) standards for the production methods of these products. The established specifications and standards appear in the Ministry of Health and Welfare Notification (No. 370, 1959), titled “Specifications and Standards for Food, Food Additives, Etc.”

When specifications or standards are established for food utensils, containers, or packaging based on Article 18, these products shall not be used or marketed unless they meet the standards or specifications.

In response to a request from the Minister, the Committee on Utensils, Containers and Packaging of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the establishment of specifications and standards for utensils, containers and packaging made of synthetic resins whose main component is PEN (polyethylene naphthalate). The conclusion of the committee is outlined below.

### **2. Outline of conclusion**

The Act specifies two types of specifications—general specifications and individual specifications—in Item 2 “Utensils, Containers and Packaging Made of Synthetic Resins” in Section D “Specifications for Utensils, Containers and Packaging According to Material” in Part 3 “Utensils, Containers and Packaging” in the Specifications and Standards for Food, Food Additives, Etc.

This time, the Ministry of Health, Labour and Welfare (“MHLW”) will newly establish individual specifications for the new category, “utensils, containers, and packaging made of synthetic resins whose main component is polyethylene naphthalate” (see Attachment).

## Attachment

### Part 3. Utensils, Containers and Packaging

#### D. Material Specifications

##### <Synthetic resins>

##### Individual specifications

##### Item 14. Polyethylene naphthalate resins

Utensils, containers and packaging made of synthetic resins whose main component is polyethylene naphthalate shall pass the following tests.

a. Migration tests

i. Germanium (Not more than 0.1 µg/ml)

The specification for germanium shall be met when the test is performed as directed in atomic absorption spectrometry or inductively coupled plasma atomic emission spectrometry, specified in Section B "General Tests," in Part 3 "Utensils, Containers, and Packaging" in the Specifications and Standards for Food, Food Additives, Etc., using 4% acetic acid as a stimulant. The germanium in the sample solution is not more than 0.1 µg/ml, if the product meets the requirement.

ii. Residue on evaporation (Not more than 30 µg/ml)

The residue shall be not more than 30 µg/ml, when the test is performed as directed in the residue on evaporation test in Section B.