

Setting of the Standards for Liquid Infant Formula

Summary

Pursuant to the provision of Paragraph 1, Article 11 of the Food Sanitation Act, from the viewpoint of public health, the Minister of Health, Labour and Welfare is authorized to establish standards for the methods of producing, processing, using, cooking, or preserving food or additives to be served for the purpose of marketing; or to establish standards for the ingredients of food or additives to be served for the purpose of marketing, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

In addition, pursuant to the provision of Paragraph 1, Article 18 of the Food Sanitation Act, from the viewpoint of public health, the Minister of Health, Labour and Welfare is authorized to establish standards for the utensils, containers and packaging, or the raw materials thereof to be served for the purpose of marketing or to be used in business, or establish standards for the production methods thereof, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

Compositional standards for milk and milk products, food principally made from milk and milk products, and containers and packaging thereof are stipulated in the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. (hereinafter referred to as "the Ministerial Ordinance on Milk, etc.") pursuant to the provision of Paragraph 1, Article 11 and Paragraph 1, Article 18 of the Food Sanitation Act.

The MHLW intends to amend the Ministerial Ordinance on Milk, etc. to establish specifications and standards for liquid infant formula based on the deliberation result of the special committee of the Pharmaceutical Affairs and Food Sanitation Council as follows.

Amendments

Specifications and standards for liquid infant formula are stipulated as follows.

1. Definition

In the Ministerial Ordinance on Milk, etc., "liquid infant formula" means the products which are obtained from product made by processing food made from raw milk, cow's milk or special-type cow's milk or made from them as principal raw materials, by adding the necessary nutrients for infants, and by reducing to liquid.

2. Standards of manufacturing

(a) Liquid infant formula shall be packed in preservation containers and sterilized by heating at 120°C for 4 minutes or using a method superior or equivalent to the former

method in pasteurization effect.

- (b) Liquid infant formula shall be sterilized using a continuous heat sterilizer and be filled aseptically in pre-sterilized container and packaging. (The liquid infant formula shall be authorized as shelf-stable food by the Minister of Health, Labor and Welfare.)

3. Compositional standards

- (a) Viable bacterial cells: Negative (the test methods shall conform to that for food packed in containers and sterilized by pressurization and heating.)
- (b) Bacterial count: 0 (per 1 mL by standard plate count method after incubation for 14 days at $30 \pm 1^\circ\text{C}$ or 7 days at $55 \pm 1^\circ\text{C}$)

4. Standards of storage

Liquid infant formula shall be stored at temperature not exceeding room temperature.

5. Standards of containers and packaging

Same standards as that of milk drink stipulated in the Ministerial Ordinance on Milk, etc. are established.

6. Other standards

The following stipulation is established in the same way as formulated milk powder.

In liquid infant formula, nothing shall be used other than milk (excluding raw goat's milk, pasteurized goat's milk and raw sheep's milk), milk products or those that received the approval of the Minister of Health, Labour and Welfare for their types and mixing ratios.