

# **Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc.**

(Ministry of Health and Welfare Ordinance No. 52, December 27, 1951)

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## **Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc.**

(Ministry of Health and Welfare Ordinance No. 52, December 27, 1951)

Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. is prescribed as follows:

Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc.

### Article 1

1. With regard to milk and milk products as well as foods using these as principal ingredients (hereafter, “milk, etc.”), Paragraphs listed below should follow this ordinance:

In case of being specified by the Ministry of Health, Labour and Welfare Ordinance designated in Paragraph 1, Article 9 of the Law (Law No. 233, 1947, hereafter, the “Law”) the compositional standards and standards of manufacturing etc. designated in Paragraph 1, Article 11 of the Law; the standard of general hygiene-controlled manufacturing or processing of milk, etc. and the hygiene control methods designated in Paragraph 2, Article 13 of the Law (including the corresponding application in Paragraph 4, Article 13 and Paragraph 2, Article 14); application procedures for approval designated in Paragraph 3, Article 13 of the Law (including the corresponding application in Paragraph 4, Article 13 and Paragraph 2, Article 14); the standards of equipments or containers/packages or their raw materials and the standard of manufacturing designated in Paragraph 1, Article 18 of the Law; foods to be labeled and guidelines for labeling designated in Article 19 of the Law.

However, besides this Ministerial Ordinance, the standards listed below should follow the requirements designated in the Standards and Regulations of Foods, Food Additives, etc. (Ministry of Health and Welfare Notification No. 370, 1959), the compositional standards and standards of manufacturing and labeling of milk, etc. to which recombinant DNA technology (a technology in which recombinant DNA molecules, prepared by recombining DNA by procedures such as digestion and ligation using enzymes, are transferred into living cells and amplified) was applied; the compositional standards and standards of labeling for food with health claims (food with health claims designated in No. 4, Paragraph 1, Article 21 of the Food Sanitation Law Enforcement Regulations (Ministry of Health and Welfare Ordinance No. 23, 1948; hereafter, “Regulations”)); the compositional standards for the limits of compositional substances of pesticides etc. (pesticides designated in Paragraph 1, Article 1-2 of Agricultural Chemicals Regulation Law (Law No. 82, 1948), agents used in feedstuffs by adding, mixing and infiltrating etc. intended for use specified by the Ministry of Agriculture, Forestry and Fisheries Ordinance that is based on the provisions of Paragraph 3, Article 2 of the Law concerning Safety Assurance and Quality Improvement of Feeds (Law No. 35, 1953) or drugs exclusively for use in animals, designated in Paragraph 1, Article 2 of the Pharmaceutical Law (Law No. 145, 1960) (hereafter, “animal drugs,” same below);(involving

substances generated by their chemical changes; same below); the compositional standards and standards of manufacturing of food additives; and the standards of equipments, or containers/packages or their raw materials and the standard of manufacturing.

## Article 2

1. In this Ministerial Ordinance, “milk” means raw milk, cow’s milk, special milk, raw goat’s milk, pasteurized goat’s milk, raw sheep’s milk, composition modified milk, low fat milk, skimmed milk, and processed milk.
2. In this Ministerial Ordinance, “raw milk” means cow’s milk just milked.
3. In this Ministerial Ordinance, “cow’s milk” means the milk of cows sold for the purpose of direct consumption and manufacturing or processing of foods using this as raw material (including delivery other than sale to unspecified or numerous persons, same below).
4. In this Ministerial Ordinance, “special milk” means cow’s milk sold as special milk
5. In this Ministerial Ordinance, “raw goat’s milk” means goat’s milk just milked.
6. In this Ministerial Ordinance, “pasteurized goat’s milk” means goat’s milk sold for the purpose of direct consumption.
7. In this Ministerial Ordinance, “raw sheep’s milk” means sheep’s milk just milked.
8. In this Ministerial Ordinance, “composition modified milk” means milk that is obtained by partial removal of milk fat or other components from raw milk.
9. In this Ministerial Ordinance, “low fat milk” means composition modified milk, other than skimmed milk, from which a part of milk fat has been removed.
10. In this Ministerial Ordinance, “skimmed milk” means composition modified milk from which almost all milk fat has been removed.
11. In this Ministerial Ordinance, “processed milk” means milk which is obtained by processing raw milk, cow’s milk or special milk, or foods manufactured using these milks as raw materials (excluding composition modified milk, low fat milk, skimmed milk, fermented milk and fermented milk drink).
12. In this Ministerial Ordinance, “milk products” means cream, butter, butter oil, cheese, concentrated whey, ice cream products, concentrated milk, concentrated skimmed milk, evaporated milk, evaporated skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder,

sweetened milk powder, formulated milk powder, fermented milk, fermented milk drink (only containing minimum 3.0% of milk solids-not-fat) and milk drink.

13. In this Ministerial Ordinance, “cream” means the product which is obtained by removal of components other than milk fat from raw milk, cow’s milk or special milk.
14. In this Ministerial Ordinance, “butter” means the product which is made by churning and working fat globules obtained from raw milk, cow’s milk or special milk.
15. In this Ministerial Ordinance, “butter oil” means the product which is obtained by removal of almost all components other than milk fat from butter or cream.
16. In this Ministerial Ordinance, “cheese” means natural cheese and processed cheese.
17. In this Ministerial Ordinance, “natural cheese” means the following products.
  - (1) The products which are made by removing part of whey from the curd obtained by coagulating almost all or part of proteins of milk, buttermilk (means the part other than fat globules obtained during the manufacturing of butter; same below), cream or their mixture with enzyme or other coagulants, or the product made by ripening it.
  - (2) Besides the products given in the preceding No., the products made by techniques including coagulation of protein of milk, etc. as the raw material and having the chemical, physical and organoleptical characteristics similar to those given in the preceding No..
18. In this Ministerial Ordinance, “processed cheese” means the product which is made from natural cheese by grinding, heating to melt, and emulsifying.
19. In this Ministerial Ordinance, “concentrated whey” means the product which is obtained by concentrate whey to solid. The whey is obtained either by fermenting milk with lactic acid bacteria, or by the addition of the enzymes or acid to milk.
20. In this Ministerial Ordinance, “ice cream products” means the products which are obtained by freezing material made by processing milk or food manufactured from milk, or material made from these as principal ingredients, provided the product contains minimum 3.0% of milk solids (excluding fermented milk).
21. In this Ministerial Ordinance, “ice cream” means the ice cream products which are sold as ice cream.
22. In this Ministerial Ordinance, “ice milk” means the ice cream products which are sold as ice milk.
23. In this Ministerial Ordinance, “lacto-ice” means the ice cream products which are sold as lacto-ice.

24. In this Ministerial Ordinance, “concentrated milk” means the product which is obtained by raw milk, cow’s milk, or special milk.
25. In this Ministerial Ordinance, “concentrated skimmed milk” means the product which is obtained by removing milk fat from raw milk, cow’s milk or special milk, and concentrating these.
26. In this Ministerial Ordinance, “evaporated milk” means the concentrated milk which is sold for direct consumption.
27. In this Ministerial Ordinance, “evaporated skimmed milk” means the condensed skimmed milk which is sold for direct consumption.
28. In this Ministerial Ordinance, “sweetened condensed milk” means the product which is obtained by concentrating raw milk, cow’s milk or special milk with the addition of sugar.
29. In this Ministerial Ordinance, “sweetened condensed skimmed milk” means the product which is obtained from raw milk, cow’s milk or special milk by removal of milk fat and concentrating with the addition of sugar.
30. In this Ministerial Ordinance, “whole milk powder” means the product which is obtained from raw milk, cow’s milk or special milk by removing almost all the water and reducing to powder.
31. In this Ministerial Ordinance, “skimmed milk powder” means the product which is obtained from raw milk cow’s milk or special milk by removing milk fat, and then removing almost all the water and reducing it to powder.
32. In this Ministerial Ordinance, “cream powder” means the product which is obtained from raw milk, cow’s milk, or special milk by removing all components other than milk fat, and then removing almost all the water and reducing to powder.
33. In this Ministerial Ordinance, “whey powder” means the product which is obtained from the whey that has been produced either by fermenting milk with lactic acid bacteria, or by the addition of enzymes or acid to milk and then removing almost all the water and reducing to powder.
34. In this Ministerial Ordinance, “protein concentrated whey powder” means the product that is obtained by removing lactose from whey that has been produced either by fermenting milk with lactic acid bacteria, or by the addition of enzymes or acid to milk, and then removing almost all the water and reducing to powder.
35. In this Ministerial Ordinance, “buttermilk powder” means the product which is obtained by removing almost all the water from buttermilk and reducing to powder.
36. In this Ministerial Ordinance, “sweetened milk powder” means either the product which is obtained from

raw milk, cow's milk, or special cow's milk by adding sugar and removing almost all the water then reducing to powder, or the product which is obtained by adding sugar to whole milk powder.

37. In this Ministerial Ordinance, "formulated milk powder" means the product which is obtained from product made by processing food made from raw milk, cow's milk or special cow's milk or made from them as principal raw materials, by adding the necessary nutrients for infants and then reducing to powder.

38. In this Ministerial Ordinance, "fermented milk" means the products which are obtained by fermenting milk, or milk, etc. containing an equal or greater amount of milk solids-not-fat with lactic acid bacteria or yeast and then forming a paste or liquid, or the frozen product.

39. In this Ministerial Ordinance, "fermented milk drink" means the drinks which are obtained by fermenting milk, etc. with lactic acid bacteria or yeast and then processing it or using it as the principal ingredient(excluding fermented milk).

40. In this Ministerial Ordinance, "milk drink" means the drinks which are obtained by manufacturing raw milk, cow's milk, or special cow's milk or food manufactured using these as principal raw materials, excluding products given from Paragraphs 2 to 11 and from Paragraph 13 to the preceding paragraph.

#### Article 3

1. In case of being specified by the Ministry of Health, Labour and Welfare Ordinance designated in Paragraph 1, Article 9, of the Law:

the compositional standards and standards of manufacturing, etc. designated in Paragraph 1, Article 11 of the Law;

the standard of general hygiene-controlled manufacturing or processing of milk, etc. and the hygiene control method designated in Paragraph 2, Article 13 of the Law (including the corresponding application in Paragraph 4 of the same article and Paragraph 2, Article 14);

and the standards of equipments or containers/packages or their raw materials and the standard of manufacturing designated in Paragraph 1, Article 18 of the Law.

#### Article 4

1. Approval of Paragraph 1, Article 13 of the Law concerning milk, etc. shall be applied for by submitting an application form describing the items listed below to the Minister of Health, Labour and Welfare.

(1) Address, name and date of birth of the applicant (in the case of legal persons, their name, location of main office, and name of representative)

(2) Category of the product

- (3) Name and location of the milk processing plant, the special cow's milk milking and processing plant or the milk product manufacturing plant
  - (4) Outline of the general hygiene-controlled manufacturing processes of products
2. The documents listed below shall be attached to the application form of the preceding paragraph
    - (1) Documents specified in Section 1-6 of Attached Table 3 the standard of general hygiene-controlled manufacturing or processing of milk, etc. and the hygiene control method.
    - (2) Documents concerning the effects of the measures in Section 2 (2) of Attached Table 3 the standard of general hygiene-controlled manufacturing or processing of milk, etc. and the hygiene control method.
    - (3) Documents concerning prepared and stored data regarding the items listed in Section 6 (4) of based upon the documents designated in Section 6 of the same standards.
  3. A revenue stamp equivalent to the charged amount shall be placed on the application form of Paragraph 1.

#### Article 5

1. The application for the approval of change of Paragraph 4, Article 13 of the Law concerning milk, etc. shall be conducted by submitting an application form describing the items listed in each of the following Nos. to the Minister of Health, Labour and Welfare.
  - (1) Item No. (1) to (4) of Paragraph 1 of the preceding article
  - (2) Numbers and dates of the obtained approval
2. The documents listed below shall be attached to the application form of the preceding paragraph
  - (1) Among the documents listed in No. 1 of Paragraph 2 and No. 2 of the same paragraph of the preceding article, those associated with items that are due to be changed (in the document of No. 1 of the same paragraph, the old/new contrast of said items shall be clearly illustrated)
  - (2) Data of No. 3, Paragraph 2 of the preceding article
3. A revenue stamp equivalent to the charged amount shall be placed on the application form of Paragraph 1.

#### Article 6

1. The application for renewal of Paragraph 1, Article 14 of the Law concerning milk, etc. shall be applied for by submitting the application form describing the items listed in each of the following sections of Paragraph 1 of the preceding article to Minister of Health, Labour and Welfare.

2. The documents listed below shall be attached to the application form of the preceding paragraph.
  - (1) Documents specified in the sections (1) and (4) to (6) in Attached Table 3: the standard of general hygiene-controlled manufacturing or processing of milk, etc. and the hygiene control method (excluding documents without changes; the old/new contrast of items describing the change shall be clearly specified).
  - (2) Documents specified in the standard sections (2) and (3) of Attached Table 3 the standard of general hygiene-controlled manufacturing or processing of milk, etc. and the hygiene control method.
  - (3) Documents concerning prepared and stored data regarding the items listed in standard sections (6)-1, (6)-2, and (6)-4 based on the documents designated in the standard section 6 of Attached Table 3 the standards of general hygiene-controlled manufacturing or processing of milk, etc. and the hygiene control method.
3. A revenue stamp equivalent to the charged amount shall be placed on the application form of Paragraph 1.

#### Article 7

1. Milk, etc. shall be the foods to be labeled according to the provisions of Article 19 of the Law. Provided, however, that this does not apply to exports.
2. Labeling of the preceding paragraph shall be performed by declaring the items given below on a readily visible location of the container/package or wrapping (in case where the container/package is wrapped for retail sale, that wrapping) in order that they can be easily seen without opening the container/package or wrapping.
  - (1) Raw milk, raw goat's milk and raw sheep's milk  
Declarations to be raw milk, raw goat's milk or raw sheep's milk and, when milked from Jersey cows, a declaration of the fact
  - (2) Milk (excluding raw milk, raw goat's milk and raw sheep's milk, same below in the following Nos.)
    - (a) Category
    - (b) Pasteurization temperature and time (for special cow's milk not pasteurized, a declaration of the fact)
    - (c) For processed milk, names of the principal ingredients and the weight percent of milk solids-not-fat and milk fat
    - (d) For low fat milk, the weight percent of milk fat
    - (e) For milk whose quality deteriorates rapidly when it is stored under the specified condition, a declaration date with the letter "the use-by date" (date indicating the period during which there is no risk of impairment of safety due to corruption, deterioration, or other deterioration in quality when

they are stored under the specified condition; same below), and for other milk . (excluding products which can be stored at room temperature (cow's milk, composition modified milk, low fat milk, skimmed milk, processed milk or milk drink which have been aseptically filled into pre-pasteurized containers/packages after pasteurization by a continuous heat pasteurizer, for which the Minister of Health, Labour and Welfare agreed that storage at 10°C or below is not required for hygiene same below )), date with the letter "the date of minimum durability" (i.e., the date indicating the period during which the expected qualities can be completely maintained when stored under the specified condition; besides these qualities might be maintained even after the mentioned expiry date; same below).

- (f) Storing method (when the storing condition of milk is designated in Section (2) ,Attached Table 2 Compositional Standards and Standards of Manufacturing, Cooking, and Storing Condition, for Cow's Milk, Special Cow's Milk, Pasteurized Goat's Milk, Composition Modified Milk, Low Fat Milk, Skimmed Milk and Processed Milk, use these condition that meet the standard.)
- (g) For products storable at room temperature, a declaration of being storable at room temperature and the date with the letter "the minimum durability" stored at room temperature.
- (h) Location of milk processing plant (for special cow's milk, special cow's milk milking and processing plant; same in Paragraph 8) and the name (in case of legal person, his name) of the manufacturer (for special cow's milk, the manufacturer of the special cow's milk milking and processing plant; same in Paragraph 8).

### (3) Milk products

- (a) Category (for cheese, classification as to natural cheese or processed cheese; for ice cream product, classification as to ice cream, ice milk or lacto-ice) and for cream, concentrated whey, cream powder, whey powder, protein concentrated whey powder, and fermented milk drink, a declaration to the effect of being a milk product
- (b) For natural cheese made by milk other than cow's milk, the kind of the animal milked
- (c) For cream and cream powder, the weight percent of milk fat
- (d) For ice cream products, fermented milks, fermented milk drinks and milk drinks, the weight percent of milk solids-not-fat and milk fat contained (for products containing fat other than milk fat, weight percent of milk solids-not-fat content, milk fat and the fat other than milk fat)
- (e) For sweetened condensed milk, sweetened condensed skimmed milk, sweetened milk powder, or formulated milk powder, the names and weight percent of the principal ingredients
- (f) For cheese, ice cream products, fermented milks, fermented milk drinks, or milk drinks, the names of the principal ingredients
- (g) For milk products containing food additives (excluding substances used for the purpose of reinforcing nutrition, processing aids (substances added in processing foods but removed prior to

completion of said foods, those which are originated in the raw materials and changed into the same components which are generally existing in said foods and which do not clearly increase the content of such components, or those whose amount contained in said foods is little so that those do not give any effect attributable to such components to said foods),

and carry-over (substances which are used in the process of manufacturing or processing raw materials of foods but which are not used in the process of manufacturing or processing said foods and the amount of such substances contained in said foods are less than the amount which allows these substances to demonstrate any effect in said foods same below and in g and d of (4) )

which are being used as the substances specified in the middle column of the Attached Table 5 of the Food Sanitation Law Enforcement Regulations,

declarations of containing those food additives and labeling indicated in the column of the bottom of the same table

For those containing other food additives, a declaration of containing such food additives.

- (h) For milk products (excluding those lacking antigenecity) containing specified raw materials other than milk (i.e., specified raw materials in g No. 1, Paragraph 1, Article 21 of the Regulation; same below), a declaration of containing said such specified raw materials as ingredients.
  - (i) For milk products containing food additives derived from specified raw materials other than milk (excluding those lacking antigenecity and flavoring agents; same in f the following No.), declarations of containing said food additives and of the food additives derived from the specified raw materials.
  - (j) For milk products containing aspartame, declaration of containing L-phenylalanine compound
  - (k) For pasteurized fermented milk drink, declaration of the fact
  - (l) Date with the letter “use-by-date” for milk products whose quality tends to deteriorate rapidly when they are stored under the specified condition and date with letter “the date of minimum durability” for other milk products (excluding those that are storable at room temperature).
  - (m) Storing condition (milk products for which the standards of the storing condition specified in Section (3) Attached Table 2 Compositional Standards and Standards of Manufacturing Cooking and Storing Condition use storing condition that meet the standard)
  - (n) For product storable at room temperature, a declaration of being able to store at room temperature and the date with the letter” minimum durability” when stored at ordinary temperature.
  - (o) Location of the manufacturing plant (for imported goods, the location of the business office of the importer) and the name of the manufacturer (in case of legal person, his name) (for imported goods, the name of the importer)
- (4) Foods made by milk and milk products as principal ingredients
- (a) Name or trade name (for fermented milk drink, declaring it.)

- (b) Declaration of containing milk or milk products as raw materials, or containing milk components as raw materials, or at least one category of milk or milk product as the principal ingredient.
  - (c) The weight percent of milk solids-not-fat and milk fat (for products containing fat other than milk fat, weight percent of milk solids-not-fat, milk fat and the fat other than milk fat)
  - (d) For those foods containing food additives which are being used as the substances specified in the middle column of the Attached Table 5 of the Food Sanitation Law Enforcement Regulations, declarations of containing those food additives and labeling indicated in the column at the bottom of the same table. For those containing other food additives, declaration of containing such food additives
  - (e) For processed foods containing specified raw materials other than milk (including food containing said processed foods as ingredients and excluding those lacking antigenecity), a declaration of containing said specified raw materials as ingredients.
  - (f) For foods containing food additives derived from specified raw materials other than milk, a declaration of containing said food additives and that the food additives present in these foods derived from said specified raw materials.
  - (g) For those products containing aspartame, declaration of containing L-phenylalanine compound
  - (h) For fermented milk drink whose quality tends to deteriorate rapidly when they are stored under the specified condition, the date with the letter, “use-by-date” ; for other fermented milk drink, the date with the letter “minimum durability” .
  - (i) For fermented milk drink, storing condition
  - (j) Location of the manufacturing plant (for imported goods, the location of the business office of the importer) and the name of manufacturer (in case of legal person, his name) (for imported goods, the name of the importer)
3. Labeling of items given in the preceding paragraphs shall be accurately performed in Japanese so that those persons, who want to buy commonly or make use of the foods, may read and understand with ease.
4. Labeling of items given in (a), No. 2, Paragraph 2 shall be performed with typeface of a size not smaller than 10.5 point;  
labeling of items given in (a), No. 3 of the same paragraph in not smaller than 8 point for fermented milks and fermented milk drinks and not smaller than 14 point for other milk products;  
and labeling of items given in (a), No. 4 of the same paragraph (only those relating to fermented milk drinks) in not smaller than 8 point.
5. Notwithstanding the provisions in Paragraph 2, if the period between the date of manufacture or processing and that of minimum durability exceeds 3 months, month and year with the letter “the date of

minimum durability “ can be used instead of day-month-year with the letter “the date of minimum durability “.

6. Notwithstanding the provisions of Paragraph 2, for milk (excluding raw milk, raw goat’s milk, and raw sheep’s milk), cream, fermented milk, fermented milk drink and milk drink filled in containers/packages tightly sealed with paper, aluminum foil and the like,  
the date with the letter “the use-by date” or “the date of minimum durability” (hereafter, “due date”) and storing condition may be substituted by a description of the day of the due date;  
for ice cream products, the due date and storing condition may be omitted.
7. Notwithstanding the provisions of (m), No. 3, of Paragraph 2 and (i), No. 4 of the same paragraph, for milk products (excluding those storable at room temperature) and fermented milk drink, labeling of being storable at room temperature may be omitted.
8. Notwithstanding the provisions of Paragraph 2, labeling of the location of milk processing plant or manufacturing plant may be substituted by descriptions of the address of the milk processor or manufacturer and a unique code of the milk processing plant or manufacturing plant (only Arabic numerals, Roman letters, hiragana, katakana, or combinations of these are permitted), which the milk processing processor or manufacturer has notified to the Minister of Health, Labour and Welfare.
9. Notwithstanding the provisions of (g), No. 3, Paragraph 2 and (d), No. 4 of the same paragraph, the labeling containing food additives which have names that are generally and widely in use, may be substituted by such names. The labeling foods containing food additives for substances listed in the upper column of the attached Table 8 of the Regulations may be substituted by the lower column of the same table.
10. Notwithstanding the provisions of (g), No. 3, Paragraph 2 and (d), No. 4 of the same paragraph, in the cases described in the following, the labeling specified in each No may be omitted.
  - (1) If the word “color” is included in the labeling of containing food additives, color or synthetic color
  - (2) If the word “thickening” is included in the labeling of containing food additives, thickener or gelant
11. Notwithstanding the provisions of (h) and (i), No. 3, Paragraph 2 and (e) and (f), No. 4 of the same paragraph, for milk products or foods containing milk or milk products as principal ingredients containing specific raw materials (excluding milk; same below in this paragraph) and for which the specific raw materials present as ingredients can easily be recognized by their names, labeling of containing said specific raw materials as ingredients can be omitted;  
for milk products or foods containing milk or milk products as principal ingredients made from processed foods containing specific raw materials, for which the specific raw materials present as

ingredients can be easily recognized by their names (hereafter, “specific processed food” in this paragraph), labeling of the specific raw materials present as ingredients can be substituted by labeling of said specific processed foods present as ingredients;

for milk products or foods containing milk or milk products as principal ingredients containing food additives derived from specific raw materials in either case the food additives containing specific raw materials or specific processed foods containing said specific raw materials as ingredients is labeled or the specific raw materials present as ingredients could be recognized easily by names of food additives, labeling of the food additives in milk products or foods made from milk or milk products as principal ingredients are derived from ,the specific raw materials can be omitted.

12. Notwithstanding the provisions of Paragraph 2, the labeling of items given in No. 3 or No. 4 of the same paragraph (excluding items given in (a) and (o), No. 3 or (a) and (j), No. 4), for milk products, or foods made from milk or milk products as principal ingredients, packaged in 10 or more containers/packages per unit of delivery and sold to those who received permission for confectionary manufacturers designated in No. 3, Article 35 of the Food Sanitation Law Enforcement Act (Ordinance No. 229, 1953), milk product manufacturers designated in No. 8 of the same article, meat product manufacturers designated in No. 13 of the same article, fish-meat cake product manufacturers designated in No. 16 of the same article, soft drink manufacturers designated in No. 19 of the same article, fermented milk drink manufacturers designated in No. 20 of the same article or prepared meals designated in No. 32 of the same article, may substitute the description on the containers/packages by the description on the invoice. In these cases, besides placing the mark on a prominent area of the outer containers/packages and in order to recognize the products without opening them, the items given in (a) and (o), No. 3 or (a) and (j), No. 4, Paragraph 2, said marking, and the name and address of the purchaser (in the case of legal persons, the name and address of the main office) shall be described on said invoice.
13. The provisions in Paragraphs 5 and 7-10 are applied mutatis mutandis in cases where the items given in No. 3 or No. 4 of Paragraph 2 are described on the invoice according to the provisions of the preceding paragraph.

#### Attached Table

[1] In case of being specified by the Ministry of Health, Labour and Welfare Ordinance designated in Paragraph 1, Article 9, of the Law

In case there shall be no affection, suspicion, and abnormality with regard to the following diseases: Cattle plague, contagious bovine pleuropneumonia, anthrax, blackwater-blacking, foot and mouth disease, rabies, encephalitis epidemica, “Q” fever, hemorrhagic septicemia, malignant edema,

leptospirosis, Johne's disease, piroplasmosis, anaplasmosis, trypanosomiasis, leukemia, listeriosis, toxoplasmosis, salmonellosis, tuberculosis, brucellosis, enzootic fever, cowpox, icterus (jaundice), actinomycosis, gastroenteritis, mastitis, tetanus, septicemia, pyemia, uremia, intoxications, septic inflammation of uterus, and fever syndrome.

[2] Compositional Standards and Standards of Manufacturing, Cooking, and Storing Condition of Milk, etc.

(1) Compositional Standards and Standards of Manufacturing and Storing Condition of Milk, etc. in General

1) Milk, etc. shall be free from antibiotics and antimicrobial substances which are chemical compounds (i.e., substances obtained by a chemical reaction other than that causing decomposition of an element or compound by chemical means, same below). However, this does not apply to cases corresponding to each of the following Nos.

1. In case the said substances are identical to the food additives and are free from the concern of harming human health as specified by the Minister of Health, Labour and Welfare according to the provisions of Article 10 of the Law
2. In case compositional standards regarding the limits of the substances that are components of pesticides etc. are specified for the said substances in the Standards and Regulations of Foods, Food Additives, etc.
3. In case the said milk, etc. is manufactured or processed by using as raw materials foods that meet the compositional standards regarding the limit of the substances that are components of pesticides etc., specified in the Standards and Regulations of Foods, Food additives, etc. (excluding an antibiotic or antimicrobial substances which are chemical compounds not corresponded to other than those specified in 2)

2) Milk shall not be taken from cow, goat or sheep corresponding to each of the following Nos.:

1. Those within five days after delivery
2. Those either having been fed or injected with medicine that has an effect on milk and being within the period when medicine remains in the milk
3. Those showing a significant reaction after the injection of biological products

3) In case of manufacturing cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, and skimmed milk, and when manufacturing processed milk and milk products (excluding sweetened condensed milk) using raw milk; raw milk or raw goat's milk of the following characteristics shall be used.

a. Raw milk

Specific gravity (at 15°C)

Taken from cows other than Jersey cows	1.028–1.034
Taken from Jersey cows	1.028–1.036
Acidity (as lactic acid)	
Taken from cows other than Jersey cows	Not more than 0.18%
Taken from Jersey cows	Not more than 0.20%
Bacterial count (per 1 mL by direct microscopic individual count method)	
	Not more than 4 ,000,000

b. Raw goat’s milk

Specific gravity (at 15°C)	1.030–1.034
Acidity (as lactic acid)	Not more than 0.20%
Bacterial count (per 1 mL by direct microscopic individual count method)	
	Not more than 4 ,000,000

4) In the manufacturing of cow’s milk, special milk, pasteurized goat’s milk, composition modified milk, low fat milk, skimmed milk, processed milk, cream, fermented milk, fermented milk drink and milk drink; filtration, pasteurization, division and sealing operations (hereafter, “processing”) shall be performed. Provided, however, that for special milk, the pasteurization operation may be omitted.

5) Processing shall be continuously performed at facilities receiving permission of milk processor for cow’s milk, pasteurized goat’s milk, composition modified milk, low fat milk, skimmed milk and processed milk; at facilities receiving permission of special milk milking and processing businesses for special milk; and at the facilities receiving permission of milk product manufacturer for cream, fermented milk and milk drink.

(2) Compositional Standards and Standards of Manufacturing and Storing Condition of Cow’s Milk, Special Milk, Pasteurized Goat’s Milk, Composition Modified milk, Low Fat Milk, Skimmed Milk and Processed Milk

1) Cow’s milk

1. Composition

Milk solids-not-fat content	Minimum 8.0%
Milk fat content	Minimum 3.0%
Specific gravity (at 15°C)	
Products other than those that use only Jersey cows’ milk as raw material	1.028–1.034
Products that use only Jersey cows’ milk as raw material	1.028–1.036

Acidity (as lactic acid)

Other milk than that which uses only Jersey cow's milk as raw material  
Not more than 0.18%

Products which uses only Jersey cow's milk as raw material  
Not more than 0.20%

Bacterial count (per 1 mL by standard plate count method)  
Not more than 50,000

Coliforms  
Negative

2. Manufacturing process

Cow's milk shall either be pasteurized by heating at 63°C for 30 minutes, the holding method or by heating having an equal or more pasteurization effect.

3. Storing condition

- a. Cow's milk shall be stored by cooling not higher than 10°C immediately after pasteurization. Provided, however, that this does not apply to product storable at room temperature.
- b. Product storable at room temperature shall be stored at temperature not exceeding room temperature.

2) Special milk

1. Composition

Milk solids-not-fat content  
Minimum 8.5%

Milk fat content  
Minimum 3.3%

Specific gravity (at 15°C)

Products other than those that use only Jersey cows' milk as raw material  
1.028–1.034

Products that use only Jersey cows' milk as raw material  
1.028–1.036

Acidity (as lactic acid)

Other milk than that which uses only Jersey cow's milk as raw material  
Not more than 0.17%

Products which uses only Jersey cow's milk as raw material  
Not more than 0.19%

Bacterial count (per 1 mL by standard plate count method)  
Not more than 30,000

Coliforms  
Negative

2. Manufacturing process

- a. Special milk shall be manufactured by processing raw milk milked at facilities receiving

permission of special milk milking and processor.

b. When pasteurized, pasteurization shall be performed by heating at 63°C–65°C for 30 minutes by the holding method.

3. Storing condition

Special milk shall be stored by cooling to not higher than 10°C immediately after processing (when pasteurized, after pasteurization)

3) Pasteurized goat's milk

1. Composition

Milk solids-not-fat content	Minimum 8.0%
Milk fat content	Minimum 3.6%
Specific gravity (at 15°C)	1.030-1.034
Acidity (as lactic acid)	Not more than 0.20%
Bacterial count (per 1 mL by standard plate count method)	Not more than 50,000
Coliforms	Negative

2. Manufacturing process

The same as for cow's milk.

3. Storing condition

Pasteurized goat's milk shall be stored by cooling to not higher than 10°C immediately after pasteurization.

4) Composition modified milk

1. Composition

Milk solids-not-fat content	Minimum 8.0%
Acidity (as lactic acid)	Not more than 0.18%
Bacterial count (per 1 mL by standard plate count method)	Not more than 50,000
Coliforms	Negative

2. Manufacturing Process and Storing Condition

The same as for cow's milk.

5) Low fat milk

1. Composition

Milk solids-not-fat content	Minimum 8.0%
Milk fat content	Minimum 0.5 and not more than 1.5%

Specific gravity (at 15°C)	1.030-1.036
Acidity (as lactic acid)	Not more than 0.18%
Bacterial count (per 1 mL by standard plate count method)	Not more than 50,000
Coliforms	Negative

2. Manufacturing process and storing condition

The same as for cow's milk.

6) Skimmed milk

1. Composition

Milk solids-not-fat content	Minimum 8.0%
Milk fat content	Less than 0.5%
Specific gravity (at 15°C)	1.032-1.038
Acidity (as lactic acid)	Not more than 0.18%
Bacterial count (per 1 mL by standard plate count method)	Not more than 50,000
Coliforms	Negative

2. Manufacturing process and storing condition

The same as for cow's milk.

7) Processed milk

1. Composition

Milk solids-not-fat content	Minimum 8.0%
Acidity (as lactic acid)	Not more than 0.18%
Bacterial count (per 1 mL by standard plate count method)	Not more than 50,000
Coliforms	Negative

2. Manufacturing process

As for the method of pasteurization, the same as for cow's milk.

3. Storing condition

The same as for cow's milk.

(3) Compositional Standards and Standards of Manufacturing Process and Storing Condition of Milk Products

1) Cream

1. Composition

Milk fat content	Minimum 18.0%
------------------	---------------

Acidity (as lactic acid)	Not more than 0.20%
Bacterial count (per 1 mL by standard plate count method)	Not more than 100,000
Coliforms	Negative
2. Manufacturing process	
The same as for cow's milk.	
3. Storing condition	
Cream shall be stored by cooling to not higher than 10°C immediately after pasteurization.	
Provided, however, that this does not apply to cream packed in a preservative container and sterilized.	
2) Butter	
1. Composition	
Milk fat content	Minimum 80.0%
Moisture	Not more than 17.0%
Coliforms	Negative
3) Butter oil	
1. Composition	
Milk fat content	Minimum 99.3%
Moisture	Not more than 0.5%
Coliforms	Negative
4) Processed cheese	
1. Composition	
Milk solids content	Minimum 40.0%
Coliforms	Negative
5) Concentrated whey	
1. Composition	
Milk solids content	Minimum 25.0%
Coliforms	Negative
6) Ice cream	
1. Composition	
Milk solids content	Minimum 15.0%
In which milk fat content	Minimum 8.0%
Bacterial count (per 1 g by standard plate count method)	

Not more than 100,000

However, this holds true provided that for ice cream that is produced by using fermented milk or fermented milk drink as the raw material, the bacterial count, excluding lactic acid bacteria or yeasts, shall be not more than 100,000.

Coliforms

Negative

2. Manufacturing process

- a. Raw water for ice cream shall be potable water.
- b. Raw materials of ice cream (excluding fermented milk and fermented milk drink) shall either be pasteurized by heating at 68°C for 30 minutes or by heating having an equal or more pasteurization effect.
- c. In case of removing ice cream from freezing tubes, the water used to warm the outside shall be potable flowing water.
- d. In case of distributing ice cream into containers/packages, distributing machines shall be used, and in case of applying lids, lid-apply machines shall be used.
- e. Melted liquid from ice cream shall not be used as raw material for ice cream. Provided, however, that this does not apply to that pasteurized by heating under the condition b.

7) Ice milk

1. Composition

Milk solids content

Minimum 10.0%

In which milk fat content

Minimum 3.0%

Bacterial count (per 1 g by standard plate count method)

Not more than 50,000

Provided, however, that, for ice milk produced by using fermented milk or fermented milk drink as raw material, bacterial count, excluding lactic acid bacteria or yeasts,

shall be not more than 50,000.

Coliforms

Negative

2. Manufacturing process

The same as for ice cream

8) Lacto-ice

1. Compositions

Milk solids content

Minimum 3.0%

Bacterial count (per 1 g by standard plate count method)

Not more than 50,000

Provided, however, that, for lacto-ice produced by using fermented milk or fermented milk drink as raw material, bacterial count, excluding lactic acid bacteria or yeasts,

- shall be not more than 50,000.
- Coliforms Negative
2. Manufacturing process  
The same as for ice cream
- 9) Concentrated milk
1. Composition
- |  |                       |
|--|-----------------------|
| Milk solids content                                      | Minimum 25.5%         |
| In which milk fat content                                | Minimum 7.0%          |
| Bacterial count (per 1 g by standard plate count method) | Not more than 100,000 |
2. Storing condition  
Concentrated milk shall be stored by cooling to not higher than 10°C immediately after concentration.
- 10) Concentrated skimmed milk
1. Composition
- |  |                       |
|--|-----------------------|
| Milk solids-not-fat content                              | Minimum 18.5%         |
| Bacterial count (per 1 g by standard plate count method) | Not more than 100,000 |
2. Storing condition  
The same as for concentrated milk.
- 11) Evaporated milk
1. Composition
- |  |               |
|--|---------------|
| Milk solids content                                      | Minimum 25.0% |
| In which milk fat content                                | Minimum 7.5%  |
| Bacterial count (per 1 g by standard plate count method) | 0             |
2. Manufacturing process  
Evaporated milk shall be sterilized by heating at not lower than 115°C for minimum 15 minutes after being packaged in containers.
- 12) Evaporated skimmed milk
1. Composition
- |  |               |
|--|---------------|
| Milk solids-not-fat content                              | Minimum 18.5% |
| Bacterial count (per 1 g by standard plate count method) | 0             |

2. Manufacturing process

The same as for evaporated milk.

13) Sweetened condensed milk

1. Composition

Milk solids content	Minimum 28.0%
In which milk fat content	Minimum 8.0%
Moisture	Not more than 27.0%
Sugar content (including lactose)	Not more than 58.0%
Bacterial count (per 1 mL by standard plate count method)	Not more than 50,000
Coliforms	Negative

14) Sweetened condensed skimmed milk

1. Composition

Milk solids content	Minimum 25.0%
Moisture	Not more than 29.0%
Sugar content (including lactose)	Not more than 58.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative

15) Whole milk powder

1. Composition

Milk solids content	Minimum 95.0%
In which milk fat content	Minimum 25.0%
Moisture	Not more than 5.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative

16) Skimmed milk powder

1. Composition

Milk solids content	Minimum 95.0%
Moisture	Not more than 5.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative

2. Manufacturing condition

- a. During the process until pasteurization by heating, raw materials shall be maintained at the temperature of not more than 10°C or more than 48°C. Provided, however, that this does not apply to cases where skimmed milk powder is continuously manufactured so that raw materials do not accumulate in process.
- b. Raw materials for skimmed milk powder shall be pasteurized by heating as cow's milk.
- c. During the process from pasteurization by heating to drying, raw materials shall be maintained at the temperature of not more than 10°C or more than 48°C. Provided, however, that this does not apply to cases where all the machines used in said process have a structure that prevents microbial contamination from outside and the temperature of raw materials is maintained at more than 10°C and not more than 48°C for less than 6 hours.

17) Cream powder

1. Composition

Milk solids content	Minimum 95.0%
In which milk fat content	Minimum 50.0%
Moisture	Not more than 5.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative

18) Whey powder

1. Composition

Milk solids content	Minimum 95.0%
Moisture	Not more than 5.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative

19) Protein concentrated whey powder

1. Composition

Milk solids content	Minimum 95.0%
Milk protein content (in a dry form)	Minimum 15.0% and not more than 80.0%
Moisture	Not more than 5.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000

Coliforms	Negative
20) Buttermilk powder	
1. Composition	
Milk solids content	Minimum 95.0%
Moisture	Not more than 5.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative
21) Sweetened milk powder	
1. Composition	
Milk solids content	Minimum 70.0%
In which milk fat content	Minimum 18.0%
Moisture	Not more than 5.0%
Sugar content (excluding lactose)	Not more than 25.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative
22) Formulated milk powder	
1. Composition	
Milk solids content	Minimum 50.0%
Moisture	Not more than 5.0%
Bacterial count (per 1 g by standard plate count method)	Not more than 50,000
Coliforms	Negative
23) Fermented milk	
1. Composition	
Milk solids-not-fat content	Minimum 8.0%
Lactic acid bacteria count or yeast count (per 1 mL)	Minimum 10, 000,000
Coliforms	Negative
2. Manufacturing process	
a. Raw water for fermented milk shall be potable water.	
b. Raw materials for fermented milk (excluding lactic acid bacteria, yeast, fermented milk and fermented milk drink) shall either be pasteurized by heating at 62°C for 30 minutes or by	

heating by a method having an equal or more pasteurization effect.

24) Fermented milk drink (those containing minimum 3.0% milk solids-not-fat)

1. Composition

Lactic acid bacteria count or yeast count (per 1 mL)

Minimum 10, 000,000

Provided, however, that this does not apply to products which, after fermentation, are either heated at not lower than 75°C for 15 minutes or pasteurized by heating having an equal or more pasteurization effect.

Coliforms

Negative

2. Manufacturing process

- a. Raw water used in the manufacture of the stock solution of the fermented milk drink shall be potable water.
- b. Raw materials used in the manufacture of the stock solution of fermented milk drink (excluding lactic acid bacteria and yeast) shall either be pasteurized by heating at 62°C for 30 minutes or by heating having an equal or more pasteurization effect.
- c. Water, etc. used for diluting the stock solution of fermented milk drink shall either be boiled for Not less than 5 minutes or pasteurized by an operation having an equal or more pasteurization effect immediately before use.

25) Milk drink

1. Composition

Bacterial count (per 1 mL by standard plate count method)

Not more than 30,000

Coliforms

Negative

2. Manufacturing process

Raw materials shall, excluding those destroyed in the process of pasteurization, be pasteurized either by heating at 62°C for 30 minutes or by heating having an equal or more pasteurization effect.

3. Storing condition

The same as for cow's milk, excluding those packed in preservation containers and sterilized by heating at not lower than 120°C for 4 minutes or by heating having an equal or more sterilization effect.

(4) Compositional Standards and Standards of Manufacturing and Storing Condition of Food Using Milk, etc. as Principal Ingredients

1) Fermented milk drink (those containing less than 3.0% milk solids-not-fat)

1. Composition

Lactic acid bacteria count or yeast (per 1 mL)

Minimum 1,000.000

Coliforms

Negative

2. Manufacturing process

The same as for fermented milk drink (minimum 3.0% milk solids-not-fat)

2) Deleted

(5) Other Standards or Specifications Related to Compositions and Manufacturing or Storing Condition of Milk, etc.

1) Product storable at room temperature shall comply with the following compositional standards given below besides complying with those standards given in 1. of 1), 1. of 4), 1. of 5), 1. of 6) or 1. of 7) in (2), or 1. of 24) in (3).

1. Cow's milk, composition modified milk, low fat milk, skimmed milk or processed milk.

Alcohol test (before and after incubation either for 14 days at  $30\pm 1^\circ\text{C}$  or 7 days at  $55\pm 1^\circ\text{C}$ )

Negative

Acidity (the difference before and after incubation either for 14 days at  $30\pm 1^\circ\text{C}$  or 7 days at  $55\pm 1^\circ\text{C}$ ; as lactic acid)

Not more than 0.02%

Bacterial count (per 1 mL by standard plate count method after incubation either for 14 days at  $30\pm 1^\circ\text{C}$  or 7 days at  $55\pm 1^\circ\text{C}$ )

0

2. Milk drink

Bacterial count (per 1 mL by standard plate count method after incubation either for 14 days at  $30\pm 1^\circ\text{C}$  or 7 days at  $55\pm 1^\circ\text{C}$ )

0

2) Milk other than processed milk, cream, concentrated milk and concentrated skimmed milk shall not have other substances mixed in (excluding steam used in direct pasteurization of cow's milk, composition modified milk, low fat milk, skimmed milk, cream, concentrated milk or concentrated skimmed milk by direct ultra-high temperature heating);

in the manufacture of processed milk, nothing shall be used other than water, raw milk, cow's milk, special milk, composition modified milk, low fat milk, skimmed milk, whole milk powder, skimmed milk powder, concentrated milk, concentrated skimmed milk, evaporated milk, evaporated skimmed milk, cream, and butter, butter oil, butter milk and butter milk powder to which no food additives have been added.

3) For cow's milk and special milk, their milk components shall not be removed.

- 4) Preservatives shall not be used for milk drink and fermented milk which are either in paste form or frozen state and fermented milk drink that have been pasteurized.
- 5) No other substances (according to the classification of the upper column of the following table, food additives given in the middle column of the same table, which are used at the amount not more than that specified in the lower column in the same table, sugar used for sweetened condensed milk, sweetened condensed skimmed milk or sweetened milk powder, lactose used to adjust protein content in skimmed milk powder and milk retentate or permeate obtained by filtration of raw milk, cow's milk, special milk, composition modified milk, low fat milk or skimmed milk are excluded.) shall be used in evaporated milk, evaporated skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder and sweetened milk powder. Provided, however, that this does not apply to the food additives that received the approval of the Minister of Health, Labour and Welfare for their types and mixing ratios.

Column 1 Milk products	Column 2 Food Additives	Column 3 Limitations Maximum limit
Evaporated milk Evaporated skimmed milk	Calcium chloride Calcium citrate Trisodium citrate Sodium bicarbonate Sodium carbonate, crystal Sodium carbonate, anhydrous Tetrasodium pyrophosphate, crystal Tetrasodium pyrophosphate, anhydrous Potassium polyphosphate Sodium polyphosphate Potassium metaphosphate Sodium metaphosphate Disodium hydrogen phosphate, crystal Disodium hydrogen phosphate, anhydrous Disodium dihydrogen phosphate, crystal Disodium dihydrogen phosphate, anhydrous Trisodium phosphate, crystal Trisodium phosphate, anhydrous	2 g/kg for each single use while 3 g/kg for combined uses (Addition level of each food additive with crystallization water shall be expressed on anhydrous basis.)

<p>Sweetened condensed milk</p> <p>Sweetened condensed skimmed milk</p>	<p>Calcium citrate</p> <p>Trisodium citrate</p> <p>Sodium bicarbonate</p> <p>Sodium carbonate, crystal</p> <p>Sodium carbonate, anhydrous</p> <p>Tetrasodium pyrophosphate, crystal</p> <p>Tetrasodium pyrophosphate, anhydrous</p> <p>Potassium polyphosphate</p> <p>Sodium polyphosphate</p> <p>Potassium metaphosphate</p> <p>Sodium metaphosphate</p> <p>Dipotassium hydrogen phosphate</p> <p>Disodium hydrogen phosphate, crystal</p> <p>Disodium hydrogen phosphate, anhydrous</p> <p>Sodium dihydrogen phosphate, crystal</p> <p>Sodium dihydrogen phosphate, anhydrous</p>	<p>2 g/kg for each single use while 3 g/kg for combined uses (Addition level of each food additive with crystallization water shall be expressed on anhydrous basis.)</p>
	<p>Lactose</p>	<p>2 g/kg</p>
<p>Whole milk powder</p> <p>Skimmed milk powder</p>	<p>Trisodium citrate</p> <p>Sodium bicarbonate</p> <p>Sodium carbonate, crystal</p> <p>Sodium carbonate, anhydrous</p> <p>Tetrasodium pyrophosphate, crystal</p> <p>Tetrasodium pyrophosphate, anhydrous</p> <p>Potassium polyphosphate</p> <p>Sodium polyphosphate</p> <p>Potassium metaphosphate</p> <p>Sodium metaphosphate</p> <p>Disodium hydrogen phosphate, crystal</p> <p>Disodium hydrogen phosphate, anhydrous</p> <p>Trisodium phosphate, crystal</p> <p>Trisodium phosphate, anhydrous</p>	<p>5 g/kg for single or combined uses (Addition level of each food additive with crystallization water shall be expressed on anhydrous basis.)</p>
<p>Sweetened milk powder</p>	<p>Trisodium citrate</p> <p>Sodium bicarbonate</p> <p>Tetrasodium pyrophosphate, crystal</p> <p>Tetrasodium pyrophosphate, anhydrous</p>	<p>5 g/kg for single or combined uses (Addition level of each food additive with</p>

	Potassium polyphosphate Sodium polyphosphate Potassium metaphosphate Sodium metaphosphate Disodium hydrogen phosphate, crystal Disodium hydrogen phosphate, anhydrous Trisodium phosphate, crystal Trisodium phosphate, anhydrous	crystallization water shall be expressed on anhydrous basis.)
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- 6) In formulated milk powder, 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.
- 7) The mouth of containers of special milk shall be covered with paper, plastics or metal.
- 8) In the case of bottling milk, cream, fermented milk, fermented milk drink or milk drink in bottles and sealing them, the process shall be performed by use of bottling machines and sealing machines.
- 9) In the case of pasteurizing milk or milk products during processing of milk and manufacture of milk products, the process shall be performed by pasteurizers with automatic record thermometers, and the records of automatic thermometry shall be kept for 3 months (for product storable at room temperature, one year).
- 10) In the case of cooling milk after removing milk fat or storing milk after pasteurization by heating during manufacture of skimmed milk powder, temperature control shall be performed by automatic thermometers, and the records of automatic thermometry shall be kept for 3 months.
- 11) The equipments and containers/packages of milk, etc. shall be cleaned and pasteurized by a suitable method before use. Provided, however, that this does not apply to containers/packages that have been already cleaned and pasteurized or manufactured by manufacturing methods having a pasteurization effect and have been handled so as not to be liable to be contaminated until use.
- 12) Vehicles or devices for transportation of milk, etc. shall, when necessary, be covered, equipped with cooling facilities, or have other measures to be taken so that milk, etc. may not be contaminated nor exceed the critical temperature.
- 13) In case of storing milk, fermented milk, fermented milk drink or milk drink inside vending machines, the foods shall either be stored in capped or sealed containers/packages.

(6) Standards of Cooking Methods of Fermented Milk Drink Cooked by Cup-Sales Type Vending Machines

- 1) Fermented milk drink used in cooking shall comply with each of the following Nos.
  1. They shall comply with the compositional standards of fermented milk drink.
  2. They shall either be heated at 80°C for 30 minutes or pasteurized by a thermal pasteurization method having an equal or more effect.
  3. Their pH values shall be not more than 4.0 and their sugar concentration not less than 50%.
  4. After manufacture, they shall be capped or sealed until shortly before being filled into the built-in tank.
- 2) The water used in cooking shall be water-supply water that either has been boiled for 5 minutes or pasteurized by an operation having an equal or more effect.
- 3) No materials other than fermented milk drink and water shall be used for cooking.
- 4) Fermented milk drink and water used for cooking (below, “liquids inside the machine”) shall be kept at not higher than 10°C inside the cup-sales type vending machines.
- 5) Parts coming into direct contact with liquids inside the machine shall be cleaned and shall either be pasteurized by immersion in hot water of approximately 95°C for 5 minutes or by other procedure having an equal or more effect, at least once a day.

(7) Testing Methods of Compositional Standards of Milk, etc.

1) Milk and milk products

1. Assay of milk solids-not-fat content of milk and milk products

Dry an aluminum flat-bottomed weighing dish of not less than 5 cm in bottom diameter in a drying oven at a temperature of 98 to 100°C until its weight becomes constant. Weigh 2.5 to 3 g of sample in the above-mentioned weighing dish. Heat it carefully on a water bath to evaporate most of the water. Then, transfer to the above-mentioned oven, dry to constant weight and measure the weight of the dry matter. From this weight percent of the dry matter, subtract the weight percent of fat determined according to the method designated in the paragraph of Assay of Milk Fat Content of Milk and Milk Products, and make this as the weight percent of milk solids-not-fat content.

Use a drying oven that can be adjusted to an air temperature of 99±1°C and that is structurally designed so that the sample is not overheated to a temperature above that designated temperature due to heat conducted from the dryer walls and shelves, heat radiated from the hot plates, etc.

2. Assay of milk solids content of milk products

- a. Assay of milk solids content of concentrated milk, concentrated skimmed milk, evaporated milk, evaporated skimmed milk, sweetened condensed milk and sweetened condensed skimmed milk

Weigh 20 g of sample, dilute with warm water and pour into a 100 mL volumetric flask and make to the mark with water, and use this as the diluted test sample. Take 5 mL (corresponding to 1g of sample) of the diluted test sample and find the quantity of dry matter in the same manner as the preceding paragraph. As far as concentrated milk, concentrated skimmed milk, evaporated milk and evaporated skimmed milk are concerned, use the weight percent of dry matter as the weight percent of milk solids content; as for sweetened condensed milk and sweetened condensed skimmed milk, subtract the weight percent of sugar assayed according to the method designated in the paragraph of Assay of Sugar Content of Milk Products from the weight percent of dry matter, and use this as the weight percent of milk solids content.

- b. Assay of milk solids content of whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder and sweetened milk powder.

Dry an aluminum flat-bottomed weighing dish of not less than 5 cm in bottom diameter until its weight becomes constant in a drying oven at a temperature of 98 to 100°C. Weigh 2 g of sample in the weighing dish, dry in the above-mentioned oven, and find the quantity of dry matter. As far as whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder and buttermilk powder are concerned, use the weight percent of dry matter as the weight percent of milk solids content; as for sweetened milk powder, subtract the weight percent of sugar assayed according to the method designated in the paragraph of Assay of Sugar Content of Milk Products from the weight percent of dry matter, and use this as the weight percent of milk solids content.

### 3. Assay of milk fat content and milk protein content of milk and milk products

- a. Assay of milk fat content of cow's milk, special milk, pasteurized goat's milk, low fat milk, skimmed milk and processed milk

Take 10 mL of sulphuric acid into a Gerber butyrometer with a sulphuric acid-use pipette, then, gradually superimpose 11 mL of milk on the sulphuric acid with a cow milk-use pipette. Furthermore, add 1 mL of pure amyl alcohol, and stopper with a rubber stopper. Shake and dissolve the milk, applying pressure to the stopper with a finger, being followed by immersing in warm water of approximately 65°C for 15 minutes. In the next place, centrifuge for 3 to 5 minutes in a centrifuge of not less than 700 rpm, immerse in warm water of approximately 65°C

again to stabilize the temperature, and read the number of degrees of the fat layer formed and make it as the weight percent of milk fat.

#### Reagents

A. Sulphuric acid of specific gravity 1.820 to 1.825 at 15°C

B. Amyl alcohol: Alcohol having boiling range of 128 to 132°C and specific gravity of approximately 0.81 at 15°C. No separation of oily substance is observed when carried out reagent blank test overnight by use of 2 mL of alcohol and 11 mL of water in the same manner as the cow milk case.

- b. Assay of milk fat content of concentrated milk, evaporated milk, sweetened condensed milk, whole milk powder, cream powder, sweetened milk powder and cream

As for concentrated milk, evaporated milk and sweetened condensed milk, take 10 mL of the diluted test sample used in the determination according to the method designated in the paragraph of Assay of the Milk Solids Content of Milk Products into a Roehrig tube. Add successively 2 mL of aqueous ammonia water (25 ~30%, colorless and transparent) and 10 mL of ethanol (95~96%), mixing well at each time.

As far as whole milk powder, cream powder and sweetened milk powder are concerned, weigh 1 g of sample (5 g in case of cream) in a small beaker, dissolve by the addition of approximately 4 mL of warm water, transfer to the Roehrig tube, then successively wash the beaker twice with each 3 mL of warm water, then with 2 mL of aqueous ammonia water and 10 mL of ethanol (95~96%), stoppering and mixing well at each time.

To the ethanol-filled Roehrig tube, add 25 mL of ether, rotate gently until the content of the tube becomes a homogeneous color, then remove the ether gas. Shake vigorously for 30 seconds horizontally. Next, add 25 mL of petroleum ether (boiling point not higher than 60°C), shake in the same manner for 30 seconds, loosen the stopper, and stand the tube still in the upright position for not less than two hours until the clear upper layer becomes wholly transparent. Remove the clear upper layer liquid into a beaker whose constant weight has previously been measured.

To the Roehrig tube, add 25 mL of ether, then 25 mL of petroleum ether, and perform in the same manner as the first time, transfer the upper transparent liquid into the beaker, wash the side tube tip with a mixture of equal volumes of ether and petroleum ether and add to the beaker.

As for whole milk powder, cream powder, sweetened milk powder and cream, perform the same operation once more.

Evaporate the solvent carefully at approximately 75°C, then dry the beaker in a drying oven at an air temperature of 100 to 105°C for one hour and make the weight increase as the milk fat content.

c. Assay of milk protein content of protein concentrated whey powder

Divide the value obtained by the method designated in b. of 1. Assay of Milk Solids Content of 5) Process Cheese and Concentrated Whey by the percent of milk solids content, then multiply the obtained value by 100 and make it as the percent of milk protein in milk solids content.

4. Determination method of specific gravity of milk

Take an approximately 200 mL of sample in a cylinder, and measure at 15°C by use of a floating-type lactometer of specific gravity 1.015 to 1.040. If determining specific gravity at a temperature other than 15°C, convert to the specific gravity at 15°C by use of the Attached 1. Whole Milk Specific Gravity Compensation Table for raw milk (omitted), raw goat's milk, cow's milk, special milk and pasteurized goat's milk, and Attached 2. Low Fat Milk and Skimmed Milk Specific Gravity Compensation Table (omitted), for low fat milk and skimmed milk.

5. Determination method of acidity of milk and milk products

Dilute 10 mL of sample with the same amount of water free from carbon dioxide, add 0.5 mL of phenolphthalein solution as an indicator and titrate with 0.1 mol/L sodium hydroxide solution until the faint pink color persists for 30 seconds. From the amount consumed in the titration, calculate the acidity as the percent of lactic acid.

One milliliter of 0.1 mol/L sodium hydroxide solution is equivalent to 9 mg of lactic acid.

The indicator solution is prepared by dissolving 1 g of phenolphthalein in 50% ethanol and by making to 100 mL.

6. Assay of moisture of milk products

Find the weight percent of dry matter by the same method as that designated in the paragraph of Assay of Milk Solids Content of Milk Products. Use the weight percent of the loss on drying as the weight percent of moisture.

7. Assay of carbohydrate content of milk products

a. Assay of lactose

As for sweetened condensed milk and sweetened condensed skimmed milk, take 20 mL of the diluted test sample used in the determination according to the method designated in the

paragraph of Assay of Milk Solids Content of Milk Products (amount equivalent to 4 g of sample) in a 200 mL volumetric flask, and dilute to the mark with water. Use this diluted solution as the test solution.

As for sweetened milk powder, take 1.5 to 1.7 g of sample and dissolve in warm water and dilute to 200 mL in the same manner as the preceding paragraph, and use this as the test solution.

As for concentrated whey, make a homogenous sample by use of a kneader, dilute to 200 mL in the same manner as the preceding paragraph and use this as the test solution.

Take each 5 mL of Fehling's solutions A and B as well as 10 mL of water into a 200 mL conical flask, put the test solution into a burette and inject the majority of the expected titration amount into the flask. Heat the solution avoiding direct heat, boil it within 2 minutes, and then reduce the temperature. After the blue color of copper sulphate has almost disappeared, gradually add 4 drops of methylene blue solution, and then continue titration by adding test solution, while boiling, until the blue color disappears. Toward the end of titration, drop one drop at a time so as not to exceed the amount. Complete the titration within 3 minutes from the start of boiling. Perform a preliminary test to determine the expected titration amount, so that the amount of test solution used in the actual test may not exceed 2 mL.

Find the "Amount of Anhydrous Lactose in 100 mL of Test Solution" from the titration number with the aid of the Attached 3. Lactose Assay Table, correct the figure by multiplying by factor of Fehling's solution A and obtain the amount of lactose per 1 g of sample.

At the same time, find the number in the table corresponding to the titration number and convert it to the number per 1 g of sample. Use this as the "Amount of Lactose per 1 g of Sample Which Can Be Assayed as Invert Sugar" based on the amount of cuprous oxide reduced by lactose during a sugar assay.

b. Assay of sugar

As for sweetened condensed milk and sweetened condensed skimmed milk, take 50 mL of the test solution for lactose assay (amount equivalent to 1 g of sample), while as for sweetened milk powder, take 1.0 to 1.5 g and dissolve in 50 mL warm water. To these solutions, add 2.5 mL of inversion-use hydrochloric acid solution (25%, specific gravity 1.125), immerse in warm water of 65°C for 20 minutes to warm and invert, then cool immediately with water and add 2 drops of phenolphthalein solution, neutralize with sodium hydroxide solution and dilute to 200 mL with water. Put the test solution into a burette, and titrate a mixture of 10 mL of Fehling's solution (5 mL each A and B) and 10 mL of water in the same manner as in the assay of lactose.

Find the amount of invert sugar corresponding to the titration number with the aid of the Attached 4. Invert Sugar Assay Table and calculate the “Total Amount of Invert Sugar per 1 g of Sample”. Next, subtract the “Amount of Lactose per 1g of Sample Which Can Be Assayed as Invert Sugar” determined by the preceding item from the above value, and multiply the remainder by 0.95 and correct the figure by factor of the Fehling’s solution A to obtain the amount of sugar per 1 g of sample.

○ Fehling’s solution

Solution A: Dissolve 34.639 g of crystalline copper sulphate ( $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ ) in water to make 500 mL. Determine the titer.

Solution B: Dissolve 173 g of Rochelle salt and 50 g of sodium hydroxide in water to make 500 mL.

○ Determination of the titer of solution A

Take accurately 10 mL of solution A, and add 40 mL of water and 4 mL of diluted acetic acid to acidify. Add 3 g of potassium iodine and titrate the liberated iodine with 0.1 mol/L sodium thiosulphate solution by use of 1% soluble starch solution as the indicator. One milliliter of 0.1 mol/L sodium thiosulphate solution corresponds to 6.357 mg of copper. Calculate the amount of copper in 10 mL of solution A from the titration number. Divide the amount of copper by 174.9 mg and use the quotient as the titer of solution A used.

Prepare the solution so that the titer comes within  $1 \pm 0.005$ .

Methylene blue solution: Dissolve 1 g of reagent-use special grade methylene blue in water and dilute to 100 mL.

## 8. Determination method of bacterial count of milk and milk products

### a. Determination method of bacterial count of raw milk and raw goat’s milk by direct microscopic individual count method

#### A. Sampling

After mixing well the milk in a container with a sterile agitator, take an approximately 25 to 30 mL specimen into a sterile collection bottle with a sterile collection tube. Keep or transport at a temperature not higher than  $4^\circ\text{C}$ . The specimen should be used for the test within 4 hours after collection. If the determination was carried out later than 4 hours, make a note to that effect in the written results.

#### B. Determination method

Shake the specimen well along with the container not less than 25 times. Suck up an

appropriate amount of the specimen with a bacteriological-use micropipette for cow milk. Wipe off the milk adhering to the outer wall of the pipette by use of a white cloth. Next, suck out the specimen in the pipette from the tip by use of a white cloth until the specimen volume becomes exactly 0.01 mL, then expel the entire amount onto a microscopic slide glass and spread uniformly over a 1 cm<sup>2</sup> area by use of a spreading needle being followed by slight warming for about 5 minutes and subsequent drying. Immerse the glass instantaneously in the separately noted staining solution to dye, immediately shake off the excess solution, rinse with water after becoming drying, and dry again to make the preparation.

Use a microscope equipped with oil-immersion lenses, adjust the diameter of the field to 0.206 mm with the objective stage micrometer slide, examine the previously noted preparation, count the number of cells of bacteria in not less than 16 representative fields individually, and find the average number per one field. Multiply this by 300,000, round off the figure by use of the top two digits as the significant figures, and use it as the bacterial count in 1 mL of raw milk or raw goat's milk.

#### C. Preparation method of staining solution

Place 40 mL of tetrachloroethane and 54 mL of absolute ethanol in a flask, warm to 70°C, mix with 1.00 to 1.12 g of methylene blue, and shake vigorously to dissolve the dye completely. Wait until cool, then gradually add 6 mL of acetic acid, filter, and store tightly stoppered.

- b. Determination method of bacterial count (viable count) of cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, cream, milk drink, concentrated milk, concentrated skimmed milk, evaporated milk, evaporated skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder, sweetened milk powder, and formulated milk powder by standard plate count method.

#### A. Sampling and preparation method of test solution

As for cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, cream and milk drink, take specimen as it is contained in containers/packages or take enough amount of specimen, by which compliance with compositional standards can be judged, aseptically into a sterile collection bottle by use of a sterile collection apparatus. As for concentrated milk and concentrated skimmed milk, take approximately 200 g of specimen by the method designated in A. Sampling of a.

Determination Method of Bacterial Count of Raw Milk and Raw Goat's Milk by Direct Microscopic Individual Count Method. In this case, the specimen should be kept and transported at a temperature not higher than 4°C. The specimen should be used for the test within 4 hours after collection. If the determination was carried out later than 4 hours, make a note to that effect in the written results.

Next, excluding concentrated milk and concentrated skimmed milk, keep as is for specimen collected in a sterile collection bottle, while transfer aseptically into a sterile wide-mouthed bottle for specimen collected as container-packaged. Shake well not less than 25 times. Prepare 10-fold and 100-fold dilutions by use of a sterile dilution bottle with a sterile cow milk-use pipette. When further dilution is necessary, prepare dilutions in the same manner with a sterile chemical pipette.

As for evaporated milk, evaporate skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder, sweetened milk powder and formulated milk powder, take specimen as it is contained in containers/packages or take enough amount of specimen, by which compliance with compositional standards can be judged, aseptically into a sterile collection bottle by use of a sterile collection apparatus. As for concentrated milk and concentrated skimmed milk, shake well not less than 25 times as is in the sterile collection bottle and take 10 g of specimen with a sterile spoon into a ground glass-stoppered conical flask (weight not more than 85 g without stopper and having a line at the 100 mL mark), dilute to 100 mL with sterile physiological solution of sodium chloride to prepare 10-fold dilution. Next, prepare dilutions in the same manner as cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, cream and milk drink.

#### B. Determination method

From the dilutions of cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, cream, milk drink, concentrated milk, concentrated skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder, sweetened milk powder and formulated milk powder, select the dilutions giving from 30 to 300 colonies per plate, and prepare two or more sterile Petri dishes for the same dilution. Take accurately each 1 mL of the dilution into the sterile Petri dish by use of sterile pipette, add approximately 15 mL of standard count agar medium previously warmed to melt and kept at a temperature from 43 to

45°C, mix by gentle rotating and tilting front and back as well as right and left, then cool to solidify.

Not more than 20 minutes shall elapse from taking the test solutions into the Petri dishes to the pouring of the media.

After the media have solidified, invert the Petri dishes and incubate at a temperature from 32 to 35°C for 48 hours (allowance±3 hours), then count the number of colonies formed. In case it is not possible to count immediately after the incubation time has passed, the Petri dishes may be taken out and stored in a refrigerator of not higher than 5°C, and the colonies should be counted within 24 hours.

Use, as a control, a mixture of 1 mL of dilution fluid, without addition of the sample, and the medium to confirm the sterility of Petri dishes, diluents, and medium as well as the completeness of the procedure.

The Petri dishes shall be of a diameter from 9 to 10 cm and a depth of 1.5 cm.

As for evaporated milk and evaporated skimmed milk, take 2 mL each of the previously prepared 10 mL of 10-fold dilution into five sterile Petri dishes, then proceed in the same manner as with cow's milk.

Enumeration of bacterial count shall be carried out as follows:

Select plates, excluding evaporated milk and evaporated skimmed milk, showing from 30 to 300 colonies per plate or plates on which, even though there are spreading colonies, the area is not more than one half of the plate and the other colonies are well dispersed, being no obstacle for enumeration. Count the number of colonies with the aid of a colony counter under constantly stable light. In case declaring the number obtained by multiplying the number of colonies on one plate or the average number of colonies on two or more plates by the dilution factor, round off the third digit from the top and declare only two digits, attaching "0" below.

The following cases shall be considered as laboratory accidents.

- (a) Cases when no colonies occur (excluding cases of product storable at room temperature, evaporated milk, evaporated skimmed milk and milk drink sterilized by heating for not less than 15 minutes at 115°C).
- (b) Cases when the area of spreading colonies exceeds one half of the plate
- (c) Cases of evident contamination
- (d) Other cases considered inappropriate

- Culture medium

Standard plate count agar medium: Combine 5 g of peptone, 2.5 g of yeast extract, 1 g of glucose and 15 g of agar with 1,000 mL of purified water, heat to dissolve and sterilize in an autoclave (pH after sterilization to be 7.0 to 7.2)

## 9. Determination method of coliforms of milk and milk products

The coliforms in this test are defined as all the aerobic and facultatively anaerobic, Gram-negative, nonsporeforming, rod-shaped bacteria capable of fermenting lactose with the production of gas.

### a. Sampling and preparation method of test solution

Follow A of b. (Standard Plate Count Method) in 8. Determination Method of Bacterial Count of Milk and Milk Products of 1) Milk and Milk Products

### b. Determination method

Inoculate each 1 mL of the specimen, 10-fold dilution and 100-fold dilution in duplicate into B.G.L.B. (brilliant green lactose bile broth) fermentation tubes, incubate at a temperature from 32 to 35°C for 48 hours (allowance  $\pm$  3 hours ), then observe the gas production.

If no gas production is observed, the sample is judged to be coliforms-negative. In case gas production is confirmed, take the fermentation tube, streak one loopful of the liquid culture on Endo medium or E.M.B. (eosin methylene blue) medium and incubate to ensure the formation of discrete colonies. After incubation at a temperature from 32 to 35°C for 24 hours (allowance  $\pm$  2 hours ), transfer a typical colony or not less than two atypical colonies from either Endo Medium or E.M.B. medium to lactose broth fermentation tubes and nutrient agar slants.

Incubate the lactose broth fermentation tubes at a temperature from 32 to 35°C for 48 hours (allowance  $\pm$  3 hours ), while the agar slants at a temperature from 32 to 35°C for 24 hours. When the gas production is observed in the lactose broth fermentation tubes, examine microscopically the corresponding agar slant. If Gram-negative, nonsporeforming, rod-shaped bacteria are observed, the sample is judged to be coliforms-positive.

- Culture media

#### A. B.G.L.B. fermentation tubes

Dissolve 10 g of peptone and 10 g of lactose in 500 mL of distilled water, add 200 mL of fresh ox bile (or 20 g of dehydrated ox bile dissolved in 200 mL of water, pH 7.0 to 7.5), make up to approximately 975 mL, adjust pH to 7.4, add 13.3 mL of 0.1% aqueous brilliant green solution, to make the total volume to 1,000 mL, filter through cotton,

dispense approximately 10 mL each into test tubes, in which are placed Durham's tubes, and sterilize by fractional steam sterilization (pH after sterilization must be within 7.1 to 7.4)

#### B. Endo medium

Warm and melt 1,000 mL of 3% nutrient agar (pH 7.4 to 7.8), add 15 g of lactose previously dissolved in a small amount of water, and mix well. Further, add 1.0 mL of saturated fuchsin solution in ethanol (approximately 11 g of fuchsin dissolved in 100 mL of ethanol), cool to approximately 50°C, then add freshly prepared solution of 10% anhydrous sodium sulphite little by little until the color of fuchsin turns to light pink.

Dispense 40 to 100 mL of this into test tubes or flasks, and sterilize by fractional steam sterilization. Melt and prepare plates immediately before use.

#### C. E.M.B. medium

Add 10 g of peptone, 2 g of dipotassium phosphate ( $K_2HPO_4$ ) and 25 to 30 g of agar in 1,000 mL of distilled water, heat to dissolve and melt, and correct the evaporated volume after boiling (pH adjustment unnecessary). Add 10 g of lactose, 20 mL of aqueous solution of 2% eosin (eosin yellow), and 13 mL of 0.5% methylene blue solution, mix well, dispense and sterilize by fractional steam sterilization. Melt and prepare plates immediately before use.

#### D. Lactose broth fermentation tubes

Add lactose to nutrient broth at a rate of 0.5%.

Dispense approximately 10 mL each into test tubes, in which are placed Durham's tubes, and sterilize by fractional steam sterilization (pH after sterilization to be 6.4 to 7.0).

### 10. Alcohol testing method of milk

Take 2 mL of sample into a small Petri dish, add the same volume of 70% (v/v) ethanol, mix, and observe the formation of coagulum. If coagulation is not observed with the naked eyes, the sample is judged to be alcohol-test negative.

## 2) Ice cream products

### 1. Sampling and preparation method of test solution

Take enough amount of specimen, by which compliance with the compositional standards can be judged, aseptically into a sterile collection bottle by use of a sterile collection apparatus. Keep or transport by maintaining the sampled temperature as much as possible. The specimen must be used for the test within 4 hours after collection.

For the preparation of test solution, melt the specimen completely at not higher than 40°C in as short a time as possible, take 10 g into a ground glass-stoppered bottle. For the determination of bacterial count (viable count), dilute 10-fold with 90 mL of sterile physiological solution of sodium chloride. From this, prepare a series of dilutions with sterile physiological solution of sodium chloride so as to give 30 to 300 colonies per plate. For the determination of coliforms, dilute 10-fold with 90 mL of sterile physiological solution of sodium chloride.

## 2. Determination method of bacterial count (viable count)

Prepare two or more sterile Petri dishes for each sample, take precisely each 1 mL of the prepared test solution into the corresponding sterile Petri dishes by use of sterile pipette. To this, add approximately 15 mL of standard plate count agar medium previously warmed to melt and kept at a temperature from 43 to 45°C, mix by gently rotating and tilting front and back as well as right and left, then cool to solidify.

This procedure must be completed within 20 minutes after taking the test solutions into the Petri dishes. After the media have solidified, invert the Petri dishes and incubate at a temperature from 32 to 35°C for 48 hours (allowance  $\pm$  3 hours). Prepare a control by mixing the same kind and amount of medium to which the test solutions have been added with 1mL of the sterile physiological solution of sodium chloride used for dilution of the specimen, gently rotate, then proceed in the same manner as with the test solution and incubate. Thus, the sterility of the Petri dishes, physiological solution of sodium chloride and medium as well as completeness of the procedure shall be checked.

The Petri dishes shall be of a diameter from 9 to 10 cm and depth of 1.5 cm.

Enumeration of bacterial count shall be carried out as follows:

Count the number of colonies of plates showing from 30 to 300 colonies per plate (in case there are no plates available showing 30 to 300 colonies per plate, use plates on which the area of spreading colonies is not more than one half of the plate, the other colonies being well dispersed without any hindrance for counting) with the aid of a colony counter under constantly stable light. Obtain the averages of the number of colonies of the plates for test solution of the same dilution factor. Multiply these average values by the dilution factors for the respective test solutions, sum up the values obtained, then divide it by the number of grades, classified by dilution factor, of effective plates and use the value, as the bacterial count.

Provided, however, that the following cases shall be considered laboratory accidents.

- a. Cases when no colonies occur
- b. Cases when the area of spreading colonies exceeds one half of the plate
- c. Cases of evident contamination

d. Other cases considered inappropriate

○ Culture medium

Standards plate count agar medium:

Combine 5 g of peptone, 2.5 g of yeast extract, 1 g of glucose and 15 g of agar with 1,000 mL of purified water, heat to dissolve and sterilize in an autoclave (pH after sterilization to be 7.0 to 7.2).

3. Determination method of coliforms

Prepare two sterile Petri dishes and take precisely 1 mL of test solution into each dish by use of a sterile pipette. To this, add 10 to 15 mL of desoxycholate agar medium previously warmed to melt and kept at a temperature from 43 to 45°C, mix by gentle rotating and tilting front and back as well as right and left, then cool to solidify. After the media have solidified, add 3 to 4 mL of the same medium on the surface and cool to solidify. Not more than 20 minutes shall elapse from taking the test solution into the Petri dishes to the pouring of the media.

After the media have solidified, invert the Petri dishes and incubate at a temperature from 32 to 35°C for 20 hours (allowance  $\pm$  2 hours), then observe the formation of colonies. Formation of dark red colonies constitutes presumptive test positive. Non-formation constitutes presumptive test negative.

When the presumptive test is positive, spread representative of the colonies onto an E.M.B. medium, and incubate at a temperature from 32 to 35°C for 24 hours (allowance  $\pm$  2 hours). Transfer typical colonies of coliforms (if no typical colonies are present, not less than two colonies resembling typical colonies) to lactose broth fermentation tubes and nutrient agar slants (when fishing out colonies resembling typical colonies, transfer the fished out colonies separately).

Incubate the lactose broth fermentation tubes at a temperature from 32 to 35°C for 48 hours (allowance  $\pm$  3 hours), while the agar slants at a temperature from 32 to 35°C for 24 hours. When the gas production is observed in the lactose broth fermentation tubes, examine microscopically the corresponding agar slant. If Gram-negative, non-sporeforming, rod-shaped bacteria are observed, the sample is judged to be coliform-positive.

The Petri dishes shall be of a diameter from 9 to 10 cm and a depth of 1.5 cm.

○ Culture media

A. Desoxycholate agar medium

Combine 10 g of peptone, 15 to 25 g of agar, 10 g of lactose, 5 g of sodium chloride, 2 g of

ferric ammonium citrate and 2 g of monopotassium phosphate with 1,000 mL of water, heat to dissolve, filter, adjust the pH of the filtrate to 7.3 to 7.5, then add 1 g of sodium desoxycholate and 0.033 g of neutral red, and readjust the pH to 7.3 to 7.5.

#### B. E.M.B. medium

Use the medium given in C. E.M.B. Medium in Culture Media of b. Determination Method in 9. Determination Method of Coliforms of Milk and Milk Products of 1) Milk and Milk Products.

#### C. Lactose broth fermentation tubes

Use the medium given in D. Lactose Broth Fermentation Tubes in Culture Media of b. Determination Method in 9. Determination Method of Coliforms in Milk and Milk Products of 1) Milk and Milk Products.

### 4. Assay of milk fat content

Take 4 g of sample in a small beaker, add 3 mL of water, mix thoroughly, then transfer to a Roehrig tube.

Wash the beaker well with 3 mL of water, add the washing to the Roehrig tube and shake, then add 2 mL of ammonia water (25 to 30%, colorless and transparent) and mix gently. Place the Roehrig tube in a 60°C water bath and warm for 20 minutes, shaking occasionally. Then proceed by the same method as shown in the method of whole milk powder, cream powder, sweetened milk powder and cream designated in the paragraph of b. Assay of Milk fat Content of Condensed Milk, Evaporated Milk, Sweetened Condensed Milk, Whole Milk Powder, Cream Powder, Sweetened Milk Powder and Cream in 3. Assay of Milk fat Content of Milk and Milk Products of 1) Milk and Milk Products.

### 5. Assay of milk solids content

Use the sum of the milk fat content obtained by the method designated in 4 and the milk solids-not-fat content obtained by the same method as designated in 1. Assay of Milk Solids-not-fat Content of 3) Fermented Milk and Fermented Milk Drink as the milk solids content.

### 3) Fermented milk and fermented milk drink

#### 1. Assay of milk solids-not-fat content

Weigh precisely an approximately 50 g of specimen (for frozen specimens, melt completely at a

temperature of not higher than 40°C in as short a time as possible), add several drops of phenolphthalein solution and gradually add 10% sodium hydroxide solution, while stirring, to make slightly alkaline.

Pour into a 100 mL volumetric flask and make to the mark with water. Take precisely 5 mL into a 150 mL Kjeldahl digestion flask, add 0.2 g of a powdered mixture of potassium sulphate and copper sulphate (9:1), furthermore add 10 mL of sulphuric acid along the inside wall of the flask. Next, gradually heat the flask until white fumes of sulphurous acid gas evolve. Strengthen the heat a little and heat until the majority of the bubbles disappear. Heat strongly until the inside solution shows clear light blue color and carbonized substances are no longer observed inside of the flask. Stop heating and let cool. After cooling, add 30 mL of water carefully and cool again.

Connect the flask to the distillation apparatus. In this case, place 30 mL of 0.05 mol/L sulphuric acid and several drops of methyl red solution in a 200 mL absorption flask and adjust so that the lower end of the condenser dips in the solution.

Next, add 40 mL of 30% sodium hydroxide solution from the funnel of the Kjeldahl distillation apparatus, wash down with 10 mL of water, close the pinch cock and immediately begin distillation. After the volume of the distillate reaches 80 to 100 mL, separate the lower end of the condenser from the liquid surface and collect further several mLs of the distillate.

After completion of the distillation, wash the end of the condenser that has dipped in the solution with a small amount of water, combine the washing to the solution inside the absorption flask, then titrate it with 0.1 mol/L sodium hydroxide solution.

Calculate the milk solids-not-fat content by the following formula:

$$0.0014 \times (A - B) / \text{amount of sample (g)} \times 6.38 \times 2.82 \times 100 (\%)$$

Where

A: Volume of 0.1 mol/L sodium hydroxide solution required to neutralize 30 mL of 0.05 mol/L sulphuric acid (mL)

B: Volume of 0.1 mol/L sodium hydroxide solution required for titration (mL)

○ Indicator

Methyl red solution: Dissolve 1 g of methyl red in 50 mL of ethanol and dilute to 100 mL with water. Filter if necessary.

## 2. Sampling and preparation method of test solution

Take enough amount of specimen, by which compliance with the compositional standards can be judged, aseptically into a sterile collection bottle by use of a sterile apparatus. Keep and transport at a temperature not higher than 4°C, and use it for the test within 4 hours after collection.

In case of pasty specimens, take 10 g into a ground glass-stoppered bottle after stirring well with a sterile pipette-like glass rod in case of liquid specimens, take 10 mL after stirring well, while in case of frozen specimens, take 10 g after complete melting at a temperature not higher than 40°C in as short a time as possible.

Dilute to 100 mL with sterile physiological solution of sodium chloride to prepare a 10-fold dilution. Furthermore, prepare a series of dilutions with sterile physiological solution of sodium chloride to give 30 to 300 colonies per plate.

### 3. Determination method of lactic acid bacteria count

Prepare two or more sterile Petri dishes for each sample, take precisely each 1 mL of the prepared test solution into the corresponding sterile Petri dish by use of a sterile pipette. To this, add approximately 15 mL of plate count agar medium with B.C.P. (bromocresol purple) previously warmed to melt and kept at a temperature from 43 to 45 °C mix by gentle rotating and tilting front and back as well as right and left, then cool to solidify.

This procedure must be completed within 20 minutes after taking the test solutions into the Petri dishes. After the media have solidified, invert the Petri dishes and incubate at a temperature from 35 to 37°C for 72 hours (allowance 3 hours).

Prepare a control by mixing the same kind and amount of medium to which the test solutions have been added with 1 mL of the sterile physiological solution of sodium chloride used for dilution of the specimen, gently rotate, then proceed in the same manner as with the test solution, and incubate. Thus, the sterility of the Petri dishes, physiological solution of sodium chloride, and medium as well as the completeness of the procedure shall be checked.

The Petri dishes shall be of a diameter from 9 to 10 cm and a depth of 1.5 cm.

Of the colonies formed after incubation, those which have changed to yellow are the colonies of lactic acid bacteria.

Enumeration of lactic acid bacteria count shall be carried out as follows:

Count the number of colonies of lactic acid bacteria of the plate showing from 30 to 300 colonies of lactic acid bacteria per plate (in case there are no plates available showing 30 to 300 colonies of lactic acid bacteria, use plates on which the area of spreading colonies is not more than one half of the plate, the other colonies being well dispersed without any hindrance for counting), with the aid of a colony counter under constantly stable light.

Obtain the average of the number of colonies of lactic acid bacteria of the plates for test solutions of the same dilution factor. Multiply these average values by the dilution factors, for the respective test solutions, sum up the values obtained, then divide it by the number of grades,

classified by dilution factor, of effective plates, and use the value, as the lactic acid bacteria count.

Provided, however, that the following cases shall be considered as laboratory accidents.

- a. Cases when the area of spreading colonies of lactic acid bacteria exceeds one half of the plate
- b. Cases of evident contamination
- c. Other cases considered inappropriate

○ Culture medium

Plate count agar medium with B.C.P.

Combine 2.5 g of yeast extract, 5 g of peptone, 1 g of glucose, 1 g of Tween 80, 0.1 g of L-cysteine and 15 g of powdered agar with 1,000 mL of water, heat to dissolve, adjust the pH to 6.8 to 7.0, then add B.C.P. (bromocresol purple) at a rate of 0.004 to 0.006% and sterilize in an autoclave.

4. Determination method of coliforms

Proceed by the method designated in 3. Determination Method of Coliforms of 2) Ice Cream Products on the 10-fold dilution designated in 2. Sampling and Preparation Method of Test Solution.

4) Butter and butter oil

1. Assay of moisture

Take precisely approximately 2 g of sample into weighing tubes, and obtain the weight of dry matter according to the method designated in the paragraph of 1. Assay of Milk Solids-not-fat Content of Milk and Milk Products of 1) Milk and Milk Products. Divide the loss on drying by the amount of sample taken. Multiply the value by 100, and use this as the weight percent of moisture.

2. Assay of milk fat content

To the weighing tubes in which moisture was assayed, add 15 mL of petroleum ether, mix well while triturating with a glass rod to dissolve completely, then transfer into a crucible-shaped ground-glass glass filter. Wash well the inside walls of the weighing tubes by use of small amounts of petroleum ether and pour into the filter. Wash the filter with 100 mL of petroleum ether broken down into several portions to dissolve out the fat. Next, dry the filter to constant weight in a boiling steam dryer and find the weight of the residue.

Calculate the differences between the weight of dry matter found by 1. and the weight of the residue, and divide this by the amount of the sample taken, then multiply the value by 100 and

use this as the weight percent of milk fat content.

### 3. Determination method of coliforms

#### a. Sampling and preparation method of test solution

Take specimen as it is contained in containers/packages or take enough amount of specimen, by which the compliance with the compositional standards can be judged, aseptically into a sterile collection bottle, keep and transport at a temperature not higher than 4°C, and use it for the test within 4 hours after collection.

Warm the specimen in an incubator of a temperature not higher than 45°C, mix well within 15 minutes by use of sterile equipment, then take 10 g aseptically in a ground glass-stoppered conical flask (weight not more than 85 g without stopper and having a line at the 100 mL mark) with a sterile spoon or sterile Komagome pipette. Dilute to 100 mL with sterile physiological solution of sodium chloride at 40°C. Use the 10-fold dilution as the test solution.

#### b. Determination method of coliforms

Use the method designated in 3. Determination Methods of Coliforms of 2) Ice Cream Products.

### 5) Processed cheese and concentrated whey

#### 1. Assay of milk solids content

Use the sum of the milk fat and milk protein contents obtained according to the following methods as the milk solids content.

As for concentrated whey, furthermore, add the lactose content found by a. Assay of Lactose in 7. Assay of Carbohydrate Content of Milk Products of 1) Milk and Milk Products to obtain the milk solids content.

#### a. Assay of milk fat content

Take 1 g of the sample into a small-size, tall beaker. Add 9 mL of distilled water and 1 mL of dilute ammonia water. Mix with a glass rod to make a homogenous emulsion. Warm slightly to soften. Neutralize with hydrochloric acid, and further add 10 mL of hydrochloric acid. Add a small amount of refined white sand, cover with a watch glass and boil gently for approximately 5 minutes. Cool and transfer the content to a Roehrig tube. Wash the beaker with 10 mL of ethanol and 25 mL of ethyl ether, and add the washings to the Roehrig tube, shake well, then proceed by the same method as the method of concentrated milk, evaporated milk, and sweetened condensed milk designated in the paragraph of b. Assay of Milk fat Content of Concentrated Milk, Evaporated Milk, Sweetened Condensed Milk, Whole Milk Powder, Cream Powder, Sweetened Milk Powder, and Cream in 3. Assay of Milk fat Content of Milk and Milk Products of 1) Milk and Milk Products.

b. Assay of milk protein content

Weigh precisely 0.2 to 1.0 g of the sample and take into a Kjeldahl digestion flask (100 to 150 mL). Add 0.5 g of digestion stimulating agent (mixture of 9 parts of potassium sulphate and one part of copper sulphate ground separately before mixing). Next, add gently 10 mL of sulphuric acid along the inside wall of the digestion flask and mix. Heat gradually on digestion stand gently mixing carefully occasionally. When evolving of white fumes of sulphurous acid gas has been observed, strengthen the flame until the majority of the bubbles disappear. Ignite and continue digestion until the contents becomes light bluish green and transparent. After becoming transparent, cool, and wash the neck of the digestion flask with a small amount of distilled water, and heat further 30 minutes more. After digestion is completed, cool and add approximately 20 mL of distilled water and leave it to cool. Wash down the digested solution into a 100 mL volumetric flask, make to the mark with distilled water and use it as the test solution.

To the receiving flask (conical flask of 100 to 150 mL) of the Kjeldahl distillation apparatus, place precisely 10 mL of 0.01 mol/L sulphuric acid. Add 1 to 2 drops of mixed methylene blue-methyl red indicator, fix the glass tube at the tip of the condenser so that it reaches the bottom of the receiving flask and is immersed in the solution. Open the drainage outlet and the sample inlet, reflux the cooling water, and pour precisely 10 mL of the test solution into the double distillation tube from the funnel of the sample inlet. Wash the funnel with a small amount of distilled water, then add 10 mL of 30% sodium hydroxide solution through the funnel. Wash the funnel again with a small amount of water. Immediately close the sample inlet, and strengthen the heat of the steam generator. After steam has come out in large amounts from the drainage outlet, close it and begin distillation inside the double distillation tube. Continue distillation 4 to 5 minutes after the front of the initial distillate has reached the receiving flask. Lower the flask and separate the glass tube at the tip of the condenser from the solution. Further, distill for 2 minutes, wash the tip of the glass tube with distilled water and remove the receiving flask from the apparatus.

Immediately titrate with 0.02 mol/L sodium hydroxide solution. As a blank test, perform exactly the same procedure, using the same amount of reagent except test solution, and titrate in the same way.

Calculate the amount of milk protein by the following formula:

$$\text{Milk protein (\%)} = 0.28 \times F(X-Y) \times (100/10) \times (1/S) \times 6.38 \times 100$$

Where

F: Factor of 0.02 mol/L sodium hydroxide solution

X: Titration volume of blank test (mL)

Y: Titration volume of sample (mL)

S: Weight of sample (mg)

## 2. Determination method of coliforms

For the determination method of coliforms in these foods, use the method designated in 3. Determination Method of Coliforms of 4) Butter and Butter Oil.

### [3] The Standard of General Hygiene-Controlled Manufacturing or Processing of Milk, etc. and the Hygiene Control Method

(1) For general hygiene-controlled manufacturing processes of products, the documents listed below shall be prepared.

1. Product description in which the product's name and type, raw materials and other necessary items are described
2. Documents concerning manufacturing and processing processes in which the performance of machinery and appliances used for manufacturing or processing and other necessary items are described
3. Drawings of the facility in which the structures of the facility and equipments, movement pathway of products, etc. and other necessary items are described

(2) Documents describing the items listed below for general hygiene-controlled manufacturing processes of products shall be prepared.

1. For all types of food hygiene hazards which may occur in respect of each product, measures shall be stipulated to prevent the occurrence of the said hazard, concerning each substance that causes the said hazard and each process that may cause the said hazards. In cases where substances associated with the said measures, the foods listed in the upper column of the following tables, do not include substances that cause the hazards listed in the lower columns of the respective tables, the reason for this shall be stated.

Classification of foods	Substances that affect food sanitation
Cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, and cream	<ol style="list-style-type: none"> <li>1. Foreign substances</li> <li>2. <i>Yersinia enterocolitica</i></li> <li>3. <i>Staphylococcus aureus</i></li> <li>4. <i>Campylobacter coli</i></li> <li>5. <i>Campylobacter jejuni</i></li> <li>6. Antibacterial substances (only chemical compositions)</li> <li>7. Antibiotics</li> <li>8. Disinfectants</li> <li>9. Salmonella spp.</li> <li>10. Cleaning agents</li> <li>11. Substances that are constituents for animal drugs (excluding substances that are defined as those for which it is clear that there is no risk of impairment to human health in accordance with the provisions of Paragraph 3, Article 11 of the Law, antibacterial substances (limited to only chemical compositions), and antibiotics, same in the following table)</li> <li>12. Pathogenic <i>Escherichia coli</i></li> <li>13. Septic bacteria</li> <li>14. <i>Listeria monocytogenes</i></li> </ol>
Ice cream products	<ol style="list-style-type: none"> <li>1. Aflatoxin (only those included in raw materials such as nuts)</li> <li>2. Foreign substances</li> <li>3. <i>Yersinia enterocolitica</i></li> <li>4. <i>Staphylococcus aureus</i></li> <li>5. <i>Campylobacter coli</i></li> <li>6. <i>Campylobacter jejuni</i></li> <li>7. Antibacterial substances (only chemical compositions in raw materials such as milk, etc. and their processed products, same in the following table)</li> <li>8. Antibiotics</li> <li>9. Disinfectants</li> <li>10. Salmonella spp.</li> <li>11. Cleaning agents</li> <li>12. Food Additives (only those whose standards of usage are determined by the provisions of Paragraph 1, Article 11 of the Law, and</li> </ol>

	<p>excluding disinfectants, same in the following table)</p> <p>13. Substances that are constituents for animal drugs</p> <p>14. Pathogenic <i>Escherichia coli</i></p> <p>15. Septic bacteria</p> <p>16. <i>Listeria monocytogenes</i></p>
<p>Evaporated milk, evaporated skimmed milk, fermented milk, fermented milk drink, and milk drink</p>	<p>1. Foreign substances</p> <p>2. <i>Yersinia enterocolitica</i></p> <p>3. <i>Staphylococcus aureus</i></p> <p>4. <i>Campylobacter coli</i></p> <p>5. <i>Campylobacter jejuni</i></p> <p>6. Antibacterial substances</p> <p>7. Antibiotics</p> <p>8. Disinfectants</p> <p>9. Salmonella spp.</p> <p>10. Cleaning agents</p> <p>11. Food Additives</p> <p>12. Substances that are constituents for animal drugs</p> <p>13. Pathogenic <i>Escherichia coli</i></p> <p>14. Septic bacteria</p> <p>15. <i>Listeria monocytogenes</i></p>
<p>Skimmed milk powder</p>	<p>1. Foreign substances</p> <p>2. <i>Yersinia enterocolitica</i></p> <p>3. <i>Staphylococcus aureus</i></p> <p>4. <i>Campylobacter coli</i></p> <p>5. <i>Campylobacter jejuni</i></p> <p>6. Antibacterial substances</p> <p>7. Antibiotics</p> <p>8. Disinfectants</p> <p>9. Salmonella spp.</p> <p>10. Cleaning agents</p> <p>11. Food Additives</p> <p>12. Substances that are constituents for animal drugs</p> <p>13. Pathogenic <i>Escherichia coli</i></p> <p>14. Septic bacteria</p> <p>15. <i>Listeria monocytogenes</i></p>

2. Among the measures in 1, those that require continuous or significantly-frequent confirmation of the implementation status shall be specified to prevent the occurrence of food hygiene hazard associated with the product.
  3. Confirmation methods for 2. shall be specified.
- (3) In case when, as a result of the confirmation stated in (2) 2., it is recognized that the measures for (2) 2. have not been implemented appropriately, documents shall be prepared which describe the methods for the improvement measures to be implemented.
  - (4) For methods associated with general hygiene-controlled manufacturing processes of products, documents describing the methods involved in hygiene control of the facility and equipments, hygiene education for employees and other necessary items shall be prepared.
  - (5) For general hygiene-controlled manufacturing processes of products, documents describing the testing methods for the products etc. and those for testing the proper prevention of the occurrence of food hygiene hazards shall be prepared.
  - (6) For the items listed below, documents describing their recording methods, and methods and term of preservation of said records shall be prepared.
    1. Items associated with the confirmation of 2. of (2)
    2. Items associated with improvement measures in (3)
    3. Items associated with methods for hygiene control in (4)
    4. Items associated with the tests in (5)
  - (7) For general hygiene-controlled manufacturing processes of products, those who shall conduct the businesses listed below (excluding those specified in (8)) by themselves or a person who provides direction for conducting them to persons, previously specified according to the contents of the businesses, shall be nominated.
    1. Check on proper implementation of measures and confirmation of 2. of (2) and preparation of its records.
    2. Maintenance management of the mechanical components used for the confirmation of 2. of (2) (including calibration of measuring instruments) and preparation of its records.
    3. Other necessary businesses
  - (8) On the tests in (5), those who shall conduct the businesses listed below by themselves or a person who provides direction for conducting them to persons, previously specified according to the contents of the businesses, shall be nominated.
    1. Products testing

2. Maintenance management of the mechanical components used for the tests in 1. (including calibration of measuring instruments) and preparation of its records
3. Other necessary businesses

[4] The Standards of Equipments or Containers/Packages. of Milk, etc or Their Raw Materials and the Standards of Manufacturing.

(1) Specifications of Equipments of Milk, etc.

- 1) Equipments used for the manufacture of milk, etc. shall comply with the following specifications.
  1. They must have the structure that can be easily cleaned.
  2. Raw materials of the parts coming into direct contact with foods must either be of rustless character or anti-corrosively processed rust-proof ones.
  3. Machines used for the subdividing, bottling, tightly-stoppering, or sealing must be easily sterilizable and protected from contamination.
- 2) Cup-sales type vending machines selling pasteurized fermented milk drink shall be of a construction complying with the following Nos..
  1. Materials of parts coming into direct contact with liquids inside the machine shall be acid-proof, waterproof, and impermeable and shall not be liable to elute out toxic or harmful substances into the liquids inside the machine.
  2. Containers storing liquids inside the machine shall be of a dust-proof, moisture-proof and insect-proof construction.
  3. Parts coming into direct contact with liquids inside the machine shall be of a construction which can be easily disassembled, cleaned and pasteurized.
  4. Machines shall be of a construction equipped with thermostat-equipped cooling machines having sufficient capacity to keep liquids inside the machine at all times at not higher than 10°C.
  5. Machines shall be of a construction equipped with thermometers indicating the temperature at which the liquids inside the machines are kept and readable from the outside of the cup-sales type vending machine.
  6. Machines shall be of such a construction that the water used for cooking may be automatically taken in from the water supply outlet of the water supply.
  7. Machines shall be of a construction equipped either with apparatus for boiling the water used for cooking for 5 minutes or with pasteurizer having equal or more effectiveness.
  8. Cups used during sales shall be made of pasteurized unused paper, plastics or aluminum foil and shall be stored in storage equipment constructed so that the cups are not contaminated by

dust or the like.

9. Machines shall be of such a construction that the fermented milk drink used for cooking may not be diluted inside the cup-sales type vending machine.
10. There shall be only one built-in tank for containing the fermented milk drink used for cooking and its capacity shall not be more than 10 liters.
11. Cup dispensers shall be of a construction shut off from outside at times other than sales.

(2) The Standards of Containers/Packages of Milk, etc. or Their Raw Materials and the Standards of Manufacturing

1) Standards of containers/packages of cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, cream, fermented milk, fermented milk drink or their raw materials and the standards of manufacturing

1. Containers/packages for sale of cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, and cream shall be glass bottles, plastics containers/packages (those made of polyethylene, ethylene·1-alkene copolymer resin, nylon or polypropylene (hereafter, "plastics", in this No.), same in this No.), plastic-processed paper containers/packages (those made of polyethylene-processed paper or ethylene·1-alkene copolymer resin paper (hereafter, "plastic-processed paper", in this No.), same in the following No.), metal cans (only those used as containers for cream, same in this No.), or combined packages/containers (mean those using plastics and plastic-processed paper for cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, processed milk, ; for cream, those using 2 or more plastics, plastic-processed papers, and metals, same in this No.), which comply with the following specifications or standards.

a. Glass bottles shall be uncolored and transparent and have a mouth inside diameter of not less than 26 mm.

b. Plastic containers/packages and plastic -processed paper containers/packages shall comply with the following conditions.

A. They shall comply with the tests based on the following test methods. In these cases, prepare the test solutions used for the tests of (a), (b) and (c) as follows: Wash the sample well with water. Use the eluting solution designated in the individual test methods. For samples which can be filled with liquid, warm the eluting solution to 60°C (25°C for n-heptane) and fill the sample. For samples that cannot be filled with liquid, place the sample on a rubber plate with the side coming into direct contact with the contents

upward, put a stainless steel or glass cylindrical tube on it, tighten with tightening fittings, then pour in the eluting solution warmed at 60°C (25°C for n-heptane) at the rate of 2 mL per 1 cm<sup>2</sup> surface area. Cover each sample with a watch glass and elute for 30 minutes (1 hour for n-heptane) stirring occasionally, while keeping at 60°C (25°C for n-heptane).

(a) Heavy metals

Prepare a test solution by use of 4% acetic acid as the eluting solution. Take 20 mL into a Nessler's tube and dilute to 50 mL with water. To this, add 2 drops of sodium sulphide test solution, mix and let stand for 5 minutes. The color developed must not be darker than the standard color prepared by adding 20 mL of 4% acetic acid to 2 mL of lead standard solution to be diluted to 50 mL with water, then proceeding in the same way as with the test solution.

Sodium sulphide test solution: Dissolve 5 g of sodium sulphide in a mixture of 10 mL of water and 30 mL of glycerin, or dissolve 5 g of sodium hydroxide in a mixture of 30 mL of water and 90 mL of glycerin, saturate a half volume of the solution with hydrogen sulphide while cooling, and mix this with the remaining half volume. Fill in a small, light-shaded bottle and stopper tightly to store. Use within 3 months after preparation.

Lead standard solution: Dissolve 159.8 mg of lead nitrate in 10 mL of dilute nitric acid (made by diluting 10.5 mL of nitric acid to 100 mL with water), and add sufficient water to make to 1,000 mL. Prepare and store this solution using glasswares not containing soluble lead salts.

Dilute 10 mL of this stock solution to 100 mL with water. Each 1 mL of this solution contains 0.01 mg of lead. Prepare this solution immediately before use.

(b) Residue on evaporation

For containers/packages of cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk, and processed milk, prepare a test solution by use of 4% acetic acid as the eluting solution. Take 200 to 300 mL (for containers/packages of cream, prepare the test solution by use of n-heptane, transfer 200~300 mL into a round-bottom flask, concentrate under reduced pressure to 2~3 mL, and wash the flask twice with approximately 5 mL each of n-heptane. Use the concentrated solution and the washings) into a platinum or quartz evaporating dish of known weight previously dried at 105°C, and evaporate to dryness on a water bath. Dry this at 105°C for 2 hours, then let cool in a desiccator. After cooling, weigh the residue of evaporation accurately. Using this residual amount (mg) as A, find the amount of

residue on evaporation by use of the following formula. The amount shall be not more than 15 ppm.

$$\text{Residue on evaporation (ppm)} = ((A-B) \times 1,000) / (\text{Amount of test solution (mL)} \times F)$$

Where

B: Residual amount of blank test obtained for the same amount of 4% acetic acid or n-heptane as the test solution (mg)

F: 1 in case 4% acetic acid was used as the eluting solution; 5 in case n-heptane was used.

(c) Consumption of potassium permanganate

Take 100 mL of water, 5 mL of sulphuric acid and 5 mL of 0.002 mol/L potassium permanganate solution into a conical flask, boil for 5 minutes, discard the liquid, then wash with water. Into this conical flask, pour 100 mL of a test solution prepared by use of water as the eluting solution, add 5 mL of sulphuric acid and 10 mL of 0.002 mol/L potassium permanganate solution in turn, heat and boil for 5 minutes, stop heating, add immediately 10 mL of 0.005 mol/L sodium oxalate solution to decolorize, then titrate with 0.002 mol/L potassium permanganate solution until the faint pink color persists.

Using this titration amount (mL) as A, find the consumption of potassium permanganate by use of the following formula. The amount shall be not more than 5 ppm.

$$\text{Consumption of potassium permanganate (ppm)} = ((A-B)F \times 1,000) / 100 \times 0.316$$

Where

B: Titration amount of 0.002 mol/L potassium permanganate solution of the blank test obtained for the same amount of water as the test solution (mL)

F: Normality factor of 0.002 mol/L potassium permanganate solution

0.002 mol/L potassium permanganate solution: Dissolve approximately 0.33 g of potassium permanganate in water and make to 1,000 mL. Store in a light-shaded ground glass-stoppered bottle and standardize with 0.005 mol/L sodium oxalate solution immediately before use.

Standardization: Take 100 mL of water, add 5 mL of sulphuric acid and 5 mL of potassium permanganate solution, boil for 5 minutes, stop heating and immediately add 10 mL of 0.005 mol/L sodium oxalate solution to decolorize. Add potassium permanganate solution dropwise until the faint pink color persists. To this solution, add 5 mL of sulphuric acid and 5 mL of potassium

permanganate solution, boil for 5 minutes, then add 10 mL of 0.005 mol/L sodium oxalate solution and immediately titrate with potassium permanganate solution.

Calculate the normality factor of the potassium permanganate solution by use of the following formula.

$$\text{Normality factor} = 10/(5+a)$$

Where

a: Titration amount of potassium permanganate solution (mL)

0.005 mol/L sodium oxalate solution: Dissolve 0.6700 g of sodium oxalate in water and make to 1,000 mL. Store in a light-shaded ground glass-stoppered bottle. Use within 1 month after preparation.

(d) Bursting strength

Cut out the central part of the container-package and use it as the test sample. Fix the sample in such a manner as shown in the Figure. Pour glycerin into the pressure chamber at a rate of  $95 \pm 10$  mL per minute, apply pressure until the package bursts, and determine the maximum value. Express the value in Pa. The value shall be not less than 196.1 kPa (for product storable at room temperature, 392.3 kPa) for containers/packages not more than 300 mL capacity, while not less than 490.3 kPa (for product storable at room temperature, 784.5 kPa) for containers/packages more than 300 mL capacity.

(e) Sealing strength

Make a hole of 0.5 to 1.0 cm diameter in the center of the side or bottom of the sealed container-package (for package with contents inside, remove them). Attach the air nozzle and connect the compressor and pressure gauge as shown in the Figure 2.

Next, start the compressor and apply pressure to 13.3 kPa for 10 seconds. There shall be neither burst nor leak in the container-package.

(f) Pinholes

Fill the container-package with a 0.4% solution of methylene blue dissolved in 10% ethanol. Place this on a sheet of filter paper and let stand for 30 minutes. There shall be no spots of methylene blue formed on the paper.

B. Areas coming into direct contact with the contents shall be polyethylene or ethylene-1-alkene copolymer resin for.

C. Additives shall not be used for plastics used for areas coming into direct contact with the contents. Provided, however, that this does not apply to cases of plastics containers/packages using not more than 2.5 g calcium stearate (only calcium stearate designated in Japan Pharmacopoeia can be used), or not more than 0.3 g of glycerin fatty acid ester (only that complying with the compositional standards of glycerin fatty acid ester designated in the Standards and Regulations of Food, Food Additives, etc. can be used), or titanium dioxide (only that complying with the compositional standards of titanium dioxide designated in the Specifications and Standards of Food, Food Additives, etc. can be used) per 1 kg of plastic.

D. Plastics used for areas coming into direct contact with contents shall comply with the tests based on the following test methods.

(a) n-Hexane extract

Weigh precisely an approximately 2.5 g of sample, take into a 2,000 mL three-necked flask equipped with a thermometer, a reflux condenser and a stirring rod, add 1,000 mL of n-hexane, gradually heat this from 20 to 25 minutes until 50°C, keep at this temperature for 2 hours, then filter the extract solution while hot. Receive the filtrate into a ground glass-stoppered conical flask of known weight, and determine the weight of the filtrate. In this case, the recovery shall be not less than 90% of the initial solvent.

Next, transfer approximately half of the filtrate into a 1,000 mL beaker, cover the beaker with a glass cover and evaporate the solvent while continuously passing nitrogen gas. While evaporating the solvent, add the remaining filtrate and the washings obtained by washing the flask twice with each 20 mL of n-hexane and concentrate the entire volume to approximately 50 mL. Transfer the concentrate into a quartz evaporating dish of known weight, wash the beaker twice with each 20 mL of warm n-hexane, and combine the washings to the evaporating dish. In case there is a warm n-hexane-insoluble residue in the beaker, add toluene, heat to dissolve it, and then combine the toluene solution to the evaporating dish. Carefully heat the evaporating dish on a water bath to dryness, then place it in a vacuum desiccator and let cool for 12 hours. Weigh accurately the residue of evaporation, making this residual amount (g) as A, find the n-hexane extract by use of the following formula. The amount shall be not more than 2.6%.

$$\text{n-hexane extract (\%)} = (A - B) / \text{Sample (g)} \times 100$$

Where

B: Residual amount of blank test obtained for the same amount of solvent as the test solution (g)

(b) Xylene-soluble substances

Weigh precisely  $5.00 \pm 0.005$  g of sample and take into a 2,000 mL two-necked flask equipped with a thermometer and a reflux condenser. Add 1,000 mL of xylene and glass boiling stones, then heat rapidly. After the start of boiling, continue heating until the reflux begins. Continue refluxing for 2 hours, and then cool the flask to  $50^{\circ}\text{C}$ . Furthermore, cool rapidly to a temperature  $25\text{--}30^{\circ}\text{C}$  with cold water, then keep in an incubator of  $25 \pm 1^{\circ}\text{C}$  for one night.

Next, filter the extract solution by use of filter paper and glass filter successively, take 450~500 mL the initial filtrate into a 1,000 mL conical flask of known weight. Weigh this accurately and make the weight of the filtrate (g) as  $W_1$ . Put a magnetic stirring rod into the conical flask, connect the flask with the cooling condenser, then begin distillation at a rate of 12 to 13 mL per minute under the infusion of nitrogen gas at a rate of 2 to 3 liter per minute and under continuous stirring.

When the volume of the solution in the flask decreased to 30~50 mL, remove it into an evaporating dish of known weight, wash the flask twice with approximately 15 mL each of xylene, and combine the washings with the solution in the evaporating dish. Next, send the nitrogen stream gently over the evaporating dish and evaporate to dryness on a hot plate with care so that the dish may not be overheated. Let cool the evaporating dish in a vacuum desiccator for 12 hours. Weigh the residual amount of evaporation accurately and make this residue amount (g) as  $W_2$ . Find the xylene soluble substances by use of the following formula. The amount shall be not more than 11.3%.

$$\text{Xylene soluble substances (\%)} = (W_2 - W_3) / W_1 \times \rho \times 10^3 / \text{Sample (g)} \times 100$$

Where

$W_3$ : Residual amount of blank test obtained for the same amount of solvent as the test solution (g)

$\rho$ : Density of xylene

(c) Arsenic

Take 2 g of sample into a digestion flask, add 20 mL of nitric acid and heat weakly until the content becomes liquefied. Cool, add 5 mL of sulphuric acid and heat until white

fumes evolve. In case the solution still shows a brown color, add furthermore 5 mL of nitric acid after cooling, and heat again. Repeat the procedure until the solution becomes colorless or faint yellow. After cooling, add 15 mL of saturated ammonium oxalate solution, and heat until white fumes evolve again. Cool, then dilute to 25 mL with water, and use this as the test solution.

Take 5 mL of the test solution and perform the test by the method using apparatus A in Arsenic Test Method, B. General Test Methods, Section 2. Food Additives of the Standards and Regulations of Food, Food Additives, etc. The color developed shall not be darker than the standard color prepared by taking 4 mL of arsenic standard solution into a digestion flask, adding 20 mL of nitric acid, then proceeding in the same way as the sample.

(d) Heavy metals

Take 2 g of sample into a platinum or quartz evaporating dish, add a small amount of sulphuric acid and heat gradually in order to almost incinerate at as low a temperature as possible. After cooling, add further 1 mL of sulphuric acid, heat gradually until almost no more vapor of sulphuric acid is generated. Strengthen the flame and heat at 450~550°C until almost white ash is obtained. To the residue, add 1 mL of hydrochloric acid, and 0.2 mL of nitric acid, evaporate to dryness on a water bath. To this, add 1 mL of dilute hydrochloric acid (prepared by diluting of 23.6 mL of hydrochloric acid to 100 mL with water, same below in this test) and 15 mL of water, heat to dissolve, cool, then add 1 drop of phenolphthalein test solution, add ammonia test solution dropwise until the solution is faintly pink colored, add 2 mL of dilute acetic acid (prepared by diluting 6 g of acetic acid to 100 mL with water, same below in the test), filter if necessary, and dilute to 50 mL with water. Use this as the test solution.

To 50 mL of this test solution, add 2 drops of sodium sulphide test solution, mix, and let stand for 5 minutes. The color developed shall not be darker than the standard color prepared by adding 2 mL of dilute acetic acid to 4 mL of lead standard solution, diluting to 50 mL with water, then proceeding in the same way as with the test solution.

Phenolphthalein test solution: Dissolve 1 g of phenolphthalein in 100 mL of ethanol.

Ammonia test solution: Dilute 10 mL of ammonia water to 30 mL with water.

Sodium sulphide test solution: Use the sodium sulphide test solution designated in (a) Heavy Metals of A.

Lead standard solution: Use the lead standard solution designated in (a) Heavy

Metals of A.

E. Container/packages of product storable at room temperature shall be light-shielding and shall not be permeable to gas.

c. Metal cans shall comply with the conditions specified in the following c.

d. For Combined containers/packages, plastics and plastic-processed paper shall comply with the specifications or standards of plastics and plastic-processed paper containers/packages (excluding those relevant to the specification of products storable at room temperature) specified in b, and metal shall comply with the specifications and standards for metal cans specified in c. In these cases, the specifications mentioned in A of b (excluding sealing strength) shall comply with the respective tests for plastics and plastic-processed paper. Cut out the central part of the container/package made of plastics and plastic-processed paper, and use it as the test sample for bursting strength. "Plastic-processed paper containers/packages" in the specification in B of b and "plastic containers/packages" in the standards specified in C of b shall be replaced with "combined containers/packages."

2. Containers/packages for the sale of fermented milk, fermented milk drink, and milk drink shall be glass bottles or plastics, containers/packages, plastic-processed paper containers/packages, plastic-processed aluminum foil containers/packages, metal cans, or combined containers/packages (containers/packages using 2 or more of plastics, plastic-processed papers, plastic-processed aluminum foils, or metals, same in the following Nos.), which comply with the following specifications or standards.

a. Glass bottles shall be transparent.

b. Plastic containers/packages, plastic-processed paper containers/packages, and plastic-processed aluminum foil containers/packages shall comply with the following conditions.

A Containers/packages shall comply with the specifications mentioned in A of the preceding No. b (excluding bursting strength) and the tests performed using the following methods. In these cases, 4% acetic acid is used as the eluting solution for the residue after evaporation.

a. Antimony (only for containers/packages using plastics containing polyethylene terephthalate as the principal component)

Follow mutatis mutandis, D Antimony, d, 1 of (2).

b. Germanium (only for containers/packages using plastics containing polyethylene

terephthalate as the principal component)

Follow mutatis mutandis, E Germanium, d, 1 of (2).

B Containers/packages shall comply with one of the following tests.

a. Bursting strength

Follow mutatis mutandis, (d) bursting strength, A, of the preceding No. b.

b. Piercing strength

Cut out the central part of the container/package and use it as the test sample. Fix the sample, and at a speed of  $50 \pm 5$  mm per minute, strike its surface with a pin that is 1.0 mm in diameter and 0.5 mm in radius with a semi-circular tip. Determine the maximum load until the pin penetrates the surface. The value expressed in N should be no less than 9.8 N.

C Areas coming into direct contact with the contents shall have be following plastics containing polyethylene, ethylene·1-alkene copolymer resin, polystyrene, polypropylene, plastics made be or polyethylene terephthalate as the principal component.

D Plastics that contains polyethylene, ethylene·1-alkene copolymer resin, or plastics made by polypropylene as the principal component and comes into direct contact with the contents shall comply with the specification mentioned in D of the preceding No. b. However, this holds true provided that the n-hexane extract in plastics that contains polypropylene as the principal component is not more than 5.5%, and xylene-soluble matter is not more than 30%.

E Polystyrene used for the areas coming into direct contact with the contents shall comply with the tests conducted by using the following methods.

a Volatile substances

(a) Preparation of test solution

Weigh precisely approximately 0.5 g of sample in a 20 mL volumetric flask, and add an appropriate amount of dimethylformamide. After the sample has dissolved, add 1 mL of cyclopentanol solution and make it up to 20 mL with dimethylformamide.

Cyclopentanol solution: Dilute 1 mL of cyclopentanol to 100 mL with dimethylformamide, and dilute 10 mL of this to 100 mL with dimethylformamide.  
(The same applies for b).

(b) Preparation of calibration curve

Weigh precisely approximately 50 mg each of styrene, toluene, ethyl benzene, isopropyl benzene, and n-propyl benzene in a 100 mL volumetric flask, and then

make it up to 100 mL with dimethylformamide. Take 1, 2, 3, 4, and 5 mL of the solution in separate 20 mL volumetric flasks, add 1 mL of cyclopentanol solution, and dilute it to 20 mL with dimethylformamide. Use these diluted solutions as the standard solutions. Test 3  $\mu$ L of each standard solution under the following conditions by using a gas chromatograph. Determine the ratio of the peak areas of styrene, toluene, ethyl benzene, isopropyl benzene, and n-propyl benzene to the peak area of cyclopentanol on the gas chromatogram, and prepare a calibration curve for each component.

Column support: Use diatomaceous earth for gas chromatography (standard wire sieve: 175–246  $\mu$ m mesh size)

Column packing: Coat 25% polyethylene glycol for gas chromatographic use on the support.

Column tubing: Use either a stainless steel or glass tube with an inner diameter of 3 to 4 mm and a length of 2,000~ 3,000 mm

Column temperature: 90°C~110°C

Injection port temperature: 220°C

Detector: Use a hydrogen flame ionization detector at approximately 220°C. Adjust the hydrogen and air flow rates to obtain the maximum sensitivity of detection.

Carrier gas: Nitrogen. The flow rate should be adjusted to obtain a cyclopentanol retention time of 15~20 minutes.

(c) Test

Test 3  $\mu$ L of the test solution under the same conditions as (b) Preparation of Calibration Curve by using gas chromatography, and determine the ratio of the peak area of each component to the peak area of cyclopentanol on the obtained chromatogram. Determine the contents of styrene, toluene, ethyl benzene, isopropyl benzene, and n-propyl benzene by using the calibration curve, and obtain the concentration of each component according to the following formula. The sum of the concentration of components shall be no more than 1,500 ppm.

$$\text{Concentration (ppm)} = \text{Content of components (mg)} / \text{Weight of sample (g)} \times 1,000$$

b Arsenic

Follow mutatis mutandis, (c) Arsenic, D. of the preceding No. b.

c Heavy metals

Follow mutatis mutandis (d) Heavy Metals, D. of the preceding No. b.

F Containers/packages for products storable at room temperature shall be those with light-blocking effect and without gas permeability.

G Plastics that contains polyethylene terephthalate as the principal component and is used in areas that come into direct contact with the contents shall comply with the following tests.

Cadmium and lead

Follow mutatis mutandis, (a) Cadmium and lead, B, of the following No. c.

c. Metal cans shall comply with the following conditions:

A. They shall comply with the tests based on the following test methods. In this case, the preparation of the test solution used in the tests shall be the same as the preparation of the test solution designated in A. of the preceding No. b.

(a) Arsenic

Prepare the test solution by use of 4% acetic acid as the eluting solution. Take 10 mL of the solution and perform the test by the method using apparatus A in Arsenic Test Method, B. General Test Methods, Section 2. Food Additives of the Regulation and Standards of Foods, Food Additives, etc.. The color developed shall not be darker than the standard color.

(b) Heavy metals

Follow mutatis mutandis (a) Heavy Metals, A. of the preceding No. b.

(c) Residue on evaporation (only for packages using plastics for areas coming into direct contact with contents)

Follow mutatis mutandis (b) Residue on Evaporation, A. of the preceding No. b. In this case, the eluting solution used shall be 4% acetic acid.

(d) Consumption of potassium permanganate (only for packages using plastics for areas coming into direct contact with contents)

Follow mutatis mutandis (c) Consumption of Potassium Permanganate, A. of the preceding No. b.

(e) Phenol (only for packages using plastics for areas coming into direct contact with contents)

Prepare the test solution by use of water as the eluting solution. Take 5 mL of the solution, add 5 drops of bromide test solution, and let stand for 1 hour. This shall not form a yellowish white precipitate.

Bromide test solution:

Pour 2 to 3 mL of bromide into a ground glass-stoppered bottle coated with vaseline around the stopper. Add 100 mL of cold water, stopper tightly, shake, and

let stand, then use the aqueous layer. Store shaded from light in a cold place.

- (f) Formaldehyde (only for packages using plastics for areas coming into direct contact with contents)

Prepare the test solution by use of water as the eluting solution. Take 10 mL of the solution, and add 1 mL of 20% phosphoric acid. Pour 5 to 10 mL of water into a 200 mL messycylinder, place the condenser adaptor into it so that it may be immersed into the water, then begin steam distillation. Stop the distillation when the distillate reaches approximately 190 mL, and dilute to 200 mL with water. Take 5 mL of the distillate into a test tube of approximately 1.5 cm in inside diameter, add 5 mL of acetylacetone test solution and mix. Heat in a water bath for 10 minutes. The color developed shall not be darker than the standard color obtained by taking 5 mL of water into a test tube of approximately 1.5 cm in inside diameter, adding 5 mL of acetylacetone test solution, mixing and heating for 10 minutes in a water bath.

Acetylacetone test solution:

Dissolve 150 g of ammonium acetate in water, add 3 g of acetic acid, 2 mL of acetylacetone and make it to 1,000 mL with water. Prepare immediately before use.

- B. Plastics used for areas coming into direct contact with contents shall comply with the tests based on the following methods.

- (a) Cadmium and lead

- a) Preparation of test solution

Fully dry the sample, then weigh precisely approximately 1 g of sample into a platinum or quartz evaporating dish, then add 10 drops of sulphuric acid. Gradually heat until the sulphuric acid is almost evaporated, then evaporate to dryness on a direct flame. Continue heating by strengthening the flame at approximately 450°C and incinerate. Moisten the contents in the evaporating dish with sulphuric acid and heat again. Repeat this procedure until almost white ash is obtained. In case polarography is adopted in the measurement, add 10 mL of electrolyte solution to the residue (in case direct current polarograph is used, furthermore add 0.2 mL of gelatin solution), let stand for 3 hours, stirring occasionally, and use this as the test solution. In case atomic absorption spectrometry is adopted, add 10 mL of 0.1 mol/L nitric acid to the residue to dissolve, and use it as the test solution for lead. Take 1 mL of this solution, dilute to 10 mL with 0.1 mol/L nitric acid, and use it as the test solution

for cadmium.

Electrolyte solution: Dilute 7.8 mL of 70% perchloric acid to 500 mL with water, add 10 mL of 0.1 N hydrochloric acid and water to be diluted to 1,000 mL.

0.1 mol/L Hydrochloric acid: Dilute 9.5 mL of hydrochloric acid to 1,000 mL with water.

Gelatin solution: To 100 mg of gelatin, add 100 mL of water. Warm to dissolve. Prepare immediately before use.

0.1 mol/L Nitric acid: Dilute 6.4 mL of nitric acid to 1,000 mL with water.

b) Test

Perform the test either by polarography or atomic absorption spectrometry.

Polarography

For this test, use direct current polarograph, alternating current polarograph or square-wave polarograph.

Take 5 mL of the test solution into the electrolytic bottle, pour in mercury until the platinum wire of the electrolytic bottle is covered, then place it in a thermostat bath of 25°C, and insert the dropping mercury electrode. After injection of nitrogen to the bottle for 15 minutes, draw a polarogram between -1,000 and -400 mv. The wave heights of cadmium and lead shall not be higher than the wave heights obtained by use of reference standard cadmium and lead solutions and proceeding in the same way as the test solutions.

Reference standards cadmium and lead solutions:

Solution I: Dissolve 100 mg of metallic cadmium in 7.8 mL of 70% perchloric acid, add 10 mL of 0.1 mol/L hydrochloric acid and dilute to 1,000 mL with water.

Solution II: Dissolve 159.8 g of lead nitrate in the electrolyte solution and dilute to 1,000 mL.

To 10 mL of solution I, add 10 mL of solution II, make to 100 mL with electrolyte solution (in case direct current polarograph is used, further add 2 mL of gelatin solution and shake well).

0.1 mol/L Hydrochloric acid: Dilute 9.5 mL of hydrochloric acid to 1,000 mL with water.

Gelatin solution: To 100 mg of gelatin, add 100 mL of water, and warm to dissolve. Prepare immediately before use.

Nitrogen: Use high purity nitrogen.

### Atomic absorption spectrometry

Switch on the light source lamp of the atomic absorption spectrophotometer (use a cadmium hollow cathode lamp for cadmium test and lead hollow cathode lamp for lead test) and adjust to the appropriate electric current. Ignite the acetylene gas or hydrogen, adjust the flow of gas and compressed air. Next, spray a part of the test solution into each flame, and determine the absorbance at the wavelength of 228.8 nm for cadmium and at 283.5 nm for lead. The absorbance of the test solution shall not be larger than the absorbance obtained by use of cadmium standard solution and lead standard solution and proceeding for each in the same way as with the test solution.

Cadmium standard solution: Dissolve 100 mg of metallic cadmium in 50 mL of 10% nitric acid. Evaporate to dryness on a water bath, add 0.1 mol/L nitric acid to the residue to be diluted to 1,000 mL. Take 1 mL of this solution and dilute to 100 mL with 0.1 mol/L nitric acid.

Lead standard solution: Dissolve 159.8 mg of lead nitrate in 0.1 mol/L nitric acid to be diluted to 1,000 mL. Take 10 mL of this solution and dilute to 100 mL with 0.1 mol/L nitric acid.

### (b) Dibutyltin compounds (only for packages using polyvinyl chloride)

#### a) Preparation of test solution

Fully dry the sample and then take 10 g in a 500 mL ground glass-stoppered flask. Add 100 mL of carbon tetrachloride and 50 mL of methanol. Attach a reflux condenser and heat in a water bath for 4 hours, shaking occasionally. Cool, then filter the solution. Evaporate the filtrate to dryness on a water bath and dissolve the residue in ethanol to make 5 mL.

#### b) Test

Draw a line with a pencil 40 mm from the bottom of a piece of chromatography paper. Apply spots on that line 3  $\mu$ L of test solution and 3  $\mu$ L of dibutyltin standard solution by use of separate micropipette, then dry in the air. In this case, the distance between the two spots shall be approximately 25 mm. Next, suspend the filter paper perpendicular to the stopper into a cylindrical glass container, filled with a mixed solvent of methanol and 1 mol/L hydrochloric acid (3:1), being careful that the filter paper does not touch the container walls. Immerse approximately 10 mm of the bottom of the filter paper into the solvent, stopper tightly and let stand. After the

front of the solvent developed 13 cm from the spotted point, remove the filter paper from the container and dry in the air. After standing the paper in ammonia vapor for 5 minutes, spray pyrocatechol violet test solution. No blue spots shall be observed at almost the same location as the spot obtained from the dibutyltin standard solution. Provided, however, that for the filter paper, use paper immersed in 10% dioctyl phthalate-methanol solution, then dried in the air.

Dibutyltin dichloride: Use reagent containing not less than 99% dibutyltin dichloride.

1 mol/L Hydrochloric acid: Dilute 95 mL of hydrochloric acid to 1,000 mL with water.

Pyrocatechol violet test solution: Dissolve 0.1 g of pyrocatechol violet in water to be diluted to 100 mL.

Dibutyltin standard solution: Dissolve 100 mg of dibutyltin dichloride in ethanol to be diluted to 1,000 mL.

10% Dioctyl phthalate-methanol solution: Dissolve 10 g of bis(2-ethylhexyl) phthalate in methanol and dilute to 100 mL.

(c) Tricresyl phosphate (only for packages using polyvinyl chloride)

a) Preparation of test solution

Fully dry the sample, then take 10 g in a 500 mL ground glass-stoppered flask. Add 100 mL of carbon tetrachloride and 50 mL of methanol. Attach a reflux condenser and heat in a water bath for 4 hours, shaking occasionally. Cool, and then filter the solution. Evaporate the filtrate on a water bath completely and dissolve the residue in ethanol to make 5 mL.

Next, place 2.5 mL of this solution in a ground glass-stoppered flask. Add 60 mL of 0.5 mol/L ethanolic potassium hydroxide solution, attach a reflux condenser and heat in a water bath for 2 hours. Cool, add 30 mL of water, and then concentrate this under reduced pressure to approximately 30 mL. Add 0.5 mol/L sulphuric acid dropwise to adjust pH to 3. Next, transfer the solution to a separatory funnel, wash the flask twice with each 20 mL of diethyl ether, combine the washings to the separatory funnel, shake vigorously, and let stand to separate into two layers.

Transfer the lower layer to another separating funnel, and extract it twice with each 40 mL of diethyl ether, and combine the ether washings to the upper layer in the first separatory funnel. Concentrate the combined ether extract on a water bath to approximately 1 mL by use of Kuderna-Danish concentrator. Dilute to 5 mL with

ethanol.

0.5 mol/L Ethanolic potassium hydroxide solution: Dissolve 35 g of potassium hydroxide in 30 mL of water and dilute to 1,000 mL with ethanol. Place in a container stoppered tightly with a ground glass-stopper or rubber stopper and let stand for 24 hours. Decant the supernatant quickly into another bottle, stopper tightly with a rubber stopper and store shaded from light.

0.5 mol/L Sulphuric acid: Gradually add 30 mL of sulphuric acid to 1,000 mL of water, while stirring, then let cool.

b) Test

Qualitative test

Take each 5 $\mu$ L of test solution and cresol standard solution and perform the test under the following gas chromatographic condition. Compare the retention time of the peak of the test solution on the chromatogram with that of cresol standard solution on the chromatogram.

Procedure condition I

Column support: Diatomaceous earth for gas chromatographic use (standard wire sieve 149 ~ 177  $\mu$ m)

Column packing: Coat trixylenyl phosphate and phosphoric acid on the support at the concentration of 10% and 0.5%, respectively

Column tubing: Use either a stainless steel tube or a glass tube of inside diameter 3 ~ 4 mm, length 3,000 mm.

Column temperature: 140°C

Injection port temperature: 220°C

Detector: Use hydrogen flame ionization detector and operate around 220°C. Adjust the hydrogen and air flow rates so that the maximum sensitivity of detection is obtained.

Carrier gas: Use nitrogen. Adjust the flow rate so that the retention time of m-cresol comes around 10 minutes.

Procedure condition II

Column support: Diatomaceous earth for gas chromatographic use (standard wire sieve 149 ~ 177  $\mu$ m)

Column packing: Coat denatured lanolin for gas chromatographic use on the support at the concentration of 10%.

Column tubing: Use either a stainless steel tube or a glass tube of inside diameter

3~4 mm, length 3,000 mm.

Column temperature: 160°C

Injection port temperature: 250°C

Detector: Use hydrogen flame ionization detector and operate around 250°C.

Adjust the hydrogen and air flow rates so that the maximum sensitivity of detection is obtained.

Carrier gas: Use nitrogen. Adjust the flow rate so that the retention time of m-cresol comes around 15 minutes.

#### Quantitative test

When the retention time of the peak of the test solution on the chromatogram in the qualitative test matches with the retention time of at least one of the peaks of the cresol standard solution on the chromatogram, carry out the following test.

Based on the test findings obtained under procedure condition I or II of the qualitative test, determine the peak area of cresol in the test solution by use of whichever condition appropriate. The area shall not be larger than the peak area of the cresol standard solution.

Cresol standard solution: Dissolve 0.044 g of m-cresol, 0.044 g of o-cresol and 0.044 g of p-cresol in ethanol and dilute to 150 mL.

Trixylenyl phosphate: Use a reagent containing not less than 98% of trixylenyl phosphate.

#### (d) Vinyl chloride (only for packages using polyvinyl chloride)

##### a) Preparation of test solution

Fully dry the sample, then weigh precisely approximately 1 g and place into a 20 mL volumetric flask, add an appropriate amount of tetrahydrofuran, and keep in a cool place shaking occasionally. After dissolving of the sample, add tetrahydrofuran cooled in methanol-dry ice bath to be made to 20 mL in the methanol-dry ice bath. Store it in the methanol-dry ice bath.

Tetrahydrofuran: To tetrahydrofuran, add ferrous sulphate or lithium aluminum hydroxide, and distill. Check that no substances that obstruct the test are contained.

##### b) Test

### Qualitative test

Take each 10 $\mu$ L of test solution and vinyl chloride standard solution and perform the test under the following procedure conditions by use of a gas chromatograph. Compare the retention time of the peak of the test solution on chromatogram with the retention time of the peak of the vinyl chloride standard solution on the chromatogram.

#### Procedure condition I

Column support: Use diatomaceous earth for gas chromatographic use (standard wire sieve 149 ~ 177 $\mu$ m).

Column packing: Coat polypropylene glycol for gas chromatographic use on the support at the concentration of 15 to 20%.

Column tubing: Use either a stainless steel tube or a glass tube of inside diameter 3 to 4 mm, length 2,000 ~ 3,000 mm.

Column temperature: 60 ~ 70°C

Injection port temperature: 150°C

Detector: Use hydrogen flame ionization detector and operate around 200°C. Adjust the hydrogen and air flow rates so that the maximum sensitivity of detection is obtained.

Carrier gas: Use nitrogen. Adjust flow rate so that the retention time of vinyl chloride comes approximately in 90 seconds.

#### Procedure condition II

Column packing: Use porous polymer beads for gas chromatographic use (standard wire sieve 149 ~ 177  $\mu$ m)

Column tubing: Use either a stainless steel tube or a glass tube inside diameter of 3 ~ 4 mm, length 1,500 mm.

Column temperature: 120°C

Injection port temperature: 150°C

Detector: Use hydrogen flame ionization detector and operate around 150°C. Adjust the hydrogen and air flow rates so that the maximum sensitivity of detection is obtained.

Carrier gas: Use nitrogen. Adjust flow rate so that the retention time of vinyl chloride comes approximately 3 ~ 4 minutes.

### Quantitative test

When the retention time of the peak of the test solution on the chromatogram in

the qualitative test matches with the retention time of the vinyl chloride standard solution on the chromatogram, carry out the following test.

Based on the test findings obtained under procedure condition I or II of the qualitative test, determine the peak height of vinyl chloride in the test solution by use of whichever condition appropriate. The height shall not be higher than the peak height of the vinyl chloride standard solution.

Vinyl chloride standard solution: Place approximately 190 mL of ethanol in a 200 mL volumetric flask, stopper with a silicone rubber stopper and weigh accurately. Cool the volumetric flask in methanol-dry ice bath, inject approximately 200 mg of previously liquefied vinyl chloride through the silicone rubber stopper, then weigh accurately to find out the weight increase in mg (a). Inject ethanol previously cooled in methanol-dry ice bath through the silicone rubber stopper into the flask to make 200 mL, then cool the mixture in methanol-dry ice bath, take 1 mL of which and add ethanol previously cooled in methanol-dry ice bath to make 200 mL. Further, take 1 mL of this and dilute to 100 mL with ethanol previously cooled in methanol-dry ice bath. Store the solution in methanol-dry ice bath.

Correction coefficient of the standard solution =  $a/200$

Ethanol: Add ferrous sulphate to 99.5% ethanol and distill. Check that no substances that would obstruct the test are contained.

d. Combined containers/packages shall comply with the following conditions.

A. They shall comply with the tests based on the following methods.

Sealing strength:

Follow mutatis mutandis (e) Sealing strength, A. of the preceding No. b.

B. Plastics, plastic-processed paper, and plastic-processed aluminum foil (excluding those used for sealing) shall comply with the specifications or standards of plastics, plastic-processed paper, and plastic-processed aluminum foil containers/packages designated in No. b (excluding those relevant to sealing strength and products storable at room temperature). Metals shall comply with the specifications of metal cans designated in No. c (excluding sealing strength). Cut out the central part of the container/package made of plastics, plastic-processed paper, or plastic-processed aluminum foil, and use it as (d) the bursting strength test sample A of the preceding No. b, which shall be applied mutatis mutandis to (a) bursting strength, B, of No. b. The maximum value of the strength

shall be no less than 490.3kPa. An identical sample is used as the (b) Piercing Strength test sample B of No. b.

C. Plastic-processed aluminum foil used for sealing shall comply with the tests based on the following methods. In this case, prepare the test solutions used for the tests of (a), (b), (c), (d), and (e) as follows: Place the sample on a rubber plate with the side coming into direct contact with the contents upward, put a stainless steel or glass cylindrical tube on it, tighten with tightening fittings, then pour in the eluting solution designated in the individual test method and warmed at 60°C, at a rate of 2 mL per 1 cm<sup>2</sup> surface area. Cover with a watch glass and elute for 30 minutes stirring occasionally, while keeping at 60°C.

(a) Heavy metals

Follow mutatis mutandis (a) Heavy Metals, A. of the preceding No. b.

(b) Residue on evaporation

Follow mutatis mutandis (b) Residue on Evaporation, A. of the preceding No. b. In this case, the eluting solution used shall be 4% acetic acid.

(c) Consumption of potassium permanganate

Follow mutatis mutandis (c) Consumption of Potassium Permanganate, A. of the preceding No. b.

(d) Phenol

Follow mutatis mutandis (e) Phenol, A. of c.

(e) Formaldehyde

Follow mutatis mutandis (f) Formaldehyde, A. of c.

(f) Burst strength

Follow mutatis mutandis (d) Burst strength, A. of the preceding No.. b (excluding the specifications relevant to products storable at room temperature). Cut out the central part of the stopper, and use it as the test sample; the maximum value of the strength should be no less than 196.1 kPa.

D. Plastics of plastic-processed aluminum foil used for sealing and for areas coming into direct contact with contents shall comply with the tests based on the following methods.

(a) Arsenic

Follow mutatis mutandis (c) Arsenic, D. of the preceding No. b.

(b) Cadmium and lead

Follow mutatis mutandis (a) Cadmium and lead, B. of c.

(c) Dibutyltin compounds (only for packages using polyvinyl chloride)

Follow mutatis mutandis (b) Dibutyltin Compounds, B. of c.

(d) Cresol ester phosphate (tricresyl phosphate; only for packages using polyvinyl chloride)

Follow mutatis mutandis (c) Cresol Ester Phosphate, B. of c.

(e) Vinyl chloride (only for packages using polyvinyl chloride)

Follow mutatis mutandis (d) Vinyl Chloride, B. of c.

3. Persons wishing to use containers/packages other than those designated in the preceding Nos. shall receive the approval of the Minister of Health and Welfare.
  4. Persons manufacturing plastics, plastic-processed paper or plastic-processed aluminum foil containers/packages shall pasteurize the containers/packages they manufacture. Persons manufacturing paper caps used for the containers/packages of the preceding Nos. or plastics, plastic-processed paper, plastic-processed aluminum foils, or metals, 2 or more of which used for the containers/packages, shall pasteurize the said paper caps, plastics, plastic-processed paper, plastic-processed aluminum foils or metals they manufacture. Provided, however, that this does not apply to them manufactured by a method having a pasteurizing effect.
- 2) The standards of containers/packages of formulated milk powder or their raw materials and the standards of manufacturing
1. Containers/packages for sale of formulated milk powder shall either be metal cans (including those where plastics are used for the sealing of openings, same below), or plastic-laminated containers/packages (containers/packages using plastering aluminum foil on plastic, or further plastering cellophane or plastering paper on it, same below) and shall comply with the following specifications and standards.
    - a. Metal cans or combined containers/packages shall be sealable structure.
    - b. Plastics used for the sealing of the opening of metal cans or combined containers/packages shall be polyethylene, ethylene·1-alkene copolymer resin or polyethylene terephthalate.
    - c. Plastics used for plastic-laminated containers/packages or combined containers/packages, the areas coming into direct contact with the contents shall be polyethylene, ethylene·1-alkene copolymer resin or polyethylene terephthalate.
    - d. The containers/packages, for which polyethylene, ethylene·1-alkene copolymer resin or polyethylene terephthalate is used on the areas coming into direct contact with the contents, shall comply with the following tests. Test solution is prepared in the following way: After washing the samples well with water, for samples which can be filled with liquid, warm the

eluting solution to 60°C and fill the sample (in case polyethylene, ethylene·1-alkene copolymer resin or polyethylene terephthalate is used for the sealing of metal cans, fill it so that the plastics part may come downwards). For samples which cannot be filled with liquid, place the sample on a rubber plate with the side coming into direct contact with the contents upward, put a stainless steel or glass cylindrical tube on it, tighten with tightening fittings, then pour in the eluting solution warmed at 60°C at the rate of 2 mL per 1 cm<sup>2</sup> surface area. Cover each sample with a watch glass and elute for 30 minutes, stirring occasionally, while keeping at 60°C.

A. Heavy metals

Follow mutatis mutandis, (a) Heavy Metals, A. of b. in 1. of 1).

B. Residue on evaporation

Follow mutatis mutandis, (b) Residue on Evaporation, A. of b. in 1. of 1).

C. Consumption of potassium permanganate

Follow mutatis mutandis, (c) Consumption of Potassium Permanganate, A. of b. in 1. of 1).

D. Antimony (only for containers/packages using polyethylene terephthalate)

Prepare test solution by use of 4% acetic acid as the eluting solution. Take 400 mL of the test solution into a digestion flask, add 5 mL of sulphuric acid and heat to concentrate until white fumes evolve. Cool, then add approximately 1 to 2 mL of hydrogen peroxide dropwise until the solution becomes clear, and heat to concentrate until white fumes evolve. If the solution becomes colored at this time, repeat this procedure. Cool, then add a small amount of water and transfer to a 50mL volumetric flask. Add 10 mL of iodine-L-ascorbic acid test solution and dilute to 50 mL with water. Separately, prepare a solution by use of 4% acetic acid and proceed in the same manner as the test solution. Using this as the control, determine the absorbance at the wavelength of 330 nm. The absorbance of the test solution shall be not greater than the absorbance of antimony standard colorimetric solution.

Antimony standard colorimetric solution: Take 500 mg of antimony and add 25 mL of sulphuric acid. Heat to dissolve. Cool, then dilute to 500 mL with sulphuric acid. Take 1 mL and dilute to 100 mL with sulphuric acid. Further take 1 mL of this in a 50 mL volumetric flask, add 10 mL of sulphuric acid and 10 mL of iodine-L-ascorbic acid test solution, and dilute to 50 mL with water.

Iodine-L-ascorbic test solution: Dissolve 112 g of potassium iodine and 20 g of L-ascorbic acid in water and dilute to 500 mL.

Hydrogen peroxide: Hydrogen peroxide solution (30%), special grade

E. Germanium (only for containers/packages using polyethylene terephthalate)

Prepare test solution by use of 4% acetic acid as the eluting solution. Take 400 mL of the test solution into a digestion flask, add 5 mL of sulphuric acid and heat to concentrate until white fumes evolve. Cool, then add approximately 1~2 mL of the hydrogen peroxide dropwise until the solution becomes clear, and heat to concentrate until white fumes evolve. If the solution becomes colored at this time, repeat this procedure.

Cool, then add a small amount of water, and transfer to a 20 mL volumetric flask. Dilute to 20 mL with water. Take 10 mL of the solution in a separating funnel. Add 30 mL of hydrochloric acid and 20 mL of carbon tetrachloride and shake vigorously for 2 minutes. Separate the carbon tetrachloride layer. Use this as the carbon tetrachloride extract.

Next, place 2 mL of 0.05% phenylfluorone test solution and 6 mL of ethanol in a 20 mL volumetric flask and mix. To this, add 10 mL of carbon tetrachloride extract. Dilute precisely to 20 mL with ethanol. Separately, prepare a solution using 4% acetic acid and proceeding in the same way as the solution. Using this as the control, determine the absorbance at the wavelength of 508 nm. The absorbance of the test solution shall be not greater than the absorbance of germanium standard colorimetric solutions.

0.05% Phenylfluorone test solution: Dissolve 0.05 g of phenylfluorone in ethanol containing 0.5 mL of hydrochloric acid, then make up to 100 mL.

Germanium standard colorimetric solution: Take 144 mg of germanium dioxide in a platinum crucible. Add 1 g of anhydrous sodium carbonate and mix well. Heat to melt. Cool, then add water to dissolve. Add hydrochloric acid to neutralize, then add 1 mL excess of hydrochloric acid. Further dilute to 100 mL with water. Take 1 mL of this solution and dilute to 200 mL with water. Take 2 mL of this in a separate funnel. Add 8 mL of water and 30 mL of hydrochloric acid. Further add 20 mL of carbon tetrachloride and shake vigorously for 2 minutes. Separate the carbon tetrachloride layer. Use this as the carbon tetrachloride extract. Beforehand, place 2 mL of 0.05% phenylfluorone test solution and 6 mL of ethanol in a 20 mL volumetric flask and mix. Add 10 mL of carbon tetrachloride extract to this. Dilute to 20 mL with ethanol.

F. Bursting strength test (only for plastic-laminated containers/packages or combined containers/packages)

Follow mutatis mutandis (d) Bursting Strength Test, A. of b. in 1. of 1). Provided, however, that the maximum value of the strength shall be not less than 196.1 kPa for plastics-laminated containers/packages of not more than 300 g capacity, while not less than 490.3 kPa for those of more than 300 g capacity. (In case the outer packaging

(packaging in which containers/packages for retail use are packed) was used, the value should be no less than 980.7 kPa in case the sum of the maximum bursting strength of the outer and containers/packages is no less than 196.1 kPa). For combined containers/packages, cut out the central part of the plastics laminate, and use it as the test sample; the maximum value of the strength should be no less than 490.3 kPa.

e. Polyethylene and ethylene·1-alkene copolymer resin used on the areas coming into direct contact with the contents shall be free from additives.

f. Polyethylene and ethylene·1-alkene copolymer resin used on the areas coming into direct contact with the contents shall comply with the tests based on the following test methods.

A. n-Hexane extract

Follow mutatis mutandis, (a) n-Hexane Extract, D. of b. in 1. of 1).

B. Xylene-soluble substances

Follow mutatis mutandis, (b) Xylene-soluble Substances, D. of b. in 1. of 1).

C. Arsenic

Follow mutatis mutandis, (c) Arsenic, D. of b. in 1. of 1).

D. Heavy metals

Follow mutatis mutandis, (d) Heavy Metals, D. of b. in 1. of 1).

g. Polyethylene terephthalate used on the areas coming into direct contact with the contents shall comply with the tests based on the following test methods.

Cadmium and lead

Follow mutatis mutandis, (a) Cadmium and Lead, B. of c. in 2. of 1).

h. Sealing strength test

Sealing strength shall comply with the test based on (e) Sealing Strength Test, A. of b. in 1. of 1).

2. Persons wishing to use containers/packages other than the containers/packages designated in the preceding No. shall receive the approval of the Minister of Health, Labour and Welfare.

3. Persons manufacturing plastic-laminated containers/packages shall pasteurize the manufactured plastic-laminated containers/packages, and persons manufacturing the plastic laminate or metal used for containers/packages manufactured shall pasteurize the manufactured plastic laminate or metal. Provided, however, that this does not apply to the packages manufactured by a method having a pasteurizing effect.

Attached 1. Whole Milk Specific Gravity Compensation Table

Lactometer degree

Whole milk temperature

Attached 2. Low fat milk and Skimmed milk Specific Gravity Compensation Table

Lactometer degree

Low fat milk and Skimmed milk temperature

Attached 3. Lactose Assay Table

Amount of test solution needed (mL)

Amount of anhydrous lactose in 100 mL test solution (mg)

Amount of anhydrous lactose per 1g sample which can be assayed as invert sugar (mg)

Attached 4. Invert Sugar Assay Table

Amount of test solution needed (mL)

Amount of invert sugar per 100 mL test solution (mg)

Figure 1

1. Upper clamping ring: Inside diameter  $30.48 \text{ mm} \pm 0.03 \text{ mm}$

2. Sample

3. Fixing ring

4. Lower clamping ring: Inside diameter  $31.75 \text{ mm} \pm 0.25 \text{ mm}$ , thickness 3.18 mm

5. Rubber diaphragm: Pure rubber, bulging approximately 9.5 mm from the face of 2 under a pressure of 34.3 kPa to 44.1 kPa, thickness 0.84 mm to 0.89 mm

6. Pressure chamber

Figure 2

Pressure gauge

Cock

Compressor