

NOTIFICATION OF MINISTRY OF PUBLIC HEALTH

No. 156 (B.E. 2537(1994))

*Re : Modified Milk for Infant and Modified Milk of Uniform Formula
for Infant and Children*

Whereas it is deemed appropriate to revise the Notification of Ministry of Public Health Re Modified Milk for Infant,

By virtue of Section 5 and Section 6(1), (2), (4), (5), (6), (7) and (10) of the Foods Act B.E. 2522(1979), the Minister of Public Health hereby issues a notification as follows:

NO. 1. The Notification of Ministry of Public Health No. 85 (B.E. 2528 (1985)) Re Modified Milk for Infant dated 10th January 1985 and the Notification of Ministry of Public Health No. 87 (B.E. 2528(1985)) Re Supplementary Food for Children dated 10th January 1985 shall be repealed.

NO. 2. Modified milk for infant and modified milk of uniform formula for infant and small children shall be specific controlled food.

NO. 3. Modified milk for infant and modified milk of uniform formula for infant and small children mean food manufactured through conversion of the composition of cow's milk to contain food substances sufficient for baby's and children's need, and it is classified as follows:

3.1 Modified milk for infant means modified milk with an aim to feed infant of one day old to 12 months old in lieu of or in substitution of mother's milk.

3.2 Modified milk of uniform formula for infant and small children means modified milk with an aim to feed infant of 6 months old to 12 months old or children from 1 year old to 3 years old.

NO. 4. Modified milk for infant and modified milk of uniform formula for infant and small children shall have the following qualities or standards:

- 4.1 containing the composition of cow's milk, exclusive of water, at not less than 60 percent of the weight;
- 4.2 having odour and flavour according to specific characteristics of modified milk for infant and modified milk of uniform formula for infant and small children;
- 4.3 having moisture not more than 5 percent of the weight for modified milk for infant and modified milk of uniform formula for infant and small children of powder or dry type;
- 4.4 being friable or in dry form, not in clots, for modified milk for infant and modified milk of uniform formula for infant and small children of powder or dry type, and when having mixed according to the directions shown in the label, it shall not be in clot, scum and the food contents shall not be coarse, and shall be suitable for feeding infant or children and can pass through natural rubber nipple or synthetic rubber nipple used generally;
- 4.5 shall not change from the form made originally for modified milk for infant and modified milk of uniform formula for infant and small children using the process under No. 7;
- 4.6 having no hormone or anti-biotics;
- 4.7 not using sweetening substances in lieu of sugar;
- 4.8 containing no preservatives;
- 4.9 containing no food colours, food odour or food flavouring substances, however, except modified milk of uniform formula for infant and small children which may be added with flavour and odour as approved by the Food and Drug Administration;
- 4.10 containing no microorganisms that cause diseases;

- 4.11 containing no toxic substances from microorganisms or other toxic substances in a quantity that may be hazardous to health;
- 4.12 no *Escherichia coli* can be detected in 0.1 gram or 0.1 millilitre of modified milk for infant and modified milk of uniform formula for infant and small children;
- 4.13 no bacteria can be detected in 0.1 millilitre of modified milk for infant and modified milk of uniform formula for infant and small children using sterilized process;
- 4.14 no bacteria can be detected in 0.1 millilitre of modified milk for infant and modified milk of uniform formula for infant and small children using UHT process;
- 4.15 bacteria presence not to exceed 10,000 in 1 gram of modified milk for infant and modified milk of uniform formula for infant and small children;
- 4.16 bacteria presence shall be as approved by the Food and Drug Administration for modified milk for infant and modified milk of uniform formula for infant and small children using other process.

NO. 5. Modified milk for infant under No. 3.1, other than having the qualities or standards under No. 4, shall also have the following specific qualities or standards:

- 5.1 in the quantity or in the mixture ratio for baby feeding as stated in the label of 100 millilitres, there shall be energy of not less than 272 kilojoules (65 calorie kilograms) and not exceeding 293 kilojoules (70 calorie kilograms), except modified milk for infant intended and suitable for feeding baby with weight when delivery less than one thousand eight hundred grams, the energy of which shall be as approved by the Food and Drug Administration;
- 5.2 containing protein, carbohydrate, fats, vitamins and minerals in the quantity that will give energy of 418 kilojoules (100 calorie kilograms), as follows:
 - 5.2.1 reference protein not less than 1.8 grams of casein, and the quantity of total protein shall not exceed 4.0 grams;

Adding of essential amino acid to improve quality of protein may be made in necessary quantity according to such objective and it must be L-form amino acid and approval therefor must be obtained from the Food and Drug Administration.

5.2.2 carbohydrate must be in lactose form at not less than 50 percent of the weight of the total carbohydrate;

5.2.3 fats not less than 3.3 grams and not more than 6.0 grams, and linoleic fatty acid not less than 300 milligrams in the total quantity of fats; in case of containing fatty acid of the kind having carbon in molecule exceeding 20 atoms, it shall not exceed 1 percent of energy at 418 kilojoules (100 calorie kilograms);

5.2.4 vitamins in the following quantity:

- (a) vitamin A not less than 75 micrograms and not more than 150 micrograms, computed in retinol;
- (b) vitamin D not less than 40 international units and not more than 80 international units;
- (c) vitamin K 1 not less than 4 micrograms;
- (d) vitamin E (alpha-tocopherol) not less than 0.7 international unit and must have vitamin E not less than 0.7 international unit per 1 gram of linoleic acid;
- (e) vitamin B 1 (thiamine) not less than 40 micrograms;
- (f) vitamin B 2 (riboflavine) not less than 60 micrograms;
- (g) niacin (nicotinamide or nicotinic acid) not less than 250 micrograms;
- (h) vitamin B 6 not less than 35 micrograms and not less than 15 micrograms per 1 gram of protein, in case of having protein in the formula for modified milk for infant exceeding 1.8 grams per 418 kilojoules (100 calorie kilograms);

- (i) folic acid not less than 4 micrograms;
- (j) pantothenic acid not less than 300 micrograms;
- (k) vitamin B 12 (cyanocobalamin) not less than 0.15 microgram;
- (l) biotin not less than 1.5 microgram;
- (m) choline not less than 7 milligrams;
- (n) vitamin C (L-ascobic acid) not less than 8 milligrams.

5.2.5 Minerals in the following quantities:

- (a) sodium not less than 20 milligrams and not more than 60 milligrams;
- (b) potassium not less than 80 milligrams and not more than 200 milligrams;
- (c) chloride not less than 55 milligrams and not more than 150 milligrams;
- (d) calcium not less than 50 milligrams;
- (e) phosphorus not less than 25 milligrams, ratio of calcium: phosphorus must not be less than 1.2 and not more than 2.0;
- (f) magnesium not less than 6 milligrams;
- (g) iron not less than 0.15 milligram and not more than 3.0 milligrams;
- (h) iodine not less than 5 micrograms and not more than 75 micrograms;
- (i) copper not less than 60 micrograms;
- (j) zinc not less than 0.5 milligrams;
- (k) manganese not less than 5 micrograms.

In case a modified milk for infant is purposely for feeding baby with abnormal digestion or with abnormal assimilation or allergic to certain kinds of food, the kind and quantity of food substances shall be as approved by the Food and Drug Administration, and the said purpose shall be shown in the label.

NO. 6. Modified milk of uniform formula for infant and small children under No. 3.2, other than having the qualities or standards under No. 4, shall have the following specific qualities or standards:

6.1 Shall have energy not less than 251 kilojoules (60 calorie kilograms) and not more than 356 kilojoules (85 calorie kilograms) in a quantity or at the ratio of mixture for feeding infant or children as stated in the label at 100 millilitres;

6.2 Shall have protein, fats, vitamins and minerals in a quantity that gives energy at 418 kilojoules (100 calorie kilograms) as follows:

6.2.1 reference protein not less than 3.0 grams of casein and total protein quantity shall not exceed 5.5 grams;

Adding of essential amino acid to improve quality of protein may be made in necessary quantity according to such objective and it must be L-form amino acid and approval therefor must be obtained from the Food and Drug Administration first.

6.2.2 fats not less than 3.0 grams and not more than 6.0 grams and shall have linoleic fatty acid at not less than 300 milligrams in the total quantity of fats; in case of having fatty acid of the kind having carbon in molecule exceeding atoms, it shall not exceed 1 percent of the energy at 418 kilojoules (100 calorie kilograms) ;

6.2.3 vitamins in the following quantities:

(a) vitamin A not less than 75 micrograms and not more than 225 micrograms, computed in retinol;

(b) vitamin D not less than 40 international units and not more than 120 international unit;

- (c) vitamin E (alpha-tocopherol) not less than 0.7 international unit and must have vitamin E not less than 0.7 international unit per 1 gram of linoleic acid;
- (d) vitamin K 1 not less than 4 micrograms;
- (e) vitamin B 1 (thiamine) not less than 40 micrograms;
- (f) vitamin B 2 (riboflavine) not less than 60 micrograms;
- (g) niacin (nicotinamide or nicotinic acid) not less than 250 micrograms;
- (h) vitamin B 6 not less than 45 micrograms, and not less than 15 micrograms per 1 gram of protein, in case of having protein in modified milk of uniform formula for infant and small children more than 3.0 grams per 418 kilojoules (100 calorie kilograms);
- (i) folic acid not less than 4 micrograms;
- (j) pantothenic acid not less than 300 micrograms;
- (k) vitamin B 12 (cyanocobalamin) not less than 0.15 micrograms;
- (l) biotin not less than 1.5 micrograms;
- (m) vitamin C (L-ascorbic acid) not less than 8 milligrams.

6.2.4 minerals in the following quantities:

- (a) sodium not less than 20 milligrams and not more than 85 milligrams;
- (b) potassium not less than 80 milligrams;
- (c) chloride not less than 55 milligrams;
- (d) calcium not less than 90 milligrams;
- (e) phosphorus not less than 60 milligrams;

- (g) iron not less than 1 milligram and not more than 2 milligrams;
- (h) iodine not less than 5 micrograms;
- (i) zinc not less than 0.5 milligram.

In case food of uniform formula for infant and small children is purposely for feeding baby with abnormal digestion or with abnormal assimilation or allergic to certain kinds of food, the kind and quantity of food substances shall be as approved by the Food and Drug Administration, and the said purpose shall be shown in the label.

NO. 7. Food for infant and food of uniform formula for infant and small children of liquid type shall be homogenized and processed by heat as follows :

- (1) sterilization;
- (2) UHT;
- (3) other process as approved by the Food and Drug Administration.

NO. 8. Food for infant and food of uniform formula for infant and small children shall not be processed by radiation or shall have no ingredients that have been radiated.

NO. 9. In manufacturing food for infant and food of uniform formula for infant and small children, if it is necessary to use food additives other than food preservatives, it shall be per the Notification of Ministry of Public Health governing food additives.

NO. 10 Food for infant and food of uniform formula for infant and small children shall be packed in airtight container that can preserve the quality or standard of the food, and it shall be per the Notification of Ministry of Public Health governing container as well.

- 11.1 Shall be per the Notification of Ministry of Public Health No. 68 (B.E. 2525 (1982)) Re Label dated 29th April 1982 amended by the Notification of Ministry of Public Health No. 95 (B.E. 2528 (1985)) Re Label (No. 2) dated 30th September 1985, except No. 3.

NO. 11. Displaying of label of modified milk for infant and modified milk of uniform formula for infant and small children shall be as follows:

- 11.1 Shall be per the Notification of Ministry of Public Health No. 68 (B.E. 2525(1982)) Re Label dated 29th April 1982 amended by the Notification of Ministry of Public Health No. 95 (B.E. 2528(1985)) Re Label (No. 2) dated 30th September 1985, except No. 3.
- 11.2 Statement shall be in Thai language, however, foreign language is allowed; and there shall at least contain the following details:
 - 11.2.1 Name of food.
 - 11.2.2 Food recipe registration number or sign showing permission to use label, as the case may be.
 - 11.2.3 Name and location of manufacturer or of person repacking the food for sale, as the case may be. For food manufactured locally, it may show the name and location of the head office of the manufacturer or of the person repacking food for sale. In case of imported food, the country of manufacture shall be shown.
 - 11.2.4 Quantity of food in metric system:
 - (a) food being in powder or dry form, net weight shall be shown.
 - (b) food in liquid form, net volume shall be shown.
 - (c) food of semi-solid and semi-liquid, net weight or net volume may be shown.
 - 11.2.5 Major ingredients of food in percentage of the weight, in order of greater quantity to lesser quantity, and it shall show energy value and quantity of food substances listed herebelow per 100 grams (or 100 millilitres) of food and per 100 millilitres of modified milk for infant and modified milk of uniform formula for infant and small children:

- (a) energy value in calorie kilogram or kilojoule;
 - (b) protein in gram;
 - (c) carbohydrate in gram;
 - (d) fat in gram;
 - (e) linoleic acid in milligram;
 - (f) vitamins according to type and unit stated in No. 5.2.4 or No. 6.2.3, as the case may be;
 - (g) minerals according to type and unit prescribed in No. 5.2.5 or No. 6.2.4, as the case may be.
- 11.2.6 Date, month and year of manufacture, with the word "manufactured" printed thereon, or date, month, year of manufacture with the word "manufactured" printed, and date, month and year of repacking with the word "repacked" printed thereon, in case of manufacture by repacking, as the case may be.
- 11.2.7 Date, month and year of expiry, with the word "expired on" printed thereon.
- 11.2.8 Recommendation for storage, specifically after opening.
- 11.2.9 Preparation method (if any).
- 11.2.10 Modified milk for infant shall contain the following statements:
- (a) statement reading "Important Message :
 - Mother's milk is the best food for infant because it has full nutrition value.
 - Should use this product under recommendation of a physician, nurse or nutritionist.
 - Incorrect preparation or mixture will be hazardous to infant."

- (b) Statement showing directions or table of recommended daily usage.

11.2.11 Modified milk of uniform formula for infant and small children shall contain the following statement:

- (a) Statement reading: "Do not use to feed infant under 6 months old" in red bold characters of not less than 5 mm. high in a rectangular frame with white background, and the colour of the frame must be in contrast with that of label background.
- (b) Statement reading "natural odour added", "artificial odour added", "Synthetic odour added", "natural flavour added" or "artificial flavour added", if so used, as the case may be.

11.2.13 Statement as prescribed by the Food and Drug Administration.

This Notification shall have no affect to the Food Recipe Registration Certificate issued under the Notification of Ministry of Public Health No. 85 (B.E. 2528(1985)) Re Modified Milk for Infant, dated 10th January 1985, and the Notification of Ministry of Public Health No. 87 (B.E. 2528(1985)) Re Supplementary Food for Children, dated 10th January 1985, specifically in the part concerning supplementary food for children of complete type. The persons granted with Food Recipe Registration Certificate under the said Notifications shall proceed with the rectification of food recipe so that it be per this Notification within one hundred and eighty days from the date of enforcement of this Notification, and after having done so, the old labels may still be used until the permission is granted or until they are informed of the rejection to use such label.

In granting permission to use new label under paragraph one, if it appears that the old labels prepared prior to the enforcement date of this Notification still remain and they are not correct under this Notification, the person granting permission may allow the use of the old labels until they run out, however, it shall not be more than one year from the date of enforcement of this Notification.

This Notification shall be enforced on and from the day following the date of its publication in the Government Gazette.

Notified this 14th day of October 1994

ARTHIT URAIRAT

Minister of Public Health

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