

Unofficial

Notification of the Ministry of Public Health

(No. 298) B.E. 2549 (2006)

Re: Production Processes, Production Equipments, and storage of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment

It deems appropriate to amend the notification of the Ministry of Public Health, and raise standard level of Production Processes, Production Equipments, and storage of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment

By the virtue of provisions of Section 5 and 6(1) (2)(6) and (7) of the Food Act B.E. 2522 (1979), in which contain provisions in relation to the restriction of Rights and Liberties of the Persons, in respect of which Section 29 and in conjunction with Section 35, Section 48 and Section 50 of the Constitution of the Kingdom of Thailand so permit by virtue of provisions of law: the Minister of Public Health hereby issues the notification as follows:

Clause 1 Ready-to-consume milk products in liquid form which passed through pasteurization heat treatment are particularly prescribed to production processes, production equipments, and storages.

Clause 2 Ready-to-consume milk products in liquid form which passed through pasteurization heat treatment are as follows : Cow' s Milk, Flavoured Milk, Other Milk Products, Cultured milk and include such products that made from milk of other animals ready-to-consume which passed through heat treatment by pasteurization.

Clause 3 The producers ready-to-consume milk products in liquid form which passed through pasteurization heat treatment for sale are prescribed in the production processes, production equipments, and storages to follow the attachments in this notification.

Clause 4 Importers of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment for sale are required to import such products from establishments that achieve the assessment by the Food and Drug Administration or organizations or agencies which the Food and Drugs Administration prescribed as processing establishments hold standards of production processes, production equipments, and foods storages not inferior to criteria as prescribed in the attachment in this notification; or providing certificates of processing establishments of import ready-to-consume milk products in liquid form which passed through pasteurization heat treatment as prescribed by the Food and Drug Administration.

In case of reason or necessity existed to verify food safety system for consumer protection; the Food and Drug Administration may prescribe establishments as stipulated above that shall achieve the assessment by the Food and Drug Administration or organizations or agencies which the Food and Drugs Administration prescribed.

Clause 5 Licensees of Food Production, Import, Food Labelling Certificate of ready- to-consume milk products in liquid form which passed through pasteurization heat treatment prior to this notification come into force shall follow clause 3 and clause 4 as the case may be within one year as from the date of this notification come into force.

Clause 6 This notification shall come into force as from the day following date of its publication in the Government Gazette.

Notified on 18th of August 2006

signed Anutin Charnverakul

(Mr. Anutin Charnverakul)

Deputy Minister of Ministry of Public Health

on behalves of The Minister of Public Health

(Published in the Government Gazette Vol. 123, Special Part 96 Ngor, dated 13th September 2006)

Certified true copy

Parichart Thitawattanakul

(Mrs. Parichart Thitawattanakul)

Food and Drug Officer Level 7

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

Attachment to the notification of Ministry of Public Health

(No. 298) B.E. 2549 (2006).

Re: Production Processes, Production Equipments, and Storages ready-to-consume milk products
in liquid form which passed through pasteurization heat treatment

Production of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment; Production Processes, Production Equipments, and Storages ready-to-consume milk products in liquid form which passed through pasteurization heat treatment shall be prescribed and considered to the followings:

| No. | Items | Descriptions |
|-----|--------------------------------------|--|
| 1 | Location and manufacturing buildings | <p>1.1 Location and surrounding of food manufacturing buildings shall locate in sound area which may not cause ready-to-consume milk products in liquid form which passed through pasteurization heat treatment to be contaminated if unavoidable there must have measures to prevent such contaminations are as follows :</p> <p>1.1.1 Buildings location and surrounding shall be clean and no accumulation of non-use materials or garbages which may hatch animals and insects including to pathogenic micro-organisms.</p> <p>1.1.2 Locate away from heavy dust area.</p> <p>1.1.3 Not to locate near repugnant area.</p> <p>1.1.4 Not to locate in dirty or flooded area and drained pipeline connectd to sewage treatment system before released to public sewage pipeline.</p> <p>1.1.5 In case of raw material is raw milk, there must have a car washed area and equipment</p> |

| No. | Items | Descriptions |
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| | | <p>for transportation of raw milk which durable, smooth, decline and no flooded floor.</p> <p>1.2 Production buildings of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment shall be at minimum as follows:</p> <p>1.2.1 Design and construction shall be durable; floor, wall, and ceiling of production buildings shall be constructed by durable, smooth and non-absorbance materials, declined, and no flooded.</p> <p>1.2.2 Enough size and space for operation</p> <p>1.2.3 Building is for food production only and operation of different kinds of food production line shall be separated from each other.</p> <p>1.2.4 Provide space for each line of production in order to prevent cross contamination</p> <p>1.2.5 Residential area, rest room, toilet shall be isolated from production area.</p> <p>1.2.6 Convenient for operation and maintain in good condition, not broken and sanitary.</p> <p>1.2.7 Be able to prevent animals and insects to pass into production area.</p> <p>1.2.8 No non-use or irrelevant materials for production in production areas.</p> <p>1.2.9 Having drainages which are designed adequately for receiving waste from that production area.</p> <p>1.2.10 Having good and adequate ventilations</p> <p>1.2.11 Having adequate lighting systems with covers in areas where contamination may be occurred.</p> <p>1.2.12 At minimum, inside production buildings shall have</p> |

| No. | Items | Descriptions |
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| | | <p>1.2.12.1 Room or area for receiving and holding of raw milk, in case of raw material is raw milk, holding tank of raw milk may be located outside the building.</p> <p>1.2.12.2 Room or area for storage of raw materials, ingredients for productions include packaging; floor shall be dried, having shelves or lifted floor to support.</p> <p>1.2.12.3 Room or area for preparation of raw materials or mixing (in case of production of flavored milk).</p> <p>1.2.12.4 Room or area for culture preparation (In case of cultured milk production).</p> <p>1.2.12.5 Room or area for pasteurization.</p> <p>1.2.12.6 Room or area for packing, having efficient measures to prevent contamination from outside, not a trespassing zone to other area, other rooms; having utensils for packaged products which lifted from operating floor.</p> <p>1.2.12.7 Cold storages or Refrigerators, for holding finished products have shelves or lifted floor to support in order to have adequate cold ventilation throughly.</p> <p>1.2.12.8 Room or area for washing and disinfecting packaging; as the case may be.</p> <p>1.2.12.9 Room or area for washing and disinfecting utensils and equipments of productions.</p> <p>1.2.12.10 Room or area for Clean In Place (CIP) equipments.</p> <p>1.2.12.11 Room or area for cleaned equipments.</p> <p>1.2.12.12 Laboratory for analysis of milk quality that have measures to prevent contamination into production area.</p> |

| No. | Items | Descriptions |
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| | | <p>1.2.12.13 Room or area for keeping non-food used chemicals to be isolated from chemicals used in food.</p> <p>1.2.12.14 Room or area for clothes change and keeping personnel belongings of employees.</p> |
| 2 | Tools, machineries and production equipments | <p>2.1 At a minimum, design shall be as follows :</p> <p>2.1.1 Surface of tools or equipments directly contact with milk, shall be made of materials that do not cause contamination into food and easy to clean and sanitize.</p> <p>2.1.2 Pumps, joints, valves seals casket which contacted with milk shall be designed for easily cleaning and sanitize.</p> <p>2.1.3 Milk pipelines shall not cause contamination into production processes; no dead ends or dead spots inside of the pipelines which introduce accumulation of debris that difficult to clean and sanitize.</p> <p>2.1.4 Milk storage tanks shall be designed to have slope at bottom, all liquid can be drained off and prevent contamination.</p> <p>2.2 Tools, machineries and equipments are installed separately in suitable locations in comply with each type of production lines, do not cause contaminations, easy for operation, examination, cleaning and repairing.</p> <p>2.3 Having sufficient and suitable of those for production; which are in working conditions, accurate and precise; at a minimum shall compose of:</p> <p>2.3.1 Receiving raw milk equipments (where raw milk used as raw material);</p> |

| No. | Items | Descriptions |
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| | | <p>2.3.2 Measurement equipments or weighing balances;</p> <p>2.3.3 Filter or filtering equipments;</p> <p>2.3.4 Machines or equipments for decreasing temperature of raw milk;</p> <p>2.3.5 Storage tanks of raw milk which be able to control temperature lower than 8°C throughout storage periods equipped with thermometer;</p> <p>2.3.6 Machines or equipments for mixing or homogenizers, as the case may be;</p> <p>2.3.7 Pasteurizing machines equipped with thermometer, temperature recorder and stirring devices where using batch pasteurization ;</p> <p>2.3.8 Flow diversion device (FDD) equipped with thermometer, temperature recorder where using continuous pasteurization, with warning system when pasteurizing temperature is not achieved the specified temperature; and having measures to prevent temperature variation in FDD.</p> <p>2.3.9 Fermented tanks (in case of cultured milk);</p> <p>2.3.10 Machines or equipments for cleaning or sanitizing of packaging;</p> <p>2.3.11 Holding tanks shall have covers with slope, be able to clean and sanitize inside of CIP including equipments for temperature measurement and be able to maintain the temperature of milk or finished products not exceed specified requirements ;</p> <p>2.3.12 Automatic filler and sealer;</p> <p>2.3.13 Stamping machines or equipments of expiry date;</p> <p>2.3.14 Machines or equipments to clean and disinfect CIP;</p> |

| No. | Items | Descriptions |
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| | | 2.3.15 Machines or equipments for adjustment of water quality; 2.3.16 Thermometers and stopped clocks, as the case may be. |
| 3 | Process control | <p>Operation of every step shall be controlled according to Good Manufacturing Practice, from checking and storing of raw materials, ingredients used in production and packaging ; mixing sterilizing, holding of products prior to filling, filling, storing of finished products, transportation during production and transportation of finished products as follows:</p> <p>3.1 Receiving of raw materials, ingredients used in production and packaging.</p> <p>3.1.1 Raw materials and ingredients used in production.</p> <p>3.1.1.1 Having quality and safety selected which is suitable for production of food for human consumption as requirements specified;</p> <p>3.1.1.2 Sampling raw milk to analyze chemical, physical and microbiological quality every time before use for production.</p> <p>3.1.1.3 Sampling other ingredients to analyze by standardized laboratories at least once a year, or every time of changing suppliers in order to have information for decision-making of making use in production.</p> <p>3.1.1.4 Storing under conditions which avoid contaminations and minimize decomposition, effective rotation based on first-in first-out principle.</p> <p>3.1.1.5 Having shelves or lifted floor supported.</p> <p>3.1.2 Containers</p> <p>3.1.2.1 Shall be made of materials which have quality or standards prescribed of food</p> |

| No. | Items | Descriptions |
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| | | <p>packaging in Notification of the Ministry of Public Health, Re : Packaging.</p> <p>3.1.2.2 Initial examination of conditions, have no defects, are in clean packages, are prevented from dust contamination; before using those shall be cleaned and sanitized and immediately filled after that, regular testing of microbial contamination of containers to confirm an efficiency of cleaning or sanitizing.</p> <p>3.1.2.3 Having shelves or lifted floors supported.</p> <p>3.2 In-process control</p> <p>3.2.1 Mixing (where applicable)</p> <p>3.2.1.1 Checking of mixing shall be complied with formula, compositions determined, stored under conditions that be able to prevent contamination and growth of microorganisms.</p> <p>3.2.2 Pasteurization</p> <p>3.2.2.1 Control of pasteurizing process by using time and temperature prescribed in relevant Notification of the Ministry of Public Health.</p> <p>3.2.2.2 After pasteurization verify efficiency every time; and record.</p> <p>3.2.2.3 In case of using plate-heated exchanger, in Regenerative section, pressure of pasteurized milk shall be controlled to be higher than raw milk or having other equivalent measures.</p> <p>3.2.3 Filling</p> <p>3.2.3.1 Fill and seal immediately with automatic machines.</p> |

| No. | Items | Descriptions |
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| | | <p>3.2.3.2 Visual examination of integrity of containers after filling, including legitimate labels.</p> <p>3.2.3.3 Temperature of pasteurized milk during filling through storing in chilled room shall not exceed the temperature prescribed in relevant Notification of the Ministry of Public Health or with regard to technical approved and safe for consumers; together with records.</p> <p>3.3 Finished products</p> <p>3.3.1 Storage of finished products shall be able to prevent contamination and decomposition of the products, temperature of the products during storage shall not exceed the temperature prescribed in relevant Notification of the Ministry of Public Health or with regard to technical approved and safe for consumers together with record.</p> <p>3.3.2 Transportation; vehicles used to transport pasteurized milk products shall not cause contamination and be able to control temperature of the products complied with relevant temperature prescribed in relevant Notification of the Ministry of Public Health or with regard to technical approved and safe for consumers together with record. In case of using ice, it shall be clean and has quality or standards regard to Notification of the Ministry of Public Health, Re : Ice.</p> <p>3.3.3 Control of quality, samples shall be taken to analyze for chemical, physical quality at least once a year and microbiological quality at least every six months by standardized laboratories, including in-house control where appropriate, to examine that those</p> |

| No. | Items | Descriptions |
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| | | <p>products have quality complied with the relevant Notification of the Ministry of Public Health.</p> <p>3.4 Utensils, equipments, devices used for transportation of raw materials, ingredients in production, in-process including finished products shall be in appropriate conditions and not cause contamination.</p> <p>3.5 Distinct keeping and identifying of each raw material, container and finished product, reprocessed product or product hold to dispose.</p> <p>3.6 Water contact with food shall be potable water, have quality or standards complied with Notification of the Ministry of Public Health, Re: Drinking water in sealed containers; and using of that in sanitary condition.</p> <p>3.7 Steam contact with food shall be potable water or have quality or standards complied with Notification of the Ministry of Public Health, Re: Drinking water in sealed containers; and using of that in sanitary condition.</p> <p>3.8 Appropriate measures for handling raw milk, in-process, finished products shall be in placed when electric power turn off; in this regard if ice is used, it shall not be contacted directly with food and ice shall have quality or standards complied with Notification of the Ministry of Public Health, Re: Ice.</p> |
| 4 | Cleaning, sanitizing and maintenance | Substances used in cleaning and sanitizing devices, machines and equipments of productions, particularly with containers, shall have information of instruction, concentration, temperature when use, contacted time of substance with surfaces to be cleaned or sanitized and it shall be tested |

| No. | Items | Descriptions |
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| | | <p>that such information of the efficiency of cleaning and sanitizing are as follows:</p> <p>4.1 Cleaning and sanitizing</p> <p>4.1.1 Documents describe steps of cleaning and sanitizing of devices, machines and equipments for productions, including packaging.</p> <p>4.1.2 Chemicals used in cleaning and sanitizing of devices, machines and equipments for productions shall have information of type, instruction, concentrations, temperature when use, and duration of cleaning and sanitizing of the chemicals.</p> <p>4.1.3 Appropriate and effective sanitization of devices, machines and equipments.</p> <p>4.1.4 Checking of efficiency of cleaning, sanitizing and chemical residuals used in cleaning and sanitizing.</p> <p>4.1.5 Keeping of equipments used in cleaning and sanitizing separate and away from areas that may cause recontamination.</p> <p>4.1.6 Conveying, transporting of cleaned utensils or equipments shall be avoided from contamination from outside.</p> <p>4.1.7 Using of chemicals, including chemicals used in production process shall be under safe condition, accompanied with label in Thai and shall have control measures for safely use.</p> <p>4.2 Having appropriate and effective Maintenance programs of devices, machines, equipments and calibration of equipments which necessary in production.</p> |
| 5 | Sanitation | Producers shall operate for sanitation as follows: |

| No. | Items | Descriptions |
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| | | <p>5.1 Water used in production establishments for other purposes shall be clean, quality adjusted where appropriate, have sufficient quantity and have signals to clearly differentiate each type of water which contacted with food and used in production area.</p> <p>5.2 Having adequate garbage bins with covers and appropriate methods to eliminate.</p> <p>5.3 Having adequate and effective drainages and not cause recontamination into process.</p> <p>5.4 Having adequate and sanitary toilets and hand washing basins for workers with full facilities to wash hands with function in sanitary and efficient manner.</p> <p>5.5 Adequate hand washing basin in production areas and install at appropriate areas with full facilities to wash and dry hands and work effectively.</p> <p>5.6 No pets in production buildings and having effective preventive control system of pests and insects.</p> |
| 6 | Hygiene of workers and personnel | <p>6.1 Workers and personnel in production area shall</p> <p>6.1.1 Not have communicable or objectionable diseases that prescribed in the Ministerial Regulation, No. 1 (B.E. 2522) or lesion that may cause contamination into food and have direction for whom that have symptom of diseases</p> <p>6.1.2 Have medical examination at least once a year;</p> <p>6.1.3 Wear clean garments, short- nail cut, not polished, not wear jewelry.</p> <p>6.1.4 Wash hands every time before start working, after contact with contaminated things and after using toilets and bathroom, especially to workers operate in receiving raw milk, mixing, adding cultures and filling.</p> <p>6.1.5 Wear intact, clean and sanitary gloves, at some step of operation that wearing gloves is</p> |

| No. | Items | Descriptions |
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| | | <p>not required, shall clean hands, nails, arms before starting work.</p> <p>6.1.6 Wear cap, hair nets or covers, apron, mouth-covered cloth while working.</p> <p>6.1.7 Have measures for shoes arrangement at some appropriate working areas, such as changing shoes in particular area or soaking shoes in disinfectant liquid before accessing into production area to prevent contamination of products.</p> <p>6.1.8 Not consume food, smoke cigarette while working or other objectionable behaviors that may cause contamination of food.</p> <p>6.1.9 Have for workers, training of general hygiene, common knowledge of production of ready-to-consume milk products in liquid form.</p> <p>6.2 Process control operators shall have qualification and knowledge of production of ready-to-consume milk products in liquid form which pass through pasteurization process. , where appropriate, as Food and Drug Administration prescribe.</p> <p>6.3 Hygiene requirements or measure for visitors or person whom not relevant to production at least shall comply with clause 6.1.1 to 6.1.8.</p> |
| 7 | Records and Reports | <p>Producers shall have at minimum following records, reports relevant to productions, kept at production establishments for a period at least 6 months:</p> <p>7.1 Analysis results of raw milk, raw materials, ingredients in productions, containers and finished products.</p> <p>7.2 Analysis results of water contact with food and those used as composition in production.</p> <p>7.3 Measurement of raw materials and ingredients in production.</p> |

| No. | Items | Descriptions |
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| | | <p>7.4 Time and Temperature of holding of raw milk, mixing, aging as the case may be, pasteurization, holding prior to fill, holding of finished products and transportation.</p> <p>7.5 Record of verification of pasteurization effectiveness.</p> <p>7.6 Type and quantity of finished products on a daily basis and recall procedures.</p> <p>7.7 Type and concentration of chemicals used for cleaning and sanitizing devices, machines and equipments in production.</p> <p>7.8 Results of efficiency of cleaning and sanitizing devices, machines and equipments for production.</p> <p>7.9 Results of checking of preparedness of functioning of machines, equipments particular with FDD (where using of continuous pasteurization) that done before start every time of production .</p> <p>7.10 Result of checking of machines and equipments according to maintenance programs defined.</p> <p>7.11 Calibration results of thermometers, clocks, weighing balances, measuring equipments which used in production.</p> <p>7.12 Results of annual medical examination of workers and history or training reports of workers.</p> |