(Unofficial)

Notification of the Ministry of Public Health
(Number 420) of B.E. 2563
Issued by the Virtue of the Food Act of B.E. 2522
Title: Food Production Processes, Processing Equipment/ Utensils and Storage Practices

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It deems appropriate to revise and harmonise the regulations regarding food production processes, processing equipment/ utensils and storage practices which were the preventive measures for food safety set forth by a number of Notifications of Ministry of Public Health in order to minimise overlapping in auditing or inspection of food premises and to increase efficiency of auditing or inspection of food premises with the aims of increasing effectiveness of consumer protection so as to provide consumer the safe and wholesome foods as well as raising standards of processed food production in order to prepare for entering into ASEAN Economic Community.

By the virtue of the provisions of the first paragraph of Section 5 and Section 6 (7) of the Food Act of B.E. 2522, the Minister of Public Health hereby issues the notification as follows:

Clause 1. The following Notifications of Ministry of Public Health shall be revoked:

(1) The Notification of Ministry of Public Health (No. 193) of B.E. 2543, Title: Production Processes, Production Equipment, and Foods Storages, issued on 19th September 2000.

(2) The Notification of Ministry of Public Health (No. 220) of B.E. 2544, Title: Bottled Drinking Water (3rd Issue), issued on 24th July 2001.

(3) The Notification of Ministry of Public Health (No. 239) of B.E. 2544, Title: Amendment of the Notification of Ministry of Public Health (No. 193) B.E. 2543, issued on 11th September 2001.

(4) The Notification of Ministry of Public Health (No. 298) of B.E. 2549, Title: Production Processes, Production Equipment, and Storage of ready-to-consume milk products in liquid form which passed through pasteurization heat treatment, issued on 18th August 2006.

(5) The Notification of Ministry of Public Health, Title: Amendment of the Notification of Ministry of Public Health (No. 193) B.E. 2543 (the 2nd issue); issued on 26th July 2010.

(6) The Notification of Ministry of Public Health Title: Amendment of the Notification of Ministry of Public Health (No. 220) B.E. 2544, issued on 26th July 2010.

(7) The Notification of Ministry of Public Health Title: Amendment of the Notification of Ministry of Public Health (No. 298) B.E. 2549; Issued on 26th July B.E. 2010.

(8) The Notification of Ministry of Public Health (No. 349) of B.E. 2556, Title: Manufacturing Procedures, Production Equipment and Appliance, and Food Storage of Pre-packaged Processed Foods, issued on 17th April 2012.

(9) The Notification of Ministry of Public Health (No. 349) of B.E. 2556, Title: Manufacturing Procedures, Production Equipment and Appliance and Storage of Low Acid and Acidified Foods in Hermetically Sealed Container, issued on 3rd January 2013.

Clause 2. Commercial foods produced in any premises shall be classified as the foods of which production processes, processing equipment/utensils and storage practices are regulated, excepts the foods produced in the following premises or areas:

(1) Any private building, place or area with or without dining areas, that is dedicated to cook or prepare foods and sale to consumer for immediate consumption at its dining area or takeout. This exemption shall not apply to the establishments for production of the Specific Controlled Foods, the Standard or Quality Controlled Foods, or the Foods that required label, as the case may be, by using either machines with a total power of at least 5 hp or equivalent or employing workers of at least 7 people.

(2) Food-selling establishments/ Food vending located in public area or way.

(3) Premises for production of edible salt.

(4) Premises for sorting and packing of some fresh vegetables and fruits which are regulated under the certain Notification of Ministry of Public Health regarding production processes, processing equipment/utensils and storage practices of some fresh vegetables and fruits.

Clause 3. Producers of the foods as stipulated in Clause 2 shall comply with the requirements regarding food production process and processing equipment/utensils and storage practices as prescribed in the Annex of this Notification.

Clause 4. Producers of foods listed below shall appoint the food process control supervisor(s) who successfully completed the FDA-approved training course(s):

(1) Bottled drinking water, natural mineral water and edible ice which is treated by a filtration process.

(2) Ready-to-consume milk products in liquid form which are processed by the pasteurization heat treatment, *i.e.* cow's milk, flavored cow's milk and cow's milk products including such products that are made from milk of other animal species and using pasteurization heat treatment. This provision also applies to the products that are frozen after pasteurization.

(3) Low acid and acidified foods packaged in hermetically sealed container, *i.e.* the foods to which the thermal process is applied to kill or inhibit growth of microorganisms after or before packaging operations. It shall include other foods with a finished equilibrium pH of greater than 4.6 and water activity of greater than 0.85 which are treated with the stated-above thermal processing and packed in hermetically sealed rigid or flexible containers that are made of metal or other materials. Such foods shall be able to keep at ambient.

Clause 5. Auditing of food production processes, processing equipment/ utensils and storage practices shall be conducted in compliance with the requirements stipulated by the Food and Drug Administration.

Clause 6. Importers of the foods stipulated in Clause 2 shall hold certifying documents showing that their standards of manufacturing practices are equivalent to or not lower than the requirements prescribed in the Annex of this Notification.

Clause 7. Licence holders who had been granted a Food Production Licence, Importation Licence or a Food Premise Registration Number prior the date of which this Notification entered into force shall comply with this Notification within a hundred and eighty days as from the date of which this notification entered into force.

Clause 8. This notification shall enter into force after the expiration of sixty days from the date of its publication in the Government Gazette.

Notified on 3rd December B.E. 2563
(Singed) Anutin Charnvirakul
Minister of Ministry of Public Health

(Published in the Government Gazette, Vol. 318, Special Part 31-Ngor, 9th February 2021)

Disclaimer: This English version of the Notification and its Annex were made to meet the need of the non-Thai speakers. In the event of any discrepancy between the original Thai and English translation versions, the original Thai version shall prevail in determining the spirit, intent, and meaning of the Notification and its Annex.

Annex

Attached to the Notification of Ministry of Public Health (Number 420) of B.E. 2563 Issued by the Virtue of the Food Act of B.E. 2522

Title: Food Production Processes, Processing Equipment/Utensils and Storage Practices

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The requirements regarding food production processes, processing equipment/utensils and storage practices comprise two parts as follows:

Part 1 General requirements

The general requirements are fundamental requirements that apply to all food premises. The main objective of this part is to prescribe preventive measures required for food producers to prevent contamination or to eliminate biological, chemical and physical hazards originated from environment, building, equipment, utensils, containers and workers involving in all steps of food production. Additionally, it prescribes requirements regarding management of sanitation and personal hygiene with the purpose of ensuring standard and safety of foods.

Part 2 Specific requirements

The specific requirements are additional requirements that apply to the certain production processes which may pose a high risk if fails to control production process properly. The objective of this part is to prescribe directions of process control, in particular the crucial point(s) in production processes that need(s) special control measure(s) to reduce or eliminate hazard(s) to an acceptable level in order to achieve the utmost safety of food. Three certain production processes that are required to apply specific requirements:

2.1 Production of bottled drinking water, natural mineral water and edible ice which is treated by a filtration process.

2.2 Production of ready-to-consume milk products in liquid form which are processed by the pasteurization heat treatment, *i.e.* cow's milk, flavored cow's milk and cow's milk products including such products that are made from milk of other animal species and using pasteurization heat treatment. The products that are frozen after pasteurization are included.

2.3 Production of low acid and acidified foods packaged in hermetically sealed container, *i.e.* the foods to which the thermal process is applied to kill or inhibit growth of microorganisms after or before packaging operations. It shall include other foods with a finished equilibrium pH of greater than 4.6 and water activity of greater than 0.85 which are treated with the stated-above thermal processing and packed in hermetically sealed rigid or flexible containers that are made of metal or other materials. Such foods shall be able to keep at ambient.

PART 1

GENERAL REQUIREMENTS

The general requirements comprise five sections:

Section 1 Location, Production Building, Cleaning and Maintenance

Section 2 Equipment, Machines, Utensils, Production tools, Cleaning and Maintenance

Section 3 Process control

Section 4 Sanitation

Section 5 Personal hygiene

Details of each section are prescribed as follows.

Section 1 Location, Production Building, Cleaning and Maintenance

1.1 Location of a production building shall be located with sufficient clearance from sources of contamination such as rubbish, hazardous substances, animal pens, dust, smoke, flooding. Effective preventive measures shall be applied in case of the location is located anywhere where it is not suitable and will create a threat to food safety.

1.2 Areas around and inside of a production building shall be clear of objects not in use or not required for manufacturing that may build up of dirt or being harborage or breeding source for animals, insects and pathogens. Additionally, measures to prevent unintended use of the damaged objects shall be applied.

1.3 Appropriate water piping or drains shall be installed outside and inside a production building with capability to collect wastewater generated from inside the building as well as to collect rainwater. Slope of the pipes or drains shall be appropriate to allow adequate drainage. The pipes or drains shall be no blockage and not cause flooding, muddy and dirty conditions. Direction of water flow shall be taken into consideration when design a drainage system.

1.4 A production building shall be sound constructed and designed to allow easy cleaning and maintenance. It shall be regularly cleaned and maintained in a good condition. The following requirements shall be complied:

1.4.1 Floor shall be made of durable and smooth material. It shall be easy to clean and have appropriate slope to allow adequate drainage. It shall be in a clean and no damaged condition.

1.4.2 Walls shall be made of durable and smooth material. It shall be easy to clean and be in a cleaned and undamaged condition.

1.4.3 Ceilings shall be made of durable and smooth material. It shall be easy to clean. Overhead fixtures shall be clean, no damage and not cause contamination.

1.5 A production building shall be capable to protect against animals and insects to enter into production areas or to come to contact with foods.

1.6 A production building shall have sufficient production area. The production area shall be separated from residential areas, dining areas and areas for production of non-food products as defined by the Food Act.

1.7 Each area of processing in a production building shall be appropriately allocated and arranged in a logical sequence of production line so as to prevent cross contamination.

1.8 Filling room or management of filling zone shall be established to prevent post-processing recontamination.

1.9 The ventilation system shall be able to control direction of airflow in such a way that air shall not flow from high contaminated areas to clean areas. Air ventilation shall be sufficient to prevent contamination and growth of moulds in production areas as well as to obtain a comfortable working condition.

1.10 Lighting shall be provided adequately, in particular the areas where improper lighting can cause mistakes during working or can affect food-hazard control measures.

Section 2 Equipment, Machines, Utensils, Production tools, Cleaning and Maintenance

2.1 Production equipment, machines and utensils that come into contact with foods shall be hygienically designed and made of materials that are non-toxic, no rust, corrosion resistant and not react with foods. They shall be easy to be cleaned and free of pockets or imperfect fusion/welding lines which make them difficult to be cleaned thoroughly.

2.2 Production equipment, machines and utensils shall be installed at appropriate locations and arranged in a logical sequence of production line. They shall be located where permits easy cleaning and maintenance and facilitates operations to be carried out.

2.3 Production equipment, machines and utensils shall be suitable to that particular type of food and processing. They shall be equipped in sufficient numbers when taking into consideration taking into consideration production capacity and be effectively function to suit its intended purpose.

2.4 Tables or work surfaces coming into direct contact with foods shall be smooth surface, non-toxic, no rust, corrosion resistant and not react with foods. They shall be so constructed that they can be easy to be cleaned. The height shall be at least 60 centimeters or at an appropriate level which that is sufficient to prevent contamination of dirt from floor during operation.

2.5 In the case of using piping to convey foods, the internal surface of the pipes including pumps, joints/couplings, gaskets and valves coming into contact with foods shall be hygienically designed and free of pockets or corners that could retain dirt or microorganism so could reduce capability of being throughout cleaned and sanitised. It shall be of such construction as to be

capable of being throughout cleaned. Any kind of cover shall be available to close an open-end of tubbing when not in use.

2.6 Production equipment, machines and utensils shall be regularly cleaned by the effective method, in particular those that come into contact with ready-to-eat foods shall be sanitised before use. The cleaned or sanitised equipment shall be tidily kept under hygienic conditions and be protected against contamination.

2.7 Production equipment, machines and utensils shall be maintained in a good condition, be able to operate effectively and not present any contamination. Appropriate records and plans of control operation including scheduled replacement programme shall be established for the equipment including its parts that have a limited lifetime, such as UV lamps, rubber gaskets, filters, filtering materials. During maintenance is being carried on, it shall not constitute cross-contamination to foods.

2.8 Balances and measuring equipment of an appropriate range, accurate and precise shall be available in adequate numbers. Calibration shall be done with appropriate frequency and at least once a year. Appropriate actions shall be performed upon the devices of which calibration results indicated deviation from an acceptable range.

Section 3 Process Control

3.1 Raw materials, Ingredients and Food Additives

3.1.1 Raw materials, ingredients and food additives that are qualified and safe shall be acquired. Safety information for each type of raw material shall be made available.

3.1.2 Raw materials, ingredients and food additives shall be kept on pallets/shelves or platforms under conditions that permit protection from contamination and minimizing deterioration of materials such as control temperature and humidity. They shall be kept separately from hazardous substances or non-food materials and materials. In case of production of allergen-free foods, they shall be kept separately from materials containing allergens.

3.1.3 Where necessary, pretreatment processes such as washing, trimming, sorting, blanching, filtering, cooling, sanitizing, shall be applied to reduce hazards that may be carryover from raw materials or ingredients

3.2 Food Contact Packaging

3.2.1 Food packaging shall be acquired based upon safety qualities and be suit with intended purpose of use. Qualities and conditions of packaging such as defects, cleanness, seam quality shall be inspected.

3.2.2 Food packaging shall be appropriately stored and transported in a manner that permits protection from contamination and damaging. The effective stock management system shall be established.

3.2.3 Where necessary, food packaging shall be washed or sanitized to remove dirt before use. The cleaned or sanitized packaging shall be handled in a way that permits protection from contamination and damaging and be immediately filled. There shall be in place the effective system to protect the cleaned/sanitized packaging against cross-contamination from environment and un-cleaned packaging if it is necessary to delay the filling step.

3.3 Mixing of ingredient

3.3.1 In the case of using food additives, it shall be in compliance with legal requirements. Measuring of food additives shall be done by the appropriate devices. Mixing of food additives into other ingredient shall ensure homogeneity. Appropriate records shall be maintained. In case of using processing aids, it shall be in accordance with the reliable safety information. The amount of food processing aids being used shall be limited to their indications given on the labels and it shall be afterward removed from foods to a certain level that is safe for consumer.

3.3.2 To control qualities and safety of a finished product, a proportion of each ingredient used other than food additives shall be reviewed to ensure that it is being used in accordance with that specified on the product's label or in the registered recipe.

3.3.3 Water and ice that are food ingredient or coming into contact with ready-to-eat foods shall possess qualities or standards as prescribed in the Notifications of Ministry of Public Health regarding bottled drinking water or edible ice, as the case may be. Testing results of its qualities or standards that analyzed at least once a year by a government laboratory or accredited laboratory shall be maintained. They shall be stored under hygienic conditions so that permits protection against contamination.

3.3.4 During production is being operated, the mixtures of ingredient shall be kept under suitable conditions that permits protection against deterioration caused by microorganisms, such as control holding temperature and time, prevent cross-contamination and be scheduled to use effectively.

3.4 A processing that is employed to reduce and eliminate microbiological hazards shall be controlled in order to reduce and eliminate microbiological hazards to be at safe level for consumption. Such processing shall be periodically reviewed. The appropriate records shall be maintained.

3.5 For the case that there is no any step of processing to reduce and eliminate microbiological hazards to be at a safe level such as mixing, repacking, cutting of fresh produces, strictly control of contaminations, such as selection of raw materials, prevention of contamination

from human, food contact surfaces and environment, shall be performed all over a production process considering particular risk of food being processed.

3.6 Container fill and close

(1) Filling and closing of containers shall be done appropriately requiring that the measures to prevent re-contamination from production equipment and workers shall be implemented. In this regard, it shall be done without delay and temperature of foods shall be appropriately controlled taken into account types food in order to prevent growth of microorganism. Use of preservatives shall comply with the relevant regulations.

(2) Quality of seal or seam shall be inspected.

(3) Labels shall be in a good condition and provide sufficient information in order that consumer would be able to consume product safely.

3.7 Transportation of raw materials, ingredients and finished products during processing shall be done in such a way that it does not cause cross-contamination

3.8 Identifiable information that is necessary for effective traceability and analysis of root-causes of non-conformity or contamination problems shall be maintained, such as identification of type, lot and sources of raw material, food additives and packaging, finished product, non-conforming product.

3.9 Finished product

3.9.1 Qualities and standards of finished products shall comply with the relevant Notifications of Ministry of Public Health. Testing results of its qualities or standards that analyzed at least once a year by a government laboratory or accredited laboratory shall be maintained.

3.9.2 Storage and transportation of the finished products to sale shall be done appropriately. Appropriate equipment or vehicles for transportation of foods shall be allocated. Such equipment or vehicles shall be capable to maintain quality of foods and it shall be easy to operate cleaning of area or surface assigned to keep foods in order to effectively protect against cross-contamination from the equipment or vehicle, human and environment.

3.10 Records of information regarding types, production volume, and sale data shall be maintained. Product recall procedures shall be established, in particular dietary supplements.

3.11 Non-conformity products shall be appropriately managed by separation or destruction in order to prevent distribution to sale or consume.

3.12 Records and reports shall be maintained for at least one year after the date shown on product labels.

3.13 At least once a year, internal quality audit (IQA) shall be carried out based on the requirements prescribed in this Notification by the internal or external competent auditor(s). Effective corrective actions shall be taken to address the non-conformity.

Section 4 Sanitation

4.1 Water for domestic use shall be clean water and be appropriately treated to suit the intended purposes of use.

4.2 Toilets and hand wash basins located outside the toilets shall be adequately provided for workers. They shall be in usable and hygienic conditions. The basic hand wash facilities, *e.g.* hand wash solution and hand drying facilities or sanitizing solution shall be adequately provided. Toilets shall be situated separately from production areas or shall not opened directly into production area.

4.3 Appropriate changing facilities including cabinets/lockers dedicated to keep personal belongings shall be adequately provided. Those facilities shall be located in suitable locations to facilitate convenience of workers and it shall not cause contamination.

4.4. Hand wash basins located in the production areas shall be clean, usable and adequate for workers. The basic hand wash facilities, *e.g.* hand wash solution and hand drying facilities or hand sanitizing solution, shall be adequately provided. Location of hand wash equipment shall be suitable for worker to use and not cause contamination into production lines and products.

4.5 The effective measures to control and eradicate pests and insects shall be implemented requiring that the pest management procedures shall not cause contamination into production lines and products.

4.6 Waste management shall be done properly in such a way that does not cause contamination. Appropriate bins shall be adequately provided and located at appropriate location. Selections of bin shall suit each step of food processing so that it shall not cause contamination such as using a bin with lid. Waste collection area shall be separated and located away from food premises. Clearance of the collected waste shall be done properly with an appropriate interval of time so that it shall not be allowed to accumulate and create environment conducive to be breeding sites of pests, insects and pathogens. Unpleasant odor shall not be produced due to the accumulated waste. Transportation of waste shall be done in such a way that does not contaminate into the food premises, production lines and products.

4.7 Measures for management of chemical substances used in food premises, e.g. pesticides, personal hygiene agents, cleaning and sanitizing agents, chemical agents used for maintenance, shall be established. Information which includes type of chemical substances, material safety data and instruction regarding safety and effective use shall be made available. Application of chemical substances shall follow the prescribed safety instruction and that it does not cause contamination into production lines and products. Tags or labels showing clear information shall be displayed in order to prevent misuse. The chemical substances shall be separately stored from the food premises in the orderly manner. The hazardous chemical substances shall be protected from the unauthorized persons to access and use without permission.

4.8 Measures regarding management of equipment used for eradication of pests and insects, cleaning, sanitizing and maintenance shall be implemented so that it shall not cause contamination.

Section 5 Personal Hygiene

5.1 Workers and personnel involved in production area

5.1.1 They shall not have diseases or being a carrier of diseases that are prescribed in the Ministerial Rule Number 1 (B.E. 2522) issued under the Food Act of B.E. 2522. They shall not have wounds. Measures shall be applied to those who have illness symptoms in order to ensure that any person coming into direct- or indirect-contact with foods would not cause contamination to foods.

5.1.2 They shall keep the body clean such as keep fingernails short and unpainted.

5.1.3 They shall always wash their hands before working or after touching sources of contamination. Hands shall be washed thoroughly before wearing gloves.

5.1.4 Gloves that are coming into contact with foods shall be intact, clean and sanitary. Gloves shall be made of food grade materials that would not constitute contamination into foods.

5.1.5 During working, a clean hat or hair-scarf/net, clean apron or cloth and clen shoes shall be worn. Face masks shall be worn if necessary.

5.1.6 During operation, they shall refrain from eating, drinking, smoking or behaviors that could result in contamination to foods. Personal effects such as jewelry, watches shall not be brough into production areas.

5.17 Personnel of each position shall be trained with appropriate training course(s). Evidences of training attendance shall be maintained. They shall strictly comply with the signs and notices of hygienic practices.

5.2 Procedures or provisions to prevent contamination shall be implemented toward persons who are not engaged in food processing and going to enter production areas.

PART 2
SPECIFIC REQUIREMENTS

Specific Requirements 1

Specific Requirements Prescribed for Production of Bottled Drinking Water, Natural Mineral Water and Edible Ice using Filtration Process

1. Production of bottled drinking water and natural mineral water by filtration process

1.1 At least once a year, physical and chemical qualities of raw water shall be tested in laboratories in order to obtain information required for designing of the appropriate and adequate water-treatment systems.

1.2 Where necessary, pretreatment of raw water shall be performed in order to reduce initial load of microorganisms prior subjected to further treatment systems. In a case of production of natural mineral water, the methods of pretreatment shall not jeopardize the essential compositions of the mineral water.

1.3 Water-treatment processes shall be established to eliminate or reduce hazards in raw water to safe levels and that shall comply with the relevant legal requirements. Equipment, devices and facilities for water treatment shall be functioning properly and relate to production rate. Performances of the equipment for filtration and disinfection being used shall be periodically checked. Records shall be maintained. For the case of production of natural mineral water, the methods of water-treatment shall not jeopardize the essential compositions of the mineral water.

1.4 There shall be measures to prevent post-contamination.

1.4.1 Food contact surfaces of the equipment used in a step of filling such as filling machines/devices, dispensers shall be appropriately cleaned and sanitized by the methods that shall not constitute contaminants to the products. Records shall be maintained.

1.4.2 There shall be measures to prevent contamination from packaging.

(1) Reusable packaging shall be washed and sanitized by the valid procedures. Measures to protect the washed and sanitised packaging from environmental post-contamination shall be carried out, such as rinse containers with treated water and fill water immediately.

(2) Single-used packaging shall be rinsed thoroughly by treated water. Otherwise, other measures to reduce or prevent contamination from packaging shall be carried out. Filling of treated water shall be done immediately.

1.4.3 Filling shall be done in clean filling-rooms and in a manner that allows protection against contamination from environment, such as operation done on a platform with appropriate height above ground; fill water directly form dispensers and immediately close a container after filled; closure shall not constitute contamination.

1.4.4 The minimum requirements or measures to prevent contamination shall be applied toward the personnel engaged in the filling process, which include wearing clean clothes, apron, hair net/cap and face mask, regularly washing hands before start working, and avoid touching an opening or inside of a container.

2. Production of edible ice by the filtration process

2.1 Water used for making ice shall possess qualities as prescribed in the Ministry of Public Health regarding edible ice. Water qualities testing shall be done by laboratories at least once a year. The water-treatment processes described for bottled drinking water as stated above in the paragraphs 1.2 and 1.3 shall be used to treat water for making ice.

2.2 A production of block ice shall apply the measures to prevent post-contamination of which the following minimum requirements shall be applied:

2.2.1 Water that is used for releasing the ice from the ice cans, that is used for washing ice or that is possibly coming into contact with ice shall possess qualities as same as water that is used for making ice. Recirculated water shall be regularly replaced. Cleanliness of water tanks or reservoirs shall be maintained.

2.2.2 Any surface that is coming into contact with ice such as platforms for dropping ice, ice conveyers, ice cutting machines or crushers, shall be regularly cleaned and sanitised. Restricted areas shall be determined with provisions to control hygienic conditions such as change into clean shoes dedicated for a specific area.

2.2.3 Conveying, cutting, crushing, packing and transportation of ice shall be carried out in a hygienic manner and in such a way that not cause contamination.

2.2.4 Measures to prevent contamination from packaging shall be implemented, in particular that the multiple-use packaging such as nylon-sacks for contain ice shall be washed, sanitized, dried and kept under hygienic conditions.

2.2.5 The minimum requirements or measures to prevent contamination shall be applied toward the workers, which include wearing clean clothes, apron, hair net/cap and face mask and regularly washing hands before start working.

2.3 A production of tube ice shall apply the measures to prevent post-contamination of which the following minimum requirements shall be applied:

2.3.1 Measures to prevent contamination from packaging shall be implemented. The multiple-use packaging such as nylon-sacks shall be washed, sanitized, dried and kept under hygienic conditions.

2.3.2 Filling shall be done in clean filling-rooms and in a manner that allows protection against contamination from environment, such as operation done on a platform with appropriate height above ground; fill the ice into a container directly form dispensers and immediately close a container after filled; closing practices shall not constitute contamination.

2.3.3 The minimum requirements or measures to prevent contamination shall be applied toward the personnel engaged in the filling process, which include wearing clean clothes, apron, hair net/cap and face mask, regularly washing hands before start working, and avoid touching an opening or inside of a container.

3. Food process control supervisor

3.1 The personnel, so called food process control supervisor, shall be assigned duties in written to oversee and control all batches of food production being undertaken at a food premise in order to ensure compliance with the relevant regulations and to review records regarding process control activities. The food process control supervisor shall be qualified to perform process control and maintain any evidence of successfully completion of the training courses on process control supervisor of bottled drinking water, natural mineral water and edible ice which conducted by either the Food and Drug Administration (FDA) or the training institutes accredited by FDA.

Specific Requirements 2
Specific Requirements Prescribed for
Production of Ready-to-Consume Milk Products in Liquid Form
using Pasteurization

1. Incoming raw milk

1.1 There shall be the measures to prevent or reduce risk of antimicrobial agents in raw milk to safe levels. Records shall be maintained.

1.2 There shall be measures to control the initial load of microorganisms in raw milk in order to prevent production of heat-stable toxins which may result in incomplete disinfection.

2. Control of pasteurization process

Pasteurization process shall be controlled. Temperature and time of pasteurization shall be in compliance with the values as prescribed in the relevant Notifications of Ministry of Public Health or as determined in the acceptable scientifically proven procedures of pasteurization which provide safe products for consumer. Appropriate records shall be maintained.

2.1 Batch pasteurization

2.1.1 A pasteurizer shall be equipped with a complete and correct set of instruments so that it can function properly. The followings are minimum requirements:

(1) The thermometers for measuring reference temperatures shall be installed at the locations where it can detect the lowest temperature of the food while pasteurization run as well as the temperature of the food after cooling section. The thermometers shall be accurate and precise and it shall be calibrated with a frequency of at least once a year. The calibration tags showing the dates of the last or next calibration shall be displayed at any position where it can be clearly observed.

(2) The agitators shall be installed at appropriate locations where it can facilitate uniform distribution of heat.

2.1.2 Temperature and time of pasteurization shall be controlled for every production batch. Records shall be maintained.

2.2 Continuous pasteurization

2.2.1 A pasteurizer shall be equipped with a complete and correct set of instruments so that it can function properly. The followings are minimum requirements:

(1) The reference temperature indicating devices such as a mercury-in-glass thermometer, a digital thermometer that is equipped with the resistance temperature detectors (RTD) or RTD PT100, or thermocouple. Other devices may be used to measure temperature if their calibration results indicate that they have

equal precision and accuracy to the reference temperature devices. The indicating thermometers shall be installed to the holding tube out prior to the cooling section and after the colling section at any location where it shall not jeopardize a flow characteristic of food which lead to incomplete pasteurization as well as not create pockets. Display of the thermometers shall be located anywhere where it is easy to read. The thermometer shall have divisions that are easily readable to 0.5 degree Celsius or 1 degree Fahrenheit and whose scale contains not more than 4 degrees Celsius per centimeter of graduated scale. The thermometers shall be accurate and precise and that it shall be calibrated with a frequency of at least once a year. The calibration tags showing the dates of the last or next calibration shall be displayed at any position where it can be clearly observed.

(2) **The automatic temperature recorders** shall be equipped with temperature sensors that are installed to the holding tube out prior to the cooling section and after the colling section at any location where it shall not jeopardize a flow characteristic of food which lead to incomplete pasteurization as well as not create pockets. There shall be a temperature recorder that receives signal from a temperature sensor. Temperature values shall be automatically recorded of which the recorded data shall not be forgery or modified. Before processing starts, the automatic temperature recorders shall be adjusted to read temperatures that agree as closely to and not be higher than the reference thermometers. Systems to prevent unauthorized adjustment made to the automatic temperature recorders shall be established. The automatic temperature recorders shall be accurate and precise. At least once a year, the instruments shall be calibrated with a calibration range covers all operating temperatures. It is required to display a calibration tag for each one showing the last and the next calibration dates. The calibration tags shall be displayed at any position where it can be clearly observed.

(3) **The automatic flow-diversion devices and alarming system** dedicated for the event that pasteurization temperature falls below the desired set levels. The system shall be equipped with temperature sensors installed into the end point of a temperature-holding tube and it shall be accurate and precise requiring calibration done with a frequency of at least once a year. It is required to display a calibration tag for each device showing the dates of the last or next calibration. The calibration tags shall be displayed at any position where it can be clearly observed. Measures to prevent unauthorized person to adjust the preset cut-in temperature must be established. The alarming system shall be installed to warn that pasteurization temperature falls below the desired set levels.

(4) **Flow rate regulators** shall be implemented with the measures to control alteration of flow rate so that it does not deviate from the set parameter.

2.2.2 Temperature and time of pasteurization shall be controlled for all production batches. Holding time shall be validated. Records shall be maintained.

2.3 Pasteurization efficiency shall be monitored and employed to release the finished products such as testing of phosphatase enzyme, peroxidase enzyme or microbial qualities. Records shall be maintained.

3. Prevention of Post-contamination

3.1 Measures to prevent contamination from packaging shall be established. Where necessary, the packaging shall be appropriately washed, sanitized or kept under conditions that permit protection against contamination.

3.2 Food contact surfaces that come into contact with pasteurized milk such as storage tanks, filling machines, milk dispensers, pipes shall be cleaned and sanitized. Cleaning and sanitizing shall be appropriately taken in a manner that does not cause contamination into products. Records shall be maintained.

3.3 Filling practices shall be done in a manner that does not result in contamination from environment, for example, filling done on a platform with appropriate height above ground; fill directly form dispensers and immediately close a container after filled; closing shall not constitute contamination.

3.4 Measures to prevent contamination shall be applied toward the workers engaged in the filling operations, which include wearing clean clothes, apron, hair net/cap and face mask, regularly washing hands before start working, and avoid touching an opening or inside of a container.

3.5 The products temperature shall be maintained at 8 degrees Celsius or below for the entire downstream processing including the pasteurization outlet, storage and further transportation. Records shall be maintained.

4. Food process control supervisors

4.1 The personnel, so called food process control supervisor, shall be assigned duties in written to oversee and control all batches of food production being undertaken at a food premise in order to ensure compliance with the relevant regulations and to review records regarding process control activities. The food process control supervisor shall be qualified to perform process control and maintain any evidence of successfully completion of the training courses on process control supervisor of production of Ready-to-Consume Milk Products in Liquid Form using Pasteurization organized by either the Food and Drug Administration (FDA) or the training institutes accredited by FDA.

Specific Requirements 3
Specific Requirements Prescribed for Production of Low Acid and Acidified Foods Packaged in Hermetically Sealed Containers using the Commercial Sterilization Processes

1. Process validation and scheduled process

1.1 The evidences of thermal process validation in order to prove that it is adequate to achieve commercial sterility of foods shall be made available as follows:

1.1.1 For in-container sterilization, reports of the studies done by the process authorities (PA) shall be made available as follows:

(1) Temperature distribution study for a new retort installed shall be carried out on site by using the sound scientific methods. Re-evaluation of temperature distribution or actions in accordance with recommendation of the process authorities shall be done for a retort of which any equipment and facility are modified and that such modifications may affect the retort performance.

(2) Heat penetration study shall be carried out by using the sound scientific methods. The study shall employ factors that are as same as those employed in the commercial production. Re-evaluation of heat penetration or actions in accordance with recommendation of the process authorities shall be done if there is any changing of production-factors such as produce new products, change product specifications, or change size and type of container.

1.1.2 Studies of temperature distribution and heat penetration are not required for a case that inhibition of germination of spores of *Clostridium botulinum* is achieved by using the certain processing that temperature of foods is directly measured during sterilization runs. The reliable reference documents showing that certain temperature and time of sterilization being operated for each product type can ensure commercial sterility of foods shall be maintained.

1.1.3 For the aseptic processing and packaging system, it is required to maintain the study reports and evidences made by the process authorities showing that the sterilization being operated is appropriate and adequate to produce commercial sterile foods.

1.1.4 Scheduled process

(1) For a processing of low acid food, a scheduled process shall be established based on a study of which parameters related to spores of the targeted microorganism which is *Clostridium botulinum* are employed and the sterilizing value (F_0) is at least 3 minutes. If other indicators are used, it shall be indicated by sound scientific evidences showing that heat resistant capacities of such indicators are equal or higher than that of spores of *Clostridium botulinum*.

(2) For a food processing that uses methods of inhibition of germination of spores of *Clostridium botulinum,* such as control pH or water activity (a_w) of foods, a scheduled process by means of pasteurization as a minimum requirement shall be established in order to ensure that, under conditions used to inhibit spore germination, pathogens are reduced to a certain level that safe for consumer. The scheduled process shall cover details of the methods used to inhibit germination of *C. botulinum* spores such as methods to regulate pH and equilibrium pH of foods, the certain retaining time and temperature to obtain acidified food for a product containing solid pieces and liquid portion, methods to regulate water activity, maximum water activity of a product.

1.2 For a continuous processing, sterilization time shall be validated.

1.3 Food producers shall establish the documented scheduled process of all food processes showing details of the thermal processes with critical factors to be controlled in order to ensure commercial sterility of food products. Examples of such critical factors such as:

- Size and type of container
- pH of the product
- Product composition or formulation
- Types and quantity of food additives used
- Water activity (aw) of product
- Storage temperature of the product
- Other factors influenced on heat transfer characteristics of product

The critical control factors in practice shall provide safety level that is equal or higher than those prescribed in the study reports made by the process authorities.

For the processing that temperature of foods is directly measured during sterilization runs as prescribed in 1.1.2, it is required to establish the additional documented procedures covering details of procedures to detect temperatures of a sterilizer interior and foods for all production batches such as number of products per batch, position of temperature detection, cold spots of a sterilizer.

1.4 The process authority may be a person or a group of people from the internal or external organization who has expert knowledge and adequate facilities to study and establish the scheduled process including determination of the critical factors affected thermal processing, alternative process establishment and making decision on the products produced from the deviated scheduled process. The process authority shall possess qualifications, knowledge and skills as follows:

1.4.1 Completed Bachelor’s degree or higher in food sciences, food technology, food engineering, agroindustry or other related fields that food processing is taught.

1.4.2 Holding certificates of successful completion in the training courses on process authority organized by the Food and Drug Administration (FDA) or the training institutes accredited by FDA

1.4.3 Having appropriate experiences in establishment of scheduled processes in respect to a food category being studied

2. Process control

Processing of low acid and acidified foods packaged in hermetically sealed containers that employs thermal processing to produce commercial sterility shall take following activities:

2.1 The critical factors shall be controlled and monitored to ensure compliance with the requirements specified in the scheduled process such as volume, fill-in weight, ratio of some ingredient added that may affect heat penetration of a product such as starch and oil, headspace of filled product containers, pH or water activity (a_w) of foods, initial product temperature, sterilization time and temperature. All equipment employed to control and monitor the critical factors shall be accurate and precise. Records shall be maintained.

2.2 Quality of seam/seal/closure and defects of containers shall be examined by the accepted scientific methodologies.

2.2.1 Visual tests shall be regularly performed during processing runs at a minimum frequency of 30-minute interval or at an appropriate frequency depending on production capacity. Records shall be maintained.

2.2.2 The quality or integrity of seams/seals/closures shall be regularly tested by appropriate methods (as the case may be) at a minimum frequency of 4-hour interval or at an appropriate frequency depending on production capacity. Records shall be maintained.

Corrections and records shall be done when any fault of seam/seal/closure is found or when a sealing/closure device is modified or jammed. The products produced within the period of discovery of the fault shall be separated and re-assessed or taken with further appropriate actions.

2.3 Measures shall be implemented toward all products produced under the processing that deviates from the scheduled process. Records shall be maintained.

2.4 The food process control supervisors shall review records of process control, sterilization process and critical control factors within 24 hours to ensure compliance with scheduled processes. Records shall be maintained.

2.5 The personnel, so called food process control supervisor, shall be assigned duties in written to oversee food production undertaken at a food premise. Such personnel shall be responsible for controlling of food processing of all batches to comply with the relevant regulations and reviewing of records regarding process control activities. The food process control supervisor shall be qualified to perform process control and maintain any evidence

of successfully completion of the training courses on process control supervisor of production of low acid and acidified foods packaged in hermetically sealed containers organized by either the Food and Drug Administration (FDA) or the training institutes accredited by FDA.

3. Destruction of spores of *Clostridium botulinum*

3.1 Retorted method

The thermal processes using retort shall be controlled appropriately. Each retort shall be equipped with the adequate and correct components that be functioning properly. The components of a retort shall be completed to meet standard of the retort model or the requirements stated in a report of heat distribution study that established by the process authorities. To ensure that food products are completely sterilized through the thermal processes, the following devices shall be employed:

3.1.1 Retorts for in-container sterilization shall be equipped with the following instruments which shall be adequate, correct and function properly. The minimum requirements are follows:

(1) The reference temperature indicating devices such as a mercury-in-glass thermometer, a digital thermometer that is equipped with the resistance temperature detectors (RTD) or RTD PT100, or thermocouple. Other devices may be used to measure temperature if their calibration results indicate that they have equal precision and accuracy to the reference temperature devices. A thermometer sensing bulb shall be directly inserted into the retort shell. If the thermometer sensing bulb is placed in a holder that is attached to the retort, the holder shall be made of at least 3/4-inch-diameter pipe with 1/16-inch-diameter steam bleeder mounted on a retort at a location where facilitates continuous flow of steam to pass through the whole length of a sensing bulb for all the times during processing runs. Display of the indicating thermometers shall be located anywhere where it is easy to read. The indicating thermometer shall have divisions that are easily readable to 0.5 degree Celsius or 1 degree Fahrenheit and whose scale contains not more than 4 degrees Celsius per centimeter of graduated scale. The indicating thermometers shall be calibrated with a frequency of at least once a year. The calibration tags showing the dates of the last or next calibration shall be displayed at any position where it can be clearly observed.

(2) Automatic temperature recording devices shall be equipped with chart recorders that have gridlines covered the operating ranges of temperature and time specified in a scheduled process and be read to less than 1 degree Celsius or 2 degrees Fahrenheit. Size of a paper chart should be compatible with the recorder. In a case that a blank paper chart is used, the recorder shall be able to make gridlines and plot a time-temperature graph onto the blank paper chart. Temperature shall be

recorded at a minimum frequency of 1-minute interval and may be recorded as digital format. A means of preventing unauthorized changes to the recorded temperatures shall be provided. Before processing starts, the automatic temperature recorder shall be adjusted so as to read temperature that agree as closely as possible to the indicating thermometer but shall be not higher than the indicating thermometer. Systems to prevent unauthorized adjustment made to the automatic temperature recorders shall be established. The automatic temperature recorders shall be accurate and precise. At least once a year, the recorders shall be calibrated with a calibration range that covers operating temperatures. The calibration tags showing the date of the last or next calibration shall be displayed at any position where it can be clearly observed.

(3) Devices for circulation of heating media

The necessary devices used to promote circulation of a heating medium shall be installed considering type of heating medium used.

(3.1) Steam

Retorts are required to have at least one bleeder of at least 3 mm-diameter (1/8 inch) tube. The bleeder shall be installed in a manner that allows the operator to easily observe its function. A bleeder shall be installed in the top and opposite the steam entry of a retort.

(3.2) Air mixed steam

A fan with alarm to indicate fan failure shall be installed. A system to control proportion of steam and air shall be installed.

(3.3) Hot water immersion

Devices or systems to promote water circulation such as pumps or pressurized air shall be adequately installed to meet requirements of sterilization. Installation of such devices or systems shall be done in such a manner that allows an even temperature distribution throughout a retort. An alarm to indicate malfunction of water circulation system shall be installed. Water level indicating devices shall be installed to indicate that water level in the retort be maintained during processing at a level of at least 15 centimeters or 6 inches over the top layer of product containers. For the case when changed water circulation system, heat distribution study shall be carried out to indicate an even temperature distribution throughout a retort.

(3.4) Hot water spray

Hot water circulating pumps shall be installed to control flow rate of hot water. A flow meters shall be installed at an appropriate location to determine flow rate of the circulating hot water. The flow meters shall be precise and accurate and shall be calibrated for at least once a year. The calibration range shall cover the

operating range. A calibration tag showing the date of the last or next calibration shall be displayed at any position where the tag is clearly observed. Alarm systems or precautions shall be installed to indicate malfunction of the pumps or departure of water flow rate from the preset rate.

(4) Over-pressure retorts

The over-pressure retorts shall have pressure gauges. The pressure gauge dial shall be of at least 4-inch-diameter to allow clearly reading and its scale shall be readable to 2 pound-force per square inch (psi). The pressure gauges shall be precise and accurate. Calibration shall be taken at least once a year with a calibration range covers the operating values. The calibration tag showing the last or next calibration date shall be displayed at any position where the tag is clearly observed.

(5) Rotary/Reel and Spiral Retorts

Devices to control rotational speed of the reel or speed of product movement shall be installed. The continuous retorts shall be installed with devices to control speed of a conveyer belt which is depend on sterilizing time.

3.2 Aseptic processing and aseptic packaging systems

3.2.1 The process flow diagrams showing critical control factors as specified in the scheduled process shall be established.

3.2.2 The aseptic processing systems shall be adequately equipped with the devices which shall be complete, correct and function properly. The minimum requirements are as follows:

(1) The reference temperature indicating devices such as a mercury-in-glass thermometer, a digital thermometer that is equipped with the resistance temperature detectors (RTD) or RTD PT100, or thermocouple. Other devices may be used to measure temperature if their calibration results indicate that they have equal precision and accuracy to the reference temperature devices. The indicating thermometers shall be installed to the holding tube out prior to the cooling section and after the colling section at any location where it shall not jeopardize a flow characteristic of food which lead to incomplete sterilization as well as not create pockets that makes it difficult to be cleaned thoroughly. The thermometers shall be located anywhere where it is easy to read. The thermometer shall have divisions that are easily readable to 0.5 degree Celsius or 1 degree Fahrenheit and whose scale contains not more than 4 degrees Celsius per centimeter of graduated scale. The thermometers shall be accurate and precise and that it shall be calibrated with a frequency of at least once a year. The calibration tags showing the dates of the last or next calibration shall be displayed at any position where it can be clearly observed.

(2) Automatic temperature recording devices shall be equipped with temperature sensors that are installed to the holding tube out prior to the cooling section and after the colling section at any location where it shall not jeopardize a flow characteristic of food which lead to incomplete sterilization as well as not create pockets that makes it difficult to be cleaned thoroughly. There shall be a temperature recorder that receives signal from a temperature sensor. Temperature values shall be automatically recorded of which the recorded data shall not be forgery or modified. Before processing starts, the automatic temperature recorders shall be adjusted to read temperatures that agree as closely to and not be higher than the reference thermometers. Systems to prevent unauthorized adjustment made to the automatic temperature recorders shall be established. The automatic temperature recorders shall be accurate and precise. At least once a year, the instruments shall be calibrated with a calibration range covers all operating temperatures. It is required to display a calibration tag for each one showing the last and the next calibration dates. The calibration tags shall be displayed at any position where it can be clearly observed.

(3) Timing/Metering pumps and flow meters The flow meters shall be precise and accurate and it shall be calibrated at least once a year. The calibration tag showing the last or next calibration date shall be displayed at any position where the tag is clearly observed. For the case that a flow meter is not installed, a positive displacement pump such as a homogenizer shall be installed to control flow rate in heating section during sterilization runs requiring a document showing relationship of revolution speed and flow rate.

(4) Back-pressure devices For a case that a processing requires the use of temperatures in excess of 100 degrees Celsius, the back-pressure devices shall be installed to prevent liquid foods from boiling and turning to vapor (flashing) as it could lead to incomplete sterilization.

(5) Differential pressure controllers shall be installed for a case that product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of an indirect heating system. The differential pressure controllers shall be precise and accurate and it is required calibration taken at least once a year. The calibration tag showing the last or next calibration date shall be displayed at any position where the tag is clearly observed.

(6) Flow diversion devices (FDD) and alarm systems shall be installed as precaution in the event of any factor influencing sterilization or sterility condition deviates from those specified in the scheduled process. A means of preventing unauthorized adjustment made to the instrument shall be provided. The instruments used to measure the factors influencing sterilization shall be precise and accurate and shall

be calibrated at least once a year. The calibration tag showing the last and next calibration date shall be displayed at any position where the tag is clearly observed.

3.2.3 Equipment and utensils used in downstream processing shall be sterilized before processing starts (pre-sterilization). Sterility condition of such equipment/utensils shall be maintained during processing runs. Appropriate records shall be maintained.

3.2.4 Aseptic surge tanks shall be provided to store the sterile products until aseptic filling. Sterility condition shall be maintained. Appropriate records shall be maintained.

3.2.5 Aseptic packaging system

(1) Packaging shall be sterilized. Factors influencing packaging sterilization efficiency shall be controlled and complied with the scheduled process. Appropriate records shall be maintained.

(2) During operation of packaging, measures to maintain the aseptic zones shall be implemented in compliance with the scheduled process. Appropriate records shall be maintained.

3.2.6 The finished products shall be stored appropriately to avoid damage to finished products which would lead to contamination and deterioration.

4. Processing Control by inactivation of germination of *Clostridium botulinum* spores

4.1 Methods of inactivation of germination of *Clostridium botulinum* spores

4.1.1 Acidification

The equilibrium pH of food products shall be maintained at not excess 4.6 within a specified period of time. For this purpose, it is required to establish the documented procedures regarding acidification, in particular that it shall provide details of the relevant critical factors influencing acidification, sampling and testing methods. Records of pH testing taken at appropriated frequency shall be maintained.

4.1.2 Control of Water Activity of Low-Acid Foods

Water activity (a_w) of food products shall be maintained at a certain level which is not excess 0.92 or lower than the minimum a_w of the food that permits growth of *Clostridium botulinum* in it. For this purpose, it is required to establish the documented procedures given detailed methods to control a_w of foods, in particular that it shall provide details of the relevant critical factors, sampling and testing methods. Records of a_w testing taken at appropriated frequency shall be maintained.

4.2 Thermal processing

The thermal processing using sterilizing facilities shall be controlled appropriately. Each model of sterilizing facility shall be adequately equipped with the correct elements and be function properly. The following devices shall be installed in order to ensure that food products are completely sterilized through thermal processing:

4.2.1 Sterilizing facilities used at atmospheric pressure to sterilize foods or in-container foods shall be adequately equipped with the correct components and be functioning properly as follows:

(1) Thermometers such as the bottom connected thermometers or other equivalent instruments, shall have divisions that are easily readable to 0.5 degree Celsius (1 degree Fahrenheit) and whose scale contains not more than 4.0 degrees Celsius per centimeter (17 degrees Fahrenheit per inch) of graduated scale. Such thermometers are not required to be installed directly into the sterilizing system. The thermometers made of glass should not be used due to possibility of breaking and contaminating food processing. The thermometers shall be precise and accurate where it is required calibration taken at least once a year. The calibration range shall cover the operating temperatures. The calibration tag showing the last or next calibration date shall be displayed at any position where the tag is clearly observed.

(2) Conveyor belt speed controlling devices used in continuous sterilizers shall associate with sterilizing time.

(3) Agitating devices shall be used for sterilizing of liquid foods to ensure an even heat distribution throughout the sterilizers

4.2.2 Continuous pasteurizers used for sterilizing of liquid foods shall be adequately equipped with the correct elements and functioning properly as follows:

(1) Automatic temperature indicating devices and recorders shall be located at the temperature holding section outlet prior cooling section in such a way that it does not jeopardize the product flow as well as does not create pockets which lead to incomplete sterilization. The recorded temperatures shall agree as closely as possible to and shall not be higher than the indicating thermometer. A means of preventing unauthorized changes in the adjustment shall be provided. The temperature recording devices shall be precise and accurate where it is required calibration taken at least once a year. The calibration range shall cover the operating temperatures. The calibration tag showing the last or next calibration date shall be displayed at any position where the tag is clearly observed.

(2) Flow diversion devices (FDD) and alarm systems shall be installed as precaution in the event of any factor influencing sterilization deviates from those specified in the scheduled process. A means of preventing unauthorized changes in the adjustment shall be provided. The FDD and alarm systems shall be precise and accurate where it is required calibration taken at least once a year. The calibration tag showing the last or next recent calibration date shall be displayed at any position where the tag is clearly observed.

(3) Flow rate regulators shall have measures to control flow rate changes so that it shall not deviate from the value prescribed in a scheduled process.

4.3 Packaging fill after sterilization

4.3.1 Surfaces that are coming into contact with foods after sterilization such as storage tanks, filling machines, dispensers, pipes shall be cleaned and sanitized appropriately in a manner that does not cause contamination into food products. Records shall be maintained.

4.3.2 Methods used to sanitize packaging shall be appropriate and capable to achieve complete sterilization of packaging such as chemical disinfection, irradiation, heat treatments such as using hot water, steam, using heated food content to sterilize packaging or other equivalent methods.

4.3.3 Filling procedures shall be done in a manner that permits protection against contamination from environment such as operation done on a platform with appropriate height above ground; fill food content directly form dispensers and immediately close a container after filled; closure and transportation shall not constitute contamination.

4.3.4 Measures to prevent contamination from workers who handle filling shall be implemented, which include wearing clean clothes, apron, hair net/cap and face mask, regularly washing hands before start working, and avoid touching an opening or inside of a container.