



National Standard of the People's Republic of China

GB 12693—2010

National Food Safety Standard Good Manufacturing Practice for Milk Products

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Foreword

This Standard replaces GB 12693-2003 *Good Manufacturing Practice for Dairy Product Factory* and GB/T 21692-2008 *Hygienic Practice for Dried Milk*.

This Standard corresponds to CAC/RCP 1-1969, Rev.4-2003 *Recommended International Code of Practice General Principles of Food Hygiene* and CAC/RCP 57-2004 *Code of Hygienic Practice for Milk and Milk Products* of Codex Alimentarius Committee (CAC), and this Standard is not equivalent to CAC/RCP 1-1969, Rev.4-2003 and CAC/RCP 57-2004. This Standard also refers to (EC) No. 852/2004 *On the Hygiene of Foodstuffs* and (EC) No. 853/2004 *Laying Down Specific Hygiene Rules for Food of Animal Origin*.

The main changes in this Standard over GB 12693-2003 and GB/T 21692-2008 are as follows:

- modifying the name of this Standard to *Good Manufacturing Practice for Milk Products*;
- adjusting the applicable scope, and emphasizing that this Standard is applicable to various dairy enterprises;
- modifying the provision framework of the Standard;
- emphasizing the requirements for food safety control in raw material entry and production process and contamination prevention in the whole manufacturing process of product transport and storage;
- adjusting the manufacturing equipment, and putting forward requirements for layout, materials and design on the manufacturing equipment in terms of preventing microbial, chemical and physical contamination;
- canceling hardware requirements in laboratory construction;
- adding relevant requirements for purchase, acceptance, transport and storage of raw materials;
- emphasizing food safety control of manufacturing process, and developing major measures for controlling microbial, chemical and physical contamination;
- adding requirements for packaging materials and their use;
- adding control targets and monitoring and recording requirements of critical control points;
- adding specific requirements for product tracing and recall; and
- adding requirements for management of records and documents.

Annex A of this Standard is informative.

The previous editions replaced by this Standard are as follows:

- GB 12693-1990, GB 12693-2003; and
- GB/T 21692-2008.

National Food Safety Standard

Good Manufacturing Practice for Milk Products

1 Scope

This Standard is applicable to manufacturers which process various milk products using cow milk (or goat milk) and its processed products, etc. as main raw materials.

2 Normative references

Documents referenced in this Standard are indispensable for application of this Standard. For dated references, only the dated edition is applicable to this Standard. For undated references, the latest edition (including all amendments) referred to is applicable to this Standard.

3 Terms and Definitions

3.1 Cleaning work area

Work areas with high cleanliness requirement, such as workshops for storage, filling and inner packing of bare semi-products to be packed.

3.2 Quasi-cleaning work area

Work areas with cleanliness requirement lower than that of cleaning work area, such as raw material preprocessing workshop.

3.3 Commonly work area

Work areas with cleanliness requirement lower than that of quasi-cleaning work area, such as milk collecting workshop, raw material warehouse, packing material warehouse, outer packing workshop and finished products warehouse.

4 Site selection and factory environment

Relevant provisions of GB 14881 shall be followed.

5 Factory buildings and workshops

5.1 Design and layout

5.1.1 All new, expansion and reconstruction projects shall be designed and constructed according to relevant national provisions.

5.1.2 The layout of factory buildings and workshops shall be capable of preventing cross contamination in processing of milk products, and avoiding contact with toxic substances and unclean substances.

5.1.3 Appropriate separating measures shall be taken for the cleaning work area, quasi-cleaning work area and commonly work area in workshops to prevent cross contamination.

5.2 Interior architectural structure

5.2.1 Roof

5.2.1.1 Indoor roofs and top corners of processing, packing and storage places shall be easily cleaned to prevent dust accumulation and to avoid moisture condensation, signs of mould or peeling off, etc. If the roofs of cleaning work area, quasi-cleaning work area and other places where food are exposed (excluding milk collecting workshops) are of structures easily hiding dirt, smooth and easily cleaned ceilings should be additionally provided; while if the roofs are of reinforced concrete structures, the indoor roofs shall be flat and seamless.

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3 / 17

GB 12693—2010

- 5.2.1.2 Flat roofs or ceilings of workshops shall be constructed with non-toxic, odorless, white or light colored waterproof materials, and in case of spraying coating, coatings that are mould proof, difficult to peel off and easily cleaned coatings should be chosen.
- 5.2.1.3 Steam, water and electricity piping shall be not installed right above exposed food, otherwise facilities capable of preventing falling of dust and condensation water shall be installed.
- 5.2.2 Walls
- 5.2.2.1 Non-toxic, odorless, smooth, waterproof, easily cleaned and light colored anti-corrosion materials shall be used for wall construction.
- 5.2.2.2 The corners and column corners of cleaning work area and quasi-cleaning area shall be reasonably structured and easily cleaned and disinfected.
- 5.2.3 Doors and windows
- 5.2.3.1 Doors and windows shall be made of smooth and adsorption-resistant materials, and easily cleaned and disinfected.
- 5.2.3.2 Doors and windows of production workshops and storage places shall be assembled tightly, equipped with dustproof facilities that keep animals and insects out and easily cleaned.
- 5.2.3.3 Doors that can close automatically (for example, equipped with automatic sensors or door closers, etc.) and (or) air curtains shall be installed at the entrances/exits of cleaning work area and quasi-cleaning work area.
- 5.2.4 Floors
- 5.2.4.1 Floors shall be constructed with non-toxic, odorless and waterproof materials, and be flat and anti-slip without crack and easily cleaned and disinfected.
- 5.2.4.2 Floors involving drainage or wastewater flows during the work and floor areas where the work environment is often wet or involves cleaning with water should be acid- and alkali-resistant and be equipped with certain drainage slope and drainage system.
- 5.3 Facilities**
- 5.3.1 Water supply facilities
- 5.3.1.1 Water supply facilities shall ensure that the quality, pressure, volume, etc. of water of productive use are in line with production requirements.
- 5.3.1.2 Water supply equipment and tools shall be awarded with product hygienic licenses in terms of health and safety of drinking water issued by health administrative agencies at or above the provincial level.
- 5.3.1.3 The inlet and outlet of water supply facilities shall be additionally provided with safety and health facilities to prevent food contamination due to entry of animals and other substances.
- 5.3.1.4 Water supply facilities using secondary water supply shall conform to provisions of GB 17051.
- 5.3.1.5 Water supply process using self-contained water sources shall conform to relevant hygienic requirements for centralized drinking water supply organizations issued by the national health administration.
- 5.3.1.6 The piping system of non-drinking water not in contact with food (e.g. cooling water, sewage or wastewater) shall be obviously distinguished and separated from the piping system of production water, without reverse flow or interaction.

- 5.3.1.7 The quality of production water shall conform to provisions of GB 5749.
- 5.3.2 Drainage system
- 5.3.2.1 Appropriate drainage system shall be equipped, and products and production water shall be protected from contamination during design and construction.
- 5.3.2.2 The drainage system shall be sloping, unblocked and easily cleaned, and the joint between the side and bottom of drainage ditches shall be round-angled. 5.3.2.3 Floor drains with water seal shall be installed at the inlet of the drainage system to prevent entry of solid wastes and escape of foul air.
- 5.3.2.4 Production water supply pipeline shall not be arranged in and below the drainage system.
- 5.3.2.5 The outlet of the drainage system shall be provided with devices to prevent intrusion of animals.
- 5.3.2.6 Indoor drainage shall flow from areas with high cleanliness requirement to areas with low cleanliness requirement, and there shall be design element of preventing reverse flow of wastewater.
- 5.3.2.7 Wastewater shall be drained to waste water treatment system or treated in other appropriate way.
- 5.3.3 Cleaning facilities
Appropriate facilities for cleaning food, tools and equipment and facilities for storing wastes, etc. shall be provided.
- 5.3.4 Personal hygiene facilities
- 5.3.4.1 Personal hygiene facilities shall conform to provisions of GB 14881.
- 5.3.4.2 Disinfection facilities shall be provided before entering cleaning work area, and a second dressing room shall be provided when necessary.
- 5.3.5 Ventilation facilities
- 5.3.5.1 Natural ventilation or artificial ventilation measures shall be taken to reduce air source contamination and control peculiar smell, so as to ensure food safety and product characteristics. The ambient temperature of cleaning work area shall be controlled in production of milk powder, and air humidity shall be controlled when necessary.
- 5.3.5.2 Air conditioning facilities shall be installed in the cleaning work area to prevent steam condensation and to keep indoor air fresh; ventilation facilities shall be installed in the commonly work area to timely exhaust humid and foul air. When the factory buildings involves air conditioning, air intake/exhaust or fans using, the air shall flow from areas with high cleanliness requirement to areas with low cleanliness requirement to prevent contamination of food, production equipment and inner packing materials.
- 5.3.5.3 Appropriate exhaust, collection or control devices shall be provided in areas where food may be contaminated by foul smell and gas (steam and toxic harmful gas) or dust.
- 5.3.5.4 The air inlet shall be more than 2 m from the ground or roofing, away from contamination sources and air outlet, and provided with air filter device. The air outlet shall be provided with easily cleaned and corrosion-resistant mesh enclosure to prevent intrusion of animals; and ventilation exhaust devices shall be easily removed for cleaning, maintenance and replacement.
- 5.3.5.5 Compressed air or other gases used for food and clean food contact surfaces or equipment shall be subject to filtration and purification treatment to prevent any indirect contamination.

5.3.6 Lighting facilities

5.3.6.1 Factory buildings shall have sufficient natural light or artificial light, the lighting coefficient of workshops shall be not lower than standard Grade IV. Mixed illuminance should be not lower than 540 lx on the working face of quality monitoring site, not lower than 220 lx on the working face of processing site, and not lower than 110 lx in other places, excluding test areas sensitive to light. Food color under light sources must not appear different from under natural light.

5.3.6.2 Lighting facilities shall be not installed right above exposed food; otherwise safety lighting facilities shall be used to prevent contamination of food due to possible crack.

5.3.7 Warehousing facilities

5.3.7.1 The enterprise shall have warehousing facilities fitting to the varieties and quantity of its milk products.

5.3.7.2 Storage places shall be separately arranged depending on different natures of raw materials, semi-finished products, finished products, packing materials, etc., and cold storages (refrigerators) shall be provided when necessary. When items of different natures are stored in the same warehouse, the items shall be properly isolated (e.g. by categories, racks or zones) and clearly labeled.

5.3.7.3 Warehouses shall be constructed with non-toxic and firm materials, have flat ground for easy ventilation, and shall be provided with devices for preventing intrusion of animals (for example, rat guards or ditches shall be arranged at the doors of warehouses).

5.3.7.4 Warehouses shall be provided with sufficient pallets (article storage racks), and an appropriate distance shall be kept between articles and walls and the ground for ventilation and articles handling.

5.3.7.5 Cold storages (refrigerators) shall be equipped with thermometers, temperature detectors or automatic temperature recorders capable of correctly indicating indoor temperature of warehouses and timely monitoring and recording temperature.

6 Equipment

6.1 Production equipment

6.1.1 General requirements

6.1.1.1 Production equipment adapted to the varieties and quantity of milk products in production and operation shall be provided, and the capacity of all equipment shall match mutually.

6.1.1.2 All production equipment shall be arranged in order according to process flow to avoid cross contamination.

6.1.1.3 Operating regulations for special equipment (e.g. pressure vessels and pressure pipeline) for use in production shall be developed.

6.1.2 Materials

6.1.2.1 All equipment and tools in direct or indirect contact with raw materials, semi-finished products and finished products shall be made of safe materials that are non-toxic, odorless, absorption-resistant, corrosion-resistant and capable of withstanding repeated cleaning and disinfection.

6.1.2.2 Materials of product contact surfaces shall conform to relevant standards of food-related products, and shall be smooth, easily cleaned and disinfected, waterproof and difficult to peel off.

6.1.3 Design

- 6.1.3.1 All production equipment shall be designed and constructed for easy cleaning, disinfection and inspection. Structures capable of preventing lubricating oil, metal debris, sewage or other substances possibly resulting in contamination from mixing with food shall be provided and conform to corresponding requirements.
- 6.1.3.2 Food contact surfaces shall be smooth and free of depression or crack to reduce accumulation of food crumbs, dirt and organic matters.
- 6.1.3.3 Storage, transport and processing systems (including gravity, pneumatic, closed and automatic systems) shall be designed and constructed for easy maintaining of their good sanitary state. Material storage facilities shall be able to be sealed.
- 6.1.3.4 Special areas for storing spare parts of equipment shall be provided so that necessary spare parts can be timely available during equipment maintenance, and storage areas for spare parts shall be kept clean and dry.

6.2 Monitoring equipment

- 6.2.1 Monitoring equipment for measuring, control and record (such as pressure gauge and thermometer) shall be regularly calibrated and maintained to ensure the accuracy and effectiveness.
- 6.2.2 If a computer system and its network technologies are employed for collection of monitoring data at critical control points and management of all records, refer to provisions of Annex A of this Standard for relevant functions of the computer system and its network technologies.

6.3 Maintenance and repair of equipment

- 6.3.1 Maintenance and repair procedures of equipment shall be developed and strictly implemented.
- 6.3.2 Daily maintenance and service plan of equipment shall be developed for regular maintenance, and record shall be properly kept.
- 6.3.3 Equipment shall be checked for normal state before each production to prevent the circumstance affecting the sanitary quality of products; failure shall be promptly eliminated, and time of failure, causes and possibly affected product batch shall be recorded.

7 Hygiene management

7.1 Hygiene management system

- 7.1.1 Hygiene management system and assessment criteria shall be developed, and post responsibility system shall be implemented.
- 7.1.2 Hygiene inspection plan shall be developed, and the implementation of the plan shall be recorded and filed.

7.2 Hygiene management of the plant and facilities

- 7.2.1 All facilities in the plant shall be kept clean, timely maintained or updated; any damage in roofs, ceilings and walls shall be immediately repaired, and the ground shall be free of damage or accumulated water.
- 7.2.2 Equipment and tools for processing, packing, storage, transport, etc., production pipelines and food contact surfaces shall be regularly cleaned and disinfected. Contamination to food, food contact surfaces and inner packing materials shall be prevented during cleaning and disinfection operations.

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7 / 17

GB 12693—2010

7.2.3 Cleaned and disinfected portable equipment and tools shall be placed at appropriate places capable of preventing food contact surfaces from recontamination, and kept in usable state.

7.3 Cleaning and disinfection

7.3.1 Effective cleaning and disinfection plans and procedures shall be developed to ensure the sanitation and hygiene of food processing places, equipment, facilities, etc so as to prevent food contamination.

7.3.2 Cleaning and disinfection method can be selected according to characteristics of product and process.

7.3.3 Equipment and tools used for cleaning and disinfection shall be stored properly at special places.

7.3.4 Cleaning and disinfection procedures shall be recorded, such as varieties, acting time, concentration, object and temperature of detergents and disinfectants.

7.4 Personal health and hygiene requirement

7.4.1 Personal health

7.4.1.1 Enterprises shall establish and implement health management system for employees.

7.4.1.2 Milk product processing personnel shall have health examination every year, and can only take the job after obtaining health certificates.

7.4.1.3 Enterprises shall appoint personnel with infectious diseases of digestive tract (including diarrhea, typhoid fever, viral hepatitis A and viral hepatitis E), personnel with active tuberculosis, ulcerative or exudative dermatosis affecting food safety, and personnel with unhealed wound to other posts not affecting food safety.

7.4.2 Personnel hygiene

7.4.2.1 Milk product processing personnel shall maintain good personal hygiene.

7.4.2.2 Milk product processing personnel shall put on neat working clothes, working hats and working shoes (boots) before entering production workshops. The working clothes shall cover outerwears, hair shall not be exposed outside hats, and masks shall be worn when necessary. Personnel shall not enter toilets, leave production and processing sites or operate across the region while wearing working clothes and working shoes (boots) for cleaning work area and quasi-cleaning work area..

7.4.2.3 Hands have to be washed and disinfected before work, after going to toilet and after contact with articles which may cause food contamination or other activities irrelevant to production. Hands shall be kept clean during production, processing and operation.

7.4.2.4 Milk processing personnel shall not varnish nails, use perfume or wear watches or decorations.

7.4.2.5 Smoking, eating or other activities affecting food hygiene are strictly prohibited at workplaces.

7.4.2.6 Personal clothing shall be stored in personal lockers in the dressing room, and other personal articles shall not be brought into production workshops.

7.4.3 Visitors

The visitors to food production, processing and operation places shall follow hygienic requirements for operators at the site.

7.5 Insect control

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10 / 17

GB 12693—2010

- 7.5.1 Insect control measures shall be developed to keep buildings in good condition and environment clean, and prevent intrusion and breeding of insects.
- 7.5.2 Insect trapping lamps (traps) shall be arranged at entrances of production workshops and storage sites. Window screens shall be provided or other measures shall be taken at places in direct connection with external environment (e.g. windows) to prevent or get rid of insects.
- 7.5.3 Factory environment and production sites shall be regularly monitored and checked for insect signs, and if insects are found, insect source shall be found out to prevent recurrence of similar situation.
- 7.5.4 Physical, chemical or biological preparations can be used, and the deinsectization method shall neither affect food safety or product characteristics nor contaminate food contact surfaces or packing materials (for example, the use of insecticides is avoided as far as possible).
- 7.6 Waste disposal**
- 7.6.1 Waste deposit and removal system shall be developed.
- 7.6.2 Containers for wastes, by-products and inedible substances or hazardous substances shall have special labels and be reasonably constructed and waterproof, and can be closed when necessary to prevent food contamination.
- 7.6.3 Temporary waste deposit facilities shall be arranged at appropriate places, wastes shall be classified for deposit according to their characteristics, and perishable wastes shall be regularly removed.
- 7.6.4 Waste deposit places shall not have unpleasant odor or escape of hazardous and toxic gas, and the breeding of insects shall be prevented so as to prevent from contaminating food, food contact surfaces, water sources and the ground.
- 7.7 Management of toxic and hazardous substances**
- Relevant provisions of GB 14881 shall be followed.
- 7.8 Sewage and dirt management**
- 7.8.1 Sewage discharge shall conform to requirements of GB 8978, and purification measures shall be taken in case of inconformity, and sewage can be discharged only after conforming to the standard.
- 7.8.2 Dirt management shall follow relevant provisions of GB 14881.
- 7.9 Working clothes management**
- Relevant provisions of GB 14881 shall be followed.
- 8 Requirements for raw materials and packing materials**
- 8.1 General requirements**
- 8.1.1 Enterprises shall establish management systems for purchase, acceptance, transport and storage of raw materials and packing materials to ensure that raw materials and packing materials used meet requirements of laws and regulations. Any substances endangering human health and life safety shall not be used.
- 8.1.2 Raw milk collection stations established by enterprises themselves shall conform to relevant national and local regulations.
- 8.2 Purchase and acceptance requirements for raw materials and packing materials**

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10 / 17

GB 12693—2010

- 8.2.1 Enterprises shall establish supplier management system to stipulate the selection, review and evaluation procedures for suppliers.
- 8.2.2 Enterprises shall establish purchasing inspection system for raw materials and packing materials.
- 8.2.2.1 Enterprises using raw milk shall inspect purchased raw milk by batches according to relevant food safety standards, faithfully record quality test situation, name and contact of supplier, purchasing date, etc., and check raw milk delivery receipt of transport vehicle. Enterprises shall not purchase raw milk from units or individuals without raw milk purchasing license.
- 8.2.2.2 At acceptance of other raw materials and packing materials, conformity certificates (enterprise self-inspection report or inspection report issued by a third party) shall be inspected; when valid conformity certificate is unavailable, the purchased raw materials and packing materials shall be inspected according to corresponding food safety standards or enterprise acceptance standards, and can be accepted and used only when qualified. Relevant information of raw materials and packing materials shall be faithfully recorded.
- 8.2.3 Raw materials and packing materials rejected shall be labeled, separately stored, and the suppliers shall be informed for further treatment.
- 8.2.4 Any food safety problem found in raw materials and packing materials shall be reported to the food safety supervision department to which the enterprise belongs.
- 8.3 Transport and storage requirements for raw materials and packing materials**
- 8.3.1 Enterprises shall transport and store raw materials and packing materials according to requirements ensuring quality safety.
- 8.3.2 Transport and storage of raw milk
- 8.3.2.1 Containers for transporting and storing raw milk shall conform to relevant national safety standards.
- 8.3.2.2 Raw milk shall be cooled to 0 – 4 °C within 2 hours after milking. Raw milk shall be transported in insulated milk tankers, and transport vehicles shall have complete certificates and records.
- 8.3.2.3 Raw milk shall be timely processed after arriving at the factory. Otherwise in case of untimely treatment, refrigerated storage facilities shall be provided and temperature and relevant indexes shall be monitored and properly recorded.
- 8.3.3 Transport and storage of other raw materials and packing materials
- 8.3.3.1 Raw materials and packing materials shall be protected from direct solar radiation, rain, violent changes in temperature and humidity, collision, etc. during transport and storage, and shall not be packed or transported together with toxic and hazardous articles.
- 8.3.3.2 Raw materials and packing materials shall be protected from pollution and damage during transport and storage, and measures shall be taken to minimize quality deterioration; raw materials and packing materials having temperature, humidity and other special requirements shall be transported and stored as required.
- 8.3.3.3 Raw materials and packing materials shall be stored by separate zones according to different characteristics, and labeled to indicate relevant information and quality status during storage.
- 8.3.3.4 Inventory raw materials and packing materials shall be regularly checked, and raw materials and packing materials which are stored for a long time and may have change in

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10 / 17

GB 12693—2010

quality shall be regularly sampled for quality confirmation; and deteriorated or expired raw materials and packing materials shall be timely disposed of.

- 8.3.4 Qualified raw materials and packing materials shall be reasonably arranged for use following the principle of “first in, first out” or “first expire, first out”. **8.4 The purchase, acceptance, storage and transport records of raw materials and packing materials shall be kept.**

9 Food safety control in production

9.1 Control of microbial contamination

9.1.1 Temperature and time

- 9.1.1.1 Methods for killing microbes or inhibiting their growth and reproduction, such as thermal treatment, freezing or refrigerated storage, shall be stipulated according to product characteristics and effective monitoring shall be implemented.

- 9.1.1.2 Temperature and time control measures and corrective actions shall be established, and regular verification shall be performed.

- 9.1.1.3 Real-time monitoring measures shall be established for processing procedures in which temperature and time are strictly controlled, and the monitoring records shall be kept.

9.1.2 Humidity

- 9.1.2.1 The air humidity shall be controlled where necessary according to product and process characteristics to reduce the reproduction of harmful microbes; critical air humidity limits shall be set and effectively implemented.

- 9.1.2.2 Real-time air humidity control and monitoring measures shall be established, regularly verified and recorded.

9.1.3 Air cleanliness in production area

- 9.1.3.1 The air in production workshops shall be kept clean to prevent food contamination.

- 9.1.3.2 Aerobic bacterial count in the air of cleaning work area shall be controlled below 30 CFU/dish determined by natural settlement method of GB/T 18204.1.

9.1.4 Microbial contamination prevention

- 9.1.4.1 Necessary measures shall be taken for the whole process from arrival of raw materials and packing materials to the delivery of finished products to prevent microbial contamination. 9.1.4.2 The operation, use and maintenance of equipment, containers and tools for transporting, handling or storing raw materials, semi-finished products and finished products shall avoid contamination to food in processing or storage.

- 9.1.4.3 Water for producing ice cubes and steam in direct contact with food during processing shall conform to provisions of GB 5749.

- 9.1.4.4 Recycle water in evaporation or drying process of food processing and recycled water are reusable, but shall have no harm to food safety and product characteristics, water treatment shall be performed when necessary and effectively monitored.

9.2 Control of chemical contamination

- 9.2.1 Management system for preventing chemical contamination shall be established to analyze possible contamination sources and ways, and control measures shall be proposed.

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15 / 17

GB 12693—2010

9.2.2 Conforming detergents, disinfectants, insecticides and lubricating oil shall be selected and used as required by product instructions; use record shall be made and properly preserved to avoid food contamination.

9.2.3 Chemical substances shall be stored separately from food, clearly labeled, and kept by a designated person.

9.3 Control of physical contamination

9.3.1 Measures such as equipment maintenance, hygiene management, site management, visitor management and processing supervision shall be taken to protect products from contamination of foreign substances (e.g. glass or metal debris and dust).

9.3.2 Effective measures (e.g. installation of screens, traps, magnets, electronic metal detectors) shall be taken to prevent metal or other foreign materials from mixing into products.

9.3.3 Electric welding, cutting, grinding, etc. shall not be performed during production to prevent the generation of peculiar odor and debris.

9.4 Food additives and nutritional fortification substances

9.4.1 Food additives and nutritional fortification substances shall be properly used in conformity with the varieties, range and amount stipulated in food safety standards.

9.4.2 Food additives and nutritional fortification substances shall be accurately weighed and properly recorded in their use.

9.5 Packing materials

9.5.1 Packing materials shall be clean and non-toxic, and conform to relevant national regulations.

9.5.2 Packing materials and packing gas shall be non-toxic, and not affect food safety and product characteristics in specific storage and use conditions.

9.5.3 Inner packing materials shall fully protect foods from contamination and prevent damage in normal storage, transport and sales.

9.5.4 Reusable packing materials such as glass bottles and stainless steel containers shall be thoroughly cleaned and subject to necessary disinfection before use.

9.5.5 Before packing operation, the label of packing materials to be put into use shall be checked to avoid misuse of packing materials, and recorded, and the information shall include product name, quantity, operators, time, etc. corresponding to packing materials.

9.6 Product information and labels

Product labels shall conform to GB 7718, national standards for corresponding products and other relevant national regulations.

10 Inspection

10.1 Enterprises can perform self-inspection on raw materials and products, or entrust an inspection agency with qualification for food inspection for inspection. Enterprises performing self-inspection shall have corresponding inspection capability.

10.2 All batches of products shall be inspected according to relevant standards, and samples shall be retained.

10.3 Quality management of laboratories shall be enhanced to ensure the accuracy and authenticity of inspection results.

10.4 All inspection records and inspection report shall be completely kept.

10 / 17

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11 Storage and transport of products

- 11.1 Storage and transport methods shall be selected according to the categories and natures of products, and conform to storage conditions marked on product labels.
- 11.2 Products shall be protected from direct sunlight, rain, violent changes in temperature and humidity, collision, etc. during storage and transport to prevent adverse effect on ingredients, quality, etc. of milk products; and products shall not be stored and transported together with odorous, toxic or hazardous articles.
- 11.3 Containers, tools and equipment for storage, transport and handling shall be clean, safe and in good state to prevent product contamination.
- 11.4 Products in warehouses shall be regularly checked and temperature and (or) humidity records shall be kept when necessary, and any abnormalities shall be timely handled.
- 11.5 The quality status of inspected products shall be marked.
- 11.6 Records on storage, transport and delivery of products shall be kept so as to the products can be quickly recalled in case of finding problems.

12 Product tracing and recall

- 12.1 Product tracing system shall be established to ensure effective tracing of products in all procedures from purchase of raw materials to sales of products.
- 12.2 Product recall system shall be established. When a batch or category of products contain or may contain factors causing harm to consumer's health, product recall procedures shall be initiated according to relevant national regulations, and the situation shall be timely reported to relevant departments and properly recorded.
- 12.3 Recalled foods shall be subject to harmless treatment, destruction, etc., and food recall and handling conditions shall be reported to relevant departments.
- 12.4 Customer complaint handling mechanism shall be established. Relevant management departments of an enterprise shall record written or oral opinions and complaints of customers, find out causes and properly handle such complaints.

13 Training

- 13.1 Training system shall be established for food safety knowledge training of all employees of the enterprise.
- 13.2 Annual training plan shall be developed according to different needs of posts for corresponding training, and personnel for special types of work shall have certificates.
- 13.3 The training plan shall be regularly reviewed and revised, training effects shall be assessed and routine inspection shall be performed to ensure effective implementation of the plan.
- 13.4 Training records shall be kept.

14 Management institution and personnel

- 14.1 A sound food safety management system of the organization shall be established, corresponding management measures shall be taken, and safety and quality control shall be performed on milk product production in the whole process from the arrival of raw materials and the delivery of finished products to ensure that the products meet requirements of laws, regulations and relevant standards.
- 14.2 Food safety management institution shall be established to take charge of food safety management of the enterprise.

- 14.3 The person in charge of the food safety management institution shall be a legal corporate representative or principal authorized by the legal entity.
- 14.4 All departments of the institution shall have definite management responsibilities, and ensure the implementation of management responsibilities associated with quality and safety. All departments shall effectively divide the work, and avoid overlapping, repetition or omission of responsibilities. Corresponding management systems shall be developed for internal and external factory environment, maintenance and management of facilities and equipment in the plant, quality and safety management in production, hygiene management, quality tracking, etc., and the person in charge of management and responsibilities shall be determined.
- 14.5 All departments of the food safety management institution shall deploy full-time or part-time food safety management personnel subject to professional training, publicize and implement food safety regulations and relevant rules and regulations, be responsible for supervising the implementation and properly make relevant records.

15 Record and document management

15.1 Record management

- 15.1.1 Corresponding record management system shall be developed to record the purchase, production, storage, inspection, sales, etc. of raw materials and packing materials in the processing of milk products in detail so as to increase the credibility and effectiveness of the food safety management system.
- 15.1.1.1 The names, specifications, quantity, supplier name and contact, purchasing date, etc. of food raw materials, food additives and food related products shall be faithfully recorded.
- 15.1.1.2 The processing of products (including process parameters, environment monitoring, etc.), storage conditions of products, inspection batch No., inspection date, inspectors, inspection methods, inspection results, etc. of products shall be faithfully recorded.
- 15.1.1.3 The names, specifications, quantity, manufacturing date, manufacturing batch No., delivery places, name and contact of consignee, delivery date, etc. of delivery products shall be faithfully recorded.
- 15.1.1.4 The names, batch No., specifications, quantity, causes for recall, subsequent rectification plan, etc. of recalled foods shall be faithfully recorded.
- 15.1.2 All records shall be reviewed, signed or sealed by executive staff and relevant supervisory staff, original records can not be crossed out so that the modified records can not be recognized in case of any modifications to record contents, and the modifier shall sign or seal near modified text after modification.
- 15.1.3 All production and quality management records shall be reviewed by relevant departments to ensure that all procedures meet requirements, and any abnormalities shall be immediately handled.
- 15.1.4 The retention period of relevant records stipulated by this Standard shall be not less than two years.

15.2 Document management

- 15.2.1 Document management system shall be established, complete quality management archive shall be built, and documents shall be filed and saved by categories. Distributed and used documents shall be currently approved texts. Repealed or invalid documents shall be unavailable at work site except for being kept for future reference.
- 15.2.2 Enterprises are encouraged to use advanced technologies (e.g. electronic computer information system) for document and record management.

Annex A
(Informative)
Requirements for Application of Computer Systems of Milk Product and Infant and Young Children Formula Food Manufacturers

The computer systems of milk product and infant and young children formula food manufacturers shall meet regulatory requirements of *Food Safety Law* and relevant laws, regulations and standards for food safety, form a complete information chain for tracing, tracking and locating food safety problems in all procedures from the arrival of raw materials to the delivery of products, and submit or remotely send relevant data as required by regulatory departments. The computer system shall meet (but not limited to) the following requirements:

- A.1 The system shall include food safety related data acquisition and record keeping functions of raw material purchase and acceptance, raw material storage and use, monitoring of critical control procedures in production and processing, delivery inspection, storage and transport of products, sales, etc.
- A.2 The system shall be able to assess and early warn food safety risks of relevant raw materials, processing techniques and products of the enterprise.
- A.3 The system and supporting database shall establish and use a complete access control mechanism to ensure compulsive use of staff account/password, and ensure that the system and database have no bug allowing unauthorized access on the aspect of security architecture.
- A.4 Based on the access control mechanism, the system shall realize perfect security policy, and set corresponding strategy group specific to different workers to determine that a particular user or role can only has corresponding access. All data generated and engaged by the system shall be saved in corresponding database, and shall not be saved as files to determine that all data access shall be subject to access control of the system and database.
- A.5 Special security strategy shall be employed for confidential information to ensure that only the information owner has the access to read, write and delete. If confidential information has to be stored and transferred beyond the safety control scope of the system and database, the following requirements shall be met:
 - A.5.1 The confidential information shall be encrypted for storage to prevent unauthorized persons from reading the information.
 - A.5.2 Check code shall be generated before transferring the confidential information, separately transferred with the information (after encryption), and used for confirming that the information is not falsified at the receiving terminal.
- A.6 If the system needs to acquire data generated by automatic testing instruments, the system shall provide a safe and reliable data interface, ensure the accuracy and high availability of interface part, and guarantee that the data generated by instruments can be timely and accurately acquired by the system.
- A.7 Comprehensive and detailed system and database log management functions shall be realized, including:
 - A.7.1 System log records user login information (user, time, IP login address, etc.) of the system and database.
 - A.7.2 Operation log records data modification conditions (including modifier, modification time, modified contents, original contents, etc.).

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- A.7.3 There shall be retention policy for system log and operation log, any users (excluding system administrator) can not delete or modify within the time limit so as to ensure the traceability at certain time.
- A.8 A detailed use and management system for the system shall be developed, which at least shall include the following contents:
 - A.8.1 A real-time recording system for original data, intermediate data, generated data and processing flow in the work flow, which ensures that the whole work process can be reproduced.
 - A.8.2 A detailed backup management system, which ensures that the whole system and corresponding data can be restored completely and quickly after faults and disasters.
 - A.8.3 The machine room shall be equipped with intelligent uninterrupted power supply (UPS) which shall be connected with the work system to ensure that the UPS can supply power and inform the work system of data storage and log operation in case of external power failure (the UPS shall be able to provide power for ensuring emergency saving operation of the system).
 - A.8.4 A complete data access management system shall be established, confidential data is strictly prohibited to be saved on shareable devices; and data sharing in the department shall also subject to the access control system to realize authorized access.
 - A.8.5 A supporting system maintenance system, including regular storage reorganization and system detection, which ensures long-term and stable operation of the system.
 - A.8.6 A safety management system, which requires regular change of user passwords at all parts of the system so as to restrict the login sites of some users, and timely delete unwanted accounts.
 - A.8.7 It shall be stipulated that users logging from external network shall not start and use user/password memory functions provided by the operating systems of external computers so as to prevent information theft.
- A.9 When real-time monitoring data of critical control points is inconsistent with the set standard value, the system shall be capable of recording the date and batch No. of deviation, specific method for correcting deviation, name of operator, etc.
- A.10 Data and relevant records of the system shall be capable of being reproduced for inspection and analysis by regulatory departments.