



# National Standard of the People's Republic of China

GB 12693-2010

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## National Food Safety Standard Good Manufacturing Practice for Milk Products

食品安全国家标准

乳制品良好生产规范

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*Disclaimer: The English version is an unofficial translation of the original in Chinese for information and reference purposes only. In case of a discrepancy the Chinese original standard will prevail.*

## Foreword

The Standard is in substitution of GB 12693—2003 Good Manufacturing Practice of Dairy Product Factory and GB/T 21692—2008 Hygienic Practice for Dry Milk Powder.

The Standard corresponds to Codex Alimentarius Commission (CAC) 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. The consistence of the Standard with CAC/RCP1-1969, Rev.4-2003 and CAC/RCP 57-2004 is non-equivalent, as well as refers to EU Regulations (EC) No. 852/2004 Regulation on the Hygiene of Foodstuffs and (EC) No. 853/2004 Specific Hygiene Rules for Food of Animal Origin.

As compared to GB 12693-2003 and GB/T 21692-2008, the Standard has made the following amendments:

- Standard name has been changed to Good Manufacturing Practice for Milk Products;
  
- The application scope has been adjusted, which is applicable to the manufacturers of all types of dairy products;
- Standard framework of clauses has been revised;
  
- The requirement of preventing contamination during transporting raw materials to plants, food safety control during the production process, and the whole process of transportation and storage has been highlighted;
  
- The production equipment has been adjusted, and requirements for layout, material quality and design of production equipment in view of preventing microbial, chemical and physical contamination have been established;
- The hardware requirement in construction of laboratories has been cancelled;
  
- Requirements relating to the purchase, acceptance, transportation and storage of raw materials have been added;
- Food safety control in production has been highlighted, and the major measures for control of microbial, chemical and physical contamination have been formulated;
- Packing materials and use requirement have been added;
  
- Requirements for control index, monitoring and recording of key control points have been added;
- Particular requirements for follow-up and call-back of products have been added;
  
- File management requirements of records have been added.

Appendix A of this Standard belongs to informative annex.

Publication status of previous versions substituted by the Standard is as follows:

- GB 12693-1990, GB12693-2003;
  
- GB/T 21692-2008

# National Food Safety Standard

## Good Manufacturing Practice for Milk Products

### 1. Scope

The Standard applies to production enterprises processing different dairy products with cow milk (or goat milk) and their fabricated products as the main raw materials.

### 2. Normative References

The clauses of the following reference are essential to the Standard by reference. For dated references, the Standard only applies to the dated revisions. For undated references, the normative document (containing all modification lists) applies to the latest edition.

### 3. Terminology and Definitions

#### 3.1 Clean Work Area

Work area with high requirement for cleanness, for example, storage area for exposed semi-finished products, filling room and inner packing area and so on.

#### 3.2 Quasi-clean Work Area

The requirement of quasi-clean work area with regard to cleanness is below that of cleaning work area, for example, pretreatment workshops of raw materials and so on.

#### 3.3 Common Work Area

The requirement for cleanness of common work area following the quasi-clean work area, such as milk collection unit, raw material warehouse, packing material warehouse, outer packing workshop and finished-product warehouse and so on.

### 4. Location and Plant Environment

It should conform to relevant requirements in GB 14881

### 5. Plant and Workshop

#### 5.1 Design and Layout

5.1.1 Any construction, expansion and reconstruction project shall be designed and executed in accordance with the relevant national regulations.

5.1.2 Any cross contamination shall be present in the process of dairy product producing and any contact with any toxic and unclean substances shall be avoid. The layout of plan and workshop shall be conformed to that.

5.1.3 Cleaning work area, quasi-cleaning work area, and common work area should be separated inside by taking appropriate measures to prevent any cross contamination.

#### 5.2 Internal Building Structure

##### 5.2.1 Roof

5.2.1.1 Interior roof of these areas, for example, processing area, packing area and storing area, should be easily cleaned to prevent dust from accumulating and avoid the circumstances like condensation, fungi-growth or falling. The roof of clean work area, quasi clean work area and other arenas of foodstuff exposure (excluding milk collect house) are the structure that can become dirty easily, it is better to install ceiling that smoothing and easy-to-clean; If it belongs to reinforced concrete structure, the interior roof should be even and seamless.

5.2.1.2 The interior flat roof or ceiling of the workshop should use non-toxic and odorless white or light-colored waterproof material. Where the paint coating and spraying is required, it is necessary to use the mould-proof paint that will not come off and can be easily cleaned.

5.2.1.3 Pipelines of steam, water and electricity must not be arranged above food exposure; otherwise, facilities shall be fixed to prevent dust and condensed water from falling down.

#### 5.2.2 Walls

5.2.2.1 The non-toxic, odorless, smooth, water-proof and easy-to-clean light-color anti-corrosion materials should be applied to the construction of Walls

5.2.2.2 The wall corners and pillar corners in the clean work area and quasi clean work area shall maintain certain radian for the convenience of washing, cleaning and sterilizing.

#### 5.2.3 Doors and windows

5.2.3.1 Smooth and anti-absorption materials shall be used, which should be easily washed, cleaned and sterilized.

5.2.3.2 For the manufacturing workshop and storage areas, doors and windows shall be tightly installed and the facilities which can prevent dust, animals and other insect attack should be arranged, which can be easily cleaned.

5.2.3.3 The exits of the clean work area and quasi clean work area should be installed with doors which can be automatically closed (for example, with auto inductor or door closer) and/or air curtain.

#### 5.2.4 Flooring

5.2.4.1 The non-toxic, odorless and impervious materials should be applied to the floor, which shall be even and non-slippery, seamless and easy to clean and sterilize.

5.2.4.2 The floor that exposed to flowing waste water in operating area and the area that frequently wet in work environment or cleaning or washing with water should be also anti-acid and anti-alkali, as well as should have certain drainage slope and drainage system.

#### 5.3 Facilities

##### 5.3.1 Water supply facilities

5.3.1.1 Be able to secure the water quality, pressure and volume that is required for production.

5.3.1.2 Product hygiene license for drinking water hygienic safety issued by provincial level health administration departments and above should be obtained to water supply facilities and instruments.

5.3.1.3 The safety and hygiene devices should be equipped to inlet and outlet of water supply facilities to prevent any harmful animal and other hazardous substances from entering, resulting in in contamination to foodstuffs.

5.3.1.4 The use of secondary water supply should conform to GB 17051.

5.3.1.5 The hygienic requirements of relevant national health administration departments regarding centralized water supply unit of drinking water should be applied to standby water sources.

5.3.1.6 The piping system for non-drinking water not in contact with foodstuffs (for example, cooling water, sewage or waste water and so on.) should be clearly divided from the piping system for foodstuff production water, and such water shall be delivered with separate pipelines without any backflow or intersection.

5.3.1.7 The quality of water for production should conform to the provisions of GB 5749.

##### 5.3.2 Drainage system

5.3.2.1 It is necessary to allocate the proper drainage system, and to avoid products or production water from being contaminated in designing and constructing process.

5.3.2.2 The drainage system should have a slope and remain unobstructed and convenient for washing; certain radian should be equipped to the juncture of sides and bottom of the drainage ditch.

5.3.2.3 To prevent any solid waste from flowing in and foul smell from coming out, a floor drain with water stop should be installed at the inlet of the drainage system.

5.3.2.4 No other pipelines shall be arranged inside and below the drainage system.

5.3.2.5 The drainage outlet shall be equipped with a device to prevent the invasion of any harmful animal.

5.3.2.6 The flow direction of indoor drainage should be from the area with higher requirement of cleanness to the area with lower requirement of cleanness, and should be designed to prevent the backflow of waste water.

5.3.2.7 Waste water shall be discharged into the waste water treatment system or disposed in other appropriate ways.

#### 5.3.3 Cleaning facilities

Appropriate facilities should be allocated for foodstuffs, apparatus and equipment cleaning and for storage of refuse and waste materials.

#### 5.3.4 Personal hygienic facilities

5.3.4.1 Such personal hygienic facilities shall conform to the provisions of GB 14881.

5.3.4.2 Before entering clean work area, sterilizing facilities should be set, and secondary changing room should be established whenever necessary.

#### 5.3.5 Ventilation facilities

5.3.5.1 To reduce the atmospheric contamination and control odor, measures of natural ventilation or artificial ventilation should be made available so as to secure the food safety and product characteristics. For production of milk power, the ambient temperature should be also controlled in the clean work area and so is the atmospheric humidity when necessary.

5.3.5.2 To prevent condensation of steam and keep the interior air fresh, the clean work area shall be installed with air conditioning facilities; to promptly exhaust humid and dirty air, the common work area shall be installed with ventilation facilities. The air flow direction should be from the area of higher cleanness to the area of lower cleanness to prevent any foodstuff, production equipment and inner packing materials from being contaminated, in case of air conditioning, ventilation and exhausting or fan application inside the plant.

5.3.5.3 In the area with odor and gas (steam and toxic and harmful gas) or dust that may contaminate foodstuffs, the allocation of proper elimination, collection and control devices shall be required.

5.3.5.4 The air inlet should be at least 2m above the floor or roof, far away from the contamination source and air outlet and provided with air filters. To prevent the invasion of any harmful animal, air outlets should be equipped with the corrosion-resistant screen covers that can be easily cleaned. The ventilating and exhausting devices should be easily removed for cleaning, maintenance or replacement.

5.3.5.5 To prevent any indirect contamination, the compressed air or other gas used for foodstuffs, clean food contact face or equipment shall be filtered and purified.

#### 5.3.6 Lighting facilities

5.3.6.1 Adequate natural lighting or artificial lighting should be equipped inside the plant. The lighting coefficient for the workshop shall not be lower than Standard IV; the mixed illumination shall not be lower than 540 lx for the work area of quality monitoring and control, not less than 220 lx for the work area of processing, and not less than 110 lx for other arenas, excluding the areas sensitive to light. The light source shall not cause any change in the color of foodstuffs.

5.3.6.2 The foodstuff should not be exposed to the lighting facilities; otherwise, safe lighting facilities shall be used to prevent to prevent any break and contamination of foodstuff.

#### 5.3.7 Storing facilities

5.3.7.1 Enterprises shall have storing facilities meeting the types and quantity of dairy products produced and operated.

5.3.7.2 Separate storage arenas should be arranged in accordance with different natures of raw materials, semi-finished products, finished products and packing materials and, when it is necessary, freezing (cooling) storages should be arranged. It is necessary to apply proper isolation (for example, by classification, rack and division) with clear identification if one want to store goods of different nature in one warehouse.

5.3.7.3 Warehouses shall be built with non-toxic, solid materials and the floor shall be level and even for ventilation and should be provided with devices to prevent the invasion of any harmful animal (for example, rat guard or ditch set up at the entrance of the warehouse).

5.3.7.4 For the benefit of air circulation and goods handling, warehouses should be arranged with adequate stack board (for placing goods) and keep the stored goods appropriately away from the walls and which should be kept away from the walls and floor.

5.3.7.5 Cooling (cold) stores should be equipped with the thermostat, temperature measuring device or temperature auto recording meter which can accurately indicate the temperature inside the warehouse and carry out the real-time control of temperature.

## **6. Equipment**

### **6.1 Production equipment**

#### **6.1.1 General requirements**

6.1.1.1 Adequate production and operation equipment should be arranged in compliance with the types and quantity of dairy products produced and operated, of which the capacity can cooperate with each other.

6.1.1.2 To ensure the smooth production and avoid any cross contamination, all the production equipment shall be orderly arranged as per technical procedures.

6.1.1.3 For the special equipment used in production (such as pressure vessel and pressure pipeline), it is crucial to formulate the relevant operating rules.

#### **6.1.2 Material quality**

6.1.2.1 All the equipment and instruments in direct or indirect contact with raw materials, semi-finished products and finished products shall be made with safe, non-toxic, smell-free or odorless, non-absorptive and corrosion-resistant materials that can take the repeated cleaning and sterilizing.

6.1.2.2 The materials used for contact surface should be conformity with relevant standards, which should have smooth surface, easy to clean and sterilize, non-absorbent and will not come off easily.

#### **6.1.3 Design**

6.1.3.1 For the convenience of cleaning and sterilizing and the easiness of checking, all the machinery and equipment shall be designed and constructed. They should have such construction as to avoid, in use, entrance of any lubricant, metal slag, sewage or other substance that may cause contamination into foodstuff and shall comply with the relevant requirements.

6.1.3.2 The contact surface with foodstuff shall be smooth and even, with no any sag or crack to reduce the accumulation of foodstuff debris, dirt and organic matters.

6.1.3.3 The storage, transportation and processing system (containing the gravity, pneumatic, enclosure and automation system) should be designed and manufactured to the convenience to keep it in a good hygienic state. The storage equipment of materials should be sealable.

6.1.3.4 For the convenience of obtaining necessary spares, there should be special area for storing equipment spares during the equipment maintenance. The storing area for spares should be kept clean and dry.

### **6.2 Monitoring Equipment**

6.2.1 Such monitoring equipment for measuring, controlling and recording as pressure gauge and thermostat should be accurate and effective.

6.2.2 The relevant functions of the computer system and the network technology thereof may be referred to the provisions of Addendum A to the Standard (Referential Addendum), in using a computer system and the network technology thereof for collection of monitoring data at the key control points and for management of different records.

### **6.3 Service and Maintenance of Equipment**

6.3.1 It is necessary to establish and strictly execute the equipment service and maintenance procedures.

6.3.2 For equipment and carry out regular overhaul and keep proper records, it is necessary to establish the daily maintenance and service schedule.

6.3.3 Each time before production, it is necessary to check if the equipment is in a normal state to avoid any impact on the hygienic quality of products; it is necessary to promptly eliminate it and record the faulting time, reason and batches of products that may be affected, in case of any fault.

## **7. Hygiene Management**

### **7.1 Hygiene Management System**

7.1.1 Enterprise shall formulate the hygiene management system and examination standards and implement the post responsibility system.

7.1.2 Enterprise shall formulate the hygiene inspection schedule and record and file the execution of such schedule.

### **7.2 Hygiene Management for Plant and Facilities**

7.2.1 All facilities inside the plant shall be kept clean and promptly maintained and replaced; repair shall be immediately carried in case of any damage to the plant roof, ceiling and walls, while the floor shall not be allowed to have any damage or water logging.

7.2.2 Equipment and tools and instruments for processing, packing, storing and transporting, production pipelines and contact surface with foodstuffs shall be regularly cleaned and sterilized. In cleaning and sterilizing, make sure to prevent any contamination to foodstuffs, contact surface with foodstuff and inner packing materials.

7.2.3 The cleaned and sterilized movable equipment and instruments shall be kept in a place that can prevent their contact surface with foodstuffs from being contaminated again and keep them in an applicable state.

### **7.3 Cleaning and Sterilizing**

7.3.1 To ensure the clean and hygienic state of foodstuff processing arenas, equipment and facilities and prevent any contamination of foodstuffs, it is necessary to formulate the effective plan and procedure to clean and sterilize.

7.3.2 Enterprises may choose the cleaning and sterilizing methods in accordance with the features of products and process.

7.3.3 Equipment and instruments used to cleaning and sterilizing shall be kept properly in a special place.

7.3.4 It is necessary to record the cleaning and sterilizing procedures, for example, the type of detergent and sterilizer, time, density, object, temperature and so on.

### **7.4 Human Health and Hygiene Requirements**

#### **7.4.1 Human health**

7.4.1.1 Enterprises shall establish and execute the employees' health management system.

7.4.1.2 Before being put into work, foodstuff production and operation personnel shall annually undertake the health check and obtain the health certificate.

7.4.1.3 Persons suffering from notifiable diseases like dysentery, typhoid and viral hepatitis, persons suffering diseases impacting the food safety, for example, active pulmonary tuberculosis, suppurative or effusive skin diseases and persons with skin injuries shall be no longer allowed to undertake any work in direct contact with dairy products.

#### **7.4.2 Personal hygiene**

7.4.2.1 Dairy product processing personnel shall maintain excellent personal hygiene.

7.4.2.2 It is a must to wear or put on the clean work uniform, cap and shoes or boots before entering the production workshop. The work uniform should cover the overcoat; hair should not come from the cap and when necessary, mask should be put on. Shoes and boots on are not allowed when entering the toilet or leaving the production and processing arenas with the work uniform.

7.4.2.3 Before being posted, such as it is necessary to wash hands and apply sterilization after going to the toilet, contacting any goods that may contaminate the foodstuffs or undertaking any other activities not related to production. The hands shall be kept clean in the process of operating.

7.4.2.4 Persons who are in direct contact with dairy product shall not use any nail oil and perfume and shall not wear watch and jewelries.

7.4.2.5 Smoking, taking food or other activities that may impact the hygiene of dairy products shall not be allowed at work.

7.4.2.6 Personal clothes shall be kept in the lockers in the locker room and other personal belongings shall not be allowed for carrying in the production workshop.

#### 7.4.3 Visitors

To enter the foodstuff production, processing and operating arenas, visitor shall comply with the hygienic requirements for the operating personnel on the spot.

#### 7.5 Pest Control

7.5.1 Formulate measures for pest control to avoid the population of pests and keep the environment neat and clean and buildings intact to prevent the invasion of pests and development of harmful animals.

7.5.2 Set up the pest-capture lights to prevent or eliminate the harmful pests at the manufacturing workshop and storage arenas.

7.5.3 Regularly monitor and check is needed when the plant environment and production arenas have any sign of pests; in case of observing any pest, trace and find out the source and stop its occurrence again.

7.5.4 Physical, chemical or biological preparation may be used for treatment, but their eliminating method shall not impact the safety and characteristics of foodstuffs and contaminate the contact surface with foodstuffs and packing materials (for example, avoid using insecticide).

#### 7.6 Disposal of Refuses

7.6.1 Formulate rules for placing and eliminating refuses.

7.6.2 To prevent any contamination to the foodstuffs, the vessels including the refuses, processing by-products and non-edible or dangerous substances shall have special labels and rational construction, and, when it is necessary, shall be closed.

7.6.3 It is necessary to set up the temporary dumping facilities a proper location for classified dumping as per characteristics of refuses, while the corruptive refuses should be regularly eliminated.

7.6.4 The dumping place of refuses shall not produce any bad smell or harmful, toxic gas. It is necessary to prevent the population of harmful animals and prevent any contamination to the foodstuffs, contact surface with foodstuff, water source and ground.

7.7 Management of Toxic and Harmful Substances Management of toxic and harmful substances shall be subject to the relevant provisions of GB 14881.

#### 7.8 Management of Sewage and Filth

7.8.1 Sewage discharge shall be compliant with the requirements of GB 8978 and those failing to conform to the standard shall be purified for qualification before being discharged.

7.8.2 Management of filth shall be subject to the relevant provisions of GB 14881.

#### 7.9 Management of Work Uniforms

Management of work uniforms shall be subject to the relevant provisions of GB 14881.

### **8. Requirements for Raw Materials and Packing Materials**

#### 8.1 General Requirements

8.1.1 In order to ensure the raw materials and packing materials used are in conformity with the requirements of the laws and regulations, production enterprises of dairy products shall establish the management system relating to the purchase, acceptance, transportation and storage of raw materials and packing materials. Any substances that may do harm to human health and safety should not be used.

8.1.2 Fresh milk collection centers constructed by production enterprises of dairy products shall in accordance with the relevant national and local regulations.

## 8.2 Requirements for Purchase and Acceptance of Raw Materials and Packing Materials

8.2.1 Production enterprises of dairy products shall set up the supplier management system, specifying the procedures for supplier selection, examination and appraisal.

8.2.2 Production enterprises of dairy products shall set up the incoming inspection system for raw materials and packing materials.

8.2.2.1 Production enterprises of dairy products with fresh milk shall test, batch by batch, the fresh milk acquired, record truly the quality inspection status, suppliers' names and contact modes, delivery date and so on, and check the fresh milk receipts of the transporting vehicles. Production enterprises of dairy products shall not be allowed to purchase any fresh milk from any unit and individual without the license of fresh milk acquisition.

8.2.2.2 It is necessary to check the qualification certification documents (enterprise's self-examination report or testing report issued by a third party) for the batch of raw materials and packing materials in inspecting and accepting other raw materials and packing materials; in case of failing to provide such effective qualification certification documents, in accordance with the relevant food safety standards or the enterprise's inspection and acceptance standard, inspect and test the raw materials and packing materials purchased, which shall be only accepted and used upon qualification. It is necessary to record truly the relevant information of raw materials and packing materials.

8.2.3 Raw materials and packing materials that are refused for acceptance upon determination shall be demarcated and separately stored and the supplier shall be notified for further action.

8.2.4 It should be reported to the food safety supervision department where the enterprise is located in case of any food safety problems of raw materials and packing materials are discovered.

## 8.3 Transportation and Storage of Raw Materials and Packing Materials

8.3.1 Production enterprises of dairy products shall transport and store raw materials and packing materials in accordance with the requirements of ensuring the quality and safety of raw materials and packing materials.

### 8.3.2 Transportation and storage of fresh milk

8.3.2.1 The vessels for transporting and storing fresh milk shall conform to the relevant national safety standard.

8.3.2.2 Fresh milk shall be, within 2 hours after milking, cooled down to  $0^{\circ}\text{C}\sim 4^{\circ}\text{C}$ ,

at which it shall be transported. The transporting vehicles shall maintain perfect certificate and record.

8.3.2.3 The fresh milk shall be promptly processed or shall be equipped with facilities for cold storage upon delivery to the factory, in the event that it cannot be timely processed. Its temperature and relevant indices should be monitored with records.

### 8.3.3 Transportation and storage of other raw materials and packing materials

8.3.3.1 In the process of transporting and storing raw materials and packing materials, avoid any direct sunlight, rain, sharp temperature and humidity change and impact. Loading and shipping with toxic and harmful goods is prohibited.

8.3.3.2 In the process of transporting and storing, avoid any contamination and damage and minimize the poor quality; According to the specified conditions, the raw materials and packing materials with requirement for humidity and temperature and special requirements shall be transported and stored.

8.3.3.3 During the storage, different raw materials and packing materials shall be divided for storage according to their respective features, for which the identification should be set up to indicate the relevant information and quality status.

8.3.3.4 Regularly check the stocked raw materials and packing materials; as for the raw materials and packing materials that have been stored for a longer period and may have observe any change in quality, regularly undertake sampling for confirmation of quality and timely dispose the raw materials and packing materials that have been deteriorated or exceeded the warranty period.

8.3.4 Follow the principle of "early expiration date and first out" for rational arrangement of use in using the qualified raw materials and packing materials.

8.4 Maintain the Records on Purchase, Acceptance, Storage, Transportation and Use of Raw Materials and Packing Materials.

## 9. Food Safety Control in Production

### 9.1 Control of microbial contamination

#### 9.1.1 Temperature and time

9.1.1.1 According to the features of products, enterprises shall specify, the method for eliminating or constraining the growth and development of microbes, for example, thermal treatment, freezing or cold storage and implement the effective monitoring and control.

9.1.1.2 Enterprises shall set up the measures for temperature and time control and rectification and carry out the regular verification.

9.1.1.3 As for the processing links with strict control over temperature and time, set up the real-time monitoring measures and maintain the monitoring and control records.

#### 9.1.2 Humidity

9.1.2.1 According to the features of productions and techniques, enterprises shall control, the atmospheric humidity in the areas requiring for humidity control in order to reduce the development of harmful microbes; formulate and effectively implement the key limits of atmospheric humidity.

9.1.2.2 Set up the real-time control and monitoring measures for atmospheric humidity, regularly verify the same and keep records.

#### 9.1.3 Atmospheric cleanness in production area

9.1.3.1 To prevent the contamination to foodstuffs, production workshop shall be kept with clean air.

9.1.3.2 Determine as per natural settlement method specified in GB/T 18204.1.

The colony count in the air of the clean work area shall be controlled with 30cfu/dish.

#### 9.1.4 Prevention against microbial contamination

9.1.4.1 To prevent any microbial contamination, production enterprises of dairy products shall take necessary measures for the whole process from intake of raw materials and packing materials to dispatch of finished products.

9.1.4.2 In operating, using and maintain any equipment, vessel and instrument used for conveying, loading or storing raw materials, semi-finished products and finished products, avoid any contamination to the foodstuffs in processing or storing.

9.1.4.3 For ice lumps and steam in direct contact with foodstuffs in processing, water used shall comply with the provisions of GB5749.

9.1.4.4 Recycling water shall be treated and it should be ensured that it will cause any hazard to the safety of foodstuffs and characteristics of products. Water treatment shall be effectively monitored. The recycling water without further treatment and the recycled water for evaporation or drying in processing foodstuff can be reused, but to the safety of foodstuffs and characteristics of products, it must be ensured that it will not result in any hazard.

### 9.2 Control of chemical contamination

9.2.1 Enterprise shall set up the management system to prevent chemical contamination, analyze the possible contamination source and contamination channel, and set forth the control measures;

9.2.2 Detergent, sterilizer, insecticide and lubricant in accordance with the requirement should be selected and used as per requirement of the product instructions; should be stored separately from the foodstuffs and demarcated clearly; taken care of by specific persons. To avoid any hazard of contaminating the foodstuffs, their use shall be registered and application records should be properly kept.

9.2.3 Chemical substances should be placed separately from foodstuffs with clear identification. There should be specially assigned persons to take care of it.

### 9.3 Control of physical contamination

9.3.1 Production enterprises of dairy products shall undertake such measures as equipment maintenance, hygiene management, spot management, management of external persons and processing supervision to ensure that products will not be contaminated by the foreign stuffs (for example, glass or metal fragments, dust, and so on).

9.3.2 Take effective measures (for example, sieve, trap, magnet, electronic metal detector and so on.) to prevent any metal or other foreign stuffs from being mixed into the products.

9.3.3 During production, these work, such as, welding, cutting and grinding shall not be carried to avoid any contamination of odor and fragment.

### 9.4 Food additives and nutrition enhancers

9.4.1 Enterprises shall use the food additives and nutrition enhancers in accordance with the provisions of the Food Safety Standard on types, application and dosage of food additives and nutrition enhancers.

9.4.2 In using, weigh and measure accurately the food additives and nutrition enhancers and maintain proper records.

### 9.5 Packing materials

9.5.1 Packing materials should be clean, non-toxic and in accordance with the national relevant regulations.

9.5.2 Packing materials or gas for packing must be non-toxic and shall not impact the safety of foodstuffs and characteristics of products under the specific conditions of storing and using.

9.5.3 The inner packing materials should be able to adequately protect, in the normal storage, shipment and sale, foodstuffs against any contamination, prevent any damage and avoid any harmful substance from entering the foodstuffs.

9.5.4 The recyclable packing materials such as glass bottles and stainless vessels should be washed clean and sterilized before being used.

9.5.5 It is necessary to check the labels of the packing materials to be used before packing, avoiding any misuse of packing materials, and keeping a record, containing the product name, quantity, operator and date.

### 9.6 Product Information and Labeling

Product labeling should be subject to GB7718, relevant national product standards as well as other national regulations.

## 10. Testing of Products

10.1 Enterprises may carry out such test independently or entrust any testing organization qualified for foodstuff testing to carry out such test. Enterprises for self-testing should be equipped with relevant testing capacities.

10.2 Enterprises shall test each batch of products according to the relevant standard and retain the samples.

10.3 To ensure the accuracy and authenticity of testing results, enterprises shall strengthen quality management of laboratories.

10.4 Enterprises shall file complete testing records and reports.

## 11. Product Storage and Transportation

11.1 According to the types and nature of products, select the mode of storage and transportation, which shall be conform with the storage requirements marked on the product labels.

11.2 To avoid any bad impact on the composition, content, and quality of dairy products, in the process of storage and transportation, avoid any direct sunlight, rain, sharp temperature and humidity change and impact. Loading and shipping with toxic and harmful goods is prohibited.

11.3 To prevent the products from contamination, the vessels, tools and equipment used for storing, transporting and handling shall be clean and safe and in an excellent state of renovation and service.

11.4 Regularly check the products stocked in warehouses, and, if it is necessary, maintain the record of temperature and/or humidity; in case of anything abnormal observed, take prompt action.

11.5 As for the tested products, indicate their quality status.

11.6 The storage and transportation of products shall be recorded and the dispatched products shall be also recorded so that they can be promptly called back in case of any problem observed.

## **12. Product Follow-up and Call-back**

12.1 Enterprises shall establish the product tracing system and maintain the relevant records of all the links ranging from purchase of raw materials to sale of products so as to ensure the effectiveness of the whole product tracing and call-back system.

12.2 Enterprises shall establish the product call-back system. Upon observing one batch or type of products contains or may contain any factor harming the health of consumers, it is necessary to actuate the product call-back procedure as per national relevant regulation, promptly notify the relevant department and keep proper record.

12.3 Foodstuff producers shall take action against the called-back foodstuffs such as rectification, harmless treatment and destruction and report to the relevant department about call-back and disposal status of the foodstuffs.

12.4 It is necessary to establish the processing mechanism for customer complaint. As for the written or oral views and complaints of customers, enterprises' relevant management department shall keep a record and find out the reason for proper processing.

## **13. Training**

13.1 Enterprises should set up the training system for food safety knowledge training of all their employees.

13.2 Enterprises should formulate the annual training program in accordance with different jobs for relevant training and certificates shall be required for the specific jobs.

13.3 In order to ensure the effective implementation of the program, it is necessary to regularly examine and revise the training program, evaluate the training effect and carry out routine inspection.

13.4 Training should be recorded.

## **14. Management Organization and Personnel**

14.1 Enterprises shall establish and perfect their respective food safety management system, undertake relevant management measures to implement the total quality and safety control over the production of dairy product containing the input of raw materials and output of finished products and ensure the products are in accordance with the requirements of the laws, regulations and relevant standards.

14.2 Establish the administration of food safety to take on the enterprise's food safety management.

14.3 Administration of food safety and relevant departments shall each have a responsible person. The responsible person of the administration shall be the legal representative of the enterprise or the responsible persons authorized by the legal representative.

14.4 To ensure the fulfillment of management duties related to quality and safety, all the departments of the administration shall have the relevant management duties. All the concerned departments shall be effectively allocated with tasks to avoid overlapping or absence of duties, formulate the relevant management rules for the plant's internal and external environment, maintenance and management of plant facilities and equipment, production quality and safety management, hygiene management, quality tracing and so on, and define the management executive and duties.

14.5 All the departments of the food safety administration shall be allocated with full time or part-time food safety management personnel especially trained to propagate and carry out the regulations of food safety and relevant rules and regulations and take on supervising and the execution and keeping the relevant records.

## **15. Management of Records and Documents**

### **15.1 Records and Management**

15.1.1 So as to increase the reliability and effectiveness of the food safety management system, enterprises shall step up the relevant record management system and keep detailed records of the purchase, production, storage, testing and sales of raw materials and packing materials in dairy product processing.

15.1.1.1 Enterprises shall set up the inbound test record system for food raw materials, foodstuff additives and food-related products to truly record the names, specifications, quantity, supplier's name and contact mode and intake date of food raw materials, foods additives and food-related products.

15.1.1.2 Enterprises shall set up the record system of food processing, storing and testing to truly record the product processing, product storing and products' testing batch number, testing date, inspectors, test results, etc.

15.1.1.3 Enterprises shall set up the record system of foodstuff ex-factory test, check the testing record and safety status of dispatched food, and truly record foodstuffs' names, specification, quantity, production date, production batch number, place of delivery, receiver's name and contact mode and date of dispatch.

15.1.1.4 Enterprises shall set up the food call-back record system to truly record the called-back foodstuff's name, batch number, specification, quantity, reason for call-back and subsequent rectification program.

15.1.2 The execution personnel and relevant supervisor shall check and sign or stamp all records; in case of any modification in the record, the original text shall not be crossed out, resulting in the failure to identify the original text, and upon modification, the modifier shall sign or stamp by the modified text.

15.1.3 The relevant department shall review all the production and quality management records to determine if all the treatment is conform to the regulations; in case of anything abnormal observed, immediate action shall be taken.

15.1.4 Enterprise shall maintain the relevant records specified hereto for at least two years.

### **15.2 Document Management**

15.2.1 Enterprises shall set up the document management system and establish complete quality management files; documents shall be filed and kept as per classification. Documents to be distributed and used shall be the approved prevailing version. The abandoned or invalid documents shall not appear in the work area excluding filing and reference.

15.2.2 Enterprises are encouraged to use advanced technical means (for example, electronic computer information system) for management of documents and records.

## Appendix A (Informative annex)

### Relevant Requirements on Computer System Application of Dairy Products and Infant Formula Products Manufacturers

The computer system for manufacturers of dairy products and infant formula products should be subject to Food Safety Law and relevant laws, regulations as well as standards regarding food safety supervision. Complete information chain from raw material incoming to product delivery is beneficial to tracing, tracking and positioning of food safety issues should be formed, and relevant data should be submitted or reported remotely as for the requirements of supervision departments. Such computer system should contain (but not limited to) the following requirements:

A.1 The system should contain functions such as data collection and record keeping during raw material sourcing as well as examination & acceptance, raw material storage and application, key control segment supervision for production as well as processing, product delivery inspection, product storage and transportation, and sales.

A.2 The system should make evaluation and early warning for food safety risks of relevant raw materials, processing techniques and products of the enterprise.

A.3 Sound access control mechanism for the system and matched database should be established to ensure the mandatory application of staff's account number/password. There should not be any bugs that allow unauthorized access in the system and database through safety framework.

A.4 Based on access control mechanism, sound safety strategy should be realized for the system. There should be corresponding strategy groups for the staffs with different roles, so that to make sure users with specific roles only have the corresponding access. All the data generated in the system should be kept in the corresponding database not in the form of documents. It should be guaranteed that all the data accesses should be managed by the access control of the system and database.

A.5 To make sure only the owner has the right to read, write and delete the information, special safety strategies should be taken for confidential information. In case confidential information needs to be stored and transmitted out of the safety control scope of the system and database, it should:

A.5.1 To prevent the users without such kind of access to read the information, we aim to make sure encrypted storage has been done for the confidential information;

A.5.2 Generate check code before the transmission of confidential information transmitting the check code and information (after encryption) separately and making sure the information has not been changed by check code at the receiving end.

A.6 In case the data generated by the automatic testing device needs to be collected by the system, it should provide safe and reliable data interface to make sure the accuracy and high availability of the interface, and the data generated by the device can be collected by the system accurately and in time.

A.7 Sound and elaborate log management function of the system and database should be realized, containing:

A.7.1 System log records of user login information (username, time, computer address and so on.) of the system and database each time.

A.7.2 Operation log records every revision of the database (containing username, revision time, revised content, original content and so on.).

A.7.3 The function of preservation should be equipped with system log and operation log.

Any user (excluding the system administrator) could not delete or revise the content within the set time to ensure the traceability.

A.8 Application and management system should be established, containing:

A.8.1 Real-time recording system, including original data, intermediate data, generated data, and processing procedure to make sure the reproduction of the whole working process;

A.8.2 Detailed backup management system to make sure the whole system and relevant data can be recovered completely after system failure;

A.8.3 To connect with the working system, the computer room should be equipped with uninterrupted power supply (UPS). To make sure it can be powered by UPS during the external power failure, the working system will save the data and log operation (UPS should be able to provide the electricity for emergency saving of the system);

A.8.4 Sound data access control system, shared devices cannot store confidential information. Access control system should also be taken for internal data sharing to realize authorized access;

A.8.5 Matched system maintenance system, containing regular storage organization and system testing, to ensure the long-term stable operation of the system;

A.8.6 Safety management system, containing changing the user passwords of the system, restricting the login place of users, and deleting the accounts that will no longer be required;

A.8.7 To prevent the information being stolen, we stipulated that users logged in from external network should not enable or use the username/password memory function provided by the operation system of the external computer.

A.9 When the real-time monitoring data of critical control point is inconsistent with the set standard value, the system will record the date, batch number, methods for correcting the deviation, and the name of operator when the deviation occurred.

A.10 To check and analyze supervision departments, the data and relevant records within the system should be able to be copied.